Duquesne University Duquesne Scholarship Collection

Electronic Theses and Dissertations

Spring 1-1-2017

The Ethical Obligation for Disclosure of Medical Error in the Intensive Care Unit

Saleh A. Alnahdi

Follow this and additional works at: https://dsc.duq.edu/etd

Recommended Citation

Alnahdi, S. A. (2017). The Ethical Obligation for Disclosure of Medical Error in the Intensive Care Unit (Doctoral dissertation, Duquesne University). Retrieved from https://dsc.duq.edu/etd/119

This One-year Embargo is brought to you for free and open access by Duquesne Scholarship Collection. It has been accepted for inclusion in Electronic Theses and Dissertations by an authorized administrator of Duquesne Scholarship Collection. For more information, please contact phillipsg@duq.edu.

THE ETHICAL OBLIGATION FOR DISCLOSURE OF MEDICAL ERROR IN THE INTENSIVE CARE UNIT

A Dissertation

Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for

the degree of Doctor of Philosophy

By

Saleh A. Alnahdi

May 2017

Copyright by

Saleh A. Alnahdi

THE ETHICAL OBLIGATION FOR DISCLOSURE OF MEDICAL ERROR IN THE INTENSIVE CARE UNIT

By

Saleh A. Alnahdi

Approved March 2^{ed}, 2017

Gerard Magill, PhD Professor of Health Care Ethics Vernon F. Gallagher Chair for the Integration of Science, Theology, Philosophy and Law (Committee Chair) Henk ten Have, MD, PhD Director and Professor Center for Health Care Ethics (Committee Member)

Joris Gielen, PhD Assistant Professor Center for Healthcare Ethics (Committee Member) Henk ten Have, MD, PhD Director and Professor Center for Health Care Ethics (Center Director)

James Swindal, PhD Professor and Dean, McAnulty College and Graduate School of Liberal Arts

ABSTRACT

THE ETHICAL OBLIGATION FOR DISCLOSURE OF MEDICAL ERROR IN THE INTENSIVE CARE UNIT

By

Saleh A. Alnahdi May 2017

Dissertation supervised by Professor Gerard Magill

The very facts that humans are fallible and that they are integrally involved in the delivery of healthcare and medical treatment guarantee that medical errors will occur despite the best of training, skills and vigilance, precautions, or preventive procedures. While medical errors occur across the spectrum of care and treatment, the propensity for their occurrence and the severity of the damage they are likely to inflict are undeniably greatest in the hospital intensive care unit (ICU).

The fundamentals of biomedical ethics require nothing less than a thorough systematic analysis of the sources of error in the ICU, along with a comprehensive, coordinated approach to preventing error to the extent humanly possible and to handling and mitigating the effects of error whenever they do occur. Through the chapters of this dissertation, the research and analysis has provided the following: 1) a detailed account,

iv

to the extent that it has been documented, of the high frequency of errors occurring in the U.S. in general and specifically in hospital intensive care units, as well as the range and extent of the harm done to patients and family members, both physically and financially; 2) a classification and analysis of the proximate, intermediate and ultimate causes of and contributing factors to medical errors, which in addition to identifying causation has formed the basis for this dissertation's recommendations aimed at developing procedures and protocols to effectively reduce errors to the greatest degree possible while minimizing their harmful impact; 3) an in-depth analysis of expectations, grounded in biomedical ethics, for dealing with the consequences of medical errors including disclosure and communication, the expectations of patients and family members, the attitudes and concerns of medical professionals, the disconnect between these two groups, and recommendations for procedures and protocols to ensure prompt, complete, and just handling of all consequences of the error; 4) an in-depth framework, based on Western religious and cultural foundations, for both those responsible for and those injured by medical errors to interact in handling the consequences of the error, as well as all of the communication which it engenders; and 5) proposals for numerous procedures and protocols, both for lessening the vulnerability of hospital ICU patients to suffering the effects of an error and for addressing and counteracting the variety of systemic problems which create or heighten the propensity for the occurrence of medical errors.

DEDICATION

To my Father, and Mother, with love and gratitude

This dissertation is dedicated to my wife. Your love and dedication throughout this long journey is deeply appreciated. Thank you for persevering with me through all the ups and downs and twists and turns as we have finally reached the conclusion of this chapter of our love story.

This dissertation is also dedicated to our beautiful children, Danah, Faris, Abduleelah, and Tariq.

This is also to all who prayed for, motivated, and supported me over the past decade.

	Page
Abstract	iv
Dedication	vi
Chapter 1. Introduction	1
Chapter 2. Extent of Medical Errors in the ICU	59
Introduction	59
Chapter 2.A. Errors Concerning the Hospital ICU	61
1. Defining Medical Errors	61
2. Potential for Medical Errors	65
3. Types and Causes of Medical Errors in the ICU	68
a. Types of Medical Errors Regarding Hospital ICUs	69
(1) Errors in Planning and Execution	69
(2) Errors in Diagnosis	70
(3) Errors in Treatment	71
(4) Preventive Errors	71
(5) Errors in Medication	73
(6) Failures of Communication and Equipment in Health System	s 74
(7) Poor Medical Management	75
b. Causes of Errors Referring to Hospital ICUs	76
(1) Adverse Events	76
(2) Adverse Drug Events	77
(3) Medication Error	79
(4) Human Errors	80
i) Fragmentation of the Health System	81
ii) Cognitive Errors	83
iii) Ineffective Skills and Inadequate Knowledge	85
iv) Long Working Hours	86
Chapter 2.B. Statistics of Medical Errors in the Hospital ICU	87
1. Medical Errors Rates and Costs	87
2. Inpatient Injuries in the Hospital ICU	93
3. Percent Occurrences by Error in the Hospital ICU	99
Chapter 2.C. Risk Factors for Medical Errors in the Hospital ICU	104

TABLE OF CONTENTS

1. Patients	. 104
(a) Severity of the Primary Illness	. 105
(b) Age Related Need for Special Care	. 106
(c) Extended Stays in the Hospital or ICU	. 109
(d) Patients under sedation	. 110
2. Medications	. 111
(a) Special Types of Medication	. 111
(b) Miscellaneous Medications	. 112
(c) The Number of Interventions	. 113
3. Environment and Equipments in the ICU	. 113
(a) The Complexity of the Environment	. 113
(b) The Need to Handle Emergency Admissions	. 115
(c) The multiplicity of care providers	. 117
Chapter 2.D. Conclusion	. 118
Chapter 3. Ethical Problems Concerning Medical Error in the ICU	. 136
Introduction	. 136
Chapter 3.A. Relevant Ethical Principles in the Hospital ICU	. 139
1. Ethical Conflicts	. 140
2. The 1847 Code of Ethics and Subsequent Developments	. 141
3. Theories of Ethics	. 143
4. Principle of Ethics and their Historical Antecedents	. 146
(i) Autonomy	. 146
(ii) Beneficence	. 148
(iii) Justice	. 150
(iv) Non-maleficence	. 151
Chapter 3.B. Ethics in the Hospital ICU	. 154
Chapter 3.C. Ethical Issues in the Intensive Care Unit	. 157
1. Futile Medical Care	. 158
2. Ethics of Allocating Limited Resources	. 163
3. Withholding and Withdrawal of Life Support	. 171
Chapter 3.D. Maintenance of Patient Autonomy and Informed Consent	. 174
1. Respect for Patient Autonomy	. 174
2. Respect for Informed Consent	. 177

Chapter 3.E. Conclusion	179
Chapter 4. Ethical Obligations in Terms of Honesty to Patients	193
Introduction	193
Chapter 4.A. Western Cultural Expectations in Relation to Medical Errors in the Hosp ICU	oital 195
1. Cultural Expectations	196
2. Cultural Competence in Disclosing Medical Errors	198
3. The Ethical Justification for the Obligation to Disclose Medical Error	204
Chapter 4.B. What Patients Desire in the Wake of Medical Errors in the Hospital ICU	211
1. Motivations on the Part of Patients	212
2. The Patient's Need for Medical Support	213
Chapter 4.C. The Concepts of Disclosure and Apology	214
1. Disclosure	214
2.Apology	215
3. Effects of Non-Disclosure on Patients and Physicians	216
a. Effects of Non-Disclosure on Patients	216
b. Effects of Non-Disclosure on Physicians	218
4. Effects of Disclosure on Physicians and Patients	222
a. Effects of Disclosure on Physicians	223
b. Effects of Disclosure on Patients	228
Chapter 4.D. The Gap between the Acknowledged Need for and the Incidence of Disclosure and Apology	231
1. The Gap between Physician and Patient Perspectives	232
2. Obstacles to Disclosure of Errors in the ICU	234
3. Other Institutional Barriers to Disclosure	234
Chapter 4.E. The Process for Disclosure of Medical Error in the Hospital ICU	235
1. Preparations for the Disclosure Meeting	236
2. The Actual Disclosure Meeting	237
Chapter 4.F. Proper Notification and Documentation Processes in the Hospital ICU	238
1. Policies and Procedures	239
2. Other Factors and Issues to Consider	240
Chapter 4.G. Conclusion	241
Chapter 5. Medical Error Disclosure Protocols in the Hospital ICU	256

roduction		
Chapter 5.A. Medical Error Disclosure Protocols Based on the Scope and Scale of th Medical Error in the Hospital ICU	le 259	
1. The Severity, Disruption, and Cost of Medical Errors	260	
2. Handoffs, 'Black Swan' Errors, and Postoperative Handovers	261	
3. Errors of Commission versus Omission	264	
Chapter 5.B. Medical Error Disclosure Protocols Based on the Ethical Acceptance of Responsibility in the Hospital ICU	f 265	
1. Medical Standards	266	
2. Physician and Medical Provider Responsibilities	268	
Chapter 5.C. Medical Error Disclosure Protocols Based on Type of Information	272	
1. Better Communication	273	
2. Communicative Competency	275	
3. Barriers to Communication	278	
Chapter 5.D. Protocols for Medical Error Disclosure Based on the Anticipated Risk Management Strategy in the Hospital ICU	280	
1. The Global Trigger Tool (GTT)	280	
2. Conditions for Informed Consent	282	
3. The Surrogate	285	
Chapter 5.E. Medical Error Disclosure Protocols Based on the Timing of Disclosure	287	
1. Advanced Directives	287	
2. Verbal Instructions	289	
Chapter 5.F. Medical Error Disclosure Protocols Based on the Stakeholders of Intere	st	
1 Communication Failuros	291	
2 Disclosure of Medical Error Information	202	
2. Disclosure of Medical Error Information	293	
a. The Fainity	293	
2. These levelyed in Transfers on Handoffs of the Detiont	294	
Charter 5 C. Medical Error Disclorum Protocola Decider the Eerror land Informal	293	
Acknowledgement of Medical Errors and Apologies	297	
1. Informal and Formal Apologies	297	
2. Apology Laws	300	
Chapter 5.H. Medical Error Disclosure Protocols Based on Compensation	303	

1. Medical Error Disclosure Protocols and Compensation	304
2. Non-Monetary Compensation	306
Chapter 5.J. Conclusion	310
Chapter 6. Systemic Endeavors to Diminish Medical Errors in the Hospital ICU	327
Introduction	327
Chapter 6.A. Prevention Planning Protocols in the Hospital ICU 1. Prophylaxis and Monitoring Procedures	329
ii Monitoring Procedures	330
2 Steps to Avoid Adverse Events	333
i The Role of Information Technology	334
ii Cleaning Disinfecting and Sterilization Procedures	336
a. Cleaning Procedures	336
b. Disinfecting Procedures	337
c. Sterilization Procedures	339
iii. Investigative and Evaluative Procedures	341
a. The Basic Concept of Checklists	341
b. The Effects of Checklists in the ICU	343
iv. Reorganizing the Medical Team in the Hospital ICU	344
a. The Effects of Teamwork in the Hospital ICU	344
b. Teamwork and Patient Outcomes in the Hospital ICU	346
Chapter 6.B. Communication Protocols in the Hospital ICU	347
1. Internal Communication	348
2. External Communication	351
Chapter 6.C. Medication Protocols in the Hospital ICU	353
1. Computerized Physician Order Entry	353
2. Elimination of Extended Physician Work	355
3. Participation of Pharmacists in ICU Rounds	357
Chapter 6.D. Equipment Failure Protocols in the Hospital ICU 1. Equipment Failure in the ICU	358 359
2. Medical Equipment Maintenance in the ICU	360
Chapter 6.E. System Failure Protocols in the Hospital ICU	361
1. Improvement in Healthcare Quality in the ICU	362

2. Root Causes Analysis	
Chapter 6.F. Needed Reforms and the Disclosure of Medical Error in t	the Hospital ICU
-	
1. Tort Reform	
2. Education Reform	
Chapter 6.H. Conclusion	
Chapter 7. Conclusion	
Bibliography	420

Chapter 1. Introduction

Standard hospital procedures and law in the United States require medical staff to disclose information to patients concerning their treatment and outcomes, as well as information not protected by patient confidentiality to relevant agencies. However, the increasing threat of lawsuits, the desire to hide negative treatment statistics, higher insurance premiums, and the threat of loss of employment all contribute to the incentive for staff to underreport medical errors. As a consequence of this gap in information, not only do hospital staff risk failing to learn from these errors, but patients also lose a measure of their autonomy. Depending on when and how these unreported medical errors occurred, patients may unwittingly be unable to prevent or plan for worst-case scenarios, provide information to their doctors that is necessary for their treatment, write their last or living wills, choose the location of their passing, and prepare for other key issues related either to their health or to their demise. The ethical issues associated with disclosure of patient information involve patient rights to obtain their medical records, choose between treatment options, refuse treatment, and make decisions about end-of-life care. These issues become more nuanced when examined in the context of the scope and timing of the disclosure of such information, as well as the circumstances that create the system of incentives and disincentives in which medical staffs operate with regard to disclosing or withholding information.

There has been significant analysis in the literature of biomedical ethics regarding medical errors and their causes. This focus has led to significant discussion of the need for appropriate discourse following the occurrence of medical errors in the field as a

whole. In terms of healthcare settings, it is widely acknowledged in the literature that the hospital intensive care unit (ICU) constitutes an area where the need for highest quality care is acute and the potential for severe harm is great. However, a thorough search through the literature in the field has failed to identify any research, analysis, or discussion specifically focusing on the crucial connection between these three topics (i.e., disclosure, medical error, and the intensive care unit).

This dissertation seeks to address this substantive gap in the literature. Because these distinct topics are intricately connected, the dissertation deals with them in an integrated manner. The analysis explains that disclosure of medical error in the intensive care unit is so important to efforts to improve patient safety that protocols must be in place to prevent these errors and to handle their consequences in a manner consistent with the highest standards of biomedical ethics when they do occur. The various reasons that disclosure of medical errors in the intensive care unit is so important include:

- A. The ICU is a constantly changing environment, which is the confluence of patients at high risk with critical, often life-threatening and immediate treatment needs and multiple care providers, who routinely manage complex interventions and intensive monitoring under stressful conditions.
- B. There exists a clearly definable correlation between certain groups of patients and the likelihood of experiencing positive health outcomes, based on patient demographics and illness or injury, with ICU patients, by definition, falling into one of the least promising of categories. For example, during 2005 among hospital ICUs throughout the U.S., 20% experienced an event with negative consequences. Among such events,

45% of which were later found to have been preventable while 13% of the latter group proved life threatening or even fatal. The rate of medical errors in ICUs is estimated to stand at 15 serious errors/100 patient-days, of which 11% are potentially life threatening; moreover, 78% of such errors occurred during treatment involving the administration of medication. The most prevalent type of errors consist of slips and lapses. First, given that patients who are in critical condition tend to be receiving on average twice the number of medications as their counterparts who are in the rest of the hospital, the severity of a patient's condition constitutes the strongest predictor of an adverse drug event (ADE). Second, given that they are in critical condition, ICU patients have fewer natural defense systems, and those that they have are severely weakened and far less able to cope with the physiological burden of ADEs. Third, even when their condition improves and ICU patients transition toward recuperation and/or less intensive levels of care, they face a significant lack of coordination and continuity in the lack of continuity of care beyond the point of discharge from the ICU. This extensively documented flaw in the medical care system creates an additional vulnerability, for the patient, to medical errors during the transition phase. In light of this weakness and its accompanying danger, coordination and communication between ICU staff and the patient's subsequent caregivers constitutes an essential, albeit neglected aspect of care.

C. The rapid advance of technology within healthcare in general and in the ICU in particular, has fostered a growing dependence on equipment and systems which are sophisticated, yet not thoroughly understood by those medical professionals who must employ them in administering essential care within the ICU. Moreover, medical

equipment failure and its associated safety risks and consequences is poorly understood at all levels. This complex clinical scenario presents the context for the bioethical analysis of the dissertation.

Two realities of the healthcare system in the United States are beyond dispute. First, as a group, patients being treated in the Intensive Care Unit (ICU) of any given hospital are the most vulnerable in terms of the seriousness and volatility of their conditions, as well as their need for extensive medical care to be delivered without delay. Second, throughout the hospital errors in the provision of medical treatment constitute a significant, even at times life-threatening danger to patients' health and well-being. Therefore, it follows that medical errors occurring in the ICU can be expected to have grave consequences and that eliminating or minimizing such errors should receive the highest priority. However, as this dissertation explores, medical errors in this part of the hospital are alarming both in respect to their frequency and to the severity of their ramifications.

The thesis of this dissertation is that there is an ethical obligation for disclosure of medical error in the ICU. Biomedical ethics facilitates a systematic analysis of the sources of error in the ICU to suggest a coordinated approach to preventing errors and to mitigating the effects of errors whenever they occur.

The analysis begins with a survey of medical errors in the ICU. This chapter is followed by a discussing of the ethical problems concerning medical error in the ICU. The subsequent chapter considers the ethical obligations of the medical staff and administration of the institution in terms of honesty to patients. Within this context of the

problem and obligations regarding medical error in the ICU, the following chapter examines protocols for disclosure and addressing the consequences of medical errors. The final analytical chapter suggests how to establish a systemic endeavor to diminish medical error in the ICU.

The following is a summary of the analysis that is described in the remaining chapters. This includes the extent of medical errors in the ICU, ethical problems that result, ethical obligations to patients, disclosure protocols in the ICU, systematic endeavors to mitigate these errors, and conclusions.

Two realities of the healthcare system in the United States are beyond dispute: first, that the Intensive Care Unit (ICU) of the hospital cares for and treats the most vulnerable patients in need of medical care; and second, that errors in the provision of medical treatment constitutes a significant threat to patients' health, up to the point of threatening their very lives. It is to be anticipated, therefore, that medical errors occurring in the ICU are of grave consequence. Indeed, as dissertation documents through an extensive survey of research to date, medical errors in this part of the hospital are alarming in their frequency and in the severity of their ramifications. As applied to this increasing problem, the fundamental principles of biomedical ethics require nothing less than: 1) a thorough, systematic analysis of the sources of error within the ICU, 2) handling the consequences of medical error with full disclosure and sensitivity to the religious and culturally expectations of patients, 3) to the greatest extent possible, reversing, mitigating, or otherwise dealing with any negative effects of errors whenever they do occur, 4) establishing protocols for handling all aspects of dealing with medical

errors, mindful of the need to counteract disincentives to full disclosure, as well as the patient's condition, needs, and concerns and 5) taking a comprehensive, coordinated approach to preventing error to the extent humanly possible.

The dissertation surveys the potential causes of error in the ICU from the smallest causes that may or may not lead to injury and loss to the largest potential causes that can lead to death. In addition, it describes in detail the extent of medical errors in the ICU, including those within the broadest scope, namely all occurrences which consist of unintended failures of one kind or another that are not caused by the disease, injury or the condition being treated. Moreover, the types of these errors will include both errors of commission (execution, planning, diagnosis, delays, medication, complex equipment failure, communication error) and omission (lack of prophylactic treatment, and missing or poor medical management). From a larger perspective, the dissertation provides overall statistics regarding the human impact and cost of medical errors.

Following this analysis of the errors themselves, the discussion focuses on the biomedical ethical challenges that medical errors pose for healthcare providers and the ethical obligations that the medical staff and institutional administration have in responding to these errors. Next the dissertation elaborates on those ethical principles, overtly expressed by the American Medical Association and the American College of Physicians, which call upon medical providers to fully disclose all relevant details of medical errors to all patients, holding themselves (the medical professionals) accountable for their actions. The dominant ethical theories that stand behind these recommendations and guidelines will be analyzed including the consequentialist theory, which focuses on

medical outcomes rather than the process; utilitarianism, which focuses upon the use of resources, delivering the greatest good to the greatest number of people; and deontology, specifically its variant – principlism – the polar opposites of consequentialist theory, in which moral process principles dominate, namely the principles of autonomy, justice, beneficence and non-maleficence. The dissertation demonstrates that while these varying approaches to ethics may disagree, and even lead to ethical dilemmas in the practice of healthcare, they are unanimous in their position on how to treat the patient who has suffered the consequences of a medical error.

In addition to these broad principles, there are also western cultural and religious ethical expectations and attitudes that specifically apply to what to do following the occurrence of a medical error. Specifically, certain principles and societal expectations hold individuals and institutions accountable for the harm they create which results in losses and costs to others. Applying these principles to medical errors in the ICU, all involved parties connected with the institution, the hospital itself and medical professionals working in that setting, are ethically responsible to disclose, fully confess, apologize with contrition, compensate victims and ask for forgiveness. Not fulfilling these expectations may further traumatize the victim psychologically and physically, in this case the ICU patient, and furthermore, may initiate legal action. Statistics attest to a significant deviation in practice from these expectations, indicating a major weakness in current medical institutional behavior; it has been estimated that there may only be 30%compliance with these expectations in the wake of medical errors in U.S. hospitals. Potential reform here would first include the proper notification and documentation of the medical errors that occur – critical procedures that are rarely followed at present.

With this foundation, the dissertation will then elaborate on protocols for disclosure and handling of the consequences of medical errors addressing scope and scale of errors, acceptance of responsibility, considerations involving risk of patient outcome and loss, management of the risk to the medical institution, anticipating consequences, disclosure timing, apologies and losses, and compensation.

Finally, the dissertation focuses on establishing the systemic, preventative approach that will be necessary in order to bring the problem of medical errors in the ICU under control. Protocols will be called for to reduce the amount and severity of medical errors including prevention planning, better communication, better medication execution, and planning to prevent, or if not possible, deal with equipment failure. The elimination or reduction of system failure and tort reform will be recommended although these two goals are beyond that which can be addressed through the establishment of protocols.

Chapter 2 provides, in broad scope, a picture of the prevalence and frequency at which medical errors of various types, causes, and characteristics occur in the intensive care units of hospitals throughout the United States. In order to proceed, it will be necessary to understand how medical errors have been defined and understood in general within the field. Further subsections will classify the types of medical errors that may occur, survey the statistics which document the frequency and severity of the problem, and analyze the principal risk factors that increase the likelihood of errors occurring.

The sub-section of the chapter defines medical errors, analyze the potential for their occurrence in general, and enumerate various types or categories into which they fall. In particular, the discussion will lay the foundation for the position that the

propensity for a type of error to occur is related to the medical setting, such as the hospital ICU and that this relationship will be important in proposing measures to combat medical error in general.

In the abstract, medical errors may be defined to include all those occurrences, actions, and their results, which are neither intended as part of the course of prescribed treatment nor directly attributable to the disease, injury, or condition being treated.1 Thus, in the hospital Intensive Care Unit (ICU), a wide range of occurrences can be classified as medical errors, including the administration of incorrect medications or dosages, the improper administration of infusions, errors in the use of medical equipment, deviations from standard protocol, as well as any other unintended variation in the course of patient care that could compromise proper medical treatment.2 The Institute of Medicine characterizes medical errors more broadly, thereby including any failure in following through to completion on a prescribed plan for treatment, as well as the intentional implementation of any inappropriate plan or steps in such a plan.3

Frequently, these errors inherently cause some form of harm or setback to the patient and his or her recuperation process; furthermore, they may vary widely in the severity of their consequences.⁴ As Angus and Carlet note, the effects of medical errors may be so slight as to cause no physiological or biochemical difference in the patient, thus requiring no rectifying action. On the other hand, over much of the continuum of severity the error adversely affects the patient, necessitating treatment specifically for the purpose of correcting or mitigating the damage and restoring the patient's health.⁵ Complicating the issue, these adverse consequences can be temporary or permanent, even

to the point of causing death. In order to provide more precision, the Ohio State University Severity Scale was created to serve as a seven level basis for assessing the severity of effect of the medical error on the patient, as follows: a) Level 0 for errors that are caught and dealt with promptly enough that the patient does not experience any effects from them; b) Level 1 for errors that cause no change in the patient's clinical outcome; c) Level 2 for errors that necessitate increased monitoring but possibly no action; d) Level 3 for errors that require additional laboratory tests, or produce any alteration in vital signs; e) Level 4 for errors the require either additional treatment or procedures, a prolonged stay in the hospital or (re)admission to it; f) Level 5 for errors that either result in admission to the ICU or necessitate invasive procedure, or otherwise cause irreversible harm; and g) Level 6 for errors that are ultimately fatal.6

Bauman and Hyzy have asserted that in spite of the intensive training which the large majority of health care professionals assigned to ICUs are required to go through, the fact that these individuals are human beings inherently means that they will from time to time, commit errors.⁷ Furthermore, the ICU, along with other hospital units, is an environment of medical care that is especially vulnerable to the occurrence of errors.⁸ Bohomol et al, credit the Institute of Medicine's 1999 report, which bears the clichéd title *To Err is Human*, with focusing the attention of the community of medical professionals on the extent and seriousness of medical errors and their adverse consequences.⁹ The very nature of the life threatening severity of illnesses and injuries that lead to admission to the ICU presupposes a significantly elevated potential for errors in treatment, along with an elevated level of seriousness in their repercussions. Fundamental to this need for constant

monitoring, intensive and complex treatment interventions, and urgent response to critical situations is the greatly increased risk of medical error.¹⁰

The potential for medical errors to occur is inextricably linked to the fragmentation of healthcare services, as opposed to their being integrated into a functioning network system.¹¹ McGowan and Healey, noted that this fragmentation forces the patient into interactions with numerous providers in various environments. These researchers contend that the resulting lack of access to complete information, coupled with the disincentive to take on expanded responsibility or admit responsibility for mistakes, creates an environment that actually fosters medical errors, increasing their likelihood and frequency.¹²

In pursuit of the goal of dealing with medical errors, various researchers have categorized potential errors according to how they occur. Among the most frequently occurring types of errors is that of execution, which involves a presumably efficacious plan for treatment that is not implemented as prescribed and thereby yields negative consequences.¹³ Distinct from errors of execution are those that result from failures of health care providers in creating a plan for treatment, either by neglecting needed steps or procedures or by calling for those that have unjustifiable risks in relation to anticipated benefits. Detailed contrastive analysis of these two types of errors leads to the conclusion that in addition to the errors themselves, errors of execution and errors of planning differ in the settings in which they most often occur, which individuals in the system most often commit such errors, and how the errors are to be remedied.¹⁴

A third distinct category of medical errors are known as diagnostic errors consist of the failure to accurately diagnose either an initial condition which the patient has or a subsequent development in the course of treatment; such errors are relatively common in the ICU.15 Obviously, safe and effective medication and treatment cannot be implemented in the absence of proper diagnosis; moreover, the consequences of such inaccuracy are far more serious and potentially life-threatening in the ICU.16 At the same time, however, delays in diagnosis prompted by an effort to be certain of accuracy have an equal potential for serious or even fatal consequences. Thus, if not thoroughly justifiable, such delays also constitute medical errors.17

Given the conditions of those patients who populate the ICU, the most rigorous measures to prevent the introduction or spread of diseases must be adhered to. Consequently, any lapse in preventative procedures or failure to provide prophylactic treatment to patients in need of it constitutes a serious medical error. Another set of medical errors closely related in terms of how they transpire arises out of the inability of ICU staff, for whatever reason, to follow through with the administration of all treatment protocols, the implementation of which necessitate continuous monitoring.18

Medication errors, by contrast, represent the commission of an inappropriate act rather than a failure to take proper action.¹⁹ This category of errors includes not only administering the wrong medicine or dosage, but also any deviation from prescribed procedures in administering the medication which would compromise the efficacy of the treatment. In the ICU, the most prevalent occurrence of this type of error stems from one of two mistakes; either a health care provider prescribes the wrong dosage or even the

wrong medicine itself, or else the healthcare worker misinterprets written instructions. Either of these errors can easily lead to critical consequences for a patient in the ICU.20

Beyond the obvious, direct medical errors of omission and commission described above are failures of those activities, entities, and technologies that need to function reliably in support of the delivery of care. One of these categories of medical errors can be characterized as failures at communicating effectively. Given the added urgency of the circumstances surrounding a patient's being in the ICU and the greater numbers of physicians, healthcare workers, and support staff involved, the need for timely and accurate communication cannot be overstated.21 ICU facilities depend upon equipment functioning properly, in some cases to provide automatic delivery of supportive care, while in other cases to monitor and deliver accurate, up-to-the-second information about the patient's status. Any technical failure of this equipment constitutes a medical error.22 Complicating the issue, the source of this failure may be either a defect in manufacture or either improper use or simply overuse of the equipment. The error may also occur due to the institution's neglecting to inspect and ensure that the equipment is functioning properly; on the other hand, the malfunction may be undetectable despite rigorous monitoring until the moment it occurs. As a defined and integrated health system, the ICU must have all support systems, whether human or mechanical, functioning dependably; otherwise, medical errors are all but inevitable.23

Given that the organizational structure of hospitals is extremely complex, effective management at all levels is essential for the coordination of interacting systems, which in turn is necessary for the prevention of medical errors.24 In spite of these

seemingly obvious considerations, the extent to which many institutions fail to address this need for effective management in the ICU is remarkable and contributes significantly to the occurrence of medical errors. Poor medical management has been documented in numerous cases as an underlying cause medical errors and their negative consequences. Conscientious management needs to be a high priority for health care institutions for a multitude of reasons, not merely for the prevention of medical errors. Given the seriousness of the conditions that place patients in the ICU, hospitals need to place the proper management of this area of the institution at the top of their priority list.25

Human error can be defined broadly and typically plays a role in the aggregate, whether it is due to negligence, substandard performance of duties, or failure to be vigilant in monitoring; as a result, human error is often viewed as the primary cause of a majority if not all errors in the hospital setting overall and especially in the ICU.26 Consequently, much of the research to date into medical errors in the ICU has concentrated on human error as the principal source. Even recently, some theorists have conceived of critical medical errors as solely the result of an anomaly within the performance of the healthcare staff, based upon the assumption that all systems of procedure and technology in the ICU would otherwise function perfectly.27

The next sub-section begins with an overview of facts and figures documenting the frequency of medical errors and their associated costs, comparing in-patient versus out-patient errors rates and explaining how despite the high level and complexity of risk for medical errors in the ICU, such factors may still be isolated and analyzed as a prerequisite to being eliminated or at least minimized.

Although precise calculation may be impossible, a recent study estimates that as many as 20% of Americans pass away after a final hospital stay involving time in the ICU. Whether or not these patients survive, they often endure prolonged pain and suffering while being obligated to pay for their treatment and care.28 Quantifying the cost, Multz has estimated that expenditures on ICU care reached approximately \$62 billion in United States in 1998, constituting 34% of hospital budgets and about 1% of U.S. gross domestic product. Both the potential benefits and the costs in the ICU are enormous, making the problem of medical errors in that part of the hospital of vital significance. Notably there are at least twice as many medical errors in the ICU as occur in any other hospital unit.29 One major study claims that for every critically ill patient spending time in the ICU, approximately 1.7 medical errors of some level of seriousness occur each day; furthermore, it is quite common for a patient to have at least one life-threatening error occur during the course of his or her treatment in the ICU.30 If anything, such statistics grossly underestimate the frequency of medical errors since their documentation depends on self-reporting – a method that has been demonstrated to be flawed in favor of underreporting. Even in teaching hospitals, where monitoring is more intensive and reporting is a high priority, a tremendous gap has existed between the intention to report and the actual act of doing so.31

While the determination as to whether an individual patient has died directly because of a medical error is complicated and in the end often a matter of judgment and dispute, generally accepted estimates have concluded that somewhere between 44,000 to 98,000 people die annually because of preventable medical errors.³² McGowan and Healey cited the Institute of Medicine's report from 1999, which claimed that 98,000

deaths per year were attributable to preventable medical errors.³³ Summarizing the scope of the problem and the inadequacy of the response, Sultz and Young contend that the medical error problem in hospitals is quite well-known in the healthcare community, but largely ignored by those with the power and authority to effect change.³⁴

The same 1999 report from the Institute estimates the annual U.S. economic losses from medical error at \$17 to 29 billion dollars. While more recent 2008 data place losses closer to the lower end of that range, the \$19.5 billion dollar figure from the Millennium Research Group is still quite high, especially in light of an estimated additional 17 billion loss each year due to prescription errors.³⁵ In comparative terms, more individuals are believed to have died from consequences of medical errors that have perished in motor vehicle accidents or succumbed to either breast cancer or HIV. This highlights the seriousness of the issue and reveals the need for initiatives to ensure that medical errors are reduced. One contributing factor to the costs is that in the ICU in particular, patients run up huge additional expenses any time that a medical error must be treated, causing extensions of stay in the ICU, along with the added costs of new, corrective, or prolonged original treatment.³⁶

While research has been undertaken to compare inpatient with outpatient care, in terms of the cost of medical error, it is primarily the cost of errors in the context of inpatient care that is the subject of the dissertation's focus.³⁷ Unfortunately, research into the specific costs of medical errors within the ICU has not been addressed to any significant extent, making accurate extrapolation to the U.S. population as a whole impossible.³⁸ What is understood is that patients admitted to the hospital have a greater

risk of suffering the consequences of a medical error than do outpatients; moreover, among inpatients, those in ICUs are at greater risk that those in the general hospital inpatient population. The overall price tag for inpatient medical errors today (including those occurring in the ICU) stands at approximately \$2.7 billion annually.39

Numerous studies have established that the frequency at which different types of medical errors occur varies, depending on the origin and type of error, as well as other related factors.⁴⁰ For instance, in considering errors that are attributable to human mistakes, certain factors such as overburdening responsibility or understaffing will tend to increase the error rate and frequency while equipment failure will not be subject to the same forces.⁴¹ Despite the apparent complexity in the interaction of influential factors, research exists documenting common trends which explain the frequency of the various types of errors.⁴² Furthermore, one overarching factor in determining the types and frequency of errors in the ICU is the healthcare system that is in place in the specific institution. Procedures for drug storage at one facility may promote the likelihood of medication errors, while another hospital might be prone to errors that stem from poor communication systems.⁴³

The desire to better understand the sources and likelihood of medical errors has led to a notable amount of research into identifying risk factors.44 This sub-section of the chapter provides an in-depth analysis of these risk factors such as patients, medications and ICU equipment, and the mechanism by which they trigger medical errors.

A variety of factors, together with characteristics of the patient constitute risk factors for medical errors, all of which have heightened significance in the environment of the ICU. These factors include:

1) Severity of the primary illness or injury.

All those admitted to the ICU by definition already have life threatening conditions. However, medical experts are quick to note that the severity of these conditions can vary widely. The more severe the case is, the greater complexity exists along with greater propensity that any need for urgent action will confuse or hamper the ICU staff.45

2) Age related need for special care.

While most ICU patients have seriously weakened bodily systems, patients at the extremes of youth and advanced age are at greater vulnerability to injury cause by medical error. Young children, for example, have immature physiological system with less tolerance for any variation their level of treatment as the result of a medical error, especially when in the ICU.46

3) Extended stays in the hospital or ICU.

More lengthy stays in the ICU correlate with more complicated conditions, which in turn require adaptive treatment strategies, and consequently a greater potential for error.47 4) Patients under sedation.

Church and MacKinnon note that many of those in the ICU are under sedation as a necessary component of their treatment. Unfortunately, sedation dulls the senses which renders patients more susceptible to the effects of medical error.48

Medication errors form a category comprising a variety of things that can occur stemming from different risk factors for medical errors in general.⁴⁹ This variety of factors and their potential causes presents challenges for the anticipation and prevention of errors, given the multiplicity of possible triggers.⁵⁰ The three primary factors include:

1) Special types of medication.

As Bucknall notes, certain medications require highly precise and inflexible protocols of administration.⁵¹ Adding to this problem is the risk of confusion, given the plethora of combinations of active ingredients, with similar sounding names.

2) The number of medications.

It is a given that patients in the ICU normally need a combination of medications, which require carefully planning and administering protocols.

3) The number of interventions.

Sometime patients in the ICU present life-threatening conditions that may require a number of different interventions to save their lives. When such an intervention becomes necessary, the interactive effects of all medications currently or soon to be in the patient's system must be anticipated and allowances for these interactions must be made.52

According to Moyen and his colleagues, the potential for malfunctioning or failure of equipment constitutes another class of risk factors for medical errors in the ICU.53 These factors include:

1) The complexity of the environment.

The equipment and facilities that provide life support to patients in the ICU are quite sophisticated, yet must function with near-perfect reliability. Moreover, the ICU staff must be fully competent in their use.54

2) The need to handle emergency admissions.

A characteristic that sets the ICU apart from other hospital units is that those staffing the unit do not have the luxury of running checks on the equipment before use. Emergency admissions to the ICU may occur in rapid succession, challenging ICU staff to heightened competency and responsiveness at the same time.55

3) The multiplicity of care providers

The round-the-clock need for intensive care and monitoring in the ICU requires staffing, which consists of rotating shifts of numerous health care providers who possess varying levels of experience and understanding of the appropriate treatment and diagnostic procedures in relation to the equipment and to the patient.⁵⁶

This chapter of the dissertation focuses on errors in the ICU and consists of a broad category of occurrences, which are unintended failures of one kind or another and which are not caused by disease, injury, or the condition being treated. There are many potential causes of error in the ICU, the results of which can range from little to no effect

all the way up to serious injury and death. These errors include errors of commission (execution, planning, diagnosis, delay, medication, complex equipment failure, communication error) and omission (lack of prophylactic treatment, and absent or poor medical management). Most errors by far are medication errors. It has been roughly estimated that annually somewhere between 44,000 and 98,000 people die of preventable medical errors in the ICU, tallying economic losses between \$17-29 billion. Furthermore, twice as many errors occur in the ICU as in the rest of the hospital. More than a third of most hospitals annual budgets is spent on the ICU. Most patients admitted to the ICU have life threatening conditions, are weak, physically vulnerable, and under sedation, as well as in need of complex drug regimens.

Chapter 3 discusses medical errors in the ICU in the context of biomedical ethics, beginning with an analysis of the major principles of ethics which apply, including: autonomy, distributed justice, beneficence, and non-maleficence. Beyond this discussion, the section focuses on the process of preserving patient autonomy and informed consent in the context of the potential for medical errors interfering with the prescribed course of patient treatment.

In the broader context of medicine, as well as in the hospital environment, ethical conflicts arise from factors as diverse as the preferences and opinions of patients or their surrogates; the duties and professional judgments of physicians, specialists, and other medical staff; the administrative concerns of hospital management and legal counsel; and social concerns over equitable allocation of medical resources. It is incumbent upon all medical professionals to be conversant with the basic fundamentals of biomedical ethics

as applicable to hospitals and other institutional healthcare settings. These functions serve as guidelines for professional ethics.⁵⁷ An understanding of ethical principles by all those involved facilitates accomplishing the mission of the ICU, especially when urgent action is called for. Principles of ethics, such as respect for the patient's autonomy, justice (particularly with regard to resource allocation), beneficence, and non-maleficence are cornerstone values in bioethics, which play an enhanced role in the ICU.⁵⁸

Recognition of the prevalence of and need to prevent, or at least minimize, the effects of medical errors has already come to family practice and post hospital-discharge medical settings.⁵⁹ Ethics guidelines for doctors, nurses, medical researchers, and others in the healthcare field are already being implemented in various global settings, monitored by established ethics committees.⁶⁰ The attention to ethics in the broader context of healthcare is not merely a response to trends in litigation, but rather is part of the growing recognition of the burden placed on society as a whole when medical errors proliferate. By comparison, recognition of the need to address the problem of medical errors from the perspective of biomedical ethics has been slow to gain attention in institutional healthcare settings, such as in hospitals and their ICUs.⁶¹

As Youngberg and Hatlie, note the code of ethics adopted by the American Medical Association (AMA) obligates physicians to inform the patient of any mistakes they (the medical professionals) have made any time the error causes complications for the patient's health or medical treatment.⁶² This ethical disclosure responsibility extends to all pertinent facts concerning the occurrence. The only significant exception to this rule is in the case of an error that results in no material consequences to the patient's health or

prognosis. Despite years of rigorous medical training and this very concrete obligation, it appears that a significant number of medical practitioners are not cognizant of the ethical responsibility that is inherent in every piece of medical advice, directive, medication, prescription, or course of treatment they choose to give. Ethical practice requires that for every case in which the disclosure would lead to improvement of the patient's health, medical ethics demands full and honest disclosure.⁶³ The American College of Physicians, concurs on these demands, to which the ethical treatment of the patient obligates the doctor, calling on the physician to fully disclose all relevant details concerning errors in both procedure and professional judgment committed in the course of care. The condition is that this information should be material to the patient's wellbeing. It is understood that while any particular unintentional medical error may not qualify as improper, negligent, or unethical, the failure to disclose the error to the patient qualifies as all of these things.⁶⁴

One of the most applicable theories of ethics, consequentialism, or teleological theory focuses on the outcome of an action as distinguished from evaluating the action itself.65 Under this approach, the goal is to identify and pursue the optimal outcome under any given set of circumstances, such as a medical error, and subsequently to follow the best course of action in order to achieve those optimal results. Utilitarianism follows from this theory, advocating for the course of action that will bring the greatest good to the greatest number of people. Understandably, in the context of the ICU, this would hold accountable those people who are directly or indirectly involved in the effects of the error.66 Going back many centuries, consequentialists have called for the application of this theory on the basis of a belief in the fundamental benevolence of human nature.67
This utilitarian perspective clearly takes a position with regard to the allocation of healthcare resources, and in particular what happens in the context of the ICU.68 A consequentialist might label as immoral, or at least unethical, the heavy expenditure of funds and resources on surgery to benefit a single patient if it means that other patients cannot be helped. In sharp contrast to this position stands non-consequentialist theory. The tension in balancing these conflicting theoretical approaches as well as considering other approaches, such as the practice of triage, is what informs the ethical practice of medicine and its consequences for treatment in the ICU.69

In contrast to both consequentialism and utilitarianism, deontology, as espoused by Kant and Rawls, posits fundamental principles of ethics that individuals, in this case medical professional in the ICU, should always endeavor to follow without exception on the basis of duty as the foundation of all moral action.⁷⁰ Deontology asserts that moral rules are the fundamental criterion for judging whether an action can be considered ethical, making the consequences of actions whether harmful or beneficial largely secondary to the action's ethical basis. Following this approach could place the quality of a decision, for example by a medical provider, a priority ahead of the patient's outcome.⁷¹ A variant of deontology in the area of applied ethics – principlism - is founded on the concept of core principles – autonomy, beneficence, non-maleficence, and justice - which control and determine ethical behavior, while allowing for their being superseded in exceptional cases by compelling reasons.⁷²

The ICU has functioned as an essential component in the U.S. hospital system for more than half a century.⁷³ From its beginning, the ICU and its specialized treatment,

care, and interventions, which include increased monitoring and special equipment such as mechanical ventilators, have often though not uniformly extended and improved the quality of life for patients with severe and urgent medical problems. By the late 1970s, the necessity of possessing a distinct skill set in order to care for ICU patients within ethical guidelines had become apparent to members of the nursing profession who focused on matters of ethics.74

Conflicts among the four basic principles of biomedical ethics constitute the source of most of the ethical dilemmas that arise in the ICU, those principles being: 1) autonomy, 2) distributed justice, 3) beneficence, and 4) non-maleficence. Ethical dilemmas today constitute an almost routine concern in the ICU, one of the most fundamental examples being whether to administer potentially lifesaving medicine to a patient who vehemently opposes doing so. Efforts to appeal to the judgments of experts in the field serve merely to create yet another dimension to the controversy.75

By virtue of their need to be there, patients in the ICU are more likely to be suffering impaired decision-making capability, sometimes even in the extreme. The patient's judgment is likely to be impeded, not only by the organic disease, condition, or injury which sent the individual to the ICU, but also by the symptoms and side effects of the condition and its treatment. Such hindrances to sound decision-making could conceivably include metabolic disturbances, pain, sleep deprivation, or sedatives.76 Therefore, the responsibility of medical professionals in the ICU is to ascertain the patient's ability to competently give informed consent prior to taking any action with potentially life-changing consequences.77 The situation is complex considering the

heightened mortality rate in the ICU, coupled with the fact that each patient's condition is unique and may involve decision-making competence in some matters, but not in others. This problem necessitates a decision based on evidence from the patient's medical history and a mental status assessment, along with input from other healthcare professionals and family members. Any suspicion or disagreement may constitute sufficient cause for gathering additional information, and possibly even a formal psychiatric consultation at the patient's request.78

As these considerations apply to medical errors, respect for the ethical principles that are overtly expressed by the American Medical Association and the American College of Physicians calls upon all providers of medical care to fully disclose all relevant details of medical errors to all patients (patients, surrogate family members, hospital, regulators, insurers) in such manner that these medical professionals hold themselves accountable for their actions. Several major theories of ethics stand behind these guidelines. In particular, consequentialist or teleological theory does so by focusing on the medical outcome rather than the process. Utilitarianism supports such accountability by focusing on the use of resources, delivering the greatest good to the greatest number. Deontology or its variation, principlism, although the polar opposite of consequentialist theory dictates that moral process principles should dominate, namely autonomy, justice, beneficence and non-maleficence. These ethical principles stand in contrast to one another, prompting biomedical ethical dilemmas almost daily in the ICU. An example of one persistent dilemma is the extent to which patients are competent to provide informed consent for various medical interventions necessary or desirable to resolve their medical needs.

Chapter 4 begins with an analysis of Western cultural and religious attitudes that shape expectations of how those involved should respond to the discovery of a medical error. The discussion leads into the more focused consideration of what patients specifically are likely to expect in such cases. Next, the section considers the process of disclosure of and apology for medical errors, including barriers to full disclosure, ethical perspectives, and the importance of having a specific, detailed, and predetermined disclosure process, as well as an examination of key features of that process.

Given the state of science and information technology, along with an increased understanding of ethical considerations, patients in western, developed nations are in a position to become aware of mistakes and errors made by medical professionals and institutions in the course of their treatment. Moreover, patients in these countries are empowered to assert their rights and take appropriate action in response to medical errors (MEs).79 Interacting with this likelihood that MEs will be detected and trigger action are certain underlying moral tenets of the Judeo-Christian tradition, which call for responses to MEs in terms of confession, repentance and forgiveness.80 Berlinger and Wu describe the impact that these traditions have on expectations of ethical conduct in relation to errors in terms of a set of functionally specified actions with expectations for both the party causing the harm and the party that has been injured. The offending individual is fully expected to disclose the error to all affected parties and apologize for it, an action often referred to as confessing.81 This action may include an explanation of the reasons for the error, but must be accompanied by an expression of contrition for the harm caused and a good faith effort to provide compensation and restitution to the extent possible. The

injured party is then expected, at the point when it becomes appropriate, to respond with some form of absolution or forgiveness.82

Based on an extensive evaluation of multiple research studies, Robbenolt concluded that the primary motivation behind lawsuits triggered by the occurrence of medical errors is the goal of establishing the ultimate causes of the error and ensuring that such errors are not allowed to recur.83 A significant additional or alternate motivation is monetary compensation, which those experiencing harm from the medical error believe is justified to alleviate the physical and emotional trauma and any monetary loss resulting from the medical error. Institutions such as hospitals typically have established policies and procedures designed to minimize medical errors and the resulting law suits in order to preserve their public reputation, goodwill, and prospects for continuing the provision of health services. However, these institutions have been less likely to have in place fully transparent internal and external policies and procedures for the disclosure of medical errors and acknowledgement of responsibility, largely due to the potential uncertainty and adverse consequences brought on by the involvement of courts, regulators, and insurers.84

Beyond monetary compensation, patients and families injured through medical errors seek to secure a commitment to and plan for correcting the physical and psychological results of the error, as well as to insure the medical and healthcare support needed to cope with the effects of the error.85 From the standpoint of ethics, disclosure of information relating to minor, less impacting medical errors is no less the duty of physicians and hospitals in cases for which it will not affect subsequent treatment.86 In addition to helping provide continuity of medical treatment, the disclosure of errors forms

an essential part of the foundation of any relationship of trust between medical professionals and their patients - a fundamental purpose behind the comprehensive codes of ethical conduct formulated by medical bodies such the American Medical Association.⁸⁷ Wolf and Hughes have analyzed various ethical considerations implicit in the reporting and disclosure of medical errors, along with any negative consequences to patients and other related parties. By respecting the autonomy of the patient, the medical professional is able ascertain whether the patient has been harmed in the first place. These authors conclude that adherence to the ethical principles of fidelity, beneficence, and non-maleficence ensures that the effects of any medical errors will be minimized.⁸⁸

The sub-section of the chapter focuses narrowly on contrasting the negative consequences of withholding information or avoiding disclosure in the wake of a medical error and the duty, along with the positive effects of full disclosure.

One situation which could foreseeably prompt hospitals and medical professionals to withhold information about medical errors would be a scenario in which the motive for withholding was to avoid causing any more distress than was necessary to patients, thereby avoiding further physically or psychologically incapacitating or traumatizing the patient.⁸⁹ Edwin provides a strong counter to this argument, by asserting the importance of physicians' and hospitals' acknowledging and disclosing errors rather than having the patients or family members learn of the errors from another source, thereby jeopardizing the trust relationship. Supportive of this argument, honest and timely disclosure has been linked to lower level of distress in patients.⁹⁰ Hammami, Attalah and Al-Qadire have found corroborating evidence in studying the direct relationship between patients'

reactions to and the source from which they learned of medical errors, with the patients showing a clear preference for being informed by the at-fault physician in the case.91

Aside from the cogency of various studies which demonstrate that the nondisclosure of medical errors on the part of staff who are at-fault can stimulate negative reactions potentially leading to legal action, physicians and other medical professionals are obligated to disclose any and all errors at the earliest time, according to codes of ethical conduct, as well as their fiduciary duties.92 Edwin asserts that the relationship between doctors and those in their care constitutes a fiduciary rather than a transactional relationship, necessitating good faith trust, confidence, and candor. Such a relationship enables the achievement of the ethical principles of autonomy, non-maleficence, beneficence, and justice for both parties at all times.93 Beyond adherence to these principles, Finkelstein et al. highlight the mandatory nature of complying with ethical, as well as fiduciary requirements, which would require physicians and institutions to both apologize for medical errors and provide monetary compensation. The foundations of medical ethics guarantee patients access to all forms of information that they might need in order to make informed decisions regarding their treatment, thus necessitating disclosure of medical errors.94

A fundamental discrepancy exists between the expectations of medical professional and those receiving treatment as to the circumstances under which disclosure of medical errors is warranted.95 Physicians and colleagues tend to see the issue as a balancing of risks against benefits both for and against disclosure, presuming circumstances in which they would appropriately decide to conceal an error. Patients in

contrast, when asked hypothetically, would say they expect complete disclosure with all relevant information regardless of the circumstances.⁹⁶ The result of this discrepancy of expectation has been analyzed statistically, showing that medical errors are followed by full disclosure and apology in no more than 30 percent of the cases where they have been documented to have occurred, often in spite of the patient's need or expressed request for full information.⁹⁷

It is imperative that both physicians and hospitals have an established, detailed process in place, along with a commitment to disclose medical errors that have threatened patient's wellbeing, following it systematically in preparation for whenever there are medical errors to be disclosed. This process begins by ensuring the discovery and documentation of all relevant information, along with its corroboration by medical specialists wherever needed.98

As part of the process of preparation for disclosure, both institutions and the procedures they implement need to anticipate, acknowledge, and prepare to deal with emotional responses from those on both sides of the occurrence. On the part of physicians and medical staff, who are or may be perceived to be at fault, there are likely to be feelings of failure, incompetence, and self-deprecation, as well as fears of legal liability.⁹⁹ These feelings may be expressed in efforts to gloss over or withhold relevant information or to deflect blame and must be countered with institutional support for full disclosure as the ethical course of action. On the part of patients and family members, there are likely to be feelings of betrayal, anger, fear of unidentified negative consequences of the error, and a tendency to suspect a cover-up by responsible

authorities, all of which can easily lead to mistrust.100 Risk management personnel are critical actors in the disclosure process, in particular if there is any likelihood that the error could lead to additional injury or trauma to the patient beyond the condition which is already being treated. At the same time, the disclosure process should include only the minimum of those directly involved, including risk management and medical staff directly, so as to avoid the patient feeling confronted by an overwhelming adversary, as well as to ethically preserve the patient's confidentiality.101

Proper notification and documentation, both of the standard implementation of procedures in treatment and of any non-routine or unanticipated results, is critical to effectiveness in disclosing MEs.102 While the institution's policies and procedures play the dominant role in how effectively the disclosure of any given error is, thoroughness in reporting and documentation encourages, as well as signals, the preparedness and willingness of the at-fault medical staff to admit and fully disclose all errors. When the mechanisms for reporting and documenting errors involve only the physicians and other staff at-fault, complete and accurate descriptions, necessary for full disclosure, as well as subsequent prevention of reoccurrence, tend to suffer. Therefore hospitals need to make sure that general physicians, risk managers, heads of relevant agencies, and specialists in patient safety play a crucial role in the process of investigating and documenting any and all errors.103 Beyond the documentation of occurrences of medical errors, hospitals should have procedures in place to document near-miss events since information about them can be invaluable in establishing patterns of heightened risk and in enabling preventative measures to be taken, or in countering allegations of a pattern of negligence.104 According to Fein et al. issues surrounding disclosure arise from several

sources. For one, healthcare professionals and institutions have issues stemming from fears of potential outcomes, as well as concerns about their training in dealing with errors and their overall professional responsibility. Issues involving patients relate to their desire for information, their sophistication in following the course of their healthcare, and the quality of their relationships with their physicians. Patients are also concerned about issues related to the extent and level of the harm caused by the error and who is aware of its occurrence. The degree to which the institution accepts the inevitability of error and maintains a supportive infrastructure has the greatest influence on the likelihood of full and accurate disclosure. An understanding and prior consideration of all the above factors enables the development of a system which can promptly detect, document, and mitigate the adverse effects of errors in the maximum number of occurrences.¹⁰⁵

Fundamentally, western cultural and religious attitudes form the basis of the medical disclosure process in that all individuals and groups are held accountable for any harm they create that results in losses and costs to others. As this applies to medical errors in the ICU, all parties connected with the ICU – the hospital, as well as medical professionals and staff are ethically responsible to disclose, fully confess, apologize with contrition, compensate victims and ask for forgiveness. This is a societal expectation. Not doing so may further psychologically and physically traumatize the victim, in this case the ICU patient. Such failure may also initiate legal action. Despite the pervasiveness of these dictates of society, there is a clear gap between the cultural and religious expectations and the behavior of medical care providers, which has been estimated to leave expectations unfulfilled in nearly 70 percent of cases, calling for major

a change in institutions' procedural behavior. Proper notification and documentation of medical errors is a critical first step in closing this gap.

Chapter 5 describes the issues involved in establishing and implementing protocols for disclosing medical errors whenever they occur. Issues which must be addressed through protocols include: ethical acceptance of responsibility, anticipation in terms of risk management, determination of known and foreseeable consequences, identification of patients in the process, and timing of disclosure. Specifically, individual protocols which need to be adopted will be discussed in relation to acknowledgement of responsibility, and compensation.

The scope and scale of medical errors in the ICU span a spectrum that begins on the low end with no error and ranges through errors termed unnoticed, inconsequential, minimally unsettling, to those deemed discomforting, all of which may be labeled as minor errors.¹⁰⁶ At the other end of the spectrum are those errors classified as major, which include those labeled as troublesome, disabling, or life threatening, all the way up to those which prove fatal. From one perspective, every medical error creates a disruption, in turn necessitating corrective action due to undue effects or at minimum a modification of prevention procedures; nevertheless, all errors do not merit the same degree of response or action.¹⁰⁷

While minor errors cause minimal injury, disruption, or damage, it is clear that the public expects full disclosure of even these types of error. One of a number of groups with similar research findings, a New England health maintenance organization (HMO) recently found that 92% of respondents in a hypothetical survey thought that every

medical error ought to be disclosed, regardless of whether it led to any injury or harm. In another study, only 12% of those surveyed felt it was acceptable not to inform an affected patient if the error had not affected his or her health. Similar attitudinal results have been obtained using focus groups.¹⁰⁸ Biomedical ethics, professional codes of conduct, and public perception are in unanimous agreement on the necessity of full disclosure of major errors, given that they endanger patients, potentially leading to death or serious physical or psychological injury, and as such demand immediate responsive action. Errors involving medication constitute the most frequent of any type in the ICU, likely because of the complexity of administering such a variety of medications, accounting for approximately 78% of all serious medical errors.¹⁰⁹

The standard protocol for the delivery of each individual medication to each ICU patient involves five steps: prescription, transcription, preparation, dispensation, and administration; these steps in turn subdivide into as many as several hundred sub-procedures with the potential for error at each step in the process. Thus, the risk of error for any given patient is high, and it is remarkable and to the credit of ICU staff that, as frequently as errors do occur, there are not many more of them.110 A study which ranked the frequency of medication errors in terms of the five steps in the process, found the majority to have occurred during the last step - administration (53%) - followed by prescription (17%), preparation (14%), and transcription (11%) in that order.111

Rooted in Judeo-Christian ethics and its traditions of confession, repentance, and forgiveness, the generic protocol presented here emphasizes accepting ethical responsibility for the medical error, fully disclosing the circumstances and consequences

of the error, and apologizing and being accountable for the error, as well as mitigating, correcting effects of and preventing future occurrences of the error.¹¹² These principles form the foundation for professional medical standards in organizations, such as the AMA, ANA, ACP, and ACEP. From another perspective, this process is a necessity for the medical professionals involved, so that they experience the absolution that leads to the self-forgiveness, which in turn allows them to continue providing medical care to others in need.¹¹³

Protocols involving disclosure need to be focused primarily on patient outcome rather than on the complex details of procedures and their implementation.114 Three principles ought to guide such disclosure: 1) the use of language should be easily comprehensible to the layperson, both in terms of vocabulary and grammar, in all communications between medical professionals and patients; 2) an explanation of medical error protocols should be provided in terms of risk or injury, rather than simply a description of the error and its antecedents; and 3) a clear explanation of corrective options for dealing with any eventualities should be included.115

Consistent with principles of ethics as applied to healthcare on a broader scale, the use of informed consent is particularly appropriate when those medical interventions such as are common in the ICU involve foreseeable, elevated risks of error, injury, or even death. As part of the protocol, the written permission should be supported by a verbal discussion of risks and benefits, conducted so as to insure that the patient or surrogate fully understands what is being prescribed as treatment.¹¹⁶

The format of the informed consent document should conform to principles of communication already discussed, should be integrated with any future communication in the event of medical error, and can even incorporate information on anticipated remedial procedures for foreseeable errors and unanticipated occurrences.117

When there is any potential for danger or harm, humans have a seemingly innate dislike of uncertainty; unfortunately, medical treatment typically involves both of these components.118 Therefore, any protocol for advance communication of the timing of and of what to expect during the course of treatment provides relief from concern or worry, circumstances which create a clear path for avoiding errors, and a means for understanding errors in context, should they occur.119 Although not always possible in the ICU, wherever it is feasible, such pretreatment disclosure incorporates the patient into the process of medical decision-making and implementation, setting the foundation for understanding the potential for medical error.120

For any case of treatment in the ICU, patients include not only the patient and his or her immediate family, but also the hospital, all members of the medical team providing direct or supportive care, the patient's insurance provider, and government regulators (as representatives of the Centers for Medicare and Medicaid Services). Proactive disclosure to patients, possibly as part of informed consent documentation, would go a long way toward minimizing unnecessary uncertainty. Such disclosure would need to cover any risks involved with anticipated interventions and outcomes, along with contingency procedures for the mitigation of harm in case of a major medical error and advance provisions for disclosure to all relevant parties.¹²¹

Medical errors that are minor in their consequences may be addressed through protocols for informal apology and would typically involve the patient and immediate family, friends or other acquaintances as the situation dictates, the medical caregiver team and colleagues.¹²² In contrast, formal apology protocols need to be established beforehand in anticipation of the consequences of major errors, as well as of the need to involve a broader range of parties, including those more indirectly connected to the event. Drafting a thorough outline for formal apologies to be given in the case of such events with provision for adding the specifics would be perspicacious, as it would reduce the potential for compounding problems through errors in communication.¹²³

On one hand, adequate and fair compensation is demanded by the principles of biomedical ethics and potentially requires adjudication and enforcement.¹²⁴ On the other hand, when compensation can be agreed to without having to resort to formal legal procedures and the creation of an adversarial relationship, the cost in terms of time and resources consumed, distraction from regular responsibilities, and emotional stress is greatly reduced. In order to achieve both of these goals simultaneously, specific protocols in terms of detailed compensation criteria, procedures for validation and payment, prescribed forms of and limits to compensation, need to be developed and made publicly available before the occurrence of any error to which they might apply.¹²⁵

In the final analysis, a critical step in improving ethical behavior involves establishing and implementing protocols for disclosing medical errors when they occur in the ICU. Protocols need to be commensurate with the scope and scale of errors and proactively address the acceptance of responsibility, considerations involving risk to

patient outcomes and loss, management of the risk to the medical institution, anticipation of consequences, identification and involvement of patients, and disclosure timing, apologies, and compensation.

Beyond the protocols relating to disclosure, as described in the previous section, the chapter 6 of the dissertation is devoted to protocols required as part of the large effort to institute systems which will function to prevent or reduce the severity of medical errors. These protocols include prevention planning, communication, administering medication, as well as preventing and managing equipment failure and system failure. Subsequently, the discussion will center on the role of and prospects for tort reform, as a means of dealing with the legal issues surrounding medical errors.

The principle goal in planning is to avoid the occurrence of medical errors when and wherever possible, which involves anticipation of the risks, along with understanding their characteristics and probability of occurring, whether in the ICU or the hospital in general.¹²⁶ Prevention planning needs to address three facets simultaneously: 1) prophylaxis, i.e, concrete preventative actions in diagnosing and administering treatment; 2) monitoring; and 3) taking steps to avoid adverse events such as near misses, slips, lapses, mistakes, omissions, and commissions.¹²⁷ Steps as simple as providing checklists for procedures have successfully and significantly reduced the rate of errors in some hospital ICUs, diminishing the severity of the consequences of those errors.¹²⁸ In other institutions, situational risk factors such as sterilization procedures have been directly targeted, decreasing the life-threatening impact of staph infections.¹²⁹ Some hospitals have made significant improvements in cutting down on medical errors by adopting

investigative and evaluative procedures comparable with those used by the Federal Aviation Administration (FAA).130 Alternatively, a number of hospitals have taken the approach of fundamentally reorganizing their medical team operations in the ICU, adopting innovative models of staffing focused on promoting increased teamwork with diminished reliance on a single specialist in any given situation.131

Accurate, effective, and timely communication is essential, not only in preventing but also in dealing with medical errors.¹³² While the education of doctors is rigorous, broad in scope and in depth, and continuous, it is remarkably deficient in building communications skills.¹³³ At the same time, the need for these skills in interactions with patients and their relatives, colleagues, hospital staff and administrators, as well as with representatives of insurance companies and government agencies is critical, all the more so when dealing with the effects of a medical error.¹³⁴ Anywhere in the hospital, but especially in the ICU, communication mistakes may well damage or end careers, in addition to compounding the costs of a medical error exponentially.¹³⁵ While most physicians understand these dangers cognitively, many are nonetheless unprepared for the situation or unwilling to remedy this deficiency of skills.¹³⁶

Hospital administrations need to make fundamental revisions to two forms of protocols, namely in external communications, something far more extensive than merely expanding the use of informed consent paperwork or increasing internal communications between the care-giving staff, administrators, and support personnel.137

Within the environment of the ICU, medication errors predominate, most frequently at the point of final administration of the medication.138 Furthermore, it is a

significant cause for concern that such errors point to systemic deficiencies in training, communications, monitoring, or carrying out of protocols.139 This fact implies that such systemic errors may be the cumulative result of numerous sequential errors, each with its own source.140 This multiplicity of causes in turn, requires a systematic in-depth response in order to determine causes, which in turn involves time consuming investigation leading possibly all the way back to the earliest diagnosis, possibly through various settings outside the ICU.141

Equipment failure is perhaps the most frustrating and potentially difficult to handle among medical errors in the ICU, given that medical professionals and hospital administrations alike lack the expertise to diagnose machine weakness or malfunction; moreover, while control and prevention is at least initially in the hands of the equipment manufacturer, the healthcare provider is proximately responsible for preventing harm.¹⁴² Adding to the complexity of these circumstances is the fact that the varieties and uses of ever more technologically sophisticated equipment are increasing rapidly. Ironically, while hospitals and their personnel are increasingly less able to handle the maintenance of the equipment, they are becoming increasingly more dependent on its flawless operation.¹⁴³ Although both involve significant additional cost, the two most promising means of forestalling equipment failure errors would be having access to a sufficient quantity of backup equipment and involving manufacturing personnel more integrally in all phases of medical planning.¹⁴⁴

Undoubtedly the most difficult of any type of medical error to find and fix is system failure occurring at the junctures where systems interface or overlap, making it a

challenge just to identify the source or sources of the failure.145 The complexity of such failures makes each occurrence relatively unique, rendering any standardized set of protocols ineffective.146 Given that the ICU is the area of the hospital that is the nexus of the greatest number of interacting systems, it should not be surprising that medication failure, possibly the quintessential example of a system failure, is so prevalent in that part of the institution.147

From a legal perspective, the process by which a patient or relatives obtain redress, including compensation, for physical and emotional damage and economic losses suffered is part of tort law, which deals explicitly with medical errors as part of civil jurisprudence. While justice for victims of medical error is the purpose of legal recourse, there is a growing consensus that the goals of providing correction of injustice and compensation, along with deterrence of future injustices, are poorly achieved at best through the current legal system. 148 The tort systems currently in effect actually discourages patients who have been legitimately injured by physicians and hospitals from seeking redress in civil court, makes their chances of prevailing slim, and allows attorneys and others entities not directly involved with the original error and its consequences to take an inordinate share of any compensation. Faced with the rise in the incidence of medical errors, reforms have been proposed, and some enacted, aiming to deter negligence on the part of physicians and other medical professionals, albeit instituted typically in order decrease liability premiums rather than increase the safety of patients.149 Gilmour notes that such tort reform commonly includes capping damage awards, offsetting payments from collateral sources, limiting the fees lawyers can charge, instituting discretionary or mandatory periodic payments of damages, restricting the

labeling of damages in terms of joint and several liability, raising the standards for designating of a potential witness as an expert, along with various other measures. All these efforts at tort reform have primarily functioned to bring down the expense of malpractice litigation and the size of awards; however, at the same time they have made it much harder for injured persons to establish the liability of any negligent party and their own right compensation.150

The status quo is unacceptable; thus, educational, institutional-administrative, and legislative reforms are all mandated. Accomplishing educational reform begins in the curricula of medicine and nursing schools, where prevention and correction of the effects of medical errors needs to become an integral part of the curriculum, along with inculcating a respect for the fundamentals of medical ethics connected to errors of all types.151

Legislative reform must shift the focus away from suppressing medical liability toward patient safety. Previously adopted measures such as capping non-economic damages or attorney fees, setting statutes of limitation, and revising joint and several liability statutes are all actions that need to be reassessed in light of placing first priority on patient safety. Two other specific areas that will make tort reform more responsive to the need for ethics and justice in the face of medical errors are establishing or raising minimal standards for 'expert' witnesses and monitoring trends in the insurance industry with an eye to ensuring justice and ethical treatment for all parties.¹⁵² Continuing modification of pay-for-performance incentives can, in the long run, support litigationbased reform, while reforms to make Medicare more efficient and effective will further

help to prevent medical errors and provide rapid, comprehensive, and compassionate response on occasions when preventable medical errors add to the patient's medical problems.153

The aggregate effect of recent legal reforms has been to foster a 'conspiracy of silence' among medical professionals, from hospital administrators and physicians on down the ranks of the institutional hierarchy; in contrast, these individuals and the institutions for which they work need to take on the challenge of fostering ethical behavior towards combating and handling medical errors, which begins with developing and implementing appropriate error-reduction protocols, beginning with the ICU.154 These measures must be directed at creating a non-punitive atmosphere based on honest, thorough mechanisms that will encourage the prompt and full reporting of and learning from errors, while at the same time ensuring organizational accountability and just compensation for patients who have been harmed.155

On a scope far broader than just disclosure and apology, protocols are called for to reduce the frequency and severity of medical errors, which include prevention planning (prophylaxis, monitoring, avoidance of adverse events, organization of team operations), better communication (doctors to patients, relatives, hospital staff, administrators, insurers, and regulators), improved administration of medication (training, communications, monitoring, and protocol execution), and prevention of equipment failure (access to backup equipment and involvement of manufacturing personnel). Preventing system failures and tort reform would significantly help in reducing medical

errors, yet while they are conceivable they are beyond being effectively brought about through protocols.

Chapter 7 provides a brief conclusion to the dissertation. The inevitability of medical errors is beyond dispute as long as humans involved in providing medical care and treatment for illness and injury. The discussion presented here demonstrates that this reality hold true despite any level of skill or rigor of training; moreover, the propensity for medical errors is compounded, not alleviated by the increasing integration of technology and equipment into care and treatment. The setting in which the likelihood of medical errors is greatest and their consequences potentially the most severe and irreversible, with the highest probability of fatality is that of the hospital intensive care unit (ICU). This dissertation seeks: 1) to assemble and provide documentation of the alarming frequency and level of harm caused by medical errors in the ICU, 2) to categorize and analyze their causes and contributing factors with the goal of identifying measures to prevent and minimize the effects of as many errors as possible, 3) to present a framework for handling incidents of medical errors, which is based on the convergence of a variety of approaches to biomedical ethics, 4) to outline religious and cultural expectations of how those on both the causing and receiving sides should respond when errors occur, and 5) to propose a variety of protocols, which target specific aspects of vulnerability to the occurrence of medical errors in the ICU, along with proposals to address the broader scope of systemic problems which tend to promote medical errors.

This dissertation makes the case that, regardless of philosophical position within

the field, the biomedical profession must accept as ethically justifiable nothing short of a constant, vigilant effort to do everything possible to prevent medical errors. When errors occur in the ICU, standards of biomedical ethics and the profession demands a response that is full and honest in disclosing errors and their potential consequences to the patient and other patients; this disclosure must include the circumstances and effects of the error, an acceptance of responsibility for its occurrence, the proposed action to mitigate or correct any negative effects or repercussions from the error both direct and indirect, and proposed arrangements to compensate the patient for all negative impacts of the error. Given the high risk of medical error in the ICU, protocols must be in place to prevent these errors to the greatest extent possible; furthermore, the highest standards of biomedical ethics must form the foundation for procedures and actions taken when medical errors inevitable occur. The final two sections of the dissertation present specifics for establishing these protocols and proposals for dealing with system-wide barriers to combating medical errors in the ICU and elsewhere in healthcare.

Endnotes

¹ Grober, Ethan D, and John MA Bohnen, "Defining Medical Error." *Canadian Journal of Surgery* 48, no. 1 (2005): 39-44.

² McGowan, Michele, and Healey Bernard J., "The Enormous Cost of Medical Errors," *Academy of Health Care Management Journal* 6, no. 1 (2010): 17-18; Runciman, Bill and Merrilyn Walton, *Safety and Ethics in Healthcare* (Ashgate, 2007), 112.

³ Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (National Academies Press, 2000), 4; Brock, Douglas M., et al., "Physician Assistants and the Disclosure of Medical Error." *Academic Medicine* 89, no. 6 (2014): 858.

⁴ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 523-524; Bohomol, Elena, et al., "Medication Errors in an Intensive Care Unit." *Journal Of Advanced Nursing* 65, no. 6 (2009): 1262.

⁵ Angus, Derek C., and Jean Carlet, "Surviving Intensive Care: A report from 2000 Brussels Roundtable." Intensive care medicine 29, no. 3 (2003): 368-77.

⁶ Bohomol, Elena, et al., "Medication Errors in an Intensive Care Unit." *Journal Of Advanced Nursing* 65, no. 6 (2009): 1260-1261; Rothschild, Jeffrey M., et al., "The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious medical Errors in Intensive Care." *Critical Care Medicine* 33, no. 8 (2005): 1694-1695; Kopp, Brian J., et al., "Medication errors and adverse drug events in an intensive care unit: direct observation approach for detection." *Critical Care Medicine* 34, no. 2 (2006): 415–425.

⁷ Bauman, Kristy A., and Robert C. Hyzy, "ICU 2020: Five Interventions to Revolutionize Quality of Care in the ICU." *Journal of Intensive Care Medicine* 29, no. 1 (2014): 13-14.

⁸ Helmons, Pieter J., et al., "Effect of Bar-Code-Assisted Medication Administration on Medication Administration Errors and Accuracy in multiple patient Care Areas." *American Journal of Health-System Pharmacy* 66, no. 13 (2009): 1204-1205.

9 Bohomol, Elena, et al., "Medication Errors in an Intensive Care Unit." *Journal of Advanced Nursing* 65, no. 6 (2009): 1259-1260.

¹⁰ Gullo, Antonino, and Philip D. Lumb, *Intensive and Critical Care Medicine*. (Dordrecht: Springer, 2009), 78-80; Rothschild, Jeffrey M. et al., "Recovery from Medical Errors: The Critical Care Nursing Safety Net." *Joint Commission Journal on Quality and Patient Safety* 32, no. 2 (2006): 63-72.

¹¹ Dykes, Patricia C., et al., "Medical errors recovered by critical care nurses." *Journal of Nursing Administration* 40, no. 5 (2010): 241-246.

¹² McGowan, Michele, and Healey Bernard J., "The Enormous Cost of Medical Errors." *Academy of Health Care Management Journal* 6, no.1 (2010): 21-22.

¹³ Bracco, D, et al., "Human Errors in a Multidisciplinary Intensive Care Unit: a 1-Year Prospective Study." *Intensive care medicine* 27, no.1 (2001): 137-145; Wachter, Robert M., *Understanding Patient Safety* (McGraw Hill, 2007), 4-13; McGowan, Michele and Bernard J. Healey, "The Enormous Cost of Medical Errors." *Academy of Health Care Management Journal* 6, no. 1 (2010): 17-24.

¹⁴ Bedevian, Rima, "Medical Errors: How Can You Avoid Them?" Retrieved from: <u>http://www.plasticsurgerypractice.com/2010/06/medical-errors-how-can-you-avoid-them/</u>. Accessed Feb 28, 2015.

¹⁵ Graber, Mark, et al., "Reducing Diagnostic Errors in Medicine: What's the Goal?" *Academic Medicine* 77, no. 10 (2002): 981–992.

16 Al-Assaf, Al F., et al., "Preventing Errors in Healthcare: A Call for Action." *Hospital Topics* 81,no. 3 (2003): 5-12.

17 Wachter, Robert M., *Understanding Patient Safety* (McGraw Hill, 2007), 70-82.

¹⁸ The Joint Commission Resources, *Improving Care in the ICU* (Oakbrook Terrace, Ill: Joint Commission Resources, 2004), 56-60.

¹⁹ Calabrese, Andrea D., et al., "Medication Administration Errors in Adult Patients in the ICU," *Intensive Care Medicine* 27, no. 10 (2001): 1592-1598.

²⁰ Ehsani, Seyyedeh Roghayeh, et al., "Medication Errors of Nurses in the Emergency Department," *Journal of Medical Ethics & History Of Medicine* 6, no. 1 (2013): 4-5; Wachter, Robert M., *Understanding Patient Safety* (McGraw Hill, 2007), 41-50; Moyen, Eric, et al., "Clinical review: Medication Errors in Critical Care." *Critical Care* 12, no. 2 (2008): 1-3.

²¹ Naylor, Robert, *Medication Errors: Lessons Learnt for Education and Healthcare* (Abingdon: Radcliffe Medical, 2002), 67-70.

22 Abramson, Norman S., et al., "Adverse Occurrences in Intensive Care Units." *JAMA* 244, no. 14 (1980): 1582-1584.

²³ Manasse, Henri, and Kasey K. Thompson. *Medication safety: a guide for health care facilities* (Bethesda, MD: American Society of Health-System Pharmacists, 2005), 45-46.

24 Elliot, Doug, et al., *ACCCN's critical care nursing* (Chatswood, N.S.W: Mosby/Elsevier, 2012), 90-91.

²⁵ Reader, Tom W., et al., "Communication Skills and Error in the Intensive Care Unit." *Current Opinion in Critical Care* 13, no. 6 (2007): 732-736; Donchin, Yoel, et al., "A look into the Nature and Causes of Human Errors in the Intensive Care Unit," *Critical Care Medicine* 23, no. 2 (1995): 294 -300.

²⁶ Gullo, Antonino, and Philip D. Lumb, *Intensive and Critical Care Medicine*. (Dordrecht: Springer, 2009), 78-80; Gopher D, Olin M, Badihi Y, et al. " The nature and causes of human errors in medical intensive care unit. *In: Proceedings of Human Factor Society's 33rd Annual Meeting*. (1989), 956-960. ²⁷ Rathert, Cheryl, and Win Phillips, "Medical Error Disclosure Training: Evidence for Values- Based Ethical Environments." *Journal Of Business Ethics* 97, no. 3 (2010): 498-500.

²⁸ Luce, John M., and Douglas B. White, "A History of Ethics and Law in the Intensive Care Unit." *Critical Care Clinics* 25, no. 1 (2009): 221-225.

²⁹ Multz, Alan S., et al., "A "Closed" Medical Intensive Care Unit (MICU) Improves Resource Utilization When Compared with an "Open" MICU." *American Journal of Respiratory and Critical Care Medicine* 157, no. 1 (1998): 1468–1473; Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care" *Critical Care* 12, no. 2 (2008): 1-3.

30 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *Canadian Medical Association Journal* 180, no. 9 (2009): 5-7.

³¹ Kaldjian, Lauris C., et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals," *Archives of Internal Medicine* 168:1 (2008): 40-43.

³² Rothschild, Jeffrey M. et al., "Recovery from Medical Errors: The Critical Care Nursing Safety Net." *Joint Commission Journal on Quality and Patient Safety* 32, no. 2 (2006): 63-72; Groves Jr, Robert H, et al., "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting," *Studies In Health Technology & Informatics* 131 (2008): 131-132; Wachter, Robert M., *Understanding Patient Safety* (McGraw Hill, 2007), 3,13; Meier, E., "Efforts Launched to Address medical Errors." *Nursing Economics* 18, no 5 (2000): 265-266.

³³ McGowan, Michele, and Bernard J. Healey, "The Enormous Cost of Medical Errors." *Academy of Health Care Management Journal* 6, no. 1 (2010): 20-24.

34 Sultz, Harry A., and Kristina M Young, *Health care USA: Understanding its Organization and Delivery* (Sudbury, Massachusetts: Jones and Bartlett Publishers, 2006), 108-109.

35 Ehsani, Seyyedeh Roghayeh, et al., "Medication errors of nurses in the emergency department," *Journal of Medical Ethics & History of Medicine* 6, no. 1 (2013): 6-7; Hobgood, Cherri, et al., "Medical Error Identification, Disclosure, and Reporting: do Emergency medicine Provider Groups Differ?" Academic Emergency Medicine13, no. 4 (2006): 443; Agency for Healthcare Research and Quality, "*Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs.*" Retrieved from: <u>http://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html</u>. Introduction, Accessed Feb 28, 2015.

³⁶ Negash, Gediwon, et al., "Medication Errors in the Adult Emergency Unit of a Tertiary Care Teaching Hospital in Addis Ababa," *Archives of Pharmacy Practice* 4, no. 4 (2013): 149-150.

³⁷ Nguyen, Anh Vu T., and Dung A. Nguyen, *Learning from Medical Errors: Clinical Problems* (Abingdon: Radcliffe, 2005), 56.

³⁸ Fairfield, Conn, "Improving the Safety of Health Care: the Leapfrog Initiative." *Eff Clin Pract* 6 (2000): 313-314.

³⁹ Moore, Carlton, et al., "Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting," *Journal of general internal medicine* 2003 18, no. 8 (2003): 646-648; Compliance, Report on Medicare, "Chance of Errors with Inpatient-Only List Abound; Medical Necessity Still a Question," *Report on Medicare Compliance* 21:45 (2012): 1-2; Dietz, Isabel, et al., "Errors in Palliative Care: Kinds, Causes, and Consequences: A Pilot Survey of Experiences and Attitudes of Palliative Care Professionals." *Journal of Palliative Medicine* 16, no. 1 (2013): 77-79.

⁴⁰ Sandars, John, and Aneez Esmail, "The Frequency and Nature of Medical Error in Primary Care: Understanding the Diversity Across Studies," *Family practice* 20, no. 3 (2003): 231-236.

⁴¹ Runciman, Bill and Merrilyn Walton, *Safety and Ethics in Healthcare* (Ashgate 2007): 114-118.

⁴² Groves Jr, Robert H, et al., "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting." *Studies In Health Technology & Informatics* 131 (2008): 131-135.

⁴³ Kale, Abhivyakti, et al., "Adverse Drug Events Caused by Serious Medication Administration Errors." *BMJ Quality & Safety* 21, no.11 (2012): 933-935.

⁴⁴ Imhof, Michael, and Constantijn Blondel, *Malpractice in Surgery: Safety Culture and Quality Management in the Hospital* (Berlin: De Gruyter, 2012), 76-77.

⁴⁵ Bohomol, Elena, et al.,"Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65:6 (June 2009): 1265-1267;H. Flaatten and O. Hevrøy."Errors in the intensive care unit (ICU)," *Acta Anaesthesiologica Scandinavica* 43:6 (1999): 614-615.

⁴⁶ Jennane, Naoual, et al., "Incidence of Medication Errors in a Moroccan Medical Intensive Care Unit. " *International Archives of Medicine* 4, no. 1 (2011): 36-38.

⁴⁷ Dietz, Isabel, et al., "Errors in Palliative Care: Kinds, Causes, and Consequences: A Pilot Survey of Experiences and Attitudes of Palliative Care Professionals," *Journal of Palliative Medicine* 16, no. 1 (2013): 76-78.

⁴⁸ Church, Rhonda, and Neil J. MacKinnon, *Take as Directed Your Prescription* for Safe Health Care in Canada (Toronto: ECW Press: 2010), 7-37.

⁴⁹ Tissot, Edgar, et al., "Observational Study of Potential Risk Factors of Medication Administration errors," *Pharmacy world and science* 25, no. 6 (2003): 264-268.

⁵⁰ Valiee, Sina, et al., "Critical Care Nurses' Perception of nursing Error and its Causes: A Qualitative Study." *Contemporary Nurse: A Journal For The Australian Nursing Profession* 46, no. 2 (2014): 210-213.

⁵¹ Bucknall, Tracey K., "Medical Error and Decision Making: Learning from the Past and Present in Intensive Care." *Australian Critical Care* 23, no. 3 (2010): 154-156.

⁵² Donchin, Yoel, et al., "A Look into the Nature and Causes of Human Errors in the Intensive Care Unit." *Critical Care Medicine* 23, no. 2 (1995): 294-300; Bucknall, Tracey K., "Medical Error and Decision Making: Learning from the Past and Present in Intensive Care," *Australian Critical Care* 23, no. 3 (2010): 150-153.

⁵³ Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215.

⁵⁴ Graf, J., et al., "Identification and Characterization of Errors and Incidents in a Medical Intensive Care Unit." *Acta Anaesthesiologica Scandinavica* 49, no. 7 (2005): 935-936.

55 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal Canadian Medical Association Journal* 180, no. 9 (2009): 936-937.

⁵⁶ Negash, Gediwon, et al., "Medication Errors in the Adult Emergency Unit of a Tertiary Care Teaching Hospital in Addis Ababa," *Archives of Pharmacy Practice* 4, no. 4 (2013): 149-153.

⁵⁷ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 10-12; Jeffery, Maren E., et al., "Ethical Issues in the Intensive Care Unit." *Pulmonary Disease* 11, no. 3 (2004): 1-2.

⁵⁸ Irwin, Richard S., and James M. Rippe, "Contemporary Challenge in the ICU," in *Irwin and Rippe's Intensive Care Medicine* (Philadelphia: Lippincott Williams & Wilkins, 2008), 2339-2345.

⁵⁹ Clark, Peter A., "Medication Errors in Family Practice, in Hospitals and after Discharge from the Hospital: an Ethical Analysis." *The Journal of Law, Medicine & Ethics* 32, no. 2 (2004): 349-351.

60 Post, Linda Farber, et al., *Handbook for Health Care Ethics Committees* (Baltimore: Johns Hopkins UP, 2007), 192-195.

⁶¹ Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (National Academies Press, 2000), 5-8.

62 Youngberg, Barbara J., and Martin J. Hatlie, *Patient Safety HandBook* (Sudbury, MA: Jones & Bartlett Learning. 2004), 550-555.

63 The Joint Commission Resources, "Ethics and Disclosure Events," in Understanding and Preventing Sentinel and Adverse Events in Your Health Care Organization (Oakbrook Terrace, IL: Joint Commission Resources, 2008), 173-175; Jesus, John, et al., Ethical Problems in Emergency Medicine: A Discussion-based Review. (Hoboken, NJ: Wiley, 2012), 242-245.

⁶⁴ Youngberg, Barbara J., and Martin J. Hatlie, *Patient Safety HandBook* (Sudbury, MA: Jones & Bartlett Learning. 2004), 524-527.

65 Hendrick, Judith, *Law and Ethics in Nursing and Health Care* (Cheltenham: Stanley Thornes, 2000), 17-20; Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient- Centered Approach* (Oxford: Radcliffe Pub, 2005), 104-105; Holland, Stephen, *Public Health Ethics* (Cambridge, UK; Malden, MA: Polity, 2007), 7-10.

66 Remington, Joseph Price, et al., *Remington: The Science and Practice of Pharmacy* (Philadelphia: Lippincott Williams & Wilkins, 2006), 24-26; Brian Cronin, *Value Ethics: A Lonergan Perspective* (Nairobi, Kenya: Consolata Institute of Philosophy Press, 2006), 43.

67 Morrison, Eileen E., *Health Care Ethics: Critical Issues for the 21st Century*. (Sudbury, MA: Jones and Bartlett, 2009), 43-45.

68 Carlson, Erik, "Consequentialism Characterized" in *Consequentialism Reconsidered* (Dordrecht: Kluwer Academic, 1995), 5-10.

⁶⁹ Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient- Centered -Approach* (Oxford: Radcliffe Pub, 2005), 104; The Joint Commission Resources, "Ethics and Disclosure Events," in *Understanding and Preventing Sentinel and Adverse Events in Your Health Care Organization*. (Oakbrook Terrace, IL: Joint Commission Resources, 2008), 19-20.

⁷⁰ Basford, Lynn and Oliver Slevin, *Theory and Practice of Nursing: An Integrated Approach to Caring Practice* (Cheltenham: Nelson Thornes, 2003), 223-224; Lippert-Rasmussen, Kasper, *Deontology, Responsibility, and Equality* (Copenhagen: Museum Tusculanum Press, 2005), 15-18.

⁷¹ Holland, Stephen, *Public Health Ethics* (Cambridge, UK; Malden, MA: Polity, 2007), 18-19; Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient- Centered -Approach* (Oxford: Radcliffe Pub, 2005), 105.

⁷² Halperin, Edward C., et al., "Methodology Clinical Trails," in *Perez and Brady's Principles and Practice of Radiation Oncology*. (Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2008),

⁷³ Luce, John M., and Douglas B. White, "A History of Ethics and Law in the Intensive Care Unit." *Critical Care Clinics* 25, no. 1 (2009): 221-225.

⁷⁴ Bosek, Marcia Sue DeWolf, and Teresa A. Savage, *The Ethical Component of the Nursing Education: Integrating Ethics into Clinical Experience* (Philadelphia, PA: Lippincott Williams and Wilkins, 2007), 39-45.

75 Walton, Douglas, *Ethical Argumentation*. (Lanham, MD: Lexington, 2009), 39-42; Maglin, Nan Bauer and Donna Marie Perry, *Final Acts: Death, Dying, and the Choices We Make* (New Brunswick, NJ: Rutgers UP, 2010), 205-210.

⁷⁶ Jeffery, Maren E., et al., "Ethical Issues in the Intensive Care Unit," *Pulmonary Disease* 11, no. 3 (2004): 3-5.

77 General Medical Council, "End of Life Treatment and Care: Good Practice in Decision-Making," Retrieved from:

http://www.gmcuk.org/CONSULTATION_DRAFT_GUIDANCE.pdf_25417410.pdf. Principles and Decision-Making Framework, Accessed Feb 2015. 78 Fink, M. P., et al., *Intensive Care Medicine in 10 Years* (Berlin: Springer, 2006), 345-350.

⁷⁹ Berlinger, Nancy, "Avoiding Cheap Grace. Medical Harm, Patient Safety, and the Culture(s) of Forgiveness." *Hastings Cent Rep* 33, no. 6 (2003): 28-36.

⁸⁰ Berlinger, Nancy, *After Harm: Medical Error and the Ethics of Forgiveness*. (Baltimore, Maryland: Jhons Hopkins University, 2005), 40-91.

⁸¹ Berlinger, Nancy, and A.W. Wu, "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Errors." *Journal of Medical Ethics* 31, no. 2 (2005): 106-107.

⁸² Mazor, Kathleen M., et al., "Communicating With Patients About Medical Errors," *Arch Intern Med* 164 (2004): 1690-1697.

⁸³ J. K. Robbennolt, "Apologies and medical errors," *Clinical Orthopaedics and Related Research* 467, no. 2 (2009): 377-378.

⁸⁴ Mazor, Kathleen M., et al., "Health Plan Members' View about Disclosure of Medical Errors," *Annals of Internal Medicine* 140:6 (2006): 409-410.

85 Erlen, Judith A., "When the family asks, 'what happened?," *Orthopaedic Nursing* 19, no. 6 (2000): 68-71.

86 Berlinger, Nancy, *After Harm: Medical Error and the Ethics of Forgiveness*. (Baltimore, Maryland: Jhons Hopkins University, 2005), 40-50.

⁸⁷ Burroughs, Thomas E., et al., "Medication Safety: Patients' Concerns about Medical Error during Hospitalization," *Joint Commission Journal on Quality and Patient Safety* 33, no. 1 (2007): 5-7.

88 Wolf, Zane and Ronda G. Hughes, "Error reporting and disclosure." Retrieved from:

http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurs eshdbk/WolfZ_ERED.pdf. 3-4, Accessed Feb 2015.

⁸⁹ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 770-771.

⁹⁰ Edwin, A. K., "Non-Disclosure of Medical Errors an Egregious Violation of Ethical Principles," *Ghana Medical Journal* 43, no. 1(2009): 34-36.

⁹¹ Hammami, Muhammad M., et al., "Which Medical Error to disclose to Patients and by Whom? Public Preference and Perceptions of Norm and Current Practice." *BMC Medical Ethics* 11, no. 1 (2010): 16-17.

⁹² Tevlin, Ruth, et al., "Improving Disclosure and Management of Medical Erroran Opportunity to Transform the Surgeons of Tomorrow." The *Surgeon* 11, no. 6 (2013): 340-341.

⁹³ Edwin, A. K., "Non-Disclosure of Medical Errors an Egregious Violation of Ethical Principles," *Ghana Medical Journal* 43, no. 1(2009): 37-39; Hannawa, Annegret

F., "Principles of Medical Ethics: Implications for the Disclosure of Medical Errors." *Medicolegal and Bioethics* 2 (2012): 1-5.

⁹⁴ Finkelstein, Daniel, et al., "When a Physician Harms a Patient by a Medical Error: Ethical, Legal, and Risk-Management Considerations." *the Journal of Clinical Ethics* 8, no. 4 (1996): 330-331.

⁹⁵ Wu, Albert W., et al., "Disclosing Medical Errors to Patients: it's not What You Say, it's What They Hear." *Journal of General Internal Medicine* 24, no. 9 (2009): 1012-1013.

⁹⁶ Mazor, Kathleen M., et al., "More than Words: Patients' Views on Apology and Disclosure When Things Go Wrong in Cancer Care." *Patient Education and Counseling* 90:3 (2013): 345-346.

⁹⁷ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors." *Journal of the American Medical Association* 289, no. 8 (2003): 1001-1003.

98 Cook, Ann Freeman, and Helena Hoas, "Ethics Conflicts in Rural Communities: Recognizing and Disclosing Medical Errors," *Psychology Faculty Publications* (2009): 244-245.

99 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies," *The American Association of Physicists in Medicine*. Retrieved from: <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error</u> <u>%20NEAAPM.pdf</u>. 3-4, Accessed Feb, 2015.

100 Kachalia Allen, "Disclosure of Medical Error," Retrieved from: <u>https://psnet.ahrq.gov/perspectives/perspective/70</u> Perspective, accessed, Dec, 6, 2015.

101 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies." *The American Association of Physicists in Medicine*. Retrieved from: <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error</u> <u>%20NEAAPM.pdf</u>. 35, Accessed Feb, 2015.

¹⁰² Donihi, A C., et al., "Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin," *Quality and Safety in Health Care* 15, no. 2 (2006): 89-91.

103 Wolf, Zane and Ronda G. Hughes, "Error reporting and disclosure." Retrieved from:

http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurs eshdbk/WolfZ_ERED.pdf. 3,4, Accessed Feb, 2015.

¹⁰⁴ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289, no. 8 (2003): 1004-1005.

105 Fein, Stephanie, et al., "A Conceptual Model for Disclosure of Medical Errors." *The National Center for Biotechnology Information Advances Science and* *Health.* Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK20500/.</u> 483-485, Accessed July 2014.

¹⁰⁶ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 524-525.

107 The Joint Commission, "TJC – Sentinel Events and Alerts." Retrieved from: <u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf</u>. Accessed Mar, 2015.

108 Nau, Konrad, "*Disclosing Medical Error to Patients*." Retrieved from: http://slideplayer.com/slide/7041421/ 7, Accessed July 22, 2014; Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 524-525.

109 The Joint Commission, "TJC – Sentinel Events and Alerts." Retrieved from: <u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf</u>. Accessed Mar,2015.

110 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 936-937.

¹¹¹ Moyen, Eric et al., "Clinical Review: Medication Errors in Critical Care." *Critical Care* 12, no. 2 (2008): 1-2.

¹¹² Segall, Noa, et al., "Can We Make Postoperative Patient Handovers Safer? A Systematic Review of the Literature." *Anesthesia & Analgesia* 115, no. 1 (2012): 102.

¹¹³ Berlinger, Nancy, and A.W. Wu, "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Errors." *Journal of Medical Ethics* 31 (2005): 107-108; Penson, Richard T., et al., "Medical Mistakes: a Workshop on Personal Perspectives." *The Oncologist* 6, no. 1 (2001): 92-93.

114 Marchev, Mimi, et al., "How States Report Medical Errors to the Public: Issues and Barriers." Retrieved from: <u>http://www.nashp.org/sites/default/files/reporting_medical_errors.pdf</u>. 22-25, Accessed Mar, 2015.

¹¹⁵ Schaefer Kristen G., and Susan D. Block. "Physician Communication with Families in the ICU: Evidence-Based Strategies for Improvement." *Current opinion in critical care* 15, no. 6 (2009): 569-577; Furrow, Barry R., "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction." *Widener L. Rev* 12 (2005): 28-31; Massachusetts Coalition for the Prevention of Medical Errors, "When Things for Wrong: Responding to Adverse Events." Retrieved from:

http://www.macoalition.org/documents/respondingToAdverseEvents.pdf. 11-15, Accessed Mar, 2015.

116 Sullivan, William P., "New Employment Contract Pitfalls to Avoid." Retrieved from: <u>http://www.acepnow.com/article/new-employment-contract-pitfalls-avoid/</u>. Indemnification, Accessed Mar, 2015. 117 Frank, Lobb, *The Great Healthcare Fraud* (Nottingham, PA: kimkris publishing, 2012), 68-70.

¹¹⁸ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289, no. 8 (2003): 1001-1002.

119 Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 770-773.

120 Sayeed Sadath A., and Robert D. Troug. "Malpractice and Disclosure of Errors." Retrieved from: https://www2.aap.org/sections/bioethics/PDFs/Curriculum_Session8.pdf. 51-56, Accessed Mar, 2015.

121 Jenicek, Milos, *Medical Error and Harm: Understanding, Prevention and Control* (New York, NY: CRC Press, 2011), 1-5.

¹²² Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 524-525.

123 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors,
Prevention and Disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 2
-3.

124 Hyman David A., and Charles Silver, "Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid." *Vanderbilt Law Review* 59 (2006): 1108-1111.

¹²⁵ Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine* 354 (2006): 2029-2032.

126 Gawande, Atul, "The Save," in *The Checklist Manifesto: How to Get Things Right*. (New York: Metropolitan Books, 2010), 187-190; Steyrer, Johannes, et al., "Attitude is Everything? the Impact of Workload, Safety Climate, and Safety Tools on Medical Errors: A Study of Intensive Care Units." *Health Care Management Review* 38, no. 4 (2013): 307-307.

¹²⁷ Kapielian, Victoria, et al., "*A system to describe and reduce medical Errors in primary care.*" Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK43616/.</u>2-5, Accessed, Mar 2015.

128 World Health Organization, *Implementation Manual: Who Surgical Safety Checklist*. Retrieved from:

<u>http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_fina</u> <u>lJun08.pdf</u>. 9-13. Accessed, Mar 2014.

129 Gawande, Atul, *Better: A Surgeon's Notes on Performance* (New Your: Picador, 2007), 14-17.

130 Hales Brigette M., and Peter J Pronovost "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 231-232; Gawande, Atul, *Better: A Surgeon's Notes on Performance*. (New Your: Picador, 2007), 14-17.

131 Gawande, Atul, *The Checklist Manifesto: How to Get Things Right*. (New York: Metropolitan Books, 2009),

¹³² Arora, Vineet and Julie Johnson, "A Model for Building a Standardized Hand-Off Protocol." *Joint Commission journal on quality and patient safety* 32, no. 11 (2006): 646-655.

¹³³ Schaefer Kristen G., and Susan D. Block. "Physician Communication with Families in the ICU: Evidence-Based Strategies for Improvement." *Current opinion in critical care* 15, no. 6 (2009): 569-577.

134 The Joint Commission: Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals.
Oakbrook Terrace, IL: The Joint Commission. Retrieved from: <u>http://www.jointcommission.org/assets/1/6/aroadmapforhospitalsfinalversion727.pdf</u>. 4-5. Accessed, Mar, 2015.

135 U.S. Department of Health & Human Services, "*Effective Communication in Hospitals*." Retrieved from:

http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication/. Effective Communication in Hospitals, Accessed Mar, 2015.

¹³⁶ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 527-531.

137 Kaldjian, Lauris C., et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals," *Archives of Internal Medicine* 168, no. 1 (2008): 44-46.

¹³⁸ Moyen, Eric et al., "Clinical Review: Medication Errors in Critical Care." *Critical Care* 12, no. 2 (2008): 3-7.

139 California HealthCare Foundation, "Addressing medication errors in hospitals: ten tools." Retrieved from:

http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/A/PDF%20addressi ngmederrorstentools.pdf . Medication Error tracking form, Accessed, Mar, 2015.

140 DeJohn, Paula, "Follow Protocols When Using Medications from Compounding Pharmacies." *OR Manager* 29, no. 8 (2013): 28-30.

141 Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 773-775.

142 Agency of Healthcare Research and Quality, "AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk." Retrieved from: http://www.ahrq.gov/research/findings/final-reports/pscongrpt/psini2.html. Most Common Root Causes of Medical Errors, Accessed Mar 2015.

143 Van Beuzekom, et al., "Patient safety: Latent Risk Factors." *British journal of anaesthesia* 105, no. 1 (2010): 52-59.

¹⁴⁴ Cooper, Jeffrey B., et al., "An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for Prevention and Detection." *Anesthesiology* 60, no. 1 (1984): 37-41.

¹⁴⁵ Van den Bemt, et al., "Frequency and Determinants of Drug Administration Errors in the Intensive Care Unit." *Critical care medicine* 30, no. 4 (2002): 846-850.

146 Tucker Anita L., and Amy C. Edmondson, "Why Hospitals don't Learn from Failures." *California Management Review* 45, no. 2 (2003): 55-72.

147 World Health Organization, "Hospital Emergency Response Checklist" Retrieved from:<u>http://www.euro.who.int/__data/assets/pdf_file/0020/148214/e95978.pdf.</u> 5. Accessed Mar 2015.

148 Commonwealth of Australia, "Reform of Liability Insurance Law in Australia," Retrieved from:

http://archive.treasury.gov.au/documents/799/PDF/complete.pdf. 3-4. Accessed Mar, 2015.

¹⁴⁹ Schoenbaum Stephen C., and Randall R. Bovbjerg, "Malpractice Reform must Include Steps to Prevent Medical Injury." *Annals of Internal Medicine* 140, no. 1 (2004): 51-53.

150 Gilmour, Joan M., "Patient Safety, Medical Error and Tort Law: An International Comparison." Retrieved from: <u>https://apps.osgoode.yorku.ca/osgmedia.nsf/0/094676DE3FAD06A5852572330059253C</u> /\$FILE/FinalReport Full.pdf. 20-21. Accessed Mar, 2015.

¹⁵¹ Furrow, Barry R., "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction." *Widener L. Rev.* 12 (2005): 7-8.

152 American College of Physicians, "Medical Liability Reform: Innovative Solutions for a New Health Care System." Retrieved from: <u>https://www.acponline.org/acp_policy/policies/medical_liability_reform_2014.pdf</u>. 15-22. Accessed Mar, 2015.

¹⁵³ Sage, William M., "The Role of Medicare in Medical Malpractice." *Journal of Health Care Law and Policy* 9, no. 2 (2009): 233-234.

154 American College of Physicians, "Medical Liability Reform: Innovative Solutions for a New Health Care System," Retrieved from: <u>https://www.acponline.org/acp_policy/policies/medical_liability_reform_2014.pdf</u>. 15-22. Accessed Mar, 2015.

155 MacCourt, Duncan, and Joseph Bernstein, "Medical Error Reduction and Tort Reform through Private, Contractually Based Quality Medicine Societies." *American Journal of Law and Medicine* 35, no. 4 (2009): 558-561.

Chapter 2: Extent of Medical Errors in the ICU

Introduction

Of all the departments in the hospital, the Intensive Care Unit (ICU) is the one in which the consequences of medical errors are potentially the most serious. This conclusion stems from the fact that patients in this section of the facility are the most vulnerable in terms of their weakened physical condition and inability to cope with stresses of any kind to their body systems. This susceptibility applies regardless of what is the source of the error or whether it is classified as one of commission or omission. Rates of medical errors in the ICU, along with those for the emergency and operating rooms, in particular have risen alarmingly, with reported estimates of error-induced fatalities as high as 98,000, spurring a great deal of concern within the U.S. healthcare system. Compounding the gravity of the situation is a growing awareness that many of these errors could have been prevented through the adoption of concrete policies and procedures calculated to head-off their occurrence. Tully et al, define medical errors in general as constituting the implementation of ineffective and deleterious strategies in the pursuit of the goals of care and treatment. While medical errors typically conjure up the notion of actions that constitute 'mistakes,' this category applies equally to any failure to implement a prescribed step in a course of treatment. In light of the severity of problems that require stays in the ICU, it is entirely foreseeable that errors, no matter how seemingly insignificant, may prove fatal.

In 1999 the Institute of Medicine (IOM) released a cogent report on how frequent
and widespread concerning the prevalence, frequency, and ramifications of medical errors. The report includes data across the board for the field of healthcare, documenting the number of individual people experiencing the consequences, neutral or adverse, from medical errors. The Institute of Medicine's findings detail the tremendous costs involved, in terms of both the abstract notions of human health and well-being on one hand, and the more tangible expenses of mitigating, rectifying, and/or compensating for errors, on the other. Among the more sobering of the statistics in the report is that medical errors account for more deaths in the U.S. than do all forms of cancer, AIDS, and automobile accidents combined. The release of the report triggered the need for advanced research on the rates of medical error and their potential adverse effects as well as the financial cost involved. This 1999 report highlighted the necessity of both further research more specifically tracking the frequency, prevalence, and consequences of medical errors, whether intangible, statistical, or financial.2

This chapter presents an overall description and assessment of scope and extent of medical errors in intensive care units of hospitals across the United States, concentrating on the prevalence and frequency of errors, in general terms, and then more specifically, the variety classifications of errors, relating to some extent to their causes or origins. An essential preliminary step in this dissertation's larger goal of analyzing the causes of medical errors and proposing ways to prevent or minimize their occurrence and to mitigate, ameliorate, or rectify their damages is to explain how medical errors have been conceptualized and categorized within the field of healthcare. Further sections of the chapter classify the types of medical errors and the causal circumstances and actions that lead to their occurrence. Beyond this, the chapter provides a survey of relevant statistics,

documenting the frequency and severity of the problem, and analyze the principal risk factors that increase the probability that errors will happen.

Chapter 2.A. Errors Concerning the Hospital ICU

This section of the chapter will examine several definitions of medical errors in the literature, providing several perspectives on what the term encompasses, analyze the propensity for such errors in general, and discuss ways in which scholars have categorized them. This analysis will present the case arguing that, to some degree, a correlation exists between certain commonly occurring types of errors and the medical settings in which they most frequently occur. The hospital ICU is one such case and its connection to certain error types will prove crucial to proposing policies and procedures aimed at preventing or minimizing medical errors in this setting. Throughout this section, the discussion will frequently relate directly to the intensive care unit as a unique setting in which there exists a pronounced tendency for certain errors to occur.

Chapter 2.A.1. Defining Medical Errors

A consensus exists in relevant literature that medical errors are not only common, but also prevalent enough to be considered a daily occurrence in medical and healthcare practice; moreover, the hospital ICU has been repeatedly the focus of investigation into this phenomenon. This attention is to be expected in that its role in the hospital is to deal with the critical, often life-threatening problems of patients who are, because of such injury or illness, in physically weakened condition with little stamina or resiliency. Predictably, whether admitted directly or transferred there, these patients need

complicated, multi-faceted treatment, for which timing is immediate or precisely calibrated, and which requires vigilant monitoring, communication, and coordination by a larger network of healthcare professionals in different locations. Ironically, the setting in which medical errors can least be tolerated due to the heightened risk of adverse consequences is the very same environment in which they are the most prone to happen. If indeed, as Grober notes, "Medical errors represent a serious public health problem and pose a threat to patient safety,"³ the intensive care unit is the environment where this problem and threat is most acute.

As a starting definition for the purpose of analysis, a *medical error* any event or situation which deviates from prescribed treatment, care, or observation of a particular patient, and which furthermore is not a characteristic of the original illness or injury being treated. This definition portrays medical errors as being very broad in scope, yet it is necessary in order to encompass the full range of incidences occurring regularly within the ICUs of most hospitals. This broad range covers missteps as diverse as errors in medications, infusions, mistakes done using medical equipment, failure to conform to standard protocol and any other human errors, which may happen in the course of the practice of medicine and healthcare. The Institute of Medicine's scope is broader yet, including errors of omission, describes as any failure to follow through to completion on a prescribed plan or individual step in of treatment, in addition to the intentional implementation of any inappropriate plan or steps in such a plan.4 Moskop et al, assert that, "In some cases, the application of this definition is unambiguous. In symmetry errors, for example, a procedure is performed on the wrong side; in medication errors, a dosing protocol or route is incorrectly administered. Other actions, particularly those

involving diagnostic processes and other cognitive processes, may be much more difficult to characterize as error, particularly given the information available to the provider at the time."5 Clearly, some types of errors are the results of chance occurrences beyond the bounds of human influence or causation. Despite the severity of their consequences, these are not identified as medical errors, as the term is conceived of here. Ultimately, such negative patient outcomes will occur despite perfectly provided and administered treatment, and thus should not be categorized as medical,6 in particular not for the purpose of investigation in this dissertation.

Yet another way of defining medical errors is to describe them as the failure to implement any designated action in the intended manner, or to implement either the wrong strategy or an appropriate strategy by the wrong procedure in spite of attempting to accomplish the goals of treatment. While not clearly implied in these definitions, medical errors typically incur adverse consequences for patients. Again Moskop et al. contend that, "Medical errors often result in harm to patients, and this explains our increased efforts to identify and minimize such errors. It is important to recognize, however, that there is no necessary connection between medical error and patient harm. Some errors may not harm the patient. For example, an obvious error may occur in a patient's treatment, such as administration of a medication prescribed for a different patient, but the patient may experience no ill effects from that medication."7 Beyond what these researchers allude to in this quote, medical errors extend over an entire continuum of severity of consequence, varying tremendously as to the level of seriousness they create. Angus and Carlet have observed that the effects of a given medical error could be so minimal that it ultimately made no discernable physiological or biochemical difference

in the patient. As such, that error would necessitate no corrective or compensating actions.8 For instance, a highly preventable adverse outcome known as the near miss, a category that can overlap with several others, is distinguished by the occurrence of an error, which however does not lead to any negative consequences. By contrast, over most of the spectrum of consequences of medical errors additional treatment is mandated beyond what the original injury or illness warranted- treatment specifically required to undo or at least ameliorate the negative effects of the error in an effort to restore the patient to the level of health prior to the error. Needless to say, that level was already in jeopardy in the case of an ICU patient; furthermore, regardless of the patient's previous condition, the effects caused by the error can be either temporary or permanent, the most severe form of the latter being fatality.9

In order to create a standard for gauging the ramifications of medical errors, researchers from the Ohio State University developed a Severity Scale bearing the institution's name and consisting of a seven level categorization for assessing the effects of the medication error on the patient. These levels include: a) Level 0, which denotes an error that is identified and handled swiftly enough that the patient suffers no ill effects; b) Level 1, which indicates that the error causes some effect but leads to no change in clinical outcome; c) Level 2, which identifies an error that will require close monitoring but may not need action; d) Level 3, which denotes an error that necessitates additional laboratory tests, or leads to an alteration in the patient's vital signs; e) Level 4, which signifies an error that requires additional treatment or procedures, including admission, readmission, or a protracted stay in the hospital; f) Level 5, which denotes an error that either necessitates admission to the ICU, requires an invasive procedure, or causes

irreversible harm; and finally g) Level 6, which means that the error so designated led to the patient's death.¹⁰

In his writings concerning medical errors, Bedevian has highlighted medical errors, as distinct from complications, which he describes as adverse reactions on the part of the patient to a medically justifiable procedure. The corollary to this assertion is that medical errors are intrinsically preventable to the extent of current medical knowledge, beyond the limits of which anything that in hindsight proved to be deleterious would not be classified an error. The fact that medical facilities routinely have in place and attempt to follow established standard operating procedures indicates an understanding that it is possible to forestall many if not all medical errors. As the specific subjects of these procedures implies, medical errors can be connected to either medical products or procedures, to general medical practices in a given setting, or to the medical system itself.11

Chapter 2.A.2. Potential for Medical Errors

The fact that all those working in the hospital ICU are, despite the intensive training they typically have undergone, fundamentally human beings, which in turn makes the inevitable that they will, at least on occasion, commit errors.¹² Furthermore, given the nature of hospitals and their intensive care units, they are setting where errors are especially likely to occur.¹³

The Institute of Medicine's 1999 report, bearing the clichéd title *To Err is Human*, deserves credit for focusing the healthcare community's attention on the

prevalence and seriousness of medical errors and their adverse repercussions for both patients and the healthcare system.14 Inherently containing a higher potential for error, given that its patients have life threatening conditions, the ICU bears a more urgent need for preventing or controlling the effects of medical errors. These conditions may include serious complications from accidents, infections, surgery, stroke, or cardiac arrest. Therefore, ICU patient are typically in need of critical care, involving continuous monitoring by the health care providers. In the process of delivering such care, a high potential exists for the occurrence of medical errors.15

The potential for medical errors is intrinsically related to the fragmentation of healthcare services, in contrast with their integration in a functioning network system.¹⁶ This fragmentation propels the patient into interactions with multiple providers of various aspects of treatment in a variety of contexts. McGowan and Healey posit that the subsequent lack of access to complete information, coupled with the disincentive on the part of healthcare professional to take on responsibilities beyond their personal involvement or to admit responsibility for mistakes, creates an environment that actually encourages medical errors, exacerbating the frequency at which they happen.¹⁷

The accreditation and licensure of medical and healthcare professionals give adequate priority to ensuring that they are trained and prepared to prevent medical errors. This deficiency is arguably one of the primary causes of errors.¹⁸ On the other hand, medical errors are also closely connected with faulty systems and processes, along with other conditions that provoke people to make mistakes, or be unable to prevent their occurrence. The clear inference is that, not all errors occur because of recklessness on the

part of health care providers. As McGowan and Healey give prominence to in their article, "The system must be better designed so that it becomes more difficult for mistakes to be made. Brownlee argues that the system requires far too many people to do everything right every time in order to arrive at a successful patient outcome. This type of system is perfect for 'latent errors.' These are mistakes in medical care delivery that are waiting to happen."¹⁹ Even though they are quite often labeled as never events they are occurring all too frequently causes health costs to rise and patients being hurt by the very system that is supposed to heal them.

Particular circumstances or combinations thereof tend to increase the probability of errors occurring. For example, a hospital or other healthcare facility may be in the practice of stocking all their drugs in high concentrations, in spite of the known toxicity of such drugs when administered as an overdose. Such a procedure may elevate the risk of a healthcare provider administering such medication without diluting it first. Such a medical error would be far more attributable to the faulty system than to the healthcare provider who neglected to dilute the substance.20 Healthcare institutions need to establish and support systems that reduce the likelihood of medical errors; in this case, it must create procedures for storing such drugs in diluted concentrations. Intensive care units need to prioritize implementing functioning systems, designed to ensure, to the greatest extent possible, the safety of the patients. If such a system fails, the chances of medical errors in the unit will increase. In addition to faulty health systems, individuals may sometimes be responsible for errors if they have neglected to maintain the required level of vigilance. The criticality of the intensive care unit seems to increase the potential of medical errors occurring.21

While healthcare professionals, scholars, and researchers in the field all concur about the continual occurrence of medical errors, statistics documenting their exact frequency prove to be elusive. Although it is evident that medical errors occur, it proves difficult to estimate or measure their exact frequency. This is because healthcare providers only report some medical errors while a broad range of other errors go unreported. Challenging the representativeness of existing data, experts concur that such statistics are an underestimate actual occurrence, making the potential for medical errors difficult to adequately quantify.22 Unfortunately, as it can be quite difficult for researchers or even other medical professionals to spot a given instance of medical error and recognize it as such, obtaining a precise, reliable estimate of the frequency of medical errors is barely possible. Given this difficulty coupled with the obstacles to fully accessing relevant data, the general consensus in the field is however, that whatever estimates are put forth are grossly underestimating the numbers of medical errors which actually occurring.23

Chapter 2.A.3. Types and Causes of Medical Errors in the ICU

This section presents a picture in the broadest scope of the prevalence and frequency at which medical errors of various types, causes, and characteristics occur in the intensive care units of hospitals throughout the United States. The first subsection surveys errors in terms of general activities into which the treatment of an individual patient may be divided. The second subsection analyzes medical errors, categorizing them in terms of general causes. Chapter 2.A.3.a. Types of Medical Errors Regarding Hospital ICUs

This subsection of the chapter presents a classification system for medical errors the kind of activity within the ICU during which certain errors are likely to occur. This system of classification consists of the following seven areas: 1) devising and setting up a course of treatment, 2) diagnosing the injury or ailment, 3) implementing the treatment plan, 4) the preventing foreseeable ill-effects or complication, 5) prescribing and administering medicines, 6) ensuring the proper functioning of communication and equipment systems, and 7) avoiding negligence in medical management.

(1) Errors in Planning and Execution

The Institute of Medicine (IOM) highlighted different types of medical errors that are considered prevalent. These different types of medical errors have been categorized and described by a variety of researchers. One of the most common types of errors is that of execution, as its name implies, occurring in the phase of carrying out a planned action. Healthcare providers may effectively planned the appropriate treatment; however, that action may not be executed in the manner in which it was intended leading to a definite error. In other cases, healthcare providers may fail in the planning process. Obviously, healthcare professionals need to plan their actions or intervention strategies effectively, in order to avoid errors. Some individuals fail in this, the initial planning phase, while others fail in the execution.24

(2) Errors in Diagnosis

Diagnostic errors form yet another category of medical errors that happen frequently in the intensive care unit, there is an accurate diagnosis of the patient's condition is a prerequisite before any treatment can be launched or medication given. 25 In the ICU, where all the patients have been diagnosed as being in some level of critical condition, effective diagnosis is indispensable. It is self-evident that any errors stemming from the diagnostic process may further threaten the life of the patient. Some diagnostic errors are simply the result of unnecessary delays of the diagnosis process.26

Prompt diagnosis, with the greatest accuracy that state-of-the-art medical knowledge and technology permit, is a prerequisite to any level of quality medical care; medical professionals and institutions are responsible for ensuring that it occurs. In practice, numerous factors can interfere with this goal. For one thing, circumstances such as work overload may force healthcare providers into delaying diagnosis. Alternatively, misinterpretation of diagnostic data or overreliance on previous experience in the decision-making process may result in an inaccurate diagnosis. Another source of diagnostic error is inaccurate or irrelevant data stemming for the failure to employ standard diagnostic procedures or reliance on outdated methods of diagnosis.27 Two documented precipitators of diagnostic errors consist of: 1) healthcare professionals using outdated diagnostic kits, even when proper procedures are followed, and 2) healthcare professionals neglecting the required monitoring and control in performing tests, for example skipping less obviously necessary steps in the diagnostic process, even when using up-to-date procedures and equipment.28 Still another cause of diagnostic error is the

tendency on the part of many healthcare providers to trust expert medical opinion even when it appears to conflict with test results or when the validity of those results may be in question. This tendency indicates that critical thinking on the part of all those involved in the diagnostic process is essential to achieving the goal of preventing or minimizing errors.29

(3) Errors in Treatment

The difference between treatment errors and diagnostic errors is that the former implies an accurate diagnosis and the optimal plan of treatment. The error consists of a failure in appropriately implementing non-diagnostic tests or other procedures ranging from changing dressings to performing major operations. Although they have been frequently categorized as medication errors, failures in administering the proper medication or dosage may also be considered treatment errors, as subsequently described. At times, follow-up procedures are not in place for healthcare workers to conduct or alternatively these workers are otherwise unable to or fail to carry out these procedures when or as required. During and in the follow-up to all treatment procedures, health care providers need to monitor the patient's condition as fully as the protocol calls for.30

In the manner that delays in diagnosis constitute medical errors, preventable delays in the treatment process must be characterized as treatment error. Alarmingly, Kleinpell et al, have documented instances in which healthcare providers have intentionally administered care inappropriately through deliberate delay.31

(4) Preventive Errors

Preventive medical errors are also common, if less well understood; easily comprehensible examples would include healthcare providers not treating as a priority to administer standard prophylactic treatment preventive errors and providers neglecting to properly monitor any treatment. Granted, it is impossible to prevent all negative developments in treatment any given patient; the failure to take feasible, reasonable safe prophylactic measures is by definition a preventable error, the consequences of which are potentially critical. Anticipatable and preventable adverse outcomes further expand the class of prevention errors.32 Among the easiest to eliminate of these causes of error are the instances in which proper planning and appropriate execution of the intended procedure is known to obviate any negative consequences. In some studies, researchers have adopted a related category, named the slip, defined as an error that result from a misdirected routine in the execution of a procedure. As a type of error, researchers note that a large number of health care providers report this error to be common, occurring frequently.33 There appears to be little evidence, however, as to whether as the name implies, this type of error tends to lead primarily to Level 0 or 1 on the Ohio State University Severity Scale.

Preventable errors can occur, simply because a health care professional fails to initiate a routine, prescribed action in the course of treatment as the result of a memory lapse stemming from a number of root causes. Alternatively, "knowledge based errors" occur when medical professionals and workers analyze a case thoroughly, yet based their treatment on either misinformation or faulty analysis. All of these errors are preventable, along with their adverse outcomes can be categorized as either errors of omission or of commission.34 Errors of omission are those in which the provider leaves a critical action

or procedure undone, while those of commission occur when a health care provider performs any action considered within medical practice to be inappropriate in this situation.35

(5) Errors in Medication

The most prevalent of this type of errors consists of slips and lapses. Exacerbating the risks of medication errors in the ICU, the situation for the typical patient in critical condition tends to have on average twice as many medications prescribed as do their counterparts in the rest of the hospital.36 With this fact in mind, unsurprisingly the severity of a patient's condition constitutes the strongest predictor of becoming the victim of an adverse drug event (ADE). On top of this risk factor, given that they are in critical condition, the fact that ICU patients are in critical condition means that they have fewer and significantly weaker natural defenses; thus they are far less able to cope with the physiological stresses of ADEs.37 Furthermore, even when the conditions of these ICU patients improves and they transition toward recuperation and/or less intensive levels of care, they face a significant lack of coordination and continuity in their care as soon as they leave the ICU. This extensively documented flaw in the medical care system creates an additional vulnerability to medical errors for the patient during this transition phase. Thus, coordination and communication between ICU staff and the patient's subsequent caregivers constitutes an essential, albeit neglected aspect of care.38 Given all these barriers to coordinated care, it is unsurprising that errors involving medication constitute the most frequent of any type in the ICU, accounting for approximately 78% of all serious medical errors.39

As has been alluded to previously in this discussion, medication errors cover the scope of all types of potentially preventable, yet frequently occurring errors involving the administration of medicine in the broadest sense of treatment.⁴⁰ In terms of administration, such errors amount to giving a drug in the wrong dosage, following the wrong protocol in giving it, or simply in giving the wrong drug. These errors, in turn, may be the result of a medical or healthcare professional prescribing either the wrong pharmaceutical agent or the prescribed agent at an inappropriate dosage. Furthermore, at any stage in the process, misinterpretation of communication or inadequate attention paid to it may torpedo the required procedures for effective, safe administration.⁴¹

Beyond the obvious errors of administering the wrong medication or in the wrong dosage, the system of prescribing, procuring, delivering, and administering medicine, particularly in hospital settings, lends itself to creating delays, which also constitute medical errors.⁴² Furthermore, what pharmacological experts understand while the healthcare providers who administer medication may not, is the necessity of continuously monitoring both the physiological and biochemical effects of drugs, individually and in concert with all other medications and procedures that the patient is undergoing. In theory, all healthcare professionals understand this. However, when healthcare providers fail to put the concept into practice, medication errors can have dire, even fatal, consequences for the patient.⁴³

(6) Failures of Communication and Equipment in Health Systems

In addition to the above categories of errors, research has revealed that within the ICU any failure to communicate effectively may actively contribute to medical errors.

Healthcare providers are obliged to develop effective channels of communication with regard the status and progress of patients in an effort to minimize the probability of errors occurring. Intensive care units rely on numerous technologies to sustain the life of each patient. Such equipment can and often does succumb to a wide range of technical failures resulting in medical error.44 Various types of equipment failure have been described as preventable because they can be avoided if health care professionals ensure that all the facilities are functioning properly, as they the providers are required to do. Sometimes, however, such checkups often fail to identify a dysfunction in the equipment eventually resulting in an error. Intensive care units usually operate using a defined health system. Any failure in this system may result in medical errors.45

(7) Poor Medical Management

Inherently, institutions such as hospital have extremely complex organizational structures, and in order to function safely and prevent medical errors, they must at all times maintain efficiently coordinated interacting systems.⁴⁶ It is, therefore, both surprising and distressing to find how often, how, and how extensively many institutions fail to address this need for effective management in the ICU. Poor management systems in hospitals are a leading contributor to the occurrence of medical errors.⁴⁷ This is because poorly managed systems or networks neither facilitate nor foster the efforts necessary to ensure that all the institution's systems are working in tandem to advance and protect patients' safety. Guard maintains that despite the efforts of a significant number of management systems, they fail to place their investigations at the level of patient safety within their respective facilities. Furthermore, poor management promotes

negligence, which in turn increases the propensity for medical errors.48 In numerous documented cases of significant medical errors, poor medical management has been ascertained to be an underlying cause, first of medical error itself, and second, of the negative consequences. Obviously, healthcare facilities must make conscientious management a high priority in their respective institutions for a numerous, wide-ranging array of reasons, beyond simply the prevention of medical errors. Because of the seriousness of the conditions of ICU patients, hospitals must give top priority to ensuring the proper management of this area of the institution.49

Chapter 2.A.3.b. Causes of Errors Referring to Hospital ICUs

Research has indicated that different factors contribute to the occurrence of medical errors. More specifically, various theories have been developed to describe the circumstances under which medical errors are more likely. It is critical to understand the complexity of causes of medical errors in order for any reduction of these types of errors are to be successful. The following discusses causes of medical errors, causes that are at least theoretically preventable. These causes may be categorized as, 1) Adverse events, 2) Adverse drug events, 3) Error in medication, and 4) Human errors which includes a) Fragmentation of the health system, b) Cognitive errors, and c) Ineffective skills and inadequate knowledge, and d) Long working hours.

(1) Adverse Events

Much of the investigative work of researchers has been directed toward the goal of identifying the principle causes of medical errors. One of these, which has been the

focus of work in recent years, is known as *adverse events*, a rather loosely defined category, but one that acknowledges the fact that multiple factors, often difficult to disentangle, contribute to the occurrence of medical errors.⁵⁰ As Bohomol et al, have indicated, "The causes of MEs are multifactorial, crossing many lines of responsibility. At the same time, they involve similar circumstances. Leapeet al. defined broad categories in which the underlying problems that result in MEs be found, such as lack of knowledge of the drug, lack of information about the patient, violations of rules, slips and memory lapses, transcription errors, faulty interaction with other services, faulty dose checking, preparation errors and others."⁵¹

There is an urgent need to adopt effective approaches to managing any medical institution, merely to ensure that all the operations in every unit of the hospital are well coordinated.⁵² The intensive care unit requires a high level of efficiency in management, given that patients' lives are at stake. Despite awareness of the need for effective management, some institutions typically fail to guarantee that proper management is implemented in the ICU. This situation alone can trigger errors in the ICU. Researchers have classified errors resulting from poor medical management as adverse events.⁵³ Like other medical errors, adverse events can be prevented if health care institutions considered proper management to be a priority. Regarding the ICU, health care institutions must ensure that proper medical management is adopted.⁵⁴

(2) Adverse Drug Events

Adverse drug events is the classification term for what is being identified as a leading causes of medical errors. This term denotes any damage caused by a faulty

medical intervention, specifically a drug administered incorrectly. Administering drugs wrongly, usually causes unwanted, often deleterious physiological and biochemical effects in the patient.55 *Medical errors* of different levels and types quite frequently involve a range of adverse drug reactions. Some of these effects include fever, vomiting, nausea, kidney failure, body rash, low blood pressure, diarrhea, heart rhythm disturbances, mental confusion, and bleeding.56 Some medical errors typically present a combination of these events, forcing health care providers to plan and implement intervention strategies, specifically to counter the consequences of these adverse drug events. All drugs have the potential to trigger adverse reactions even when administered properly.57 Nonetheless, adverse drug events stemming from medical errors are potentially preventable if the right drug is administered properly and in the right dosage. Normal adverse drug reactions, resulting from properly prescribed and administered medicines, are not classified as medical errors, given that they are usually beyond human control. In the United States and many Western nations, drug testing and licensing procedures are in place to ensure that any such adverse drug reactions are manageable and do not cause any permanent organ damage. In contrast, adverse drug events due to medication errors have the potential of inflicting permanent organ damage.58 Thus, adverse drug events usually require health care providers to develop prompt intervention strategies in an effort to alleviate the adverse consequences. It is possible to prevent adverse drug events if the proper prescription and administration of drugs occurs. Therefore, healthcare workers need to be alert for any signs of improper medication this vigilance will help prevent critical adverse drug events that might otherwise lead to death or serious complications. Certain studies have found that medical errors may occur as

health care providers prepare or dispense drug solutions. Some drugs need dilution, a factor that needs the health care providers to have adequate knowledge on the proper ratios for doing so.59 There is evidence that health care providers make mistakes relatively frequently in the dilution process and when transferring drug solutions from larger to smaller containers. This finding underscores the need for management systems to ensure that these procedures are properly monitored, to ensure that errors are minimal.60

(3) Medication Error

Far more than that more commonly envisioned process of obtaining medication through visits to a physician and a pharmacist, the process of prescribing, dispensing, and finally administering medicine to in-hospital patients is vulnerable to many types of error, whether or not they are ICU patients. Predictably, this latter group will need the most medications in terms of both number and complexity of administration of any group in the facility.₆₁ As an obvious means of simplifying and minimizing delays in deliver, along with keeping costs as low as possible, institutions typically set up their own systems of procuring, storing, handling, and dispensing drugs, separating bulk medication in large containers to smaller, often diluted doses units for administration to individual patients. The system for managing this complex process within the institution plays a critical role in either augmenting or reducing the risk of medication errors, as well as the nature and severity of the effects they produce.₆₂ The delivery of every specific medication to each individual patient in the ICU involves five steps: prescription, transcription, preparation, dispensation, and administration; as stated, this procedure is

overly simplistic however in that there can be several hundred sub-procedures There exists, of course, a risk of various forms of error at each stage in the process. Thus, the risk of error for any given patient is high; it is therefore noteworthy and laudable to ICU staff that the frequency and severity of errors, alarming and harmful as it is, is not far greater.⁶³ As an example of one of the many opportunities for errors with medication, Dhillon reports that some health care providers have registered errors when prescribing dosages of drugs.⁶⁴ According to David et al, in relatively serious cases, health care providers exhibited delays in responding to patients' needs, and at other times failed to make any attempt to reversing wrong procedures which constitute medical errors.⁶⁵

(4) Human Errors

According to Donchin et al, human errors are considered to have possible the highest potential for causing medical errors.⁶⁶ The following subdivision of this section of the chapter analyze specific forms that human errors can take, leading to a variety of medical errors. Health care related institutions are dependent on the expertise and skill of professionals on many different levels within the broadest sense of the field of medicine. The Institute of Medicine's 1999, acknowledges that it is an inherent part of human nature to make mistakes, clearly leading to the corollary that over a long enough period it is impossible for human being to consistently perform flawlessly.⁶⁷ While many human errors occurring in medical settings pose no significant threat to the well-being of a patient may easily be overlooked, human negligence is also at the root of errors that lead to serious and at times irreparable harm, even to the point of fatality. Among the authors in the literature who have indicated that that human errors account for 80% of all medical

errors,68 Bohomol et al, go on to assert that this statistic highlights the need for emphasizing enhanced vigilant and caution in the fight to prevent and minimize the effect of medical errors.69 In recent years, researchers have posited a number of explanations in analyzing the role of human error plays in the constantly increasing number of errors in medical settings. One of the most popular of these constructs is the bad apple theory.70

The assumptions behind this perspective of medical errors leads administrators and researchers to view the staff member and medical professional whose actions led to the error as being individually negligent or incompetent, and subject to isolation from the larger group of competent healthcare professionals so that the 'bad apple' will not corrupt the rest.71 While such attitudes and action validate the feeling of those at whom no blame is being directed (whether or not they are actually culpable), this conceptualization is fundamentally inadequate when it comes to explaining human errors, addressing many of the ultimate causes, or combatting the problem of medical errors in general. Other recent research has shown that numerous health systems such as hospitals operate largely in a state of dysfunctionality, a flaw in the system that puts health care professionals in circumstances which exacerbates any tendency they have to commit an error.72

4.i) Fragmentation of the Health System

One of the ultimate reasons for dysfunction in healthcare systems is the lack effective communication, especially in relation to the numerous health care providers, whose activities the hospital must coordinate. One main symptom of a dysfunctional health system is poor channels of communication.⁷³ Poor communication contributes to a range of medical errors because health care providers are unable to update each other on

the level of care needed for specific patients. Furthermore, distributed and dispersed responsibility, whether fragmented or not, inherently necessitates better-coordinated and ultimately more extensive communication.74 Thus, the dysfunction of many healthcare systems results from fragmentation. A fragmented system guarantees miscommunication, which inevitably leads to medical errors.75 One study found that, "A communication failure among services' caused 8% of MEs. In these instances, institutional routines were not obeyed. These types of errors were particularly related to high-alert medications, such as psychotropic or sedation drugs that could only be requested using a handwritten special formulary. Failure to complete this special formulary often prevented the nurse and pharmacist from processing the request."76 Boettger contends that this fragmentation stems from the absence of proper designation of authorities and responsibilities within the hierarchy of the facility or institution. Consequently, many responsibilities remain unassigned and the actions they represent remain unexecuted because each agent in the system assumes that someone else should and will carry out the particular duty.77 McGowan and Healey explain saying, "The current health care delivery system is a fragmented system of care that usually requires patients to see multiple providers in many locations virtually guaranteeing that these providers do not have access to complete patient information. Making matters worse, there is no incentive to improve safety and quality of care. These medical errors are caused by a faulty system that actually encourages mistake."78

Among the results of this fragmentation is a level of general confusion, as levels of authority among staff members are unclear, precluding the effectively performance of responsibilities. Compounding this problem is the tendency of those overseeing faulty

healthcare systems to assume that automating a system will guarantee the elimination of medical errors.⁷⁹ While this solution sounds good in theory, in practice it is fully counterproductive in that the automated systems themselves necessitate constant monitoring and administration by properly trained experts in order to do their jobs without become another source of medical errors.⁸⁰ Research has shown that the absence of effective information sharing systems in some hospitals has contributed to a causing greater numbers of errors.⁸¹ In hospitals and in the ICU in particular, a large number of different staff members attend to any individual patient. When these workers are prevented from sharing information and coordinate their actions with those of other healthcare professional errors will occur. This lack of information sharing severely impedes the accurate assessment of a patient's medical condition, as well as the monitoring of treatment, all of which contribute to medical errors.⁸²

4.ii) Cognitive Errors

One major group who are prone to a specific form of human, cognitive error are physicians who fall into a type of thinking, which does not conform to logic or reason. Such thinking processes constitute cognitive pitfalls and may be a type of occupational hazard. At times, some doctors hold certain beliefs held that hinder their level of clear judgment.⁸³ For instance, a medical professional may hold fast to an interpretation of initial data concerning a patient and then ignore conflicting data from later phases of treatment that present a different picture of the case. In other cases, dramatic events in medical practice often impede the physician's critical judgment exhibited. Such cognitive errors are significant factors that contribute to human errors in medical practice.⁸⁴

Hurst declares that, along with errors of commission, cognitive errors of omission are undoubtedly among the most prevalent types of medical errors. These errors can be broken down into two types; those that result lack of or incorrect knowledge and those that occur as the result of misusing or not using knowledge. Although almost all healthcare providers commit these medical errors on occasion, it is apparent that such errors can be minimized.85 In this regard, physician-patient communication is very important in healthcare settings. The doctor needs to have an appropriate feedback from the patient before introducing medication; otherwise, lack of information can lead to cognitive, and in turn, medication error. Given that certain diseases have distinct subsets requiring divergent forms of treatment, a generalist needs to screen all aspects of the patient and to collect a complete set of data in order to identify correctly the patient's actual condition.86

The application of knowledge is at the heart of the type of care the patient receives. Often, the physician lacks all the known information needed in caring for a patient. Beyond diagnostic related information, it is crucial for medical professionals to have feedback on the treatment decisions they make, promptly as implemented.⁸⁷ This involves first ensuring that what the physician writes, says, thinks, and does correlates with what is documented in the medical record. In addition to this, the healthcare providers must ensure that all subsequent information produced in the course of treatment is duly recorded and compared with the initial data, diagnosis, and prescribed treatment plan. All this important information must be kept in an uncluttered form and displayed conspicuously for rapid retrieval.⁸⁸

Obviously, healthcare professionals need to be continuously improving their knowledge base, and thus avoid cognitive errors rooted in out-of-date information while providing care for their patients. Improving knowledge is the responsibility of healthcare providers for their entire careers in medical activities and research. In tandem with this, it is apparent that prevention of cognitive errors cannot be achieved if the trainees are not only trained with the most up-to-date information, but also are molded into the time of professional who is continually seeking out new knowledge, understandings, and techniques.89 Additionally, it is advisable for all healthcare providers, up to and including the most compassionate of doctors, to seek professional help when in doubt concerning any aspect related to treating a patient. Healthcare providers need to try as much as possible to avoid cognitive errors, but it is equally crucial for medical decision makers to appreciate the impact and contributions of cognitive errors in medicine. Everyone in the field should endeavor to prove false the notion that cognitive diagnostic errors are unavoidable, in addition to dismissing the pessimism that impairs approaches to reducing cognitive bias.90

4.iii) Ineffective Skills and Inadequate Knowledge

Boettger contends that a significant number of human errors are attributable to ineffective skills and inadequate knowledge, deficiencies that compromise the effective performance of health care providers.⁹¹ Many of the institutions preparing healthcare trainees do not prioritize offerings in the required training that would equip health care providers to minimize medical errors, especially if they find themselves working in the ICU. Unfortunately, such training institutions often do not recognize the seriousness of

medical errors and their potential effects on patients. Health institutions, at times hire such healthcare providers to work in the intensive care unit, even though these new employees do not understand the pressing need to reduce medical errors through increased vigilance.92

Yet another area in which there is a lack of skill or knowledge in the ICU are the healthcare providers who have not received the proficiency training required to operate the specialize highly complex equipment routinely used in the unit. Moreover, some healthcare institutions do not offer advanced training on the use of modern diagnostic kits, which are the products of the new technologies.⁹³ Such health care professionals are then unable to utilize new technologies and techniques, critical to care of ICU patients. Undoubtedly, some negative patient outcomes seemingly arise because of chance and do not appear to be attributable to any specific medical error; nonetheless, they may be preventable with best practices for minimizing errors.⁹⁴

4.iv) Long Working Hours

One of the most significant human factors, contributing to the increase medical errors is system of scheduling healthcare providers to work long hours at a stretch, leaving them exhausted long before they are able to rest and recuperate. Even breaks between workdays or shift are frequently insufficient. Such constant fatigue affects their capacity to think and carry out tasks accurately, making them much more prone to error.95 Evidence from the field of psychological has established that fatigue affects one's level of concentration, a critical faculty in even greater demand when working in the ICU. Healthcare workers are well aware of the strain they are under in such circumstances, and

thus ironically their motivation to deliver the highest quality care in spite of the fatigue level they feel adds to the stress of they experience, potentially triggering further errors.⁹⁶ As mentioned above, healthcare providers are too often working in a state of sleep deprivation, further eroding the quality of care they are able to deliver. Since these workers must deliver constant care in the ICU, most health care providers in the environment are physiologically engaged in a constant internal battle with sleep while attempting carry out medical procedures. This explains why medical errors are higher in intensive care units whenever health care professionals are assigned longer working hours.⁹⁷

Chapter 2.B. Statistics of Medical Errors in the Hospital ICU

This section of the_chapter begins with an overview of statistical data, which document the cost of ICU care under the best of circumstances, frequency of medical errors and their associated costs both in general and specifically in the intensive care unit, comparing in-patient versus outpatient errors rates. This discussion attempts to demonstrate that, despite the frequency and causal complexity of risks factors for medical errors in the ICU, these factors are nonetheless amenable to isolation and analysis as a prelude to their elimination or at least minimization and mitigation.

Chapter 2.B.1. Medical Errors Rates and Costs

In the absence of precise statistics, Curtis et al. have posited that an estimated 20% of people in the U.S. who have passed away in recent years have in the prior months spent time in a hospital ICU. However, regardless of the outcome of a patient's stay, it

will involve significant pain or discomfort, along with enormous financial obligations in its wake. According to the researchers cited above, approximately one quarter of the average individual's lifetime healthcare costs re incurred during the final year of his or her life. Curtis et al. go further by suggesting a limitation on the time that patients with unstable medical conditions due to life-limiting, usually chronic, illnesses spend in the ICU, reducing suffering, expense, and risk of medical error all at the same time.98

In their effort to put concrete cost estimates on ICU care in general, Multz has calculated a figure of approximately \$62 billion for United States in 1998, and has given that figure context by characterizing it as 34% of a typical hospital's budget and about 1% of U.S. gross domestic product.99 Obviously, the potential benefits of feasible and properly administered treatment are as enormous, if less quantifiable, as are the costs of ICU care. All these considerations serve to magnify the vital significance of the problem with medical errors in this unit of the hospital.100

While the expenses incurred by a stay in the ICU are tremendous, not all of them can be justified. According to Garland et al, physicians working in or with patients destined for stays in the ICU exercise broad discretion in ways that influence the costs, deciding which patients to admit to the unit and what tests, therapies, and medications to order, for example radiology imaging, lab tests, blood bank, or echocardiography.¹⁰¹ Unfortunately, while this discretionary authority influences spending and thus costs, it has demonstrated neither quantitative or qualitative difference in terms of better clinical outcomes. According to Garland et al, found on the first day alone, of an ICU stay, the median discretionary costs was \$1343 for 10.6 hours of stay while the costs created by

intensivists and their attending assistants, amounted to an interquartile range of \$788-\$2208.102 A lack of cost awareness on the part of ICU intensivists is likely a major contributing factor in this problem; at the same time, it should be noted that every added test, treatment, or procedure carries the inherent additional chance of a medical errors happening at some point during the course of treatment. Backing up this contention, albeit with international data, a study of French ICU physicians found that only 29% of their estimates of the true hospital costs of 46 common prescriptions were within 50% of the true cost. The most widely (and by the greatest amount) underestimated cost were those for expensive medications.103

Significantly, the medical error rate for the ICU in comparison any other hospital unit was two-to-one or greater.¹⁰⁴ In a major study, Camiré, et al assert that for every critically ill patient who has spent time in an ICU, approximately 1.7 medical errors of some level of seriousness have occurred. Chillingly, these researchers found it to be quite common that any given patient will experience at least one life-threatening error at some point in his or her ICU stay.¹⁰⁵ Best estimates of other researchers concur in that this statistic represents a gross understatement as to frequency of medical errors, given that the above statistic way based on self-report data, known to be extremely vulnerable to underreporting. Even in teaching hospitals with their intensive monitoring procedures and the high priority that they stringently place on reporting, a huge gap is believed to exist between the intention to report and the act of doing so.¹⁰⁶

Admittedly, it is extremely complicated to ascertain conclusively whether any the death any given patient is the direct consequence of a medical error, and most evaluations

end with judgments that are open to subsequent debate.107 In contrast, consensus exists that a reasonably accurate general estimate stands at somewhere between 44,000 to 98,000 annual death, directly attributable to preventable medical errors.¹⁰⁸ This figure would constitute approximately 2%-4% of the total annual deaths in the U. S.109 in making these claims, McGowan and Healey turn for support to the 1999 Institute of Medicine report. The report found that that up to 98,000 deaths per year were attributable to preventable health care errors, resulting primarily in adverse drug events (ADEs) and preventable complications, such as inadequate nutrition, incontinence, falls, pressure ulcers, and delirium.110 Coincidently, older adults, more frequently the patients in intensive care units, exhibit greater risk of experiencing these types of errors. While in this latter context, they are typically reported as geriatric syndromes, they consist of specifics that include pressure ulcers, delirium, functional declines, and falls.111 In response to the severity of the problem and the lack of institutional responses, Sultz and Young have charged that the problem of medical errors in hospitals is well known throughout the healthcare community, but is for the most part ignored by those with the power and authority to effect change.112

In the 1999 report by the Institute of Medicine's Committee on Quality of Health Care in America entitled *To Err is Human: Building a Safer Health System*, Kohn et al. asserted that the annual cost associated with adverse events caused by medical errors was 17 - 29 billion dollars.¹¹³ According to Vlayen et al, *adverse events* constitute health care management processes that result in unintentional complications, errors, morbidities, mortalities, or extended hospital stays.¹¹⁴ According to more-recent data from the Millennium Research Group in 2008, such losses amount to a more modest \$19.5 billion;

nevertheless, this total is still distressingly high, particularly when added to the estimated \$17 billion lost each year through prescription errors.115 Underscoring the severity of the problem, several studies assert that more individuals have died from consequences of medical errors than those who have been killed in motor vehicle accidents or died from either breast cancer or HIV. In response to this, the Center for Medicare and Medicaid Services (CMS) instituted a major policy change beginning on October 1, 2008, which identified eight categories of medical errors and denied payments for their consequences, describing them as preventable hospital-acquired conditions (HACs), preventable medical errors (PMEs), or occurrences they called never events. These include pressure ulcers, falls, trauma, surgical site infections, vascular-catheter infections, urinary tract infections, administration of incompatible blood, air embolisms, and foreign objects remaining in the body after surgery. The CMS refuses to pay for correcting these conditions unless they are preconditions, which existed prior to hospital admission. Two more conditions were added to the list in 2009 following the CMS final ruling, namely deep vein thrombosis associated with knee and hip replacements and manifestations of poor glycemic control.116

One factor adding to the costs of medical errors is that patients in the ICU run up huge additional expenses any time a medical error must be corrected, extending their stays in the unit along with the added costs of new, corrective procedures and/or prolonged original treatment.¹¹⁷ According to Nilsson et al, a full 20% of patients in Swedish hospital ICUs typically suffer from adverse events (AEs); 50% of these were judged preventable and probably consisting of medical errors, despite being typically labeled procedural complications. These included bleeding after a tracheostomy, low

saturation during the tracheostomy, nosocomial infections, and adverse drug events (ADEs); each of these "complications" correlated with 6-8 unanticipated days of hospital stay.118

Medication errors constitute a sizeable percentage of medical errors in U.S. hospitals in general, and likely the ICU specifically; according to Rothschild et al, such errors probably amount to two thirds of medical errors in these settings.119 Approaching this phenomenon from another perspective, Gorbach et al estimate that each patient in the U.S. is likely to experience at least one medication error per day of hospital stay. These researchers further estimated that each ADE increases patient time in the hospital by 1.74 days that translating into approximately \$2,000 for each ADE. In total, the annual cost of preventable ADEs in the U.S. is estimated to amount to \$3.5 billion in 2006 dollars.120 One of the most striking findings of this study is that medication errors increased as a function of the number of orders verified by each pharmacist during any given shift; specifically, any excess of 400 orders per pharmacist per shift correlated closely with the highest risk of error. Since most hospital systems only employ a voluntary reporting system, these researchers caution that their findings need to corroboration from additional studies at various hospital facilities. It is generally conceded that ICU patients are administered more drugs and have twice as many ADEs as non-ICU patients. Risk factors are also elevated due to the high potency of these drugs, their complexity of administration, such as through gastric tubes and central venous catheters, not to mention the life-threatening context of the ICU itself.121

Chapter 2.B.2. Inpatient Injuries in the Hospital ICU

While relevant literature includes research comparing inpatient and outpatient care, 122 the subject of this dissertation's focus is the cost of medical errors occurring during institutional inpatient care, specifically within the ICU, and therefore such comparative research is only addressed here to the extent that it can provide context or insights not available elsewhere in the literature. Unfortunately, research into the specific costs of medical errors occurring during stays in the ICU, even in the context of specific regions or hospitals, is virtually nonexistent, making accurate estimation for the entire U.S. woefully imprecise.123 Unquestionably, any patient admitted to the hospital for any purpose will incur an elevated risk of suffering from the effects of a medical error than would an individual entering the same institution on an outpatient basis. Furthermore, among all those of the general hospital inpatient population, those in the ICU are at greatest risk. One known cost of medical errors is that for all hospital inpatient medical errors combined, including the ICU, which in recent years has reached and perhaps surpassed \$2.7 billion annually.124

Although the largest portion of the combined costs described above involve medical errors related to inpatient care, outpatient medical errors are also included in that statistic, albeit to a largely unknowable extent. Contribute a share of errors and costs, although they are mostly unknown. On one hand, many of the underlying causes of or circumstances leading to medical errors, such as staff fatigue, the handling specimens and related laboratory work, misdiagnosis, and medication errors may all occur as easily in

the hospital's process of providing care and treatment on an outpatient basis. Moreover, those receiving outpatient care are particularly susceptible to some of the same risks from discontinuity of care as do many elderly ICU patients when they are transferred from one care setting to another or when they transition from inpatient to outpatient status, both situations which are discussed in detail later in this section. Outpatient care inherently creates built dangers for patients with chronic conditions including diabetes, hypertension, lipid disorders, depression, and coronary heart disease.

One risk factor in particularly with regard to a phenomenon known as *clinical inertia*. While the statistical prevalence of this condition is difficult to ascertain, much less the extent to which it leads to medical errors in the ICU or elsewhere, its causes and mechanisms of operation have been the subject of some research. *Clinical inertia* has been defined the failure to intensify pharmacotherapy when evidence-based clinical goals for the patient are not achieved within a critical period of time. Clinical inertia always incurs preventable negative consequences, ranging from elevated treatment costs to disability and even death. According to O'Conner et al, the causes of critical inertia can be comparatively quantified, with about 50% attributable to physician factors, 30% to patient factors and 20% to office system factors.¹²⁵

The category physician factors refers to behaviors and attitudes on the part of medical professionals that would tend to increase the likelihood or exacerbate the extent of clinical inertia or its consequences. These factors would include: 1) a mindset or habits of reactive rather than proactive care, 2) not allotting enough time with patients for effective communication, 3) neglecting to investigate and deal with comorbid conditions,

4) setting inappropriate or unattainable goals, and 5) delays in beginning treatment as promptly as warranted. Several attitudes or presumptions common among physicians can increase the tendency towards clinical inertia. For example, many physicians may exaggerate the quality of their own patient care, at least in their own perceptions, and in the process miscalculate the number of patients who actually need intensified pharmacotherapy.126 Some doctors rationalize the avoidance of intensifying care, invoking such pseudo-justifications as faulting the patient for supposedly not following previous directions or prescriptions, not being able to raise the issue at office visits due to time constraints, or by presuming that the patient will resist any proposal to intensify care.127 Moreover, other physicians will offer as defense the lack of everything from training to tools to time to office infrastructure in order to assert that they are ill prepared to cope with the changing needs of patients with chronic diseases.128 Besides standard treatment, effective chronic disease management requires attention to various other inherent considerations which explains and supports the idea that many physicians are not well prepared to resist clinical inertia and are thus more frequently prone to errors. 129 The changing circumstances of any chronic disease in a given patient over time necessitate more intensive record keeping via distinct procedures in order to accurately chart and track both the condition, along with decisions concerning how to management it. Such decisions include: 1) target identification and goal setting, 2) organized attempts to discover optimal treatment, and 3) the titration of treatment in order to achieve the initial goals, as the disease or condition changes. Medical errors can occur either in the context of making these decisions or in implementing them. For instance, goal setting is a dynamic process needing continual reevaluation change over time, yet this may be
handled in such a way as lacks consistency to the point that the overall goal is never achieved; there exists a name for this phenomenon, thematic vagabonding.130 Treatment goals may themselves be inappropriate based on a physician's familiarity with the medical condition as opposed to the particular patient's needs. In such cases and in terms of the patient, the goals of rehabilitation and restoration of health have not been reached due to goal fixation.131 Without adequate monitoring on the part of the physician, treatment trials may fail to provide critical information or feedback in a time-sensitive manner, distorting the results as they relate to the reality of the situation, stripping away the physician's understanding of or control over the circumstances as the patient is experiencing them.132 At minimum, there are three kinds of errors that can occur in the context of titration of treatment: 1) adhering to incorrect or non-existent timing,133 2) choosing an ineffective treatment or inefficiently coordinating multiple actions over the course of their implementation,134 and 3) pursuing action despite a poor understanding of its potential side effects.135 Medical errors occurring for any or all of these reasons can result in the deterioration of the patient's health or other unforeseen negative consequences.136

The second source of clinical inertia, patient factors, consists of attitudes and circumstances that while residing within the patient should not be interpreted as making the patient culpable for medical errors; these include: 1) denial of disease or affliction, 2) illiteracy concerning health or medicine, 3) taking too many or poorly coordinated medications, 4) lack of effective communication with the physician, 5) mistrust of the physician, 6) depression, and 7) substance abuse. A patient's mental model of various aspects of healthcare, such a disease, medication and treatment, the role of a physician,

can create obstacles to effective treatment that amount to clinical inertia. Refusing to accept that a disease or condition exists, is happening to oneself, or is causing poor health can lead to not making a decision or taking appropriate, timely action. Motivations aside, pharmaceutical companies understand, to their credit, the power of their marketing pitches in persuading people of the reality of certain diseases and of potentially effective remedies and therapies. Thus, despite their potential for fostering unwarranted concern, such marketing does promote the right mental model for combatting clinical inertia.137

The third significant source of clinical inertia lies with deficiencies in office systems, namely; 1) an absence of outreach efforts, 2) incomplete or ineffective communication among staff or between staff members and physicians or others involved, 3) the absence of leadership or coordination required for a team approach, and an absence of clinical guidance.138Furthermore, physicians who do not individualize their practices to match the diversity of their patients, not to mention the numerous ways in which various chronic diseases present at different stages and in different may well compound the problems of clinical inertia.139

As mentioned above, while it is difficult to quantify medical errors related to the discontinuity of care that occurs when as inpatients are discharged and continue to receive care in another setting, even possibly as outpatients of the same institution, the risk is undeniably heightened. The Institute of Medicine defines this discontinuity as medical error whenever it leads to non-completion of planned and intended care or treatment.¹⁴⁰ Typically, hospital physicians prepare discharge plans for patients leaving their direct care; such plans will specify medications, test procedures, and designated

recipients for test results, normally the patient's primary care provider (PCPs). Unfortunately, Moore et al. have documented a rate of receipt that is less than 50% on the part of the PCP, thus corroborating earlier research contentions. The primary result is an increased likelihood of rehospitalization, along with the attendant increased costs. Obviously, had the primary care physician also been the attending hospital physician, there would have been continuity of care, with less chance of rehospitalization and a better patient outcome.¹⁴¹ However, such a situation is growing more infrequent as healthcare becomes more complex and specialized, and moreover, is especially unlikely in the ICU of a hospital.

Further contributing to the difficulty in accurately assessing the extent of medical errors in the ICU is that the predominant group making up the patient population in this part of the hospital are senior citizens, who are typically receiving medical care in various settings under the auspices of multiple facilities or institutions, for example between or among any of the following: the ICU unit of a hospital, rehabilitation centers or nursing homes, clinics, or at home. The involvement of multiple administrations and staffs greatly increases the need for coordination and efficient, timely, and thorough communication. To achieve all this cooperation requires significant outlay of time and resources while the lack of any part leads to a high likelihood of discontinuity resulting in less than optimal health care at best and the severest of medical errors at worst. The period of transition from being under the care of one facility and staff to that of another constitutes the period of highest risk of errors, arising from the following: 1) physician-patient breakdowns in communication, 2) issues concerning preparation for transfer, 3) unmet health care needs not communicated to the receiving caregivers, 4) dosing and

administration errors with regard to medications, 5) misplaced diagnostic results and updates, and unanticipated needs for treatment or care.¹⁴² The role of clinicians during these hazardous periods are undefined or poorly defined as Critical to the potential for problems and the increased risk of medical errors going unnoticed or escalating in severity of consequences is that no one physician is given responsibility and the authority necessary to coordinate and ensure continuity of care.¹⁴³ One study delineated time constraints, high staff turnover, the absence of communication protocols, a scarcity of staff performance feedback, and the lack of patient access to appropriate clinicians, as being among the most significant obstacles to effective care and treatment, while at the same time contributing to the occurrence of medical errors.¹⁴⁴

Chapter 2.B.3. Percent Occurrences by Error in the Hospital ICU

A variety of studies have documented the varying frequency of different types of medical errors, in relation to the origin and type of the error, as well as other interconnected factors.¹⁴⁵ For example, in the context of medical errors arising from human mistakes, either overburdening individuals or the staff in general with excessive responsibility or understaffing, which precipitates the same situation, tends to increase both the rate and frequency of errors. In contrast, equipment failure is not influenced by the same forces.¹⁴⁶ According to Blot et al, a positive correlation exists between the length of shifts that ICU nurses are required to work and the rate of medical errors in that particular ICU. The stress and tension of managing critically ill patients on a daily basis dealing with death, suffering, and grief can be wearing, distracting and lead to psychological impacts such as depression, burnout, and PTSD.¹⁴⁷ Camiré et al. report that

interns working 77-81 hours per week on a critical care clinical rotation made 17.3% more errors than a similar group of interns following a 60-63 hour workweek.¹⁴⁸ Supporting these findings, Landrigan et al. concluded that sleep deprivation on the part of interns led to 35.9% more identified serious medical errors, and 56.6% more nonintercepted serious errors; this depravation was defined by their working frequent 24 hour shifts, as opposed to working shorter shifts in the ICU.¹⁴⁹

Despite the apparent complexity in the interaction of contributing factors, the research reveals undeniable common trends, which go a long way toward explaining the relative frequency of specific kinds of medical errors.¹⁵⁰ Despite the complexity of analyzing rates of individual types of errors, one overarching factor in determining the types and frequency of those errors that occur in the ICU is the healthcare system that is in place in the specific institution in question. Procedures for drug storage at one facility may contribute to a tendency to experience medication errors, while another institution might be vulnerable to other types of errors owing to flaws in its communication systems.¹⁵¹

One factor which extensively impedes efforts to accurately and thoroughly document the occurrence of adverse events in the ICU, events that are directly related to medical error, is that reporting at all levels is voluntary. This leads typically to an underestimate of the incidence, frequency, and magnitude of any phenomenon where negative consequences, in this case patient harm, can be anticipated, along with culpability and blame. In terms of attempting to document medical errors in the general setting of a hospital, alternatives such as direct observation and comprehensive chart reviews are much too labor intensive and thus not cost effective. In the ICU, such methods could even conceivably interfere with the appropriate and necessary care and monitoring of patients. Australian researchers have a procedure they named a trigger tool, a form of systematic randomized screening of medical records for pre-defined event markers, to detect detected 25 times more adverse events than voluntary reporting in a pediatric ICU, where they tested the method. This tool was able to detect 90.1% of all adverse events, using both the trigger tool and voluntary reporting. Because of its success, this tool is considered reliable for use with the general adult hospital populations.¹⁵²

Medical errors differ extensively in terms of the severity of their impact. Among those with the greatest potential for causing serious consequences to ICU patients in the ICU are errors related to the labeling and handling of specimens. These can occur even prior to admission to the Unit, in fact anytime specimens are collected, labeled, transported from the ICU to the hospital laboratory, handled there by clinicians, or the results are recorded and disseminated. Particularly vulnerable to mistakes are samples of blood, urine, sputum, stool, and issues of fluid or viscous substances.¹⁵³ Given that laboratory testing has a 60-70% stake in ensuring that each ICU patient is accurately diagnosed and receives the proper treatment,¹⁵⁴ errors with the labeling of specimens can have among the most severe of consequences.¹⁵⁵ Even the minority of these errors which appear to only delay, impede, or misdirect options can have ramifications leading to irreparable injury or death.¹⁵⁶ Furthermore, when the consequences are catastrophic, both the ICU and the laboratory, the ICU, as well as the hospital, suffer financially and in terms of the reputation. Unfortunately, in spite of the many sophisticated procedures and

technology that are already in place to prevent or minimize specimen errors, such as barcode matching of patients to specimens with wristband and bedside readers and scanners, electronic health records, and computerized entry for doctors' orders, far too many specimen errors still occur.157

Studies by Bhat et al; Green; and Kaushik and Green found that errors happen more frequently during the preanalytic phase of a patient's stay in the ICU than they do in all the subsequent phases combined.158 Specifically, Green found that preanalytic errors may amount to as much as three-quarters of all medical errors in this category. 159 Beyond that statistic, this researcher calculated incorrect patient identification to be among the top four most frequent forms of pre-analytic error.160 Similarly, Dunn and Moga found in a root cause study of the Veterans Health Administration, that 182 of 227 (or 80%) of error involved misidentifying the patient, and that 132 out of 182 (or 79%) of these misidentifications happened during the pre-analytic phase.161 Prominently occurring mistakes included putting the wrong wristband on a given patient, removing specimens from the bedside or from their place in the lab and then mislabeling them, and making typographical errors in a patient's identifier code.162 Ultimately, these types of human error proved the most recalcitrant to eliminate or even reduce. According to Martin, Metcalfe, and Whichello, one of the more surprising finding was the unexpectedly large number of errors resulting from the nurses deliberately overriding the barcoding.163

Undoubtedly, reliance on technology in terms of automating infrastructure and support system functions in the ICU has the potential to reduce both the frequency and the severity serious errors in the ICU medical errors, not to mention those occurring in

other parts of hospital or clinical facility. Nonetheless, some of this automation may simply trade the risk of one type of error for another. For instance, Idemoto et al., report that in applying a computerized systems for dispensing medication according to an order entry system provided several benefits, namely reducing patient disruptions, fostering task efficiency, increasing safety, and cutting down on prescription errors.¹⁶⁴ At the same time, other researchers have documented unforeseen problems created by this reliance on automation.¹⁶⁵ For example, dependence on the automated system has led to errors in relation to the timing in administering medication, resulting in doses administered too close together. Infrequently as such errors have so far been documented, they can be extremely dangerous for weak and vulnerable ICU patients, who may thus receive double doses of medications the likes of antithrombotic agents, narcotics, opioids, or insulin.

Control systems are in place in some institutions designed to alert medical staff to such potential problems, yet these systems are themselves dependent upon human monitoring, which has its own propensity for error. In the ICU, as elsewhere in the hospital, the technology for maintaining and accessing computerized health records has the potential to improve the timing, safety, efficiency and accuracy of patient interventions.¹⁶⁶ On the other hand, according to Carayon et al, the implementation of electronic health records (EHR) in the ICU increased the time that doctors had to spend on review and documentation by 40% or 50%. These researchers also found that the use of the EHR system led to increases in alternating among multiple tasks from 117 to 154 per hour (an increase of 32%) for residents although for attending physicians the same statistic decreased from 138 to 106 (a decline of 23%). While the frequency of conversations between physicians and patients in their care did not change, the limited

ability of many ICU patients to communicate extensively may have been a factor. While the study could not answer questions about possible improvement in patient care or possible reduction in the rate of medical errors, it did document increased attention to and prioritization of clinical review and documentation. This increase of switching between tasks was significantly disruptive and distracting although not so much as to be atypical of hospital intensive care units in general. Given that to date many hospital ICUs have only short term experience with the system, more research will significantly into the future will be needed to assess the ultimate benefits and impacts of electronic health records.167

Chapter 2. C. Risk Factors for Medical Errors in the Hospital ICU

Researchers have sought to highlight risk factors for medical errors in the intensive care unit. It emerges that several factors can be categorized as potential risk factors that increase the occurrence of medical errors.¹⁶⁸ This section of the chapter presents an indepth analysis of the different risk factors elaborating how they prove to be triggers for medical errors. These risk factors may be categorized as relating to: 1) the patient, him or herself, 2) the medications involved in treating the patient, 3) the ICU equipment used in treatment, and 4) the multiplicity of providers involves in the care and treatment of the patient.

Chapter 2.C.1. Patients

Several factors surrounding the patient have been grouped as risk factors for medical errors in the intensive care unit as highlighted below. This sub-section of the Chapter discusses: 1) the severity of the patient's primary illness or injury, 2) any age related seeds the patient may have for special care, 3) whether the patient is in the hospital or ICU for an extended stay, and 4) whether, as is likely, the patient is under sedation.

(a) Severity of the Primary Illness

Admission into the intensive care unit can be triggered by a considerable range of life threatening conditions. Despite this classification, the severity of these conditions differs.169 Health care providers may find themselves confused by the atypical characteristics of some of these most severe illnesses. In addition to the severity of their conditions, patients may be suffering from multiple complications, each of which medical professionals must disentangle and isolate, in order to treat simultaneously. Many patients admitted to the ICU are experience dysfunction with multiple physiological systems; thus, the level of complications and severity of the condition in general is, for any given patient, a primary risk factor for medical error. In handling and treating patients with severe or urgent cases, healthcare professionals are markedly more prone to committing errors. In a bid to save the life of a patient, these professionals may feel pressured into making hasty decisions or executing the wrong treatment strategy.170 Moreover, given their greater vulnerability, patients with complicated medical conditions are significantly more likely to suffer negative consequences from medical errors. These propensities have been documented in the work of numerous researchers who have analyzed differing aspects of this issue.171 For example, Tourgeman-Bashkin and Zmora have found that medical errors occur more readily in situations in which a patient's

condition represents a complex medical case. This tendency explains why the recorded number of medical errors is highest in the hospital's ICU; patients admitted to this department require critical, often emergency care.172 Marik asserts that whenever the severity of illness necessitates hospitalization, the likelihood of medical errors occurring increases significantly. Patients with the most complicated medical conditions or those who require the most complicated regimens of treatment are susceptible to the greatest burden in terms of the consequences of medical errors simply to the extent that their conditions demand critical care and treatment. Ultimately, healthcare providers are bound to commit mistakes as they strive to offer highly complex and demanding regimens of care and treatment.173

(b) Age Related Need for Special Care

According to Taib et al, the age of patients correlates closely with their susceptibility to medical errors. Patients admitted to the intensive care unit are of different ages and present a variety of life threatening conditions.174 However, research has revealed that patients at the two extremes of the human life cycle are in need of more delicate handling as patients in the ICU, namely very young children,175 and seniors of advanced age. Compared to patients of school age, adolescence, and adulthood, young children require special medical care because of the lack of development of the biological systems, with the need for special medical care increasing exponentially when a life threatening condition is involved. Given the immaturity of physiological processes in children, healthcare professional face additional challenges when handling young children.176 Children require dosages of medication and treatment procedures, which are different from those commonly administered to adults, and which moreover, involve much narrower margins of tolerance for over or under administration. Furthermore, making wise decisions on the type of care for to children in the ICU represents an experiential gap in the knowledge of many health care providers, causing them to be more prone to error. As with patients of all ages, some errors may cost the life of children while others may be rectified with effective intervention strategies; however, with young children the former category is proportionally greater. In order to minimize the potential severity of the consequences of medical errors, healthcare professionals need to be much more assiduous in monitoring and administering care to young children in the intensive care unit, tasks already under-performed with regard to ICU patients as an entire group.177

Within the context of voluntary reporting, health care workers tend to report an increased number of medical errors while treating and caring for children, a situation to be anticipated given the developmental stages children are progressing through both physically and mentally. Rathert et al note that it is easy to confuse the types of healthcare a child requires and the ways in which they are distinct from those of an adult leading to a variety of medical errors.¹⁷⁸ Moreover, children become highly depend on caregivers when ill or injured, particularly when hospitalized. Since children are unable to be proactive in taking care of their needs, caregivers must operate with special skill in order to elicit the relevant information needed to provide the required care. According to Nguyen et al, this dependency itself constitutes an additional risk in that it increases the likelihood of medical error.¹⁷⁹ Moreover, certain diseases exhibit distinct epidemiological symptoms in juvenile patients from those which are typical in adults,

placing children, especially the very young, in need of special care and increasing their risk for suffering adverse effects from any medical errors. Furthermore, children from various demographic groups, especially those already hampered by poverty and racial disparities in health care, may be at increased risk of suffering negative consequences from medical errors. Naylor contends that their reliance solely on public insurance and need to seek services in government hospitals should be deemed a risk factor for medical errors by itself.180

Toward the other end of the life cycle are the elderly, who also require specialized care compared with adults in general. The aging process coincides with numerous health conditions; moreover, various biological systems tend to deteriorate toward dysfunctionality with age. This makes the elderly as a group more vulnerable to life threatening conditions such as dementia. The physiological challenges that come with age intensify the challenge of delivering appropriate and efficacious medical care that senior citizens need when in the ICU. Statistics from various studies have documented the increased tendency that healthcare professionals have for making errors with this age groups, particularly in terms of administering medications or implementing treatment procedures.¹⁸¹ Individuals within this age group may be highly responsive to some medical procedures yet far less sensitive to others. Such circumstances constitute dilemmas for the healthcare providers who handle their cases. These dilemmas and the confusion they engender only function to trigger medical errors.¹⁸²

Valiee et al have noted that diseases associated with older adults, such as diabetes, dementia, and heart attacks require critical care, which may compound other injury or illness that has caused their admission to the ICU. As healthcare providers strive to provide such care, they are more likely to incur medical errors.183 According to Mattox, the risk is higher among hospitalized elders, relying on nursing care to manage their conditions.184

(c) Extended Stays in the Hospital or ICU

The length of time an individual spends in the ICU may constitute a risk factor for medical errors. Some patients with complicated illnesses spend months or years in the unit. During these prolonged periods, medical care providers try to intervene using different strategies to save the individual's life and stimulate his or her recuperation. If a patient does not respond to the various strategies used, the case only becomes more complicated.185 Healthcare providers face the dilemma of whether to search for different, and potentially more efficacious, treatment procedures at the risk of causing setbacks or even harm. Such confusion may lead to potential errors that may compromise the safety of the patient.186 Sometimes, the situation of patients only worsens with time, prompting doctors to alter the treatment procedures with other alternatives, leading to a heightened probability of medical errors. The occurrence of any error will almost certainly prolong the patient's stay in the intensive care unit, as medical professional must now work to correct the situation using relevant intervention strategies. For example, patients who spent a long time in the ICU are highly prone to serious of infections resulting from medical errors. A clear illustration is the development of sepsis in long term ICU patients.187

(d) Patients under sedation

According to Church and MacKinnon, sedation comprises the administration of different drugs to reduce the patient's responsiveness to stimuli, along with awareness of surroundings.188 ICU patients usually need some degree of sedation, although the need varies from patient to patient. Prior to the development of modern treatment procedures and equipment, patients in the ICU relied on different tubes inserted into the body in order to ensure the proper functioning of their biological systems, usually causing some degree of irritability and agitation.¹⁸⁹ This circumstance necessitated heavy sedation. By contrast, modern ICU ventilators more efficiently and painlessly guarantee that the patient has access to ventilation; thus, tubes are becoming less useful in many critical care units. However, for other reasons, sedation is still fairly common depending on the diverse needs of each patient. One of the reasons why critical care patients require sedation is because of the pain associated with many life-threatening conditions.190 Regulations exist as to how much sedation is necessary, given the patient's condition. Regardless of level, sedation incurs certain consequences, and various researchers have identified it as a potential risk factor for medical errors. Since the sedated patient displays limited and subdued physical response, if any, to different treatment procedures, it becomes easier for healthcare providers to implement some procedures.¹⁹¹ Yet at the same time, it becomes easier to commit errors in the diagnostic, the treatment, or the medication phases, and to do so without immediate feedback in terms of negative response in the patient. Therefore, the probability of a medical error arising is much greater in dealing with highly sedated patients.192

Chapter 2. C.2. Medications

Medications forms yet another classification of risk factors for medical errors. Different factors associated with medication serve to present health care providers with potential challenges, hence triggering the occurrences of medical errors. Three of these factors, as described below, are: 1) special types of medication, 2) the number of medications a patient is taking, and 3) the number of intervention that a patient is undergoing.

(a) Special Types of Medication

Accodering to Bucknall, certain types of medication demand a degree of stringency as to the specific conditions and procedures by which they are administered. While these medications are recommended only for particular patients with specific physiologies or conditions, presently numerous brand names exist for pharmacologically identical drugs or compounds, circumstances that may serve to confuse the healthcare provider.¹⁹³ This may occur in the process of prescribing, ordering, or even administering medication; even a doctor may confuse the different types of medications during his prescription for a patient in the ICU. In other cases, the nurse responsible for administering the medication or the pharmacist may confuse the different types of medications available. Such confusion happens because of the different types of medications and often leads to a medical error.¹⁹⁴

Dodek has documented that with the emergence of new technologies, various different types of medications, many of which health care providers are not familiar with,

have become available within recent years. Sometimes, the availability of different types of medication may bring confusion as to side effects and dosages. For example, two different types of medication may be used to treat a similar illness but in different recommended dosages. Health care providers may easily confuse the two types and administer the safe and efficacious dosage of one in place of that of the other.195

(b) Miscellaneous Medications

The norm for patients in the ICU is a combination of medications to address the different symptoms that they are experiencing, as well as to enhance the capacity of their internal systems to recuperate. This combination demands professional competency in its coordinated administration. For example, some pairs or triads of medication may cause counter-effects in conjunction with each other; therefore, they cannot be given at the same time.196 On the other hand, some medications need to work concomitantly in order to create an efficacious potency. Healthcare providers can easily become confused when a patient in a critical condition requires many medications within the same time frame. Thus, it becomes quite easy inadvertently to trigger an error by administering a drug in the wrong way or in the wrong dosage. The chance for error involving a patient requiring only one medication is significantly lower than for one who requires a number of different medications.197 The reality that healthcare providers work in shifts, inhibiting their opportunity for adequate communication may engender further confusion as to the number of medications to be administered to a particular patient in the ICU. Although doctors and pharmacists try to be clear with respect to the dosage, timing, procedures, and caveats in administering medication to a given patient, errors still occur. These are

the reasons why the number of medications constitutes a significant risk factor for medical errors.198

(c) The Number of Interventions

Given the life-threatening conditions that send patients to the intensive care unit for admission, it is unsurprising that multiple, simultaneous interventions are often required in order to save a life.¹⁹⁹ When a patient needs a variety of interventions, extra vigilance crucial to their successful execution, in order to ensure that their interaction poses no threat.²⁰⁰ The developers of different therapies have described the order in which they need to be executed, which may vary with different patients. In contrast to the hospital general population patient, who requires only a single intervention, the ICU patient requiring multiple interventions is considerably more likely to be the victim of medical error. The challenging environment of the ICU and the level of expertise needed to deliver high quality care, when multiple interventions are a necessity, may spur an increase in the rate of error if the health care provider is not superbly competent.²⁰¹

Chapter 2.C.3. Environment and Equipments in the ICU

Moyen and his colleagues have asserted that since some medical errors are attributable to faulty equipment, different types of intensive care equipment should be an identified category of risk factors for medical errors. The following risk factors relate specifically to ICU equipment.202

(a) The Complexity of the Environment

The rapid advancement of technology serving the healthcare field as a whole has, especially the ICU, facilitated an increasing dependence on sophisticated equipment and systems, which those medical professionals who must use them to deliver vital care, monitoring, and treatment in the ICU do not adequately understand. Furthermore, from the level of patient contact to the upper most level of administration, the safety risks and consequences associated with medical equipment failure are at best poorly understood. In this context it is impossible to overstate the complexity of the ICU environment. Compared to other hospital units, the intensive care unit proves to be very complex; working in it demands an extremely high level of vigilance.203 Researchers have labeled this complexity in the ICU as a potential risk factor for medical errors in and of itself. This characterization is because the various equipment providing life support to ICU patients needs to operate properly in order to yield maximal functionality. There are different modes of ventilation that support patients in normal physiological functioning. Healthcare professional working in the ICU must be fully competent in operating different systems of equipment.204 By themselves, these systems, whether fully automated or manually controlled, may develop technical issues triggering the occurrence of technical errors. In other cases, the errors arising involving the use of such equipment and systems may be attributable to human deficiencies, such as the lack of competency in handling the system. Concerning the ICU environment, one research noted that, "Intensive care units (ICU) are specifically prone to having a greater incidence of MEs caused by the treatment of extremely ill patients, with polymedication prescriptions and frequent stressful situations for the staff, commonly occurring in conjunction with work overload in a busy area."205

(b) The Need to Handle Emergency Admissions

In a significant proportion of healthcare institutions and facilities, the ICU is the only unit equipped and staffed to handle emergency cases in which patients require urgent care and attention. Consequently, at times the typical ICU will receive multiple emergency admissions at once or in short order, necessitating a high degree of competence and responsiveness on the part of ICU staff.²⁰⁶ Emergency admissions into the ICU test of their expertise and critical judgment in offering healthcare that is, at once, both immediate and of the highest quality. Such cases normally require urgent interventions and solutions to pressing medical problems; thus, the probability of error is higher, compared to other situations affording time for thorough diagnosis and deliberation. Typically, the urgent need to preserve life runs concurrent with the need for doctors or other healthcare providers to brainstorm the most efficient treatment procedures for the patient, who presents with a case is far from 'textbook' in nature. Such critical decisions may precipitate higher than usual rates of medical errors.²⁰⁷

Considering the society, its demography, and advances in medical science, it is unsurprising that the demand for critical care is rising, partly due to an aging population prone to critical diseases and more complex ailments, which in the past few would have lived long enough to experience. This trend runs concurrent with the development of higher-risk medical treatments and therapies. Apart from steep rise in the numbers of ICU beds, the roles played by critical care specialists extend beyond the ICU.208 They act not only as members of emergency teams, but also as staff at acute care hospitals. Therefore, the gap between the appeal for critical care as well as the specialists available to offer it continues to widen, placing increased demands on those medical professionals.209 Given the current financial constraints on healthcare besides the cost associated with hiring more specialists, many ICUs cannot adopt the high-intensity intensive staffing model needed to adequately handle the increasing number of critically ill or injured patients. As a result of this growing gap, many errors are made in handling ICU admissions. For instance, an ICU staff may be forced to admit patients without running the recommended checks on the operating functionality of the equipment prior to putting into use in the course of urgently needed treatment. Any rapid succession of emergency admissions to the ICU further challenges its staff since they are required to operate simultaneously with heighten competency and responsiveness in the face of this increase in numbers of critical care seekers.210 Such conditions are among the factors contributing to unsafe behaviors in the care of patients, which invariably lead to human medical errors. Impossible as it may seem in the face of these circumstances, these errors can be reduced in order to enhance the provision of quality patient care;211 thus, they are legitimately classified as medical errors. Some scholars might contend that advances in medicine, together with the equipment and techniques they have engendered, promise to relieve much of the current pressure experienced in the ICU. However, it must be acknowledged that the applicability of these advances in the provision of care goes along with challenges such as start-up costs and the lack of staff trained and knowledgeable about their use, factors which create a propensity for various other types of medical errors.²¹²

(c) The multiplicity of care providers

Given that health care providers in the ICU typically work in shifts while ICU patients need round the clock care, various staff members attend to each patient. With varying qualifications and competencies and a diverse range of experience, these healthcare professionals may have conflicting convictions about the most appropriate diagnostic or treatment procedure for the patient.²¹³ For this as well as many others reasons, the likelihood of a medical error is higher when the patient is under the care of different individuals who are this diverse in their backgrounds. If the health care system neglects to ensure effective communication and sharing of ideas among the multiple health care providers, the chances of errors occurring are greatly increased. Furthermore, different health care providers may observe different factors in the patient's condition or response to treatment, leading to a confusion concerning the most appropriate next step in the prescribed treatment or procedure.²¹⁴

Adequate physician staffing is indispensable to the effective and appropriate delivery of healthcare services.²¹⁵ Research has documented, however, that currently physicians' shortages exist in both specialties and geographic areas. An inadequate number of physicians inevitably means delayed care and the medical errors that go along with it, as well as a propensity for various other forms of human error. In the ICU, this shortage can lead to further deterioration in the conditions of patients and even cause premature death.²¹⁶ An over-abundance of physicians can also impair the quality of healthcare for patients because, as described above, an increase in the number of professionals may exacerbate the risk of medical errors. The make-up of the physician

population also affects the health of patients, in the ICU, as well as elsewhere. Numerous number of studies have demonstrated that areas in which a significant number of primary care physicians are active realize better health outcomes than do those areas with an imbalance.217

Unfortunately, medical professionals trained for specialized units such as the ICU, surgery, or dialysis are often need or are required to make themselves available and continue working even after their regular shifts are finished. Consequently, the majority of them are prone to making errors because of the fatigue associated with working overtime.218 Compounding the effects of fatigue, the increased work intensity may also affect the accuracy of the healthcare provider's care.

Chapter 2. D. Conclusion

This chapter of the dissertation has categorized the broad range of medical errors, which are typical occurrence within the Intensive Care Unit of the average hospital. These errors consist of unintentional failures to provide proper care and treatment, known either as errors of commission or as errors of omission. The former include errors carried out in terms of execution, planning, diagnosis, delay, in correct administration of medication, complex equipment failure, and miscommunication. The latter type of error normally involves either the lack of prophylactic treatment or the absence or poor implementation of medical management. One common characteristic of medical errors is that they and their consequences are not the direct result of the disease, injury, or the condition for which the patient is undergoing treatment. The possible consequences of error in the ICU can be as varied as their causes, ranging from little to no effect to the extremes of serious injury or death. Within this broad spectrum of errors, those involving medication predominate. The costs of preventable medical errors in the ICU are staggering, including 44,000 to 98,000 preventable deaths, compounded by 17 to 29 billion dollars in economic losses. Moreover, the ICU has the dubious distinction of accounting for over one third of all the medical errors in a given hospital, both in terms of number of incidents and in the percentage of the hospital's annual budget, which must be spent on the ICU when the costs of errors are factored in. It is not surprising in the least that the ICU is a high-risk area experiencing frequent negative outcomes. After all, the patients cared for in this part of the hospital are in life threatening situations, possess little physical stamina or resiliency, have been sedated, and need complicated regimens of medication.

¹ Tully, Mary, et al., "The Causes of and Factors Associated with Prescribing Errors in Hospital Inpatients," *Drug Safety* 32, no. 10 (2009): 819-836.

² Donchin, Yoel, et al., "A look into the nature and causes of human errors in the intensive care unit," *Quality & Safety In Health Care* 12, no. 2 (2003): 143-147.

³ Grober, Ethan D., and John MA Bohnen, "Defining medical error," *Canadian Journal of Surgery* 48, no. 1 (2005): 39-44.

⁴ McGowan, Michele, and Healey Bernard J., "The enormous cost of medical errors," *Academy Of Health Care Management Journal* 6, no. 1 (2010): 17.

⁵ Moskop, John C., et al., "Emergency physicians and disclosure of medical errors," *Annals of emergency medicine* 48, no. 5 (2006): 523.

⁶ Bigatello, Luce M., *Critical care handbook of the Massachusetts General Hospital* (Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010),
67.

⁷ Moskop, John C., et al., "Emergency physicians and disclosure of medical errors," *Annals of emergency medicine* 48, no. 5 (2006): 523.

8 Angus, Derek C., and Jean Carlet, *Surviving Intensive Care* (Berlin: Springer, 2003), 65.

9 Nilsson Lean, A. et al., "Adverse events are common on the intensive care unit: results from a structured record review," Acta Anaesthesiologica Scandinavica, 56:8 (2012), 959-965.

¹⁰ Bohomol, Elena, et al., "Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65, no. 6 (2009): 1261.

¹¹ Bedevian, Rima, "Medical Errors: How Can You Avoid Them?," Retrieved from: <u>http://www.plasticsurgerypractice.com/2010/06/medical-errors-how-can-you-avoid-them/</u>. Accessed Feb 28, 2015.

¹² Bauman, Kristy A., and Robert C. Hyzy, "ICU 2020: Five Interventions to Revolutionize Quality of Care in the ICU," *Journal of Intensive Care Medicine* 29, no.1 (2014): 13-14.

¹³ Helmons, Pieter J., et al., "Effect of Bar-Code-Assisted Medication Administration on Medication Administration Errors and Accuracy in multiple patient Care Areas," *American Journal of Health-System Pharmacy* 66, no. 13 (2009): 1204-1205.

¹⁴ Bohomol, Elena, et al., "Medication Errors in an Intensive Care Unit," *Journal* of Advanced Nursing 65, no. 6 (2009): 1259-1260.

¹⁵ Gullo, Antonino, and Philip D. Lumb, *Intensive and critical care medicine*, (Dordrecht: Springer, 2009), 78.

¹⁶ Dykes, Patricia C., et al., "Medical errors recovered by critical care nurses," *Journal of Nursing Administration* 405 (2010): 241-246.

¹⁷ McGowan, Michele, and Healey Bernard J., "The Enormous Cost of Medical Errors," *Academy of Health Care Management Journal* 6, no. 1 (2010): 21-22.

18 Bigatello, Luca M., et al., *Critical care handbook of the Massachusetts General Hospital*. Lippincott Williams & Wilkins, 2010), 67.

¹⁹ McGowan, Michele, and Healey Bernard J., "The enormous cost of medical errors," *Academy Of Health Care Management Journal* 6, no. 2 (2009): 27-30.

²⁰ Kale, Abhivyakti, et al., "Adverse drug events caused by serious medication administration errors," *BMJ Quality & Safety* 21, no. 11 (2012): 1-6.

²¹ Jennane, Naoual, et al., "Incidence of medication errors in a Moroccan medical intensive care unit," *International archives of medicine* 4, no. 1 (2011): 33.

²² Negash, Gediwon, et al., "Medication errors in the adult emergency unit of a tertiary care teaching hospital in Addis Ababa," *Archives Of Pharmacy Practice* 4, no. 4 (2013): 149.

²³ Marini John J., and Arthur P. Wheeler, *Critical care medicine: the essentials* (Philadelphia: Wollters Kluwer/Lippincott Williams & Wilkins, 2010), 87.

²⁴ Bedevian, Rima, "Medical Errors: How Can You Avoid Them?," Retrieved from: <u>http://www.plasticsurgerypractice.com/2010/06/medical-errors-how-can-you-avoid-them/</u>. Accessed Feb 28, 2015.

25 Graber, Mark, et al., "Reducing diagnostic errors in medicine: what's the goal?," *Academic Medicine* 77, no. 10 (2002): 981-992.

²⁶ Kuhn, Gloria J., "Diagnostic errors, " *Academic Emergency Medicine* 9, no. 7 (2002): 740-750.

27 Graber, Mark, et al., "Reducing diagnostic errors in medicine: what's the goal?," *Academic Medicine* 77, no. 10 (2002): 981-992.

²⁸ Marini John J., and Arthur P. Wheeler, *Critical care medicine: the essentials* (Philadelphia: Wollters Kluwer/Lippincott Williams & Wilkins, 2010), 87-90.

²⁹ Imhof, Michael, *Malpractice in Surgery: Safety Culture and Quality Management in the Hospital.* Vol. 6 (Walter de Gruyter, 2012), 76.

³⁰ Kuhn, Gloria J., "Diagnostic Errors." *Academic Emergency Medicine* 9, no. 7 (2002): 740-50.

³¹ Kleinpell, R., et al., "Targeting Errors in the ICU: Use of a National Database," *Critical Care Nursing Clinics Of North America* 18, no. 4 (2006): 510.

32 Leape, Lucian L., "Error in medicine," Jama 272, no. 23 (1994): 1851-1857.

³³ Groves, R., al., "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting," *Studies In Health Technology & Informatics.* 131 (2008): 131-135.

34 Angus, Derek C., and Carlet, J., *Surviving intensive care* (Berlin: Springer, 2003), 65.

³⁵ Graf, J; vonden Driesch, et al., "Identification and characterization of errors and incidents in a medical intensive care unit,"*Acta Anaesthesiologica Scandinavica* 49, no. 7 (2005): 932.

³⁶ Kopp, Brian J., et al., "Medication errors and adverse drug events in an intensive care unit: direct observation approach for detection," *Critical care medicine* 34, no. 2 (2006): 415-425.

³⁷ Negash, Gediwon, et al., "Medication errors in the adult emergency unit of a tertiary care teaching hospital in Addis Ababa," *Archives of Pharmacy Practice* 4, no. 4 (2013): 147.

³⁸ Calabrese, Andrea D., et al., "Medication administration errors in adult patients in the ICU," *Intensive care medicine* 27, no. 10 (2001): 1592-1598.

³⁹ Bohomol, Elena, et al., "Medication errors in an intensive care unit," *Journal* of Advanced Nursing 65, no. 6 (2009): 1259-1267.

⁴⁰ Naylor, Robert, *Medication errors Lessons for education and healthcare* (Abingdon: Radcliffe Medical Press, 2002), 67.

⁴¹ Ehsani, Seyyedeh Roghayeh, et al., "Medication errors of nurses in the emergency department." *Journal of Medical Ethics & History of Medicine* 6, no. 1 (2013): 4-5.

⁴² Manasse Henri R., and Kasey K. Thompson, *Medication safety: a guide for health care facilities* (Bethesda, Md: American Society of Health-System Pharmacists, 2005), 45.

⁴³ Keers, Richard, et al., "Causes of medication administration errors in hospitals: a systematic review of quantitative and qualitative evidence," *Drug Safety* 36, no. 11 (2013): 1045-1067.

⁴⁴ McGowan, Michele, and Healey Bernard J., "The Enormous Cost of Medical Errors," *Academy of Health Care Management Journal* 6, no. 2 (2009): 27-29.

⁴⁵ Cooper, Jeffrey B., et al., "An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for," *Anesthesiology* 60 (1984): 34-42.

⁴⁶ Helmreich, Robert L., "On error management: lessons from aviation," *BMJ: British Medical Journal* 320, no. 7237 (2000): 781-785.

47 Bedevian, Rima, "Medical Errors: How Can You Avoid Them?," Retrieved from: <u>http://www.plasticsurgerypractice.com/2010/06/medical-errors-how-can-you-avoid-them/</u>. Accessed Feb 28, 2015.

⁴⁸ Giard, R. W. M., "The epidemiology of medical errors: A few issues in methodology," *International Journal of Risk & Safety In Medicine* 18, no. 1 (2006): 65-72.

⁴⁹ Reader Tom W., et al., "Communication Skills and Error in the Intensive Care Unit," *Current Opinion in Critical Care* 13, no. 6 (2007): 732-736. Donchin Yoel, et al.,

"A look into the Nature and Causes of Human Errors in the Intensive Care Unit," *Critical Care Medicine* 23, no 2 (1995): 294 -300.

⁵⁰ Nilsson Lean, A., et al., "Adverse events are common on the intensive care unit: results from a structured record review," Acta Anaesthesiologica Scandinavica, 56:8 (2012), 959-965.

⁵¹ Bohomol Elena, et al., "Medication errors in an intensive care unit," *Journal of Advanced Nursing* 65, no. 6 (2009): 1260.

⁵² Elliott Doug, et al., *ACCCN's critical care nursing* (Chatswood, N.S.W.: Mosby/Elsevier, 2012), 90.

⁵³ Donchin, Yoel, et al., "A look into the nature and causes of human errors in the intensive care unit," *Quality & Safety In Health Care* 12, no. 2 (2003): 143.

⁵⁴ Nilsson Lean, A., et al., "Adverse events are common on the intensive care unit: results from a structured record review," Acta Anaesthesiologica Scandinavica, 56:8 (2012), 959-965.

55 Kale, Abhivyakti, et al., "Adverse drug events caused by serious medication administration errors," *BMJ quality & safety* 21, no. 11 (2012): 933-938.

⁵⁶ Zineldin, Mosad, et al., "Approaches for reducing medical errors and increasing patient safety: TRM, quality and 5 Qs method," *TQM Journal* 26, no. 1 (2014): 63-74.

⁵⁷ Manasse Henri R., and Kasey K. Thompson, *Medication safety: a guide for health care facilities* (Bethesda, Md: American Society of Health-System Pharmacists, 2005), 45. Weingart, Saul N., et al., "Epidemiology of Medical Error," *BMJ: British Medical Journal*, 320, no. 7237 (2000): 774-777.

58 Agency for Healthcare Research and Quality, "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." Retrieved from: <u>http://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html</u>. Introduction, Accessed Feb 28, 2015.

⁵⁹ Kopp, Brian J., et al., "Medication errors and adverse drug events in an intensive care unit: direct observation approach for detection," *Critical care medicine* 34, no. 2 (2006): 415-425.

⁶⁰ Marini John J., and Arthur P. Wheeler, *Critical care medicine: the essentials* (Philadelphia: Wollters Kluwer/Lippincott Williams & Wilkins, 2010), 87.

⁶¹ Camiré Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 936-937.

⁶² Helmons, Pieter J., et al., "Effect of bar-code-assisted medication administration on medication administration errors and accuracy in multiple patient care areas," *American Journal of Health-System Pharmacy* 66, no. 13 (2009): 1205.

63 Bohomol, Elena, et al., "Medication errors in an intensive care unit," *Journal of Advanced Nursing* 65, no. 6 (2009):1259-1267.

64 Dhillon, Balbir S., *Human Reliability and Error in Medical System* (River Edge, N.J.: World Scientific Pub, 2003), 68.

65 David Guy, et al., "Economic Measurement of Medical Errors Using a Hospital Claims Database," *Value In Health* 16, no. 2 (2013): 305-310.

66 Donchin, Yoel, et al., "A look into the nature and causes of human errors in the intensive care unit," *Quality & Safety In Health Care* 12, no. 2 (2003): 143.

67 Olden, Peter C., and William C. McCaughrin, "Designing Healthcare Organizations to Reduce Medical Errors and Enhance Patient Safety," *Hospital Topics* 85, no. 4 (2007): 4-9.

⁶⁸ Kopec, D., et al., "Human errors in medical practice: systematic classification and reduction with automated information systems," *Journal of medical systems* 27, no. 4 (2003): 297-313.

69 Bohomol, Elena, et al., "Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65, no. 6 (2009): 1259-1267.

⁷⁰ Dekker, Sidney WA, and Nancy G Leveson, "The bad apple theory won't work: response to 'Challenging the systems approach: why adverse event rates are not improving'by Dr Levitt," *BMJ quality & safety* 23, no. 12 (2014): 1050-1051.

⁷¹ Dekker, Sidney WA, and Nancy G Leveson, "The bad apple theory won't work: response to 'Challenging the systems approach: why adverse event rates are not improving'by Dr Levitt," *BMJ quality & safety* 23, no. 12 (2014): 1050-1051.

72 Elliott, Doug, et al., *ACCCN's critical care nursing* (Chatswood, N.S.W.: Mosby/Elsevier, 2012), 90-95.

73 Zeggwagh, A., et al., "Preventability of death in a medical intensive care unit at a university hospital in a developing country," *Indian Journal Of Critical Care Medicine* 18, no. 2 (2014): -88-89.

⁷⁴ McGowan, Michele, and Healey, Bernard J., "THE ENORMOUS COST OF MEDICAL ERRORS," *Academy Of Health Care Management Journal* 6, no. 2 (2009): 27-29.

⁷⁵ Zeggwagh, A., et al., "Preventability of death in a medical intensive care unit at a university hospital in a developing country," *Indian Journal Of Critical Care Medicine* 18, no. 2 (2014): 89-94.

⁷⁶ Bohomol, Lais Helena Ramos, and Maria D'Innocenzo, "Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65, no. 6 (2009): 1262-1264.

77 Boettger, Ryan K., "Types of errors used in medical editing tests," *Journal of the American Medical Writers Association Journal* 27, no. 3 (2012): 99-104.

⁷⁸ McGowan, Michele, and Healey, Bernard J., "THE ENORMOUS COST OF MEDICAL ERRORS," *Academy Of Health Care Management Journal* 6, no. 2 (2009): 27-29.

⁷⁹ Rathert, Cheryl, and Win Phillips, "Medical Error Disclosure Training: Evidence for Values-Based Ethical Environments," *Journal Of Business Ethics* 97, no 3 (2010): 493.

⁸⁰ David Guy, et al., "Economic Measurement of Medical Errors Using a Hospital Claims Database," *Value In Health* 16, no. 2 (2013): 307.

⁸¹ Tourgeman-Bashkin, O., et al., "Causes of near misses in critical care of neonates and children," *Acta Paediatrica* 97 no. 3 (2008): 300.

82 Nguyen, Anh Vu T., and Dung A. Nguyen, *Learning from medical errors: clinical problems* (Abingdon: Radcliffe, 2005), 56-60.

83 Leape, Lucian L., "Error in medicine," Jama 272, no. 23 (1994): 1853.

⁸⁴ Flaatten, H.,and O. Hevrøy, "Errors in the intensive care unit (ICU)," *Acta Anaesthesiologica Scandinavica* 43, no. 6 (1999): 615.

85 Hurst Willis, "Cognitive Errors (Can They Be Prevented?)," *The American Journal of Cardiology* 101, no. 10 (2008): 1513-1517.

⁸⁶ Groopman Jerome E., *How Doctors Think*, (New York: Houghton Mifflin Harcourt, 2008), 227-231.

87 Leape, Lucian L., "Error in medicine," Jama 272, no. 23 (1994): 1853.

88 Croskerry, Pat, "Cognitive forcing strategies in clinical decision making," *Annals of emergency medicine* 41, no. 1 (2003): 110-120.

89 Leape, Lucian L., "Error in medicine," Jama 272, no. 23 (1994): 1853.

⁹⁰ Croskerry, Pat, "Achieving quality in clinical decision making: cognitive strategies and detection of bias," *Academic Emergency Medicine* 9, no. 11 (2002): 1184-1204.

⁹¹ Boettger, Ryan K., "Types of errors used in medical editing tests," *Journal of the American Medical Writers Association Journal* 27, no. 3 (2012): 101.

⁹² Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse* 30, no. 2 (2010): 66. Boettger, Ryan K., "Types of errors used in medical editing tests," *Journal of the American Medical Writers Association Journal* 27, no. 3 (2012): 101.

⁹³ Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse* 30, no. 2 (2010): 65.

94 Bigatello, Luca M., et al., *Critical care handbook of the Massachusetts General Hospital* (Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010), 67.

⁹⁵ Rothschild, Jeffrey M. et al., "The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care," *Critical Care Medicine* 33, no. 8 (2005): 1694-1700. 96 Naylor Robert, *Medication errors: lessons learnt for education and healthcare* (Abingdon: Radcliffe Medical, 2002), 67.

97 Rothschild, Jeffrey M. et al., "The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care," *Critical Care Medicine* 33, no. 8 (2005): 1694-1700.

⁹⁸ Curtis, J Randall, et al., "End-of-Life Care in the Intensive Care Unit: Can We Simultaneously Increase Quality and Reduce Costs?," *American journal of respiratory and critical care medicine* 186, no. 7 (2012): 587-92.

⁹⁹ Multz, Alan S, et al., "A "Closed" Medical Intensive Care Unit (Micu) Improves Resource Utilization When Compared with an "Open" Micu," *American journal of respiratory and critical care medicine* 157, no. 5 (1998): 1468-73. Luce, John M., and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit," *Critical care clinics* 25, no. 1 (2009): 221-37.

100 Garland, Allan, "Effect of Collaborative Care on Cost Variation in an Intensive Care Unit," *American Journal of Critical Care* 22, no. 3 (2013): 232-38.

101 Garland, Allan, et al., "Physician-Attributable Differences in Intensive Care Unit Costs: A Single-Center Study," *American journal of respiratory and critical care medicine* 174, no. 11 (2006): 1206-10.

¹⁰² Garland, Allan, "Effect of Collaborative Care on Cost Variation in an Intensive Care Unit," *American Journal of Critical Care* 22, no. 3 (2013): 232-38.

¹⁰³ Hernu, Romain, et al., "Cost Awareness of Physicians in Intensive Care Units: A Multicentric National Study," *Intensive Care Medicine* (2015): 1402-1410.

104 Multz, Alan S, et al., "A "Closed" Medical Intensive Care Unit (Micu) Improves Resource Utilization When Compared with an "Open" Micu," *American journal of respiratory and critical care medicine* 157, no. 5 (1998): 1468-73. Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care," *Crit Care* 12, no. 2 (2008): 208-215.

105 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 936-43.

¹⁰⁶ Kaldjian, Lauris C, et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals," *Archives of internal medicine* 168, no. 1 (2008): 40-43.

¹⁰⁷ Rothschild, Jeffrey M, et al., "Recovery from Medical Errors: The Critical Care Nursing Safety Net," *Joint Commission Journal on Quality and Patient Safety* 32, no. 2 (2006): 63-72.

¹⁰⁸ Groves Jr, Robert H, et al., "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting," *Studies in health technology and informatics* 131 (2008): 131-46. 109 Wachter, Robert M., *Understanding Patient Safety* (McGraw Hill, 2007), 3,13. Meier, E., "Efforts Launched to Address medical Errors," *Nursing Economics.* 18, no. 5 (2000): 265-266.

¹¹⁰ McGowan, Michele, and Healey Bernard J., "The Enormous Cost of Medical Errors," *Academy of Health Care Management Journal* 6, no. 1 (2010): 20-24.

111 Rowell, David, et al., "How Different Are Complications That Affect the Older Adult Inpatient?," *Quality and Safety in Health Care* 19, no. 6 (2010): e34. Francis, D. and J. Lahaie, Iatrogenesis, "The nurse's role in preventing patient harm," in *Evidence-based geriatric nursing protocols for best practice* (4th ed.), eds. M. Boltz, E. Capuzuti, T. Fulmer, and D. Zwicker (New York: Springer, 2012), 200-228.

112 Sultz, Harry A., and Kristina M Young, *Health care USA: Understanding its Organization and Delivery* (Sudbury, Massachusetts: Jones and Bartlett Publishers, 2006), 108-109.

113 Kohn, Linda T., et al., *To err is human: Building a safer health system* (Washington, D. C.: National Academy Press, 2000), 2.

¹¹⁴ Vlayen, Annemie, et al., "Incidence and Preventability of Adverse Events Requiring Intensive Care Admission: A Systematic Review," *Journal of evaluation in clinical practice* 18, no. 2 (2012): 485-97.

115 Ehsani, Seyyedeh. et al., "Medication errors of nurses in the emergency department," *Journal of Medical Ethics & History of Medicine* 6:1 (2013): 6-7. Hobgood, Cherri, et al., "Medical Error Identification, Disclosure, and Reporting: Do Emergency Medicine Provider Groups Differ?," *Academic Emergency Medicine* 13, no. 4 (2006): 443-51. Agency for Healthcare Research and Quality, "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." Retrieved from: <u>http://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html</u>. Introduction, Accessed Feb 28, 2015.

¹¹⁶ Weingarten, RM., "Preventable Medical Errors: What's the Cost?." *The Pennsylvania nurse* 68, no. 2 (2013): 4-9.

117 Negash, Gediwon, et al., "Medication Errors in the Adult Emergency Unit of a Tertiary Care Teaching Hospital in Addis Ababa," *Archives of Pharmacy Practice* 4, no. 4 (2013): 149-150.

118 Nilsson, Lena, et al., "Adverse Events Are Common on the Intensive Care Unit: Results from a Structured Record Review," *Acta anaesthesiologica Scandinavica* 56, no. 8 (2012): 959-65.

¹¹⁹ Rothschild, Jeffrey M., et al., "The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care," *Critical care medicine* 33, no. 8 (2005): 1694-700.

120 Gorbach, Christy, et al., "Frequency of and Risk Factors for Medication Errors by Pharmacists During Order Verification in a Tertiary Care Medical Center," *American Journal of Health-System Pharmacy* 72, no. 17 (2015): 1471-74. 121 Benoit, E, P Eckert, et al., "Streamlining the Medication Process Improves Safety in the Intensive Care Unit," *Acta anaesthesiologica Scandinavica* 56, no. 8 (2012): 966-75.

122 Nguyen, Anh Vu T, and Dung A Nguyen, *Learning from Medical Errors: Clinical Problems* (Abingdon: Radcliffe, 2005), 56.

123 Fairfield, Conn, "Improving the Safety of Health Care: The Leapfrog Initiative," *Eff Clin Pract* 6 (2000): 313-16.

124 Moore, Carlton, et al., "Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting," *Journal of general internal medicine* 18, no. 8 (2003): 646-648. Compliance, Report on Medicare, "Chance of Errors with Inpatient-Only List Abound; Medical Necessity Still a Question," *Report on Medicare Compliance* 21, no. 45 (2012): 1-2. Dietz, Isabel, et al., "Errors in Palliative Care: Kinds, Causes, and Consequences: A Pilot Survey of Experiences and Attitudes of Palliative Care Professionals," *Journal of palliative medicine* 16, no. 1 (2013): 77-79.

¹²⁵ O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 293-308.

126 Phillips, L S. et al., "Clinical Inertia. *Annals of Internal Medicine* 136 no. 9 (2001): 825-834.

¹²⁷ Helseth, Lynn D., et al., "Primary care physicians' perceptions of diabetes management. A balancing act," *Journal of Family Practice* 48 no. 1 (1999): 424-428.

128 Casalino, L., et al., "External incentives, information technology, and organized processes to improve health care quality for patients with chronic diseases," *JAMA* 289 no. *4* (2003): 434-441.

129 O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 298.

¹³⁰ Brehmer, Berndt, "Dynamic decision-making: human control in complex systems," *Acta Psychological*, 81 no. 3 (1992): 211-241.

¹³¹ Doerner, Dietrich, "The logic of failure," *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 327, no. 1241 (1990): 463-473.

¹³² Weick, Karl E., "Technology as equivoque: Sensemaking in new technologies," in Technology and Organizations, eds. P S. Goodman and L S. Sproull (San Francisco, CA: Jossey-Bass, 1990), 1-5.

133 O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 299.

¹³⁴ Weick, Karl E., "Technology as equivoque: Sensemaking in new technologies," in Technology and Organizations, eds. P S. Goodman and L S. Sproull (San Francisco, CA: Jossey-Bass, 1990), 6-15.

¹³⁵ Doerner, Dietrich, "The logic of failure," *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 327, no. 1241 (1990): 463-473.

¹³⁶ O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 299.

¹³⁷ O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 299.

¹³⁸ O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in *Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology)*, eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 298.

139 O'Connor, Patrick J., et al., "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 300.

140 Kohn, Linda T., et al., *To Err is Human: Building a Safer Health System*, (Washington, D.C.: Institute of Medicine, National Academy Press, 2000), 26-29.

¹⁴¹ Moore, Carlton, et al., "Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting," *Journal of General Internal Medicine* 18 no. 8 (2003): 646-651.

142 Schoenborn, Nancy L., et al., "Clinician Roles and Responsibilities During Care Transitions of Older Adults," *Journal of the American Geriatric Society*, 61 no. 2 (2013): 231-236.

¹⁴³ Schoenborn, Nancy L., et al., "Clinician Roles and Responsibilities During Care Transitions of Older Adults," *Journal of the American Geriatric Society*, 61 no. 2 (2013): 231.

144 Schoenborn, Nancy L., et al., "Clinician Roles and Responsibilities During Care Transitions of Older Adults," *Journal of the American Geriatric Society*, 61 no. 2 (2013): 235.

¹⁴⁵ Sandars, John, and Aneez Esmail, "The Frequency and Nature of Medical Error in Primary Care: Understanding the Diversity across Studies," *Family practice* 20, no. 3 (2003): 231-36.

146 Runciman, Bill and Merrilyn Walton, *Safety and Ethics in Healthcare: A Guide to Getting It Right*, (Ashgate 2007): 114-118.

147 Blot, Stijn, et al., "Recent Advances in Multidisciplinary Critical Care," *American Journal of Critical Care* 24, no. 1 (2015): 75-86.

148 Camiré, Eric, et al., "Medication errors in critical care: Risk factors, prevention and disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009) 936-943.

149 Landrigan, Christopher P. et al., "Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units," *New England Journal of Medicine* 351, no. 18 (2004): 1838-1848.

¹⁵⁰ Groves Jr. Robert H., et al., "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting," *Studies In Health Technology & Informatics* 131 (2008): 131-135.

¹⁵¹ Kale, Abhivyakti. et al., "Adverse Drug Events Caused by Serious Medication Administration Errors," *BMJ Quality & Safety* 21, no. 11 (2012): 933-935.

¹⁵² Hooper A J., and J Tibballs, "Comparison of a Trigger Tool and voluntary reporting to identify adverse events in a paediatric intensive care unit," *Anaesthesia and Intensive Care Journal* 42, no. 2 (2014): 199-206.

153 Martin, Heather, et al., "Specimen Labeling Errors: A Retrospective Study," *Online Journal of Nursing Informatics*. Retrieved from: <u>http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=42740</u>. Accessed Nov, 03,2015.

¹⁵⁴ Strobel, Mark D., "The technology is there: Options for preventing lab labeling and tracking errors," *Medical Laboratory Observer* 45 no. 2 (2013): 22.

155 Green, Sol F., "The cost of poor blood specimen quality and errors in preanalytical processes," *Chemical Biochemistry 46* no. 13 (2013): 1175-1179.

156 Rin, Giorgio, "Pre-analytical workstations as a tool for reducing laboratory errors," Journal of Medical Biochemistry 29 no. 4 (2010): 315-324.

157 Martin, Heather, et al., "Specimen Labeling Errors: A Retrospective Study," *Online Journal of Nursing Informatics*. Retrieved from: <u>http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=42740</u>. Accessed Nov, 03,2015.

158 Bhat, Vivek, et al., "Analysis of laboratory sample rejections in the preanalytical stage at an oncology center," *Clinical Chimica Acta* 26 no. 1 (2012): 1203-1206. Green, Sol F., "The cost of poor blood specimen quality and errors in pre-analytical processes," *Chemical Biochemistry* 46 no. 13 (2013): 1175-1179. Kaushik, Nitin., and Sol Green, "Pre-analytical errors: Their impact & how to minimize them," *Medical Laboratory Observer* 46 no. 5 (2014): 22-24.

¹⁵⁹ Green, Sol F., "The cost of poor blood specimen quality and errors in preanalytical processes," *Chemical Biochemistry* 46 no. 13 (2013): 1175-1177.

160 Green, Sol F., "The cost of poor blood specimen quality and errors in preanalytical processes," *Chemical Biochemistry* 46 no. 13 (2013): 1178-1179. 161 Dunn, Edward, and Paul Moga, "Patient misidentification in laboratory medicine: A qualitative analysis of 227 root cause analysis reports in the Veterans Health Administration," *Archives of Pathology & Laboratory Medicine* 134 no. 2 (2010): 244-255.

162 Kaushik, Nitin, and Sol Green, "Pre-analytical errors: Their impact & how to minimize them," *Medical Laboratory Observer* 46 no. 5 (2014): 22.

163 Martin, Heather, et al., "Specimen Labeling Errors: A Retrospective Study," *Online Journal of Nursing Informatics*. Retrieved from: <u>http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=42740</u>. Accessed Nov, 03,2015.

164 Idemoto, Lori M., et al., "Implementation of a custom alert to prevent medication-timing errors associated with computerized prescriber order entry," *American Journal of Health-System Pharmacy*, 72 no. 17 (2015): 1481-1484.

¹⁶⁵ Campbell, Emily M., et al., "Types of unintended consequences related to computerized provider order entry," *Journal of American Medical Information Association* 13 no. 5 (2006): 547-556. Koppel, Ross, et al., "Role of computerized physician order entry systems in facilitating medication errors," *JAMA* 293 no. 10 (2005): 1197-1203.

166 Carayon, Pascale, et al., "Impact of electronic health record technology on the work and workflow of physicians in the intensive care unit," *International Journal of Medical Informatics* 84 no. 8 (2015): 578-594.

¹⁶⁷ Carayon, Pascale, et al., "Impact of electronic health record technology on the work and workflow of physicians in the intensive care unit," *International Journal of Medical Informatics 84* no. 8 (2015): 579.

168 Imhof, Michael. and Constantijn Blondel, *Malpractice in Surgery : Safety Culture and Quality Management in the Hospital* (Berlin: De Gruyter, 2013),76.

169 Bohomol, Elena, et al., "Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65, no. 6 (2009): 1265.

170 Flaatten, H., and O. Hevrøy, "Errors in the intensive care unit (ICU)," Acta Anaesthesiologica Scandinavica 43, no. 6 (1999): 614.

171 Camiré, Eric. Et al., "Medication errors in critical care: risk factors, prevention and disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 936. Sidebotham, David, *Cardiothoracic critical care* (Philadelphia, Pa: Butterworth-Heinemann, 2007), 78.

¹⁷² Tourgeman-Bashkin, O., et al., "Causes of near misses in critical care of neonates and children,"*Acta Paediatrica* 97, no. 3 (2008): 299-303.

173 Marik, Paul Ellis, *Handbook of evidence-based critical care* (Springer Science & Business Media, 2010), 56.

174 Taib, Ibrahim Adham, et al., "A review of medical error taxonomies: a human factors perspective," *Safety Science* 49, no. 5 (2011): 607-615.
175 Jennane, Naoual, et al., "Incidence of medication errors in a Moroccan medical intensive care unit," *International archives of medicine* 4, no. 1 (2011): 32.

176 Marcin, James P. et al., "Long-stay patients in the pediatric intensive care unit," *Critical care medicine* 29, no. 3 (2001): 652-657.

177 Wheeler Derek S., et al., *Pediatric critical care medicine: basic science and clinical evidence* (London: Springer Science & Business, 2007), 64.

178 Rathert, Cheryl, and Win Phillips, "Medical Error Disclosure Training: Evidence for Values-Based Ethical Environments," *Journal Of Business Ethics* 97, no. 3 (2010): 491-503.

179 Nguyen, Anh Vu T., and Dung A. Nguyen, *Learning from medical errors:* clinical problems (Abingdon: Radcliffe, 2005), 78-87.

180 Naylor, Robert, *Medication errors: lessons learnt for education and healthcare* (Abingdon: Radcliffe Medical, 2002), 25-30.

181 Church Rhonda, and Neil J. MacKinnon, *Take as directed your prescription for safe health care in Canada* (Toronto: ECW Press, 2010), 90.

182 McGowan, Michele, and Healey Bernard J., "The enormous cost of medical errors," *Academy Of Health Care Management Journal* 6, no. 1 (2010): 20.

183 Valiee, Sina, et al., "Critical care nurses' perception of nursing error and its causes: A qualitative study," *Contemporary Nurse: A Journal For The Australian Nursing Profession* 46, no. 2 (2014): 206-213.

184 Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse* 30, no. 2 (2010): 67.

185 Dietz Isabel et al., "Errors in Palliative Care: Kinds, Causes, and Consequences: A Pilot Survey of Experiences and Attitudes of Palliative Care Professionals," *Journal of Palliative Medicine* 16, no. 1 (2013): 76.

186 Dhillon, Balbir S., *Human Reliability and Error in Medical System* (River Edge, N.J.: World Scientific Pub, 2003), 68.

187 Dodek Peter, "2 or more medical errors with adverse consequences, affecting 2.6% of patients, increased mortality in intensive care units," *ACP Journal Club* 152, no. 5 (2010): JC5-12.

188 Church, Rhonda, and Neil MacKinnon, *Take as directed: Your prescription for safe health care in Canada* (Toronto: ECW Press, 2010), 90

189 Bauman Kristy A., and Robert, Hyzy, "ICU 2020: Five Interventions to Revolutionize Quality of Care in the ICU," *Journal Of Intensive Care Medicine* 29, no. 1 (2014): 13. Ruth Kleinpell et al., "Targeting Errors in the ICU: Use of a National Database," *Critical Care Nursing Clinics Of North America* 18, no.4 (2006): 510.

190 Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse* 30, no. 2 (2010): 64. 191 Dhillon, Balbir S., *Human Reliability and Error in Medical System* (River Edge, N.J.: World Scientific Pub, 2003), 68.

192 Church Rhonda, and Neil J. MacKinnon, *Take as directed your prescription for safe health care in Canada* (Toronto: ECW Press, 2010), 90. Taib, Ibrahim Adham, et al., "A review of medical error taxonomies: a human factors perspective," *Safety Science* 49, no. 5 (2011): 607-615.

¹⁹³ Bucknall Tracey K., "Medical error and decision making: Learning from the past and present in intensive care," *Australian Critical Care* 23, no. 3 (2010): 154.

194 Valiee Sina, et al., "Critical care nurses' perception of nursing error and its causes: A qualitative study," *Contemporary Nurse: A Journal For The Australian Nursing Profession* 46, no. 2 (2014): 210.

¹⁹⁵ Dodek Peter, "2 or more medical errors with adverse consequences, affecting 2.6% of patients, increased mortality in intensive care units," *ACP Journal Club* 152, no. 5 (2010): JC5-12.

¹⁹⁶ Cullen, David J., et al., "Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units," *Critical care medicine* 25, no. 8 (1997): 1289-1297. Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215.

197 Donchin, Yoel, et al., "A look into the nature and causes of human errors in the intensive care unit," *Quality & Safety In Health Care* 12, no. 2 (2003): 143.

¹⁹⁸ Cullen, David J., et al., "Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units," *Critical care medicine* 25, no. 8 (1997): 1289-1297. Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215.

¹⁹⁹ Stambouly, J. J., et al., "Complications of care in a pediatric intensive care unit: a prospective study," *Intensive care medicine* 22, no. 10 (1996): 1098-1104. Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215.

200 Bucknall Tracey K., "Medical error and decision making: Learning from the past and present in intensive care," *Australian Critical Care* 23, no. 3 (2010): 153.

²⁰¹ Stockwell David C., and Anthony D. Slonim, "Quality and Safety in the Intensive Care Unit," *Journal Of Intensive Care Medicine* 21, no. 4 (2006): 199. Marik, Paul Ellis, *Handbook of evidence-based critical care* (New York: Springer, 2010), 56.

202 Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215.

²⁰³ Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215. David Guy, et al., "Economic Measurement of Medical Errors Using a Hospital Claims Database," *Value In Health* 16, no. 2 (2013): 309.

²⁰⁴ Donchin, Yoel, and F Jacob Seagull, "The hostile environment of the intensive care unit," *Current opinion in critical care* 8, no. 4 (2002): 316-320. Graf, J, A Von den

Driesch, et al., "Identification and characterization of errors and incidents in a medical intensive care unit," *Acta Anaesthesiologica Scandinavica* 49, no. 7 (2005): 935.

205 Bohomol Elena, et al., "Medication errors in an intensive care unit," *Journal Of Advanced Nursing* 65, no. 6 (2009): 1260.

206 Andrews, Lori B, et al., "An alternative strategy for studying adverse events in medical care," *The Lancet* 349, no. 9048 (1997): 309-313. Camiré Eric, et al., "Medication errors in critical care: risk factors, prevention and disclosure," *Canadian Medical Association Journal* 180, no. 9 (2009): 936.

²⁰⁷ Brennan, Troyen A., et al., "Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I," *New England journal of medicine* 324, no. 6 (1991): 370-376.

208 Courtright, Katherine R., and Meeta Prasad Kerlin, "Intensive care unit staffing and quality of care: challenges in times of an intensivist shortage," *Revista Brasileira de terapia intensiva* 26, no. 3 (2014): 205-207.

209 Halpern, Neil A., et al., "Critical Care Medicine in the United States: Addressing the Intensivist Shortage and Image of the Specialty," *Critical care medicine* 41, no. 12 (2013): 2754-2761.

²¹⁰ Andrews, Lori B, et al., "An alternative strategy for studying adverse events in medical care," *The Lancet* 349, no. 9048 (1997): 309-313.

²¹¹ Wise, Kristin R., et al., "Hospitalists and intensivists in the medical ICU: a prospective observational study comparing mortality and length of stay between two staffing models," *Journal of Hospital Medicine* 7, no. 3 (2012): 183-189.

²¹² Angus, Derek C., et al., "Current and projected workforce requirements for care of the critically ill and patients with pulmonary disease: can we meet the requirements of an aging population?," *JAMA* 284, no. 21 (2000): 2762-2770.

²¹³ Bria, William F., and M. Michael Shabot, "The electronic medical record, safety, and critical care," *Critical care clinics* 21, no. 1 (2005): 55-79.

²¹⁴ Moyen, Eric, et al., "Clinical review: medication errors in critical care," *Crit Care* 12, no. 2 (2008): 208-215. Negash Gediwon, et al., "Medication errors in the adult emergency unit of a tertiary care teaching hospital in Addis Ababa," *Archives Of Pharmacy Practice* 4, no. 4 (2013): 149.

²¹⁵ Pape, Tess M., "Applying airline safety practices to medication administration," *Medical-Surgical nursing: official journal of the Academy of Medical-Surgical Nurses* 12, no. 2 (2003): 77-93.

²¹⁶ Bria, William F., and M. Michael Shabot, "The electronic medical record, safety, and critical care," *Critical care clinics* 21, no. 1 (2005): 55-79.

217 Heisler, Elayne J., "Physician Supply and the Affordable Care Act," *Congressional Research Service. op. bna. com/hl. nsf/id/crsdoctor. pdf January* 15 (2013): 24.

²¹⁸ Polifko-Harris, Karian, *The Practice Environment of Nursing* (New York: Cengage Learning, 2009) 78-81.

Chapter 3. Ethical Problems Concerning Medical Error in the ICU

Introduction

This chapter places medical errors in the ICU within the framework of major principles biomedical ethics, namely beneficence, non-maleficence, distributive justice, and autonomy and informed consent, each of which are analyzed in detail. Ensuring the last two of these principles in the context of the potential for medical errors hindering patient care and treatment will constitute a significant focus of discussion in the Chapter. Included in the analysis will be the daily ethical dilemmas faced by ICU staff in the course of decision-making and its consequences in the context of providing optimal care and treatment while maintaining ethical standards.

As in every other health-care environment, medical professionals at all levels in the ICU are typically committed to the ideals of bioethics, ideals that physicians and medical teams strive to achieve in the ICU. However, particularly in this context, various of these ethical principles and standards can easily come into conflict, given the critical, immediate response demanded by the medical realities of the environment. For instance, ethics dictates that each patient be provided with complete information about his or her affliction, along with the options for care and treatment by means of thorough elucidation leading to informed consent. Moreover, autonomy demands that the patient have unimpinged-upon-freedom of autonomy in choosing or avoiding any and all care and treatment options, whatever the disease, injury or medical emergency. On the other hand, informed consent requires competency in terms of background knowledge and understanding of causes, related factors, possible consequences of potential courses of treatment, and above the mental alertness and acuity to deliberate over options and make rational choices. The pace needed to guarantee this ideal inherently conflicts with the high pressure and urgency and rapid response demanded by the nature of medical emergencies the ICU. Furthermore, the circumstances that bring patients to this unit of the hospital guarantee that physicians and clinical staff will have limited knowledge about the patient, and therefore much uncertainty about the individual's response to treatments or procedures, exacerbating staff stress and pressure. Given the fact that health care professionals are human and fallible, all these factors combine to create an elevated risk of medical error under the best of circumstances.

At times, the very nature of the tension between the ethical principles of patient autonomy, distributive justice, beneficence, and/or non-malfeasance on the abstract, philosophical level and the limited options of practical reality force medical professionals to pursue the least detrimental alternative. A case in point is the patient whose disease, injury, or condition is such as to make restorative treatment futile even in the near term, and yet the patient's family is insistent on every conceivable heroic effort being made. Compounding the issue are the typically exorbitant costs of such measures, the doctors' consciences, and the internal conflicts between saving life, preventing suffering, fairly allocating resources.

Two fundamental goals, which cannot normally both be maximized in the ICU are equity in access to care and treatment, related to distributive justice and efficiency in distributing resources, related to what is least costly, is most cost-effective, or saves the

most lives. What must always emerge from the tension between these two motivations is an optimal compromise. In terms of prioritization, given the limits of ICU time, facilities, and staffing, many conflicting principles exists, such as: 1) first-come, first-served versus some form of lottery; 2) the most gravely ill or injured first versus the greatest number who can be treated with limited resources; 3) those with the most urgent need versus those with the best chance of recovery; and 4) those whose lives most depend on care versus those who will likely have the longest and potentially most productive futures ahead of them. Beyond these choices, there are issues of racial, cultural, and gender equality, as well as age, quality of life and ability to contribute to society following successful treatment.

All of these questions are nearly identical to those that arise in the context of disaster relief, the distribution of prophylactics or treatment during epidemics, access to hemodialysis, the prioritization of organ transplant recipients, and the general rationing of scarce medical personnel, among patients in any crisis. Relative to these choices, a number of while some healthcare institutions see the most ethical method of equitably rationing as being a balanced combination of priorities, others have made clear choices in their prioritization of one consideration over its alternatives, such as for example, choosing quality of life outcome along with maximizing the number of added years of life the patient is likely to gain.

Ultimately, rationing choices in the ICU take the form of decisions over if and when to withhold or withdraw life support systems, as well as when not to escalate treatment. Modern technological advances in life-support systems, including mechanical

ventilators, artificial nutrition or hydration, mechanical circulatory technology, chemotherapy, vasopressors, renal dialysis, and antibiotics have greatly increased the stakes in making these decisions, particularly in the ICU. The withholding and withdrawing of life-support are not the only forms of rationing care or treatment. Sedatives and pain medication also fall under this category of possibilities; nor is this possible allotting of ICU services always passive in nature. Transfer from the ICU to palliative or hospice care is an active step, which may become necessary. Decisions about whether to withhold, withdraw, or not escalate treatment can be ethically justified by extraordinary situations involving costs or levels maintenance care, either of which become unsustainable; extremely grim prognoses or even futility of treatment; or substantial and irreversible, uncompensatable disability. There are other ethical factors in such situations that have been proven to be impossible to fulfill – in particular the equivalence thesis that medical treatment is permissible to be withdrawn if it is also permissible to withhold the same treatment and vice versa. Even while philosophers, bioethics researchers, and professional societies officially support the judgment that withdrawal and withholding of treatment are morally equivalent, clinicians in practice normally find withdrawal of treatment to be significantly more difficult than withholding or refraining from escalation, in part because of their feelings of duty to the patient and the profession.

Chapter 3.A. Relevant Ethical Principles in the Hospital ICU

This section of Chapter 3 of the dissertation examines several inherent conflicts within the ICU as a medical environment which lead to both ethical dilemmas and the

propensity for medical errors in this context. In order to provide a framework for discussion, the section traces the development of codes of ethical behavior from 1847 to the present, and examines numerous relevant theories of ethics, including consequentialist, utilitarian, and the deontological theory of principlism. Beyond this analysis of theories of ethics, this section of the chapter will examine the principle of autonomy and its limitations, distributive justice, beneficence, and non-maleficence, as principles in the field of bioethics together with the historical antecedents of each.

Chapter 3.A.1. Ethical Conflicts

The entire field of medicine and all endeavors of healthcare come under the purview of bioethics and the issues which arise from balancing the goals of satisfying patient preferences, following advanced directives, fulfilling the duties of the physician, and equitably handling social concerns such allocating limited resources for care and treatment, that contribute to ethical conflicts. It goes without saying that every professional in the field of medicine needs to have a working understanding of the fundamental principles that constitute bioethics, as well as their practical application in the healthcare facilities where the professional working.1

Such working knowledge must be deeply internalized in settings like the ICU, where rapid, yet appropriate decisions are routinely called for. The dependency of most ICU patients on the physicians and unit staff creates a situation necessitating constant vigilance in protecting autonomy and self-determination of patients, while ensuring beneficence and justice in the equitable distribution of resources, and the absence of maleficence.² Obviously however, giving in to a patient in every instance is not the

solution, as illustrated by San Francisco General Hospital study in which 22 out of 24 patients' families concurred with neurosurgeons against the patients themselves in terms of prognosis and treatment plans.³ For this reason, various ethicists have promulgated guidelines for doctors, nurses, and other medical professionals to follow in providing optimal healthcare to patients. Internationally, bioethicists have collaborated to create protocols and guidelines with the goal of formalizing ethical standards globally.4 In circumstances in which these standards of bioethics are not in place due to cultural or legal conflict, it is the society at large that is disadvantages in suffering both the financial and physicians and other medical professionals are considered in violation of professional conduct if they fail to disclose medical errors. The AMA itself is the most explicit in this regard with its obligatory ethical intangible loss from medical errors.5 Research findings indicate that as many as 5 percent of ICU deaths involved patients lacking advanced directives, in situations in which healthcare alone had to make most decisions about the patient's care and treatment in the absence of ethics committee review.6 In the wake of a patient's death, a ethic committee has little function or input.7

Chapter 3.A.2. The 1847 Code of Ethics and Subsequent Developments

The 1847 Code of Ethics put forth by the American Medical Association (AMA) represented a revolution in the approach to medical practice. Five subsequent versions from 1903, 1957, 1980, and 2001, as well as the AMA's latest revision of 2004,8 have attempted to keep pace with the changing nature of society, technology, and medical practice. Moreover, the AMA code is merely the best known of numerous declarations of ethical principles that have had a powerful effect on medical ethics in this country.9

Along with these others, the AMA code stipulates that a doctor has an ethical obligation to apprise a patient about any mistake which causes even minor medical complications for that patient.¹⁰ This responsibility extends to informing the patient concerning all relevant details regarding the causes, circumstances, damages or harms, steps to rectify and prognosis for recovery from the consequences of the error. Errors which do not result in any material consequences for the patient's health are the only mistakes not covered by this ethical standard, which mandates official reporting.¹¹ Despite the clarity and renown of this standard, it is likely that not every physician is aware of the extend of his or her ethical responsibility in the matter.

Unfortunately, to date his ethical standards of responsibility for disclosure has yet to be legally codified at federal, state, or any other level.¹² Nonetheless, precedent has been established in the courts as to a fiduciary relationship between the patient and the healthcare provider, so if a surgeon's negligence leads to an accident, the at fault doctor may not hide behind non-disclosure.¹³ For many years, the hospitals and similar facilities were considered culpable for the errors of physicians and medical professionals they had work for them. More recently in addition, the hospitals have be been able to hold physicians legally responsible to the institution, as well as to the patient. As a whole, healthcare facilities and institutions have carried on a tradition of responsibility for disclosure of mistakes apart from any errors to their patients. Thus, even in the absence of statutes or legislation, the judicial system has created a clear presumption that the duty to disclose medical errors does indeed exist.¹⁴ Furthermore, it is part of the explicit position of professional medical societies that ethics renders their members duty-bound to disclose medical errors to any patient experiencing their effects; consequently, disclosure

guidelines for both practicing doctors and medical trainees.¹⁵ Such candor in physicianpatient communication is essential to the discovery of the circumstances surrounding the error so as to mitigate its effects and prevent its recurrence. In the same manner, the 6th edition of American College of Physicians' (ACP) Ethics Manual, asserts that doctors are expected reveal any and all information concerning errors whether of judgment or in administering a procedure errors at any time during care and treatment.¹⁶ This disclosure should include all facts and circumstances that have a bearing on the patients' wellbeing. Unintentional medical errors do not automatically fall into the category of improper, negligent or unethical behavior, but a failure to disclose anything to the patient is, in fact, all three of these things. Although objectively speaking, physicians should have no cause to worry about an honestly admitted mistake having negative effects on their reputation for integrity and candor, concerns possibly over reputation for competence, legal liability, or similar matters has significantly affected their willing to acknowledge mistakes, as well as the promptness and extent of their disclosures.¹⁷

Chapter 3.A.3. Theories of Ethics

Teleological, also known as consequentialist, theory focuses primarily on the outcome of an action rather than on the action itself.¹⁸ An outgrowth of this theory, utilitarianism, has optimization as its cornerstone principle with the goal of achieving the greatest good for the most people, considering all the consequences under a given set of circumstances, resting on the assumption of basic benevolence in human nature.¹⁹ In terms of bioethics, the consequentialist would judge the investment in resource draining, expensive surgery for a single patient ethically unjustifiable when the same resources

could possibly have helped hundreds of others.²⁰ Along these theoretical lines of thought, ethics in the ICU is fundamentally about the outcomes of the care that a patient receives while there. The environment of the ICU clearly involves urgent, yet complex decisions be made, particularly with regard to patients in critical condition, thus placing significant stress on the ICU staff, who must simultaneously handle concerned family members, as well as ethical dilemmas in the ICU, all the while using their best professional training on the patient.²¹ The human dimension of this aspect of medical practice is sadly too often neglected in one's medical education.²²

Utilitarian theory becomes problematic in that it places a duty on medical professionals to individualize their care and treatment for each patient. The large majority of professional codes of medical ethics call for respecting patient privacy and confidentiality.23 The principle of autonomy compounds this situation by declaring the patient's right of choice with regard to the treatment options available. On the other hand, utilitarianism would overrule this right whenever 'the greater good' would conflict with it. Moreover, theorists raise questions as to how a theory such as consequentialism that is first and foremost outcome-based ever incorporate respect for the attitudes, feelings, and wishes of the patient. John Stuart Mill and Alexis de Tocqueville both labeled this presupposition shared by consequentialism and utilitarianism as "the tyranny of the majority," noting its occurrence in any circumstance in which the greatest good for the group as a whole is not in the best interests of certain individuals.24 In contrast, deontology as asserted by Immanuel Kant and John Rawls advocated the fundamental moral and ethical principle they referred to as deontology, promoting the concept of a moral duty, rather than results or outcomes, as the moral foundation for ethical behavior.

This contrast of founding assumptions and values places deontology, in many practical medical situations, as the antithesis of consequentialism and utilitarianism. At the same time, however, this preoccupation in deontology with the moral correctness of decisions with little consideration for their effects impinges on the autonomy of the individual, unique patient.25

The concept of principlism promises a resolution to such dilemmas in the practice of medicine by asserting that in the circumstance of multiple moral principles claiming applicability, one must be honored while the other is justifiably suspended in the particular situation.²⁶ While this sounds good in theory, in practice it gives no means of deciding between conflicting principles in various real-life circumstances. One such circumstance would be that of the healthcare professional who is caught between respecting the autonomy of the patient who wants to pursue options or courses of action that the medical professional considers morally untenable. Deontology and its corollaries allow no flexibility for compromise despite the individuality of each patient. Refusal by the physician to recommend any form of treatment may be the only option in such difficult cases, but even this choice runs into conflict with beneficence at some point. Furthermore, even a refusal recommended treatment can also be characterized as tantamount to negative autonomy.²⁷

The concept of a guiding moral framework for dealing with the day to day dilemmas of healthcare in practice has so far been neglected in the literature of research in bioethics, which has concentrated on how medical professionals arrive at the moral basis for their behavior. The linkage between the ethics of abstract philosophical principles and ethics as it plays out in the routine difficulties of medical practice remains to be worked out.28 Various moral and ethical questions came into clear focus following World War II with revelations about lying to or failing to disclose information to patients, as well as active euthanasia to relieve suffering.29 What came of all this examination was the unanimous understanding that some human rights are sacrosanct, and thus beyond impingement, even for the good of everyone else in society. As an extreme example, if a surgeon cannot sacrifice the life of a healthy individual, making him or her an organ donor, no matter how many other lives might be saved and even if the healthy individual agreed to do so. Today, both public opinion and the laws of almost all societies would prevent such atrocity.30

Chapter 3.A.4. Principle of Ethics and their Historical Antecedents

(i) Autonomy

Among the most fundamental of ethical principles in biomedicine is patient autonomy, which ensures that is a primary concern -enabling patient has the ultimate say in deciding his or her care and course of treatment. Autonomy has be advocated in two distinct forms: 1) the optional model, which affirms the active decision making role that the patient needs to be given, but allows the patient to defer to others, as opposed to 2) the mandatory model, which asserts that the patient must, in all case, exert his or her autonomy, or nothing may be done.³¹ Choosing to undergo or refuse any particular care or treatment is an integral component of both models; nevertheless, in practice and especially in the ICU, the inability of patients to make informed decisions frequently becomes a critical stumbling block to providing essential treatment interventions in a prompt enough manner. While abstract principles are context for discussion of biomedical ethics, patients in the ICU patients may be unable to exercise their autonomy, yet the lives may depend on immediate decision-making.32

In more practical terms, as a hypothetical example of the dilemmas that crop up in the ICU, suppose a patient goes into cardiac arrest after receiving incorrect medication. When a family member asks for an update on the patient's condition, should the nurse reveal the error of neglecting to check the patient's medical record for any history of allergies? Ethical guidelines exist to assist medical professionals in making such decisions; in this case, the overriding ethical principle would be justice.33

Patient autonomy has limitations, which may be classified into three categories, namely contextual, existential, and conceptual. When a patient is incapable of making informed decisions due to delirium, depression, senility, or similar circumstance, the limitations are considered contextual and is a common occurrence in the ICU. The necessity of prompt action, possibly to save the patient's life overrides even previously and competently stated wishes; the assumption is that were the patient competent at the time, he or she would agree with the physician's actions. On the other hand, if the outlook is more certain and the need less urgent, the autonomous choices of the rational patient would govern the course of treatment.34

The second category, existential limitations, applies when the results of the illness or injury interfere with the patient exercising unfettered, leading to the commonly reported situation in which a patient tries to yield decision making to the physician.35 The third category, conceptual limitations, describes an inherently restricted circumstance in

which it becomes necessary to sidestep a patient's autonomy in the name of the patient's best interests, with the goal of preventing harm or enabling healing. Obviously, these three sets of circumstances do in theory, and can easily in practice come into direct opposition with the concept of totally unconstrained patient autonomy.36

(ii) Beneficence

Beneficence represents the duty of medical professionals to always work toward the betterment of the patients' health and well-being. While there are those who focus on and advocate for either autonomy or beneficence as the preeminent principle to the exclusion of the other, in reality the two concepts are most often compatible and frequently mutually reinforcing. Seen in this light, the patient's exercising his or her autonomy and informed consent is by definition in that patient's best interest, and therefore beneficence includes preserving and promoting autonomy.37

Beneficence, synonymous with kindness, mercy, and charity takes two forms: *positive beneficence* and *utility. Positive beneficence* refers to the act of securing or providing tangible benefits to patients. Utility or optimal usefulness calls upon the medical professional to weigh the benefits against the risks and costs in among given proposed courses of action in order to find and select the optimum. Altruism, love, and humanity are other concepts closely linked to beneficence. As it is typically used in bioethics, this term denotes broadest scope of actions undertaken for the patient's good.₃₈ In totality, beneficence is the moral obligation to act for the good or welfare of others, even though the actions taken in furtherance of this goal may not be obligations in and of themselves. According to Beauchamp and Childress, positive beneficence consists of a

foundation for various more concrete obligations on the part of medical professionals, such as directly preventing harm to the patient, eliminating or restructuring conditions that would present danger or the risk of harm, defending the patient's rights, helping the patient to surmount barriers caused by disability.³⁹ Beauchamp and Childress conceive of this obligation to beneficence as morally coming into play anywhere and anytime the medical professional becomes aware of another person's need or danger, is able to help without personal sacrifice or imperilment, and is in an advantaged position to assist. In the language used by these two scholars, it becomes clear that they allow for conflicting obligations in certain circumstances to take precedence over beneficence.⁴⁰

Within the context of beneficence as an abstract concept, Beyond these considerations, both general and specific forms exist, with the former applying to all who make up humanity as individuals while the latter relates to designated groups, such as family and friends, children and the elderly as classes of individuals, and patients as a group for the medical professional.⁴¹ In this regard, certain groups, such as children or friends, inherently command beneficence from anyone. According to W. D. Ross, a full definition of general beneficence encompasses the broader scope in the issue of how one can actively improve the lives of his or her fellow human beings. Shelly Kagan expands the concept even further to include sacrifice in the absence of limits or constraints for the ultimate welfare and improvement of humanity.⁴² In contrast, other scholars contend that in practice, the duty of beneficence is limited to removing and generally preventing while promoting good. Even as restricted, this position compels an individual, such as a doctor or healthcare worker to act so as to prevent negative occurrences whenever it can be accomplished without personal loss.⁴³ Despite their frequent convergence, in biomedical ethics the autonomy of patient and beneficence always have the potential to conflict under specific circumstances, raising the issue of which should take precedence.

(iii) Justice

Insofar as healthcare is inherently related to the society as a whole, social justice is inextricably linked to medicine and healthcare, including all the controversial aspects of providing healthcare, such as inequalities in terms of its access, affordability, and quality. In fact, significant number of scholars have asserted that access to the highest quality care at affordable prices is a human right that society is required to make available to all.44

Definitions of the term *justice* have focused on three closely related perspectives with scholars and philosophers thinking in terms of the individual receiving what is fair, what he or she deserves, or what he or she can rightly expect. A key axiom in the study of human society is that all individuals, by virtue of their existence, are entitled to certain benefits, as well as redress and/or compensation should they endure certain misfortune or injustice. This assumption leads directly to the necessity of agreed upon societal standards to ensure that such entitlements, whatever the society defines them as including, are available to every one of its members. According to Beauchamp and Childress, asserted that this concept of fairness, equity, and suitability is known as distributive justice and that its ultimate origin and delineating characteristics are rooted in the cooperative social structure of the society in question. The concept of justice described here must be considered distinct and discussed apart from forms of justice such as punitive, rectifying, or compensatory justice, in that these latter types begin when there

has been a transgression of justice and harm done to victims. In the sense asserted by these two scholars, justice arises from something like a social contract, with breaches such as malpractice occurring either as incidents or as an ongoing unethical state of affairs.45

Two rather abstract principles apply to making judgments about what is ethically considered just in any given situation, in healthcare as in all fields, namely the principle of formal justice and the material principle of justice. The principle of formal justice or formal equality states the individuals with equal status or standing must receive the same treatment. However, being stated in the abstract this principle neglects to specify what constitutes equality, either in terms of the individuals or the circumstances. The material principle of justice focuses more on considerations outside the individuals themselves, characteristics either physical or qualitative in the environment that must be taken into account in any fair distribution of benefits or burdens.46

(iv) Non-maleficence

For the healthcare professional, as a principle of ethics non-maleficence means avoiding any behavior that would or could foreseeably cause harm to a patient, which in practice becomes much more complicated than it sounds. For example, healthcare professionals do not even need to be physically with a patient in order to cause injury through maleficence; it can occur as easily as by not returning a phone call to a patient with a reputation for malingering or being a hypochondriac. Something as simple as neglecting return could cause a patient harm in the form of unneeded stress, making communication failures a type of medical error that causes harm. Whether or not the failure involves any intent or is attributable to an electronic or human error, or whether messages are inaccurate, delivered to the wrong recipients, or involve damage to equipment, any breach in the flow of correct, timely, communication to all relevant parties constitutes a medical error of potential, possibly even life-threatening harm.47

While the occurrence of a medical error undeniably violates the principle of nonmaleficence to the extent that the error has caused any harm, it is not clear when and how the principle applies in the aftermath of an error, particularly if the physician is not responsible for the error or if the patient's knowledge of the error or certain aspects about it, would cause harm through worry, possibly even more harm that the error itself. Given the present day status of the physician-patient relationship, it is difficult to hold a tenable position against disclosing medical errors, yet at the same time, non-maleficence dictates avoid anything that will cause harm to the patient, whether that damage is physical, mental, or psychological.48

Two factors give physicians a unique status and position in the community and society at large. First, their patients are, by definition, in a singularly vulnerable position, and with this dependence normally comes a unique level of trust. Second, a doctor is presumed to have an almost inexhaustible array of knowledge, skills, and expertiseseemingly even to the point of infallibility. This admittedly exaggerated perception makes it all the easier for health professionals or physicians avoid disclosing medical errors, the consequences of which the patient may simply attribute to unexpected complications of the injury or illness. Given the ease of and natural impulse to conceal medical errors, the frequency of non-disclosure is to be expected; what is difficult to

fathom, given the clarity of professional obligations and the strong stance of bioethicists for disclosing any and all medical errors, is that there are those in the professionals in the field who openly argue against doing so. Regardless of the controversy, according to numerous research finding patients want to know about medical errors when they occur and specifically, in terminology they can understand, the answers to two questions, namely why the error happened and what can and is being done to prevent it from happening again.⁴⁹

While accurate statistics are inherently difficult to obtain, the available findings reveal physicians themselves admitting that large majority of medical errors go unreported to patients who must endure their consequences, despite the doctor's ethical obligation to the contrary. Approximately 76% of the doctors interviewed in one study confessed that, at one point or another, they had failed to disclose a serious error to patients.50 The reason they offered was disclosure becomes complicated when different various hospital departments had been involved in the error, making disclosure to the patient a complicated and controversial affair. Although other research findings point to a somewhat higher rate of disclosure, one study reported as many as 22% of the surveyed doctors saying that they would not disclose certain medical errors, even if potentially fatal, given the inherent emotionally disturbing discussions and conversation that would inevitably ensue.51 Considering all these factors working against disclosure, it is predictable that an inverse correlation exists between the severity of harm from a medical error and the likelihood of disclosure to patients and family. On top of every other disincentive to disclosure is the sense of personal failure it engenders in the mind of the medical professional.52

Unfortunately, no manual exists with concrete procedures for disclosing medical errors. "Physicians must offer professional and compassionate concern toward patients who have been harmed... An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help in reducing the risk of liability".53

Chapter 3. B. Ethics in the Hospital ICU

This section of Chapter 3 relates the roughly 50 years history of ICUs in United States hospital in relation to their implementation of biomedical ethics and the principles it advocates. Over this period, adherence to such principles has greatly benefited many critically ill patients, and yet such principles of ethics have not been universally adopted in hospital ICU. A variety of factors work against uniform and full implementation of bioethics in the ICU, with some factors being inherent in the setting and its mission and others the results of factors that can be altered.⁵⁴

According to one study, as many as one-fifth of all Americans die while in the hospital ICU in pain and suffering due to a terminal illness or injury.55 According to Multz, ICU costs in the U.S. accounted for approximately a third of hospital budgets, translating into roughly \$62 billion in healthcare costs, which was about one percent of the nation's GDP that year. While ICU benefits can be great, so are their costs, making them emblematic of the miraculous possibilities and tremendous burdens of modern medical care.56

One of the cornerstones of bioethics in the broader field of medicine are Childress and Beauchamp's four principles elaborating on the ethics of beneficence: 1) nonmaleficence, the avoidance of whatever might harm the patient, 2) a respect for patient autonomy, 3) the patient's right to self-determination, and 4) the equitable distribution of medical resources.⁵⁷ These principles are too abstract to serve as a manual of ethical practice,; however, they are useful in recognizing situations and defining issues in which goals of ethical practice are coming into conflict, such as when the goals of respecting patient autonomy and justice may lead to contradictory courses of action if a patients demands access to limited medical resources that should go to other patients who have priority for other reasons or might derive greater benefit from them.⁵⁸

Although Johnson asserts that beneficence and non-maleficence have long existed as principles of bioethics, until more recently these principles did not imply any need for proper disclosure to the patient. Given the norms of the physician's role of near omniscience in society, not to mention widespread acceptance of the concept of one human owning another, i.e, slavery, the absence of expectations of disclosure is not surprising. In concord with the thinking of that era, Percival's 1803 medical text, while incorporating medical ethics, provided no statement that could be used to support the idea of patient making medical choices for themselves. Even the AMA Code of Ethics from 1847 and based on Percival's does not appear to even foresee rise of autonomy as fundamental concept of biomedical ethics. In fact, it was the mid of 20th century before

informed consent was clearly established in the literature as a principle of ethics. One reason for this breakthrough was a growing legal acceptance of the right of every to give or withhold informed consent.59

In some form or another, the rights of patients to accept or reject medical care has been acknowledged for several centuries, in part through common law in England and the U.S. In the last 70 years or so, the principle of informed consent while a subject of debate has been elevated to the status of legal right through the response to revelations of World War II atrocities committed under the guise of medicine, not just in Axis Europe but also in studies such as the Tuskegee syphilis case, as well as in response to the movement for greater equality and civil rights for minorities. From the outset, the physician's duty to practice beneficence has been construed to protect patients from suffering any harm not the direct result of the injury or illness. This precedent is particularly relevant to the frequent issues of withholding ICU care from patients ICU given the more cost effectiveness of home care, a situation that has occurred repeatedly with patients suffering from cancer or AIDS.60 Until the 20th century, neither English nor American courts had deemed informed consent a prerequisite to intervention for treatment or research. Court records of this period document a few instances of healthcare professionals supporting the notion of informed consent through their testimony, but none in which they advocated patient autonomy.61

Beginning in the early 20th century, various U.S. court case rulings created and expanded the precedent for legally mandating informed consent. In Schloendorff v. Society, 1914, the U.S. Court of Appeals in New York ruled against a hospital, stating

explicitly that every adult person had the right to decide what could or would be done with his or her body. Some four decades later, in 1957 the U. S. Court of Appeals of California ruled that clinicians must disclose all relevant facts affecting a patient's rights and interests. By 1970, the Supreme Court of California had further defined the scope of the physician's legal duty, in terms of disclosure to the patient, as being measured by the patient's need to know any and all relevant information material to decisions concerning care and treatment, with Cobbs v. Grant serving as the basis for their ruling.62

An examination of the transcripts of these cases leads to the conclusion that informed consent in this country was motivated by a growing resistance to the paternalistic model of medicine, based on an ethics which permitted doctors to define the best interest of a patient without concern for his or her wishes or opinion. What has emerged from this historical shift has been participatory clinical decision-making, eschewing rigid medical paternalism, but concurrently ushering in greater complexity in doctor-patient communication and relationships.63

Chapter 3.C. Ethical Issues in the Intensive Care Unit

This section of the Chapter 3 describes the concept of *futile medical care*, issues involving the ethics of allocating limited resources, and the controversies and realities surrounding the withholding and withdrawal of life support in the ICU. In order to frame the discussion of these topics, all of which have engendered considerable debate, it is first necessary to briefly examine the special circumstances of ICU patients with regard to autonomy and their informed consent, as well as the special responsibilities that these circumstances place on the ICU staff.

Presenting fundamental challenges to ethical principles such as autonomy, ICU patients frequently have diminished ability to make informed decisions due to any or several of various hindrances, such as confusion, disorientation, psychosis from organic illness, metabolic upheavals, pain, sleep deprivation, or medications such as sedatives. These consideration make it imperative that ICU staff be vigilant about their responsibility to ensure that patient is given every opportunity to exercise what capacity he or she possesses at the moment when critical decisions need to be made. The goals of preserving patient autonomy and informed consent must be balanced with avoiding lifethreatening delays in decision making, while allowing for a patient's possible ability to make some, but not all, decisions about his or her care. The medical staff of the ICU team needs to be vigilant and constantly prepared to reassess a patient's capacity for decision making, knowing when to bring in outside experts for a formal cognitive or psychiatric assessment.64

Chapter 3.C.1. Futile Medical Care

The term *futile medical care* implies that used to describe medical treatment that has little or no, or at most meager hope of achieving the goals set for it, such as regaining function the patient has lost through injury or illness, or improving the patient's quality of life.65 This phrase is loaded with connotative meaning for almost all parties involved, including medical staff, families, surrogates, and stakeholders have interpreted the meaning of 'futile medical care' differently and sometimes contentiously from each; thus, predictably it has frequently thwarted attempts to communicate among attending physicians, other ICU staff, patients themselves, their family members and/or surrogates.

From an exclusively rational perspective, the ICU is the setting where the end-of-life is a very real consideration and the idea of futility is likely to become a possibility under certain circumstances. However, these same circumstances do not tend to promote rational thinking on the part anyone with emotional concern for the patient. Probably precisely because of medical and technological advances, leading to heroic life saving through such measures as cardiopulmonary resuscitation (CPR), mechanical ventilation, pacemakers, and dialysis, life may be sustained for a potentially indefinite period even in the face of an incurable condition.66

The rise in prioritization of patient autonomy has had a profound effect on the nature of physician-patient relationships.67 The power which the growing emphasis on autonomy as a pillar of biomedical ethics provides to patients and their surrogates, along with relatives in some cases, can encourage them to put a medical professional in position of going against the latter's conscience and conflicting ethical principles in providing care that goes against professional evaluation. In such cases, doctors, nurses, or other ICU staff may find it impossible to deal with stress of the moral and ethical conflict and will consequently withhold or withdraw treatment, either by conscious or subconscious action, rationalizing the effort as futile and interpreting beneficence according to their professional ethics as requiring them to treat only patients who can truly benefit from the care.68

In an attempt to settle some of the disquiet surrounding the term, certain scholars have posited a distinction between physiological and qualitative futility. A hypothetical situation involving chemotherapy serves to illustrate the difference; a doctor rejecting the

treatment judging that it will not arrest the progress of a cancer is assessing it to be physiologically futile, whereas the same doctor upon deciding that the same patient could not endure the negative side effects of the chemotherapy, that would be assessing the identical regimen to be qualitatively futile. The value in distinguishing these notions of futility is that it allows specifying the motivations for making the determination in ways that are possible to more easily communicate and accept.69

Yet another attempt at circumventing the immediate emotional responses to the term futility in medicine has been to speak in terms of low survival or success rates of what are sometimes called futile therapies. In this light, Peberdy et al. note that among patients receiving CPR in European hospitals, at most 6% are successfully resuscitated, and of those CPR, and merely 17% eventually left the hospital alive.⁷⁰ By it very nature, CPR, especially in the ICU, does violence to the human body, insofar as it involves procedures such as the administration of electric shocks, the intubation of airways, the injection of heart medication, or the direct massaging of the heart in an open chest.⁷¹ However, in spite of the exceedingly slim odds of its success, many palliative patients and family members continually push for it, even when they are aware of the odds, because of the social and cultural ritual that has become rather than because of its functionality or prospect for success.⁷²

According to Mohammed and Peter, one the important aspects and functions of CPR is its symbolism in affirming that the medical staff pursued every conceivable avenue in the effort to sustain the life of a patient, despite any apparent futility.73 Thus, the staff removes any logical possibility of attributing death, should it be the outcome, to a failure of human effort. Furthermore, these researchers contend that the typical ICU protocol of withdrawing technological life support technology at a slow, deliberate pace is aimed at replicating the natural process of dying, permitting the family of the patient to prepare themselves psychologically through the gradual shift from medical intervention to nonintervention.74 To this end, some ICUs have proposed encouraging the members of a patient's family to witness CPR or other resuscitation efforts so that they may be a part of the process leading to the patient's in a way that is more open and meaningful.75

When disputes arise over whether a given course of intervention or treatment is futile and the existing physician-patient or surrogate relationship is incapable of dealing with the issue, mechanisms, protocols, and procedures, either formal or informal have been emerged for resolving the issue.⁷⁶ One such formal procedure, known as the Houston Policy for Medical Futility was developed in that city and was in operation until the Texas Advanced Directives Act with its broader scope involving patients, surrogates, and physicians replaced the policy and incorporated an interdisciplinary committee from the facility and a procedure to resolve disputes.⁷⁷ On a national scale, the American Medical Association (AMA) published recommendations for a multi-phase resolution procedure, notable for providing a mechanism for patients or their surrogates to have a different attending physician, or even move to another medical institution if agreement cannot be reached.⁷⁸

Taking into account the three aspects of patient treatment, namely its effectiveness, its benefits, and its drawbacks and cost, financial and otherwise, Edmund Pellegrino created a guideline system for determining the best course for a given patient in his or her individual circumstances.⁷⁹ According to Pellegrino, while the effectiveness would be best evaluated by the medical professional, the patient would be the best judge of benefits in the subjective terms of his or her lifestyle, with the assessment of burdens and cost arrived at through a collaborative effort of the physician and the patient. In this model, each person would be responsible for deciding upon the best approach. In this context, the person or group responsible for their segment of through this process, Pellegrino envisions a balanced consensus emerging as to whether any course of medical care or treatment should be considered futile.⁸⁰

Advocating distinctly against Pellegrino's model, Grossman and Angelos warn that it is likely to cause a communications breakdown, especially when it comes to the concept of futility.⁸¹ Moreover, these authors contend that the very notion of futility inherently puts the physician back into the authoritarian role of the past while it undermines patient autonomy. Grossman and Angelos posit the use of the term "goals of care" instead of "futility" so as to foster physician-patient dialogue and discourage contentiousness, especially given that patient's surrogates and family members may also be involved. According to these scholars, the idea of establishing goals, clear expectations, and advanced directives with such features as "do not resuscitate orders" and "required reconsideration" go a long way to forestalling conflict when critical decisions of this nature confront those involved.⁸²

Insofar as they command the trust of all those directly involved with the patient's care, third parties such as ethics consultants or palliative care teams,⁸³ social workers, chaplains, patient advocates, or medical committees are in a position facilitate consensus

on questions of futility of care. Such 'external' groups or individual bring broader perspectives, help diffuse the emotional ramifications of potential decisions, sideline ethical issues such as cost and rationing of resources and thus reduce their potential for conflict, and alert the other parties to additional or unconsidered options for care and treatment.84

According to Bradley and Brasel, surgical ICUs in particular could benefit by establishing the following five circumstances as automatic thresholds for calling on the services of palliative care specialists, which these authors distinguish from hospice care and which they arrest will avoid futility becoming an independent point of contention: 1) by request of the family, 2) by the medical team's determination of futility, 3) by contentious family disagreement, 4) by an assessment that the end-of-life is imminent, or 5) simply by one month having elapsed with the patient in continuous ICU care.85

Chapter 3. C.2. Ethics of Allocating Limited Resources

Through history and in all societies, medical services and resources have been almost always insufficient to meet the community's needs causing ethical dilemmas in terms of equitable allocation.⁸⁶ There have been those who, on the basis of moral imperative, are against any limiting of medical care even for the terminally ill, resulting in the cost of care and treatment rising far beyond either the willingness or the ability of individuals or society to pay.⁸⁷ Lest this position seem an exaggeration, 2013 statistics for health care spending in the U.S. reveal a total of spent \$9,255 for each individual, healthy as well as ill or injured. This adds up to a total of \$2.9 trillion dollars, in excess of a four-fold increase from the \$714 billion spent in 1990 and totals 17.4% of the nation's

2013 gross domestic product (GDP); furthermore, it amounted to two to three times as any other industrialized nation for that year.88 Of even greater concern, forecasts anticipate additional growth to average 5.8% yearly through 2024 reaching 19.6% of GDP.89

The fraction of this staggering amount which is being directed towards end-of-life care is far greater than proportional under any system of categorization.90 Evidence shows this disproportionate spending to be stable over the long term, as annually from 1978 to 2006 approximately 5% of Medicare patients accounted for between 25.1 to 28.3% of the program's payments during the final year of life, typical of these patients was repeated hospitalization and greater use of ICU services, especially during the final few months.91 Statistics confirm that for any given patient, approximately one-third of their lifetimes Medicare bills are for care and treatment during the last month of life.92 Numerous scholars and policy advocate contend that such imbalances make the rationing of limited medical resources economically inevitable and even morally justified, no matter how unpalatable.93 End-of-life care is the most visible, yet not the only, intensive consumer of medical resource; for instance, premature neonatal care can encompass many months of hospitalization and expensive care at times exceeding \$1 million per child. Such situations, as with other disproportionately expensive care, occurs within some sector of the ICU.94

Possibly due in part to the inherent nature of the medical care it provides, the hospital ICU has not been able to find an optimum balance of efficiency, effectiveness, and ethical acceptability, which has avoided spirited controversy. Difficult situations,

which are likely to involve the ICU, include emergency or disaster triage, priority for organ transplantation, access to vaccines during epidemics, priority for ICU admission in general and its forms of critical care in particular, and the decision of when to suspend futile end-of-life care.⁹⁵ Beyond any denial is the assessment that the equitable allocation of resources and the life and death decisions involved constitute one of society's most morally and ethically difficult challenges.⁹⁶ Any given procedural proposal can be challenged on the ground that it sacrifices fairness to efficiency or vice versa, too complex to be implementable or else too efficient to be applicable to enough specific situations, or otherwise too controversial in one respect or another.⁹⁷ In theory, the ethical principles of beneficence, non-maleficence, autonomy, and justice should provide guidance in any medical situation; however, in practice they may easily come into conflict with each other, leaving no clear guidance for the specific decision. The following examples from research illustrate concrete situations and quandaries that has raised difficult ethical issues.⁹⁸

In terms of prioritizing kidney transplant recipients, the *first-come, first-served* is relatively straightforward to comprehend, defend as being equitable, and administer efficiently, yet it shuts out consideration of the realities of medical need and the quality of the outcome. Well documented in research literature are cases of hospitals being forced to significantly amend or even abandon this guideline in the face of heated controversy. In some instances, critics contended that the first-come, first-served rule discriminates against those with a lower standard of living who are disadvantaged in terms of communication and transportation technology. In such an example, favoring efficiency may prevent tragic outcomes should something go wrong in the system, while insisting on equity may lessen contention. However, in most cases both goals cannot be fully satisfied.99

While lotteries for access to limited medical resources, such as in the ICU enjoy the precedent of proven use in the military draft, immigration and receiving green card status, as well as the distribution of vaccines, these systems themselves have not occurred without challenges to their fairness. On the positive side, selection by chance can be quickly, simply, and efficiently administered; moreover, they ostensibly ignore the obvious and egregious form of inequity. This blindness to individual considerations, however, is the very source of objection to lotteries precisely because many scholars, medical professionals, and members of the general public feel strongly that without taking into account these ignored differences, no lottery type system can claim to be ethical.100

In the United States, according to established guidelines, priority in admission into the ICU goes to patients being readmitted over first time admissions despite the relative urgency of their conditions. Thus, given limited bed space in the ICU, even a new patient in need of immediate life-saving procedures cannot supercede a patient needing to return to the unit, creating an ethical dilemma. In these circumstances, resource limitations prevent medical professionals from acting in each patient's best interest. From a different perspective, this guideline unfairly prioritizes existing doctor-patient-ICU relationships over similar relationships that as yet do not involve the ICU even when those other patients may derive greater benefit from ICU care. Needless to say, such a rule while ethical in the sense of being clearly set down beforehand and administered

consistently, has been highly controversial, with many scholars and practitioners advocating revision with the goal of maximizing the number of lives that can saved through ICU treatment and care.101

The prioritization of patient admissions for hemodialysis is an example of the dilemmas faced by the ICU in dealing with inadequate resources. If the chances of successful treatment are calculated from a medical perspective and prioritized, patients with the best prognosis would be treated first, which could in the process consign sicker patients to pain and fatality.¹⁰²

Treatment of those who are the sickest first prioritizes those with the worst future prognosis ahead of all others. This rule follows the moral principle of the rescue rule in the face of imminent death. By contrast, prioritizing those patients whose need is most critical, as is done with vital organ transplant and disaster triage typically maximizes the saving of lives.¹⁰³ However, opponents argue that requiring those who appear healthier to wait allows their progressive conditions to worsen, ultimately costing more, and possible causing them to miss a window of opportunity for being cured or stabilized with much less impairment. Opportunities lost in delaying treatment of those with the best chances can even end up as a lost opportunity to save a life.¹⁰⁴

The pros and cons of prioritizing the youngest patients tend to mirror the arguments for and against prioritizing the worst off. The reasoning is that those who had the least opportunity to live should, in fairness, be given a more equal chance at a normally long life. The often heard counter argument would point to a hypothetical young adult who has been the recipient of much more family and societal investment of
time, energy, and resources than an infant, and yet has had no more opportunity to live so as to represent a return on that investment.¹⁰⁵

Two example of prioritizing the goal saving the most lives has been the allocation of influenza vaccine106 and responses to bioterrorism,107 predicated on the assumption that the opportunity to save ten lives trumps the chance to save just one. Nevertheless, relying on numbers is too simplistic for concrete, critical situations in healthcare, such as can be common in the ICU where among other things the numbers tend to be not so heavily lopsided. Ethically laden judgments often must be made over whether to prioritize women and children over men, whether to prioritize educational attainment or other greater potential to benefit society, whether to prioritize those with potentially longer to live and thus contribute more, or whether to prioritize those with the greatest prospect for survival. These questions must be dealt with when performing triage in the wake of disasters, when distributing limited supplies of penicillin, or when creating priority lists for receiving organ transplants.108 Saving the most lives will not aid in allocating resources it these questions of who and how many are to be selected first have not been determined authoritatively prior to the emergency or other urgent situation.109

As implied in several of the questions above, social usefulness has at times been utilized as ethical criteria for who will be prioritized.¹¹⁰ The justification in this case resides within specific individual rather than a particular value applied equally to all.¹¹¹ One form of this criterion is known as *instrumental value allocation*, characterized by the hypothetical situation in which a government agency such as the Centers for Disease Control and Prevention (CDC), would endorsed individuals such as key political leaders

as being indispensable and therefore prioritized above the otherwise first-come, firstserved basis for the rest of the community, This would be justified by the rationale that certain leadership functions would be necessary for the society to cope with whatever prompted calamity. Yet another possible prioritizing scheme based on social usefulness is *Reciprocity value allocation*, which would in a sense reward individuals who may have, for example, put their lives at risk for their nation or community, donated organs to save lives, or volunteered in an important, critical capacity for the public good.112

It becomes clear that, first, no individual guideline for allotment can satisfy all relevant moral principles in the attempt to ethically allocate insufficient resources, and that, second, the basic principles of autonomy, justice, beneficence and non-maleficence are almost certain to come into conflict with one another.113 Regardless of the allocation system, whether on a single method of selection or a combination, objections can and have been made that its disadvantages are significantly great as to render the system unworkable, unethical, or both. A number of organizations have promulgated hybrid allocation systems although they have typically ended up with some degree of complexity issues.114

Persad et al. have analyzed the hybridized principle systems put forth by the following four groups: 1) the United Network for Organ Sharing point system, 2) the Quality-Adjusted Life Years allocation system, 3) the Disability Adjusted Life Years allocation system, and 4) the Complete Lives system.

Merging three prioritization options, The United Network for Organ Sharing (UNOS) utilizes a combination of the first-come, first-served and sickest-first principles

with the prognosis principle, adapted for antigen, antibody, and blood type matching of donors to recipients. In practice, weighting of the principles depends on the type of organ that is donated, creating flexibility. Criticisms have focused on the lesser weighting prognosis, the susceptibility to fraud or bias by those misrepresenting their urgency of their need, the use of multiple transplantation lists, and of permitting multiple organ transplants per individual instead of possibly saving more lives.116

The procedure developed as the Quality-Adjusted Life Years (QALY) allocation hybridizing the priorities of quality of life-years and prognosis with the former being dominant and others disregarded. This method has been criticized as inherently biased against the disabled, disregarding fundamental human equality, and ignoring the other principles.117

The Disability Adjusted Life Years (DALY) allocation, like the QALY, avoids distribution based on factors, while attempting to create some equity in terms of disability, ultimately ranking a person's life-year with his or her age as a weighting modification. Although it carries the endorsement of the World Health Organization (WHO), the DALY system has been criticized for inherently favoring patients who are younger and for justifying selection on the basis of instrumental value.118

As its name suggests, five distinct principles are incorporated into the Complete Lives system: 1) youngest-first; 2) prognosis; 3) save the most lives; 4) lottery; and 5) instrumental value, only in terms of public health emergencies.¹¹⁹ The use of youngestfirst in this system actually emphasizes adolescents over infants, given that they represent a greater investment by parents and society, as well as greater personality development. The Complete Lives system also weights prognosis for living a full life span. In this respect, one criticism is that it works against those with a poor prognosis who are in poor condition or are less likely to fully recover. The principle of saving the most lives is interpreted in terms of more people having more complete lives. Those between the ages of 15 and 40 are prioritized because they have the best prospect for doing so. Advocates claim various advantages for the system, namely that it 1) prioritizes younger people, improving data tracking and leading to greater protection from abuse of the system, 2) motivates attending physicians to endeavor to improve each patient's condition as much as possible, and 3) achieves the optimal degree of distributive justice by weighting human lives as opposed personal qualities experiences, in spite of its bias against those of advanced years. While the Complete lives system is undeniably complicated, and in some circumstances unwieldy, many researchers consider it the best available.120

Unfortunately, none of these systems directly addresses one of the most important causes behind the need for an ICU to make resource allocation decisions. In the hospital ICU, the lack of capable personnel may prove to be the most widespread trigger for the need to prioritize patients, either because the needed specialists are not geographically accessible or are preoccupied with other medical commitments, or have scheduling conflicts preventing timely attention to a patient's medical needs.121

Chapter 3.C.3. Withholding and Withdrawal of Life Support

Forgoing life-sustaining medical care can take any of three forms, namely withholding life support, withdrawing life support, or not escalating the level of treatment when otherwise called for. As the names imply, withholding must be chosen before treatment commences; afterward, it is withdrawing life support. Deciding not to escalate treatment implies continuing treatment at its current level either because it would give no additional benefit or would not be needed at the time of the decision.122 Life sustaining technologies and treatment regimens likely to be involved in such decisions include: 1) mechanical ventilation, 2) artificial nutrition and/or hydration, 3) mechanical circulation, 4) chemotherapy, 5) vasopressors, 6) renal dialysis, and 7) courses of antibiotic treatment. A decision to withholding or withdraw care should not be construed to involve all care and treatment of a particular patient, nor should it be interpreted as passive; for instance, withdrawal or withholding often coincides with the administration of sedatives and opioids for relief from pain.123

Withholding and withdrawing life support is The ethical justification for withholding or withdrawing life support from a patient rest in circumstances such as a course of treatment so extremely difficult to maintain as to be burdensome, a great probability the end of life is imminent, or a substantial likelihood of severe disability even if the treatment is non-fatal and non-futile. Further criteria are employed but individual institutions and espoused by some ethicists; for instance, the University of Utah and Intermountain Medical Center make it part of stated policy to withdraw life support regardless of other considerations when: 1) a surrogate asked to have it done it, 2) an external standard of reasonability is fulfilled, 3) a minimal time period, allowing for the patient to make requests has elapsed, and 4) certain psychiatric morbidity thresholds have been crossed.124

As many as a quarter of all patients admitted to the ICU die there;125 most

frequently in the wake of a decision to withhold, withdraw or not escalate life-sustaining treatment.126 It is common that medical staff in the ICU make decisions to withhold, withdraw or not escalate life support.127 The Equivalence Thesis (ET) is a principle of ethics avowing that withholding, withdrawing, and not escalating life support treatment are all legally and ethically equivalent. The ET holds that it is permissible to withdraw medical treatment if it is also permissible to withhold the same treatment and vice versa. In contrast, Non-Equivalence (NE) considers it acceptable to withhold treatment while it would not be permissible to withdraw the same treatment once started.128 While ET has the endorsement of many scholars, philosophers, bioethicists, and professional guidelines,129 it is nonetheless controversial with numerous opponents,130 and is far from being the consistent practice of the medical profession.131

One group that has resisted the Equivalence Thesis are physicians in the ICU, in part due to concerns over the possible legal interpretations of withdrawing something previously acquired and in part because it feels like a violation of non-maleficence.132 Furthermore, some religious authorities such as Orthodox Judaism consider any prohibition of treatment even at the end of life as potentially causing premature death. The dominant position among medical professionals is based on NE even though that position has resulted in both absurd and unacceptable situations.133 Medical staffs have an inherent bias, both psychologically as human beings and as professionals towards not actively stopping even questionable treatment once it has begun.134 Moreover, in many concrete case with particular patients, specifics of the case would weigh in favor of NE.135 Thus, it is understandable that many medical professional are not persuaded by the Equivalence Thesis despite guidelines, scholarly recommendations, or even some

court ruling. Ironically, even resource limitations that force allocation decisions in the ICU often favor the NE position given the prioritization principles they follow. In the context of this controversy, several compromise solutions have been tried, including short term trial therapy with an ICU patient for whom the efficacy is questionable before committing to the intervention as treatment, and pre-establishing a lower mortality threshold for withdrawal.¹³⁶

Chapter 3.D. Maintenance of Patient Autonomy and Informed Consent

This section of Chapter 3 describes ethical principle and issues involving respect for patient autonomy, and in particular for informed consent in the ICU. At the heart of these considerations is the determination of a patient's capacity, as distinguished from the legal concept of competence, a determination which is critical in upholding autonomy and informed consent in the ICU.

Chapter 3.D.1. Respect for Patient Autonomy

Typically, the source of ethical dilemmas concerning ICU patients lie with conflicts, which grow out of interpretations the four fundamental principles of bioethics: 1) patient autonomy, 2) distributed justice, 3) beneficence, and 4) non-malfeasance as they apply to a given case. For instance, a hospital's ethics committee might have to weigh conflicts among these principles over whether healthcare professionals should give to employ lifesaving medicine and heroic treatment with its prognosis in doubt, when the medical staff pushes for it in spite of either contradictory expert opinion or the patient's unwillingness to give consent.¹³⁷

The policy on patient autonomy of the American Medicine Association illustrates how ethical issues can arise concerning principles such as full disclosure and informed consent. Legally established precedent and biomedical ethics concur in the absolute right of a patient to refuse any form of medical care or treatment, even if is the only way to sustain life. However, this position presumes the patient to be fully capable of analyzing the options and understanding the ramifications of any decision. In considering the issue from a medical perspective the concept of *capacity* must be distinguished from *competency* since legally all adult are presumed competent unless a court has formally ruled otherwise, 138 while any individual under the legal age of adulthood, legally competency, regardless of their intelligence or maturity, except in formal court ruling of emancipation. On the other hand, capacity is more fluid and functionally determined, meaning that a given patient, due to his or her condition, may migrate in and out of capacity or be capable in terms of some decisions but not others. Criteria for initially determining a patient's capacity include: 1) the ability to comprehend information about his or her condition, 2) an understanding his or her right to choose from the possible treatment options, as well as the right of complete refusal, and 3) an understanding of the risks and consequences of the available options. Beyond these fundamentals of comprehension, in order to have capacity, a patient must be able to assess all this medical information in relation to personal values, morals, and goals, so as to weigh alternative choices. Ultimately, the patient must be able to communicate the decisions made, consistently and meaningfully.139

Children and minors constitute a unique situation within the field of Biomedical ethics needs to give special consideration to issues of informed consent when children or

minors are the patients. A cornerstone of the ethical approach known as principlism is that all competent individuals have the right to choose the option that accords with their best interest. Obviously, in medicine, as in other fields, many children lack in the cognitive development to understand various aspects of their situation and, thus, cannot give informed consent.¹⁴⁰ By strict definition, informed consent can only be given by the individual directly experiencing the consequences of the decision. According to abstract ethical standards, what even a parent or guardian decides is not informed consent if it on behalf of a child, despite the adult having legal custody. Thus, some scholars and clinicians have coined the term *informed permission* for such cases. Although not instinctively obvious to the physician, With minor such as older adolescents, the physician must determine whether the patient exhibits sufficient maturity to qualify and be treated as an adult with respect to that minor's capacity for making informed choices, and therefore needs to be treated, for bioethics purposes, as an adult.¹⁴¹

From the standpoint of bioethics, the ultimate responsibility for ensuring that a minor's well being and best interests are carried out rests with the physician, regardless of parental or surrogate's objections. If resolution between parties looking out for the child cannot resolve the issue, Legal avenues exist for situations that cannot be resolved, for example, if a medical determination of needed treatment conflicts with a guardian's religious beliefs.¹⁴² The child patient should be brought into the discussions as far as feasible even though his or her consent may not needed nor his or her wishes respected; in all cases, the child has the right to be informed to the extent of his or her ability to comprehend, ask questions, and to communicate his or her desires, concerns, or fears. Should parents insist on prohibiting a proposed treatment, the case becomes a legal

matter and increasingly complicated; the physician needs to look for mutually acceptable alternative options suitable to the child's medical needs.143 In the absence of these, the physician must look to ethical or legal avenues in order to obtain permission for treatment.144

Chapter 3.D.2. Respect for Informed Consent

While the abstract principle of informed consent principle makes straightforward sense, in practice the concept of providing the patient with options for treatment pushes the medical professional towards a model of care reminiscent of a store clerk offering a customer models or brands of a type of product. This model tends to neglect the role of the clinician's expertise and appears to expect the doctor to stand back and follow whatever the patient chooses.145 Nonetheless, the patient's having and being informed of all options, whenever feasible alternatives exist, as well as being free to select or reject in fundamental and critical to protecting the patient from unwanted interventions and inappropriate paternalism. While healthcare professionals are responsible for explaining all nursing procedures to the patient it is the patient must be the one to decide whether a treatment option would be more burdensome than beneficial and ultimately whether to reject anything as simple a pain reliever or as involved as a surgical procedure,146 frequently the only context in which doctors habitually think about informed consent as an inherent part of the process.147

Both Autonomy and informed have the patient's competence to deliberate and arrive at rational decisions.¹⁴⁸ In practice, ensuring these principles in ICU treatment is a complex process, rich in nuance, and inseparably linked to the conditions which have

brought patients to this unit of the hospital, inhibiting their cognitive recognition and comprehension and thus limiting what autonomy some patients can exercise. An additional layer of complicating the process of ensuring autonomy and informed consent is the narrow scope of the nursing perspective, which is restricted to ascertaining whether the patient actually signed the appropriate informed consent documents, and had received all required-to-be transmitted information prior to signing it?149

Patients themselves may hesitate to exercise their autonomy in making choices out of a lack of confidence in having received or understood the medical information that they have indeed been given. Consequently, such a patient may view the efforts to preserve his or her autonomy as abandonment by those whose expertise and wisdom the patient has put faith in. this feeling is especially likely when healthcare professional limit themselves describing the various possible treatments without explaining the rationale for specific choices, and most important if nothing is recommended. Regardless of the complexity or difficulties involved, informed consent is a requirement in all medical circumstances, not just the ICU, and must include information about procedures and protocols in the event of fatality, should there be even the remotest possibility. The information required for legally provided informed consent include: 1) the name of the patient, 2) the hospital, 3) the medical procedure to be performed, 4) the names of medical professionals directly involved, 5) the risks of any alternative procedures and treatments, 6) signature of patient or guardian, 7) a statement averring that the procedures were explained to the patient, the signature of the patient or surrogate, and 9) the signature of a witness. In the ICU, as well as in any other setting, assuming the timing of circumstance permits having a friend or someone from whom the patient can derive

psychological support present during the explanations is desirable. Showing respect for autonomy means conveying complete and accurate information to the patient concerning his or her condition to the extent that the patient fully understands the medical risks, either consenting to the procedure and its timing, or refusing it; regardless, the patient's confidentiality and privacy must be guaranteed.¹⁵⁰

Chapter 3.E. Conclusion

All the previous descriptions of ethical principles in practice relate directly to cases of medical error, these ethical principles as affirmed explicitly by both the American Medical Association and the American College of Physicians require all medical professionals, organizations, and facilities involved to provide complete disclosure, including every relevant detail of errors, and to share them with all those involved (patients, surrogate family members, hospital, regulators, insurers). To this extent, both medical institutions and professionals are to hold themselves accountable for their actions.

The guidelines mentioned above are grounded in consequentialist or teleological theory with their concern for the outcomes of medical care, as well as by utilitarianism which advocates such accountability for medical errors through its concern with use of resources and prioritizing of delivery of the greatest good for the greatest number of individuals. Even though the antithesis of consequentialism, deontology and principlism are no less silent or adamant that autonomy, justice, beneficence and non-maleficence must be preserved in the face of medical errors, whatever the cause.

Although these ethical principles concur in terms of the need for full disclosure of medical errors, they remain stand in contradiction concerning their implications for handling many biomedical ethical dilemmas that are routine to the ICU environment, with the issue discussed at length above about questions concerning patient capacity for giving informed consent being a frequent example. Yet another of the areas in which ethical principles come into conflict, again as discussed at length in this chapter, is that of medically or psychologically futile situations such as end-of-life care, which are prone to arising more frequently in the ICU that in any other part of the hospital. In spite of the futile prognosis, a patient or family members will at times demand that every effort and expense be spent fighting the inevitable. As the analysis in the chapter has revealed, forcing the medical staff to conduct procedures that cause them personal moral dilemmas about violating their consciences and professional ethical standards.

Other ethical dilemmas discussed in this chapter include the equitable distribution of limited resources, particularly in the ICU, where terminal illness is a common situation. In these circumstances, treating each patient in his or her best interest is just not possible. In the face of the impossibility of doing everything medically imaginable, painful decisions with fatal consequences must be made without time for extended consideration in terms of whom to admit to the ICU. The chapter has examined numerous allocation strategies such as treating everyone equally in order, favoring those in the most dire condition, maximizing the number helped and the extent of benefit (i.e, utilitarianism), or promoting and rewarding social usefulness. As the discussion has shown, no single principle was either predominantly acceptable or objectively fully ethical. Thus, systems that integrate multiple principles go further toward satisfying

more ethical principles, yet do so at the expense of greater complexity, which can itself cause frustration and dissatisfaction. Finally, the chapter has addressed the issues surrounding the withholding and withdrawing of life-saving treatment, actions typically the precursor to death in the ICU, and a source of conflict as to whether the two actions are ethically or legally the same. Choices such as those described in this Chapter constitute the daily required routine of the ICU. It is in this context that medical errors occur and is the context within in which they must be handled. Endnotes

¹ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 10-12; Jeffery, Maren E., et al., "Ethical Issues in the Intensive Care Unit," *Pulmonary Disease* 11, no. 3 (2004): 1-12.

² Irwin, Richard S, and James M Rippe, *Irwin and Rippe's Intensive Care Medicine* (Lippincott Williams & Wilkins, 2008), 2339-2345.

³ Bersten, Andrew, D., and Neil Soni, *Oh's intensive care manual* (China: Elsevier Health Sciences. 2013), 55-57.

⁴ Clark, Peter A., "Medication Errors in Family Practice, in Hospitals and after Discharge from the Hospital an Ethical Analysis" *The Journal of Law, Medicine & Ethics* 32, no. 2 (2004): 349-57; Post, Linda Farber, et al., *Handbook for Health Care Ethics Committees* (Johns Hopkins University Press, 2007), 192-195.

⁵ Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy, 2000), 18-21.

⁶ Houghton, Douglas, "End-of-life and Palliative Care" in *Critical Care: Concepts, Role, and Practice for the Acute Care Nurse Practitioner,* ed. Wychoff, Mary (New York, NY: Springer Pub., 2009), 459-480.

⁷ Schwartz, Denise Baird, "Ethical Considerations in the Critically Ill Patient" in *Nutrition Support for the Critically Ill Patient: A Guide to Practice*, ed. Cresci, Gail (Boca Raton: Taylor & Francis, 2015), 635-652.

⁸ Gohsman, Robyn, *Law and Ethics* (Philadelphia: Wolters Kluwer Health/ Lippincott Williams & Wilkins, 2009), 210-212.

⁹ Dreeben, Olga, *Patient Education in Rehabilitation* (Sudbury, MA: Jones and Bartlett Publishers, 2010), 296-297.

¹⁰ Youngberg, Barbara J., and Martin J. Hatlie, *Patient Safety HandBook* (Sudbury, MA: Jones & Bartlett Learning. 2004), 550-555.

11 Joint Commission Resources, "Ethics and Disclosure Events" in Understanding and Preventing Sentinel and Adverse Events in Your Health Care Organization (Oakbrook Terrace, IL: Joint Commission Resources, 2008), 173-175; Jesus, John, et al., Ethical Problems in Emergency Medicine: A Discussion-based Review (Hoboken, NJ: Wiley and Sons, 2012), 242.

¹² Youngberg, Barbara J., and Martin J. Hatlie, *Patient Safety HandBook* (Sudbury, MA: Jones & Bartlett Learning. 2004), 524-527.

¹³ Tay, Catherine, and Sim Leng, Tien, *Biomedical Ethics and Medical Law in Blood Transfusion Practice: Case Scenarios* (Singapore: Armour Pub., 2010),89-100.

¹⁴ Youngberg, Barbara J., and Martin J. Hatlie, *Patient Safety HandBook* (Sudbury, MA: Jones & Bartlett Learning. 2004), 505-555.

15 Lo, Bernard, *Resolving Ethical Dilemmas: A Guide for Clinicians* (Philadelphia: Lippincott Williams & Wilkins, 2012),199, 228.

¹⁶ American College of Physicians, American College of Physicians Ethics Manual, 6th ed. Annals of Internal Medicine, 156 no. 1 part 2 (2012): 73-104.

17 Bernat, James L., *Ethical Issues in Neurology* (Lippincott Williams & Wilkins Philadelphia, 2008), 67-69.

18 Hendrick, Judith, *Law and Ethics in Nursing and Health Care* (Nelson Thornes, 2000), 17-20; Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach* (Radcliffe Medical Press, 2005), 104-105; Holland, Stephen, *Public Health Ethics* (Cambridge, UK; Malden, MA: Polity, 2007), 7-10.

¹⁹ Remington, Joseph Price, et al., *Remington: The Science and Practice of Pharmacy* (Philadelphia: Lippincott Williams & Wilkins, 2006), 24-26; Cronin, Brian, *Value Ethics: A Lonergan Perspective* (Nairobi, Kenya: Consolata Institute of Philosophy Press, 2006), 43; Morrison, Eileen E., *Health Care Ethics: Critical Issues for the 21st Century* (Jones & Bartlett Publishers, 2009), 43-45.

²⁰ Carlson, Erik, "Consequentialism Reconsidered" In *Consequentialism Reconsidered* (Dordrecht: Kluwer Academic, 1995), 5-10; Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach* (Radcliffe Medical Press, 2005), 104.

²¹ Joint Commission Resources, Understanding and Preventing Sentinel and Adverse Events in Your Health Care Organization (Oakbrook Terrace, IL: Joint Commission Resources, 2008), 19-20; Rocker, Graeme, et al., End of Life Care in the ICU: From Advanced Disease to Bereavement (Oxford: Oxford UP, 2008), 208; Crippen, David, ICU resource allocation in the new millennium: Will we say "no"? (PA: Springer Science and Business Media, 2012), 23.

22 Jonsen, Albert R., A Short History of Medical Ethics (Madrid: Oxford UP, 2000), 5-8.

²³ Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach* (Radcliffe Medical Press, 2005), 105; Butts, Janie B., and Karen L. Rich, *Nursing Ethics: Across the Curriculum and into Practice* (Sudbury, MA: Jones and Bartlett, 2005), 93.

²⁴ Wilber, Charles K., *Economics, Ethics, and Public Policy* (Lanham, MD: Rowman & Littlefield, 1998), 127-133; Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach* (Radcliffe Medical Press, 2005), 105.

25 Lippert-Rasmussen, Kasper, *Deontology, Responsibility, and Equality* (Copenhagen: Dept. of Media, Cognition and Communication, U of Copenhagen, 2005), 15-18; Johnstone, Megan-Jane, *Bioethics: A Nursing Perspective* (Elsevier Health Sciences, 2011), 63-69.

²⁶ Wong, JD., and J Rabin, *Encyclopedia of Public Administration and Public Policy* (Taylor & Francis, 2003), 339-340; Basford, Lynn, and Oliver Slevin, *Theory and Practice of Nursing: An Integrated Approach to Caring Practice* (Cheltenham: Nelson Thornes, 2003), 223-224.

27 Johnstone, Megan-Jane, *Bioethics: A Nursing Perspective* (Elsevier Health Sciences, 2011), 63-69. Taylor, Helen, *Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach* (Radcliffe Medical Press, 2005), 105.

²⁸ Cooper, Mary Carolyn, "Principle-oriented Ethics and the Ethic of Care: A Creative Tension" *ANS Adv Nurs Sci* 14, no. 2 (1991): 22-31.

29 Baker, Robert, *The American Medical Ethics Revolution: How the AMA's Code* of Ethics Has Transformed Physicians' Relationships to Patients, Professionals, and Society (Baltimore: Johns Hopkins UP, 1999), 115-120.

³⁰ Giersson, Heimir, and Margaret R. Holmgren, *Ethical Theory: A Concise Anthology* (Peterborough, Ont.: Broadview Press, 2000), 147-150.

³¹ Entwistle, Vikki A., et al., "Supporting Patient Autonomy: The Importance of Clinician-patient Relationships" *Journal of General Internal Medicine* 25, no. 7 (2010): 741-45; Schneider, Carl, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions* (New York: Oxford University, 1998), 3-5.

³² Bersten, Andrew, D., and Neil Soni, *Oh's intensive care manual* (China: Elsevier Health Sciences, 2013), 55-60; Jeremias, Allen, and David L. Brown, *Cardiac Intensive Care* (Philadelphia, PA: Saunders/Elsevier, 2010), 9.

³³ Bosek, Marcia Sue DeWolf, and Teresa A. Savage, *The Ethical Component of Nursing Education: Integrating Ethics into Clinical Experience* (Philadelphia: Lippincott Williams and Wilkins, 2007), 21-24.

³⁴ Pellegrino Edmund D., and David C. Thomasma, "Limitations of Autonomy and Paternalism: Towards a model of beneficence" *in For Patient's Good* (Oxford University Press, 1988), 11-16.

35 Pellegrino Edmund D., and David C. Thomasma, "Limitations of Autonomy and Paternalism: Towards a model of beneficence" *in For Patient's Good* (Oxford University Press, 1988), 17.

³⁶ Pellegrino Edmund D., and David C. Thomasma, "Limitations of Autonomy and Paternalism: Towards a model of beneficence" *in For Patient's Good* (Oxford University Press, 1988), 18.

³⁷ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 207.

³⁸ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 197.

³⁹ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 198-199.

⁴⁰ Gert, Bernard, et al., *Bioethics. A Systematic Approach* (New York: Oxford university Press, 2006), 118.

⁴¹ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 199.

⁴² Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 200; Ross, W. D., *The Right and the Good* (Oxford: Clarendon, 1930), 21.

⁴³ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 200-201; Gill, Robin, *Health Care Ethics and Christian Ethics* (New York: Cambridge University Press, 2006), 102-104.

⁴⁴ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 240.

⁴⁵ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 241.

⁴⁶ Beauchamp, Tom L, and James F Childress, *Principles of Biomedical Ethics* (Oxford university press, 2001), 242.

⁴⁷ Silva, Mary Cipriano, and Ruth Ludwick, "Interstate Nursing Practice and Regulation: Ethical Issues for the 21st Century" *Online Journal of Issues in Nursing* 4, no. 2 (1999):

www.nursingworld.org//MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/ TableofContents/Volume41999/No2Sep1999/InterstateNursingPracticeandRegulation.as px. Accessed December, 6, 2015.

⁴⁸ Waite, Michael, "To tell the truth: The ethical and legal implications of disclosure of medical errors" *Health Law Journal* 13, (2005): 6-8.

⁴⁹ Silva, Mary Cipriano, and Ruth Ludwick, "Interstate Nursing Practice and Regulation: Ethical Issues for the 21st Century," *Online Journal of Issues in Nursing* 4, no. 2 (1999):

www.nursingworld.org//MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/ TableofContents/Volume41999/No2Sep1999/InterstateNursingPracticeandRegulation.as px. Accessed December, 6, 2015.

⁵⁰ Waite, Michael, "To tell the truth: The ethical and legal implications of disclosure of medical errors" *Health Law Journal* 13, (2005): 7-9.

⁵¹ Kalra, Jay, *Medical Errors and Patient Safety: Strategies to Reduce and Disclose Medical Errors and Improve Patient Safety* (Berlin: De Gruyter, 2011),78-81; Waite, Michael, "To tell the truth: The ethical and legal implications of disclosure of medical errors," *Health Law Journal* 13, (2005): 7; Banja, John D., *Medical Errors and Medical Narcissism* (Jones & Bartlett Learning, 2004), 173-176.

⁵² Waite, Michael, "To tell the truth: The ethical and legal implications of disclosure of medical errors" *Health Law Journal* 13, (2005): 7.

⁵³Association, American Medical, *Ethical Responsibility to Study and Prevent Error and Harm*, online: American Medical Association: <u>http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/code-medical-ethics/opinion8121.page</u>? Accessed December, 6, 2015.

54 Luce, John M, and Douglas B White, "A History of Ethics and Law in the

Intensive Care Unit" Critical care clinics 25, no. 1 (2009): 221-223.

55 Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit" *Critical care clinics* 25, no. 1 (2009): 223-225.

⁵⁶ Multz, Alan S., et al., "A "Closed" Medical Intensive Care Unit (Micu) Improves Resource Utilization When Compared with an "Open" Micu" *American journal of respiratory and critical care medicine* 157, no. 5 (1998): 1468-1473.

57 Curtis, J. Randall, and Gordon D. Rubenfeld, *Managing Death in the ICU: The Transition from Cure to Comfort* (Oxford: Oxford UP, 2000), 8.

⁵⁸ Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit" *Critical care clinics* 25, no. 1 (2009): 221-222.

⁵⁹ Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit" *Critical care clinics* 25, no. 1 (2009): 221-222.

⁶⁰ Kegley, Jacquelyn Ann K., "A new Bioethics Framework for Facilitating better Decision- Making about Genetic Information" in *Public Health Policy and Ethics*, ed. Boylan, Michael (Springer Science & Business Media, 2006), 93-97.

⁶¹ Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit" *Critical care clinics* 25, no. 1 (2009): 221-222.

⁶² Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit" *Critical care clinics* 25, no. 1 (2009): 221-222.

⁶³ Brendel, David H., "Healing Psychiatry: A Pragmatic Approach to Bridging the Science/Humanism Divide" *Harvard review of psychiatry* 12, no. 3 (2004): 150-157; Luce, John M, and Douglas B White, "A History of Ethics and Law in the Intensive Care Unit," *Critical care clinics* 25, no. 1 (2009): 221-222.

64 Fink, M. P., et al., *Intensive Care Medicine in 10 Years* (Berlin: Springer, 2006), 345.

65 Grant, Scott B., et al., "Futility and the Care of Surgical Patients: Ethical Dilemmas" *World Journal of Surgery* 38, no. 7 (2014): 1631-1637.

66 Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics 16*, no. 3 (2009): 292-302.

⁶⁷ Grant, Scott B., et al., "Futility and the Care of Surgical Patients: Ethical Dilemmas" *World Journal of Surgery* 38, no. 7 (2014): 1631; Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics* 16, no. 3 (2009): 292.

68 Grant, Scott B., et al., "Futility and the Care of Surgical Patients: Ethical Dilemmas" *World Journal of Surgery* 38, no. 7 (2014): 1632.

69 Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics 16*, no. 3 (2009): 294.

⁷⁰ Peberdy, Mary Ann, et al., "Cardiopulmonary resuscitation of adults in the hospital: A report of 14,720 cardiac arrests of Cariopulmonary Resuscitation" *Resuscitation* 58, no. 3 (2003): 297-308.

71 Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics 16*, no. 3 (2009): 294.

72 Ackroyd, Rajeena, et al., "Views of oncology patients, their relatives and oncologists on cardiopulmonary resuscitation (CPR): questionnaire-based study" *Palliative Medicine* 21, no. 2 (2007): 139-144.

⁷³ Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics 16*, no. 3 (2009): 294-299.

⁷⁴ Harvey, Janet, "The Technological Regulation of Death: With reference to the technological regulation of birth" *Sociology* 31, no. 4 (1997): 719-735.

75 Mohammed, Shan, and Elizabeth Peter, "Rituals, Death and the Moral Practice of Medical Futility" *Nursing Ethics 16*, no. 3 (2009): 299.

⁷⁶ Halevy, Amir, and Baruch A. Brody, "A Multi-Institution Collaborative Policy on Medical Futility" *JAMA* 276, no. 7 (1996): 571-574.

77 Fine, Robert L. "The Texas advance directives act of 1999: politics and reality" In *HEC Forum* 13, no. 1 (2001): 59-81.

78 Plows, C. W., et al., "Medical futility in end-of-life care-Report of the Council on Ethical and Judicial Affairs." *JAMA-JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION* 281, no. 10 (1999): 937-941.

79 Pellegrino, Edmund D., "Decision at the End-of-Life: Use and Abuse of the Concept of Futility," In *The Dignity of the Dying Person: Proceedings of the Fifth Assembly of the Pontifical Academy for Life*, edited by Juan De Dios Vial Correa and Elio Sgreccia, (Vaticano: Italy: Libreria Editrice Vaticanoz, 2000), 219-241.

80 Pellegrino, Edmund D., "Decision at the End-of-Life: Use and Abuse of the Concept of Futility," In *The Dignity of the Dying Person: Proceedings of the Fifth Assembly of the Pontifical Academy for Life*, edited by Juan De Dios Vial Correa and Elio Sgreccia, (Vaticano: Italy: Libreria Editrice Vaticanoz, 2000), 219-241.

⁸¹ Grossman, Eric, and Peter Angelos, "Futility: What Cool Hand Luke Can Teach the Surgical Community" *World Journal of Surgery* 33, no. 7 (2009): 1338-1340.

⁸² Grossman, Eric, and Peter Angelos, "Futility: What Cool Hand Luke Can Teach the Surgical Community" *World Journal of Surgery 33*, no. 7 (2009): 1335.

⁸³ Dunn, Geoffrey P., et al., "Surgical palliative care: a resident's guide" *American college of surgeons. Chicago: Cuniff-Dixon Foundation* (2009): 107-132.

⁸⁴ Halevy, Amir, and Baruch A. Brody, "A multi-institution collaborative policy on medical futility," *JAMA* 276, no. 7 (1996): 571-574.

85 Bradley, Ciarán T., and Karen J. Brasel, "Developing guidelines that identify patients who would benefit from palliative care services in the surgical intensive care unit" *Critical Care Medicine* 37, no. 3 (2009): 946-950.

86 Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet*, 373, no. 9661 (2009): 423-431.

⁸⁷ Fleck, Leonard M, "Just Caring: Health Care Rationing, Terminal Illness, and Medically Least Well Off," *Journal of Law, Medicine & Ethics* 39, no. 2 (2011): 156-171.

88 Greene, Jan, "Who Will Get Care" Trustee 61, no 9 (2008): 8-11.

89 Centers for Medicare and Medicaid Services, *National Health Expenditures* 2014 Highlights (2014): 1-3. Retrieved from: <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-</u>

<u>Reports/NationalHealthExpendData/downloads/highlights.pdf</u>. Accessed December 14, 2015.

90 Zhang, Baohui, et al., "Health Care Costs in the Last Week of Life: Associations with End of Life Conversations" *Archives of Internal Medicine* 169, no. 5 (2009): 480-488.

91 Riley, Gerald F., and James D. Lubitz, "Long-Term Trends in Medicare Payments in the Last Year of Life," *National Institutes of Health Journal* 45, no. 2 (2010): 565-576.

⁹² Emanuel, Ezekiel J., et al., "Managed Care, Hospice Use, Site of Death, and Medical Expenditures in the Last Year of Life" *Archives of Internal Medicine* 162, no. 15 (2002): 1722-1728.

⁹³ Fleck, Leonard M., "Just Caring: Health Care Rationing, Terminal Illness, and Medically Least Well Off" *Journal of Law, Medicine & Ethics* 39, no. 2 (2011): 156-171.

94 Rosner, Fred, "Allocation or Misallocation of Limited Medical Resources" *Cancer Investigation*, 22, no. 5 (2004): 810-812.

95 Gruenewald, David A., "Can Health Care Rationing Ever be Rational?" *The Journal of Law, Medicine & Ethics,* 40, no. 1 (2012): 17-25; Hope, Tony John Mcmillan, and Elaine Hill, "Intensive Care Triage: Priority Should Be Independent of Whether Patients Are Already Receiving Intensive Care" *Bioethics,* 26, no. 5 (2012): 259-266; Huesch, Marco D., "One and done? Equality of opportunity and repeated access to scarce, indivisible medical resources" *BMC Medical Ethics,* 13, no. 1 (2012): 1-12; Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 423-431.

⁹⁶ Huesch, Marco D., "One and done? Equality of opportunity and repeated access to scarce, indivisible medical resources" *BMC Medical Ethics* 13, no. 11 (2012): 1-12.

97 Rosner, Fred, "Allocation or Misallocation of Limited Medical Resources" *Cancer Investigation* 22, no. 5 (2004): 810-812.

⁹⁸ Vawter, Dorothy, J. et al., "Dueling Ethical Frameworks for Allocating Health Resources" *American Journal of Bioethics* 10, no. 4 (2010): 54-56; Kerstein, Samuel J., and Greg Bognar, "Complete Lives in the Balance" *American Journal of Bioethics* 10, no. 4 (2010): 37-45; Persad, Govind, et al., "Principles for allocation of scarce medical interventions," *Lancet* 373, no. 9661 (2009): 423-431.

⁹⁹ Hoffmaster, Barry, and Cliff Hooker, "Tragic Choices and Moral Compromise: The Ethics of Allocating Kidneys for Transplantation" *The Milbank Quarterly* 91, no. 3 (2013): 528-557; Rosner, Fred, "Allocation or Misallocation of Limited Medical Resources," *Cancer Investigation* 22, no. 5 (2004): 811.

100 Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 423.

101 Hope, Tony John Mcmillan, and Elaine Hill, "Intensive Care Triage: Priority Should Be Independent of Whether Patients Are Already Receiving Intensive Care" *Bioethics* 26, no. 5 (2012): 259-266.

¹⁰² Rosner, Fred, "Allocation or Misallocation of Limited Medical Resources" *Cancer Investigation* 22, no. 5 (2004): 811.

103 Jonsen, Albert R., "Bentham in a Box: Technology Assessment and Health Care Allocation" *Law, Medicine & Health Care* 14, no. 3-4 (1986): 172-174.

¹⁰⁴ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 426-427.

¹⁰⁵ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 426.

¹⁰⁶ Emanuel, Ezekiel J., and Alan Wertheimer. "Who should get influenza vaccine when not all can" *Public Health Ethik* 1, (2010): 191.

¹⁰⁷ Phillips, Sally, "Current status of surge research" *Academic Emergency Medicine* 13, no. 11 (2006): 1103-1108.

¹⁰⁸ McGough, L J., et al., "Which patients first? Setting priorities for antiretroviral therapy where resources are limited," *American Journal of Public Health* 95, no. 7 (2005): 1173-1180.

109 Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 426-427.

¹¹⁰ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 425-426.

111 Harris, John, *The Value of Life: An Introduction to Medical Ethics* (London, UK: Routledge, 2006), 90-94.

¹¹² Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 425-426.

¹¹³ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 426.

114 Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 425-426.

¹¹⁵ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 427.

¹¹⁶ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 427.

¹¹⁷ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 428.

¹¹⁸ Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 429.

¹¹⁹ Emanuel, Ezekiel J., and Alan Wertheimer. "Who should get influenza vaccine when not all can" *Public Health Ethik* 1, (2010): 191.

120 Rawls, John, *A theory of justice* (Harvard university press, 2009), 242-247; Nagel, Thomas, *Mortal questions* (Cambridge University Press, 2012), 107-113; Persad, Govind, et al., "Principles for allocation of scarce medical interventions" *Lancet* 373, no. 9661 (2009): 430.

121 Rosner, Fred, "Allocation or Misallocation of Limited Medical Resources" *Cancer Investigation 22*, no. 5 (2004): 811.

¹²² Lautrette, Alexandre, et al., "Respective impact of no escalation of treatment, withholding and withdrawal of life-sustaining treatment on ICU patients' prognosis: a multicenter study of the Outcomerea Research Group" *Intensive Care Medicine* 41, no. 10 (2015): 1763-1772.

123 Bibler, Trevor M., "Why I No Longer Say "Withdrawal of Care" or "Life Sustaining Technology"" *Journal of Palliative Medicine* 16, no. 9 (2013): 1146-1147.

¹²⁴ Brown, Samuel M., et al., "Withdrawal of Nonfutile Life Support After Attempted Suicide," *The American Journal of Bioethics* 13, no. 3 (2013): 3-12.

125 Metcalfe, M. Alison, et al., "Mortality among Approximately Referred Patients Refused Admission to Intensive-care Units *The Lancet* 350, no. 9070 (1997): 7-11.

126 Brieva, Jorge L., et al., "Withholding and Withdrawal of Life-sustaining Therapies in Intensive Care: An Australian Experience" *Critical Care and Resuscitation* 11, no. 4 (2009): 266-268; Eidelman, Leonid A., et al., "Foregoing life-sustaining treatment in an Israeli ICU" *Intensive Care Medicine* 24, no. 2 (1998): 162-166; Prendergast, Thomas J., et al., "A national survey of end-of-life care for critically ill patients" *American Journal of Respiratory and Critical Care Medicine* 158, no. 4 (1998): 1163-1167.

127 Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 127-137.

¹²⁸ Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 128.

¹²⁹ Snyder, Lois, and Cathy Leffler, "Ethics Manual: Fifth Edition" *Annals of Internal Medicine* 142, no. 7 (2005): 560-582; Vincent, Jean Louis, et al., "Withholding and withdrawing life prolonging treatment in the intensive care unit: a current European perspective" *Chronic respiratory disease* 1, no. 2 (2004): 115-120.

130 Sulmasy, Daniel P., and Jeremy Sugarman, "Are Withholding and Withdrawing Therapy Always Morally Equivalent?" *Journal of Medical Ethics* 20, no. 4 (1994): 218-224.

131 Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 128.

¹³² Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 129.

133 Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 128.

¹³⁴ Aberegg, Scott K., et al., "Omission Bias and Decision Making in Pulmonary and Critical Care Medicine" *Chest Journal* 128, no. 3 (2005): 1497-1505.

135 Wilkinson, Dominic, and Julian Savulescu, "A Costly Separation Between Withdrawing and Withholding Treatment in Intensive Care" *Bioethics* 28, no. 3 (2014): 131.

¹³⁶ Vincent, Jean-Louis, "Withdrawing may be Preferable to Withholding" *Critical Care* 9, no. 3 (2005): 226-229.

137 Maglin, Nan Bauer, and Donna Marie Perry, *Final Acts: Death, Dying, and the Choices We Make* (New Brunswick, NJ: Rutgers UP, 2010), 221-222. Walton, Douglas N., *Ethical Argumentation* (Lanham, MD: Lexington Books, 2009), 46-47.

138 Crippen, David, *End-of-life Communication in the ICU: A Global Perspective* (New York: Springer Science & Business Media, 2007), 82-85.

¹³⁹ Wyszynski, Antoinette Ambrosino, and Bernard Wyszynski, *Manual of Psychiatric Care for the Medically Ill* (Washington, DC: American Psychiatric Publishing, 2008), 233-236.

140 Rossi, Michael J. et al., "Video Informed Consent Improves Knee Arthroscopy Patient Comprehension" *The Journal of Arthrosopic and Related Surgery* 21, no. 6 (2005): 739-743.

141 Rossi, Michael J. et al., "Video Informed Consent Improves Knee Arthroscopy Patient Comprehension" *The Journal of Arthrosopic and Related Surgery* 21, no. 6 (2005): 742. 142 Schroter, Sara, et al., "Reporting Ethics Committee Approval and Patient Consent by Study Design in Five General Medical Journals" *Journal of Medical Ethics* 32, no. 12 (2006): 718-723.

143 Slevin, M., et al., "Volunteers or Victims: Patients views of randomized cancer trials" *British Journal of Cancer* 71, no. 6 (1995): 1270-1274.

144 Snowdon, Claire, et al., "Making Sense of Randomization: Responses of Parents of Critically III Babies to Random Allocation of Treatment in a Clinical Trial" *Social Science and Medicine* 45, no. 9 (1997): 1337-1355.

¹⁴⁵ Entwistle, Vikki A., et al., "Supporting Patient Autonomy: The Importance of Clinician-patient Relationships" *Journal of General Internal Medicine* 25, no. 7 (2010): 741-745.

146 Perrin, Kathleen Ouimet, and James McGhee. *Quick look nursing: Ethics and conflict* (Jones & Bartlett Publishers, 2008), 95-101.

147 Iyer, Patricia W., Nursing Home Litigation: Investigation and Case Preparation (Tucson, AZ: Lawyers & Judges Publishing, 2006), 650-652.

148 Fitzpatrick, Joyce J., and Meredith Wallace Kazer, *Encyclopedia of Nursing Research* (New York: Springer Publishing., 2006), 297-299.

149 Garber, Jeannie Scruggs, et al., *Avoiding Common Nursing Errors* (Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010), 324; Entwistle, Vikki A., et al., "Supporting Patient Autonomy: The Importance of Clinicianpatient Relationships" *Journal of General Internal Medicine* 25, no. 7 (2010): 741.

¹⁵⁰ Tweedy, James. T., *Healthcare hazard control and safety management* (CRC Press, 2005), 316- 320.

Chapter 4. Ethical Obligations in Terms of Honesty to Patients

Introduction

In medicine, virtually complete and readily accessible information about the status of a patient's health history and condition is considered a prerequisite for providing the best care and treatment. All these characteristics, however, are vulnerable to a variety of human errors. To the extent that patients and family are aware of the possibility, they will have expectations of the hospitals and other institutions involved. Not only will these healthcare providers be expected to be forthright in taking responsibility, thorough in explaining the causes and consequences, and diligent in pursuing corrective or mitigating actions, but also to be prepared for the eventuality by having pre-established procedures for preventing and for handling such events when they inevitably occur.

Among the expectations society has of individual physicians are that they will prioritize the treatment and care of the patient over any other aspect of conducting their practice, which includes the way in which they deal with medical errors. One clear example of this idea is the importance of properly handling the emotional impact of communicating to a patient the circumstances, especially the consequences, known or potential, of such an error.1

In accord with the trust inherent in any physician-patient relationship and the ethical principle of non-maleficence, it becomes paramount that the physician not cause additional harm in the form of anxiety or emotional trauma.² Both the American Medical Association (AMA) and American College of Emergency Physicians (ACEP) explicitly

require completely honesty in such matters as a standard of the profession.³ Moreover, consensus exists that the principle of beneficence dictates full truthful disclosure of medical errors even to the detriment of a physician's finances or professional reputation.⁴ It goes without saying that medical errors in the ICU necessitate the physician taking every step that is possible, non-harmful, and potentially efficacious to remedy the damage done. All of this depends on complete honesty; such is the ethical standard for the practice of medicine in the event of any medical error.

While professional duty in terms of communication is thus broadly construed, it does not mean that every fact or detail must be provided, apart from all that is directly related to the patient's medical condition and treatment.⁵ This limitation would rule out sharing information that: 1) is so technical as to be confusing or worrisome, 2) would be too psychologically traumatic if disclosed, 3) is irrelevant or insignificant, especially if confusing, or 4) would be in violation of another person's privacy or confidentiality to communicate.⁶ Even these guidelines for what to communicate and what not to are sufficiently imprecise as to leave doctors unsure in dealing with errors in the ICU, assuming the best of intent to uphold ethical standards of honesty.

Bioethics offers another tool for physicians' to gage whether to disclose information about a medical error by invoking the principle of informed consent as a guide; in other words, asking whether the patient would need particular details in order to make an informed decision concerning treatment options. Just as a patient will need to know what could go wrong and the potential consequences before consenting to a procedure, in the aftermath of a medical error, he or she would need to know what did

happen and the need for any new or corrective treatment, risks, consequences, and so forth. Conversely, extraneous information, especially if it would confuse or unduly worry the patient would be omitted in disclosing an error, just as equivalent details would be prior to obtaining consent. Furthermore, special procedures, such as those that involve written acknowledgement and consent, along with plans of action and understanding of any elevated risk of error, injury, or death, can be applied in the same manner when dealing with the consequences of medical error, in the ICU or elsewhere. Applying these same protocols for documentation can be seen as a minimum acceptable standard for handling a medical error.7

Chapter 4.A. Western Cultural Expectations in Relation to Medical Errors in the Hospital ICU

This section of the chapter commences by analyzing the attitudes derived from Western cultures and religious beliefs, which have led to expectations of how medical professional should deal with the occurrence and response to medical errors, with special consideration of anticipated patient expectations. As these expectations feature aspects of disclosure and apology, the section continues with an evaluation of the barriers to full disclosure and the ethical principles involved. The section stresses the necessity of a preset disclosure process that is specific in its details and examines the key characteristics of such a process. Thus, the section is divided into three subsections covering; 1) western cultural expectations, 2) cultural competence in medical errors, and 3) a justification for the obligation to disclose errors.

Chapter 4.A.1. Cultural Expectations

In what are termed Western societies, many factors contribute to the increased likelihood that a patient, as well as his or her relatives and associates will become aware of a mistake or medical error should it occur and, in addition, will be more motivated and better empowered to be proactive in addressing the situation. Furthermore, Judeo-Christian traditions, which have historically been dominant in these societies, form a conceptual foundation for responding to injury such as that cause through a medical error, specifically the concepts of confession, repentance and forgiveness. Berlinger and Wu assert that, "When one misses the mark in terms of another person, Jewish and Christian traditions prescribe a series of concrete, reciprocal practices: confession, which includes disclosure and apology; repentance, which includes the actions that the person who has harmed another undertakes to compensate for the error; and forgiveness, through which the person who has been harmed signals that he or she has been adequately compensated. These practices may serve as a lifelong reference point for ethical conduct".8

Cultural expectations are built upon these Judeo-Christian traditions and, in turn, become the framework for creating procedures to address the occurrence of medical errors.⁹ In particular, it is anticipated that, in terms of the physician-patient relationship, the process of resolution consists of confession or disclosure, an expression of repentance in the form of apology and, ultimately, forgiveness by the patient, as well as selfforgiveness on the part of the physicians. More specifically, following Judeo-Christian tradition, confession entails disclosing all relevant information and judgments about the situation, while repentance entails apologizing in the form of accepting responsibility and

expressing regret for any harm done.¹⁰ Moreover, this second step inherently involves actions to reverse or, if not possible, mitigate damages and to compensate the injured individual.¹¹ The final step in the process, in this case between doctor and patient, is forgiveness, involving the offering and accepting of compensation, along with a sincere commitment to prevent recurrence, which formalizes the restoration of the relationship with the acceptance by the patient and the absolution of guilt.¹²

Thoroughly understanding the assumptions, emotional reactions, and expectations of the affected individual is a prerequisite for developing policies and procedures for the disclosure and apology in the wake of medical errors, all the more important in the ICU because as part of a medical institution, many complicating factors become involved, which may diminish the focus on the injured patient. For example, whereas an apology made be of paramount concern to a patient and his or her relatives, such an apology may be tantamount to admitting fault, and thereby legal liability, from the institution's (and the court's) point of view.

While the term *repentance* is the most overtly theological of the three concepts, in the context of medical errors, it indicates actions and communication, which represent to the patient and relatives who have been harmed that the medical professionals involved understand, take seriously, and regret the injury caused by the error, along with accepting their culpability. According to the traditions described here, these forms of repentance and confession, place the injured party, the patient, under some measure of pressure in the expectation that he or she will grant forgiveness; at the same time, the apology has already given the patient an elevated standing in the relationship, and forgiveness restores the original relationship.

Robbennolt defines the act of apologizing by stating that, "An apology is a statement given by one who has injured another that includes recognition of the error that has occurred, admits fault and takes responsibility, and communicates a sincere sense of regret or remorse for having caused harm. At their most complete, apologies may also include promises to refrain from engaging in similar conduct in the future and compensation for the harm that has been done".13 Continuing her analysis of the process, Robbenolt cites a number of effects that an apology predictably exerts on its recipients through its admission of fault, sincere expression of remorse, and at least the implied promise to prevent any recurrence; all these should stimulate the impulse to forgive, in line with Judeo-Christian traditions.14

Chapter 4.A.2. Cultural Competence in Disclosing Medical Errors

The U.S. is increasingly becoming a culturally diverse nation. As evidence of increasing diversity in the United States, the 2000 Census calculated the nation's population to consist of 30% racial and ethnic minorities.¹⁵ The following, 2010, enumeration reported 36.3% who claimed racial or ethnic minority status. population rose to 36.3%; moreover, in the Western region of the country, the figure was as high as 47% self-identified minorities. More specifically, the states of Texas, California, Hawaii, New Mexico, and Texas, as well as the District of Columbia all reported that those identifying as minorities actually constituted a majority of their population.16 The terms *shattering culture*, and *cultural environments of* hyperdiversity have been coined and used in the literature to describe this phenomenon. This rapidly increasing heterogeneity has prompted scholars and bioethicist to assert the need for medical professionals to develop greater cultural competence, on only in the interest of providing better healthcare, but specifically to counter the increased risk of medical errors stemming from cross-cultural and crosslinguistic misunderstanding.17 This potential for miscommunication either owes its existence to patients not comprehending the nuances of medical language, understanding the "culture of medicine," or misinterpreting medical directions, or alternatively to biases, stereotyping, or general insensitivity on the part of medical professionals, which only becomes evident in non-verbal communication.18 The ways in which culture influences doctor-patient relationships, as well as interactions with healthcare workers, has prompted the Department of Health and Human Services to promote cultural competency and education toward achieving this goal.19 In contrast to this endeavor, some researchers in anthropology and related fields note that the effect of such education has been to create a plethora of stereotypic cultural identities and their expected behaviors, ignoring the and dynamic overlapping components of race, ethnicity, national origin, language, educational background, cultural affiliation.20 Consequently, these scholarly argue against the use of culture as a vehicle for understanding and combating the problems of miscommunication between healthcare professionals and their patients or the disparities in the quality of treatment that some of the latter group experience.21 For this group of scholars, individual inquiry of each patient and they

aspects of culture he or she chooses to embrace is more effective in preventing inaccurate assumptions, stereotyping, and miscommunication,22 insofar as group internal cultural diversity is frequently more determinative how to effectively communicate than are cross-cultural differences.

As a result of these realities, the doctor-patient relationships is currently examined most often in terms of its dynamic qualities and effectiveness on the level of the individual encounter and interaction of each medical visit. This approach rests on the assumption has a far more decisive role in the relationship than does the overall understanding that either party has of general culture attributes.23 One factor which contributes to this state of affairs is the broadness and abstract nature of culture as a concept, which encompasses everything from first language to taste in food or music to religion to moral and ethical values to gender role expectations to concepts of politeness, such as turn taking in conversation.24 Communication barriers in any given physician-patient relationship could be rooted in any combination of the aforementioned aspects of culture, as well as in others too numerous to list here.25 Beyond all these group components of culture, the communication styles and assumptions related roles and anticipated patterns of interaction expectations are liable to diverge between medical professional and patient.26 Consequently, as is quite possible between any two individuals, the physician is likely take a different interpretation of what has just occurred in an encounter, including the issues, priorities, and feasible options for treatment, as well as patient understanding and concerns, from that with which the patient leaves the encounter. In this interaction of the two parties, a satisfactory outcome depends on,

but only in part on, the norms and expectations of each person's culture.27

The most important factors in determining the degree of success in the results of any doctor-patient interaction are: 1) how comfortable the patient feels about the encounter immediately thereafter, 2) how well the patient follows the doctor's counsel and prescription for treatment, and 3) how the patient's health improves within the realistic prognosis for the patient's illness, injury, or infirmity.28 Another set of cultural norms and expectations that influence the quality of communication between doctors and their patients: 1) how the patient handles the unequal power dynamic with the physician; 2) how the doctor and the patient adapt to their differences on a temporal basis, and 3) how the two handle their distinctive communication styles.29 A patient who is comfortable with relationships on a closer to equal footing may anticipate greater interaction and reciprocity than a physician is prepared to give;30 on the other hand, a patient who envisions the doctor as being on a much higher level of status in the situation may want a significantly more authoritarian stance from that physician. Differences in communication style are also responsive to differences in status; for example, patients who see themselves on a footing closer to equal will tend to expect more direct spoken, two-way interaction with far more questions for them to answer, in contrast with those who put the physician on more of a metaphoric pedestal and thus will high-power distance patients more indirect or one-way declarative communication and spend more time listening.31 One result of diverging communication style between doctor and patients may be a reluctance by the latter to fully disclose information needed for accurate diagnosis and treatment; 32 another may be a disinclination by the former to

adapt either medical explanations or the diagnosis and treatment process to the patient's needs and sensibilities, in other word to culturally tailor the message. Any obstacle to a full, trust-based candid exchange of information, ideas, concerns, and preferences may prove to be the ultimate cause of medical errors.33

Putting cultural competence in perspective, while language and other cultural differences can be barriers that prevent clear patient-physician understanding, extant research has revealed that it is principally the quality of the patient-physician interaction - specifically high quality communication that ultimately determines successful patient outcomes including the avoidance of medical errors caused by miscommunication Even with the current emphasis on promoting cultural competency, research continues to show that achieving and maintaining a high level of quality in the nature of each individual physician-patient relationship is the greatest factor in avoiding miscommunication based medical errors.₃₄ The hallmark of such quality in the doctor-patient communication is consistently effective clarity and reciprocal understanding of the content conveyed in both directions.35 The prerequisites to this type of communication are consistent effort to build an enduring relationship founded on mutual attentiveness; diligence in eliciting, interpreting, and fully conveying information; understanding and empathy with the other's viewpoint; communication in terms of transparent and understandable information; patient participation and autonomy; and adroitly handled, collaborative decision-making.36 Indications that a given doctor-patient relationship is functioning optimally would include mutually understood directions for treatment plans, expectations that are adaptable and appropriate to the

circumstances, and self-management in terms of compliance and adherence by the patient as called for.³⁷ Patients experiencing long enduring or chronic infirmities, comorbidities, or any serious illness that requires repeated physician-patient encounters will necessitate effective communication due to the inherently complex nature of the decision-making process.³⁸

While the characteristics of such a doctor-patient relationship may be ideal in a generalized sense, various studies have indicated that many individuals on both sides do not feel naturally at ease with such interpersonal interaction.³⁹ Aside from the personalities of these individuals, factors that have the potential to create barriers include differences in cultural background, in the medical setting in which the interaction takes place, the nature of the patient's medical or healthcare needs, and increasing in modern specialized medical practice the anticipated duration of the relationship. Regardless of factors that can inhibit the ideal physician-patient relationship as it is currently envisioned, the underlying dynamic is socially and psychologically interactive, in contrast to older models, which were dominated by the doctor as knowledgeable expert and paternalistic authority.40 Under this new model of the relationship, the ability of the medical professional to engage in active listening becomes crucial,41 and, furthermore, has come to be what patients expect.42 Key components of active listening involve asking open-ended rather than yes-no, multiple option, or "one-word answer" type questions, along with paraphrasing and summarizing received communication, and asking follow-up questions for clarification, all for the purpose of confirming mutual understanding in situations, such as negotiating treatment options or clarifying instruction for taking
medication. At its most fundamental level, this type of relationship leads to considerable empathy felt and expressed by the medical professional, which is evident in the ability to get the patient to be forthcoming about concerns and feelings, the time taken to process and reflect on comments, staying with the topic as the patient sees it, and being attuned to the patient's, as well as the physician's own, non-verbal communication.43 On the other hand, behavior such as neglecting to actively listen to the patient, providing a combination of glib advice and reassurance, and dealing in inquiry that is compartmentalized and close-ended, as with that which merely elicits yes-no or multiple choice answers, tends to squelch deeper communication, lead to misunderstanding, and make medical errors more likely.44 One of the regrettable trends in modern healthcare has been the transition from long-term, close, interpersonal dynamic of the doctor-patient relationship towards care managed through casual contact or even specialists unknown to the patient, supported by state-of-the-art technology, but which leaves the patient feeling in the hands of an impersonal, uncaring entity instead of a concerned fellow human being.45

Chapter 4.A.3. The Ethical Justification for the Obligation to Disclose Medical Error

In recent years, a slow migration away from a prevalent attitude among those working in the medicine that medical errors are best handled by denying whenever possible and when not defending against any culpability has been underway. The direction of this attitudinal shift has been towards full disclosure on the premise that patient safety is paramount and that being forthright reduces the likelihood of malpractice litigation.46 This shift, however, proceeds in the face of numerous obstacles, including the basic dysfunctionality of the healthcare system, along with specific real or potential cultural, psychological, legal, and economic, deterrents, making it necessary to risk various ramifications in fully disclosing the circumstances of a medical error.47 One factor spurring on this attitudinal change is realization that numbers of medical errors and their resulting expenses are increasing exponentially, not to mention the attendant adverse impact on individuals and society. This growing understanding of the problem has led to a realization of the need to reexamine the ethical foundations of the relationship between patients and the healthcare system, as well as the understanding of medical errors from the level of a concept on down to the specific occurrence.48

Pioneering in the history of medical ethics in the United States Dr. Richard Cabot drew upon the works and ideas of Ralph Waldo Emerson, C. S. Peirce, William James, and Josiah Royce, as he brought together theories of medical ethics in his practice at Massachusetts General Hospital and his teaching at Harvard Medical School.⁴⁹ Cabot's approach was anchored in the axiom that medical practitioners, being human, were inherently fallible. What follows from this, Cabot asserted, is that ethical advancement depends on the doctor being aware of and acknowledging responsibility, thus providing the foundation of moral responsibility. Cabot saw virtue as being grounded in accountability, with the latter being the only mechanism driving change and improvement through a process of real growth through trial and error, evaluation, and revision. Unfortunately, the clinical practices which Cabot pioneered are in present use, much more so than his ethical practices.⁵⁰

The 1969 work by Beauchamp and Childress, entitled *Principles of Biomedical Ethics*, has been instrumental in spurring the modern development of this branch of ethics as an independent field. However, it was not until 1994, when the authors added a chapter specifically arguing that, for medical professionals and institutions, fully disclosing medical errors constitutes a moral and ethical obligation, that the healthcare community began to prioritize the issue.51 The core foundation of these authors' contention, building on Cabot's position, is that particular components of character form a set of qualities every healthcare profession must possess in order to provide effective care and treatment. According to Beauchamp and Childress, these traits include: 1) compassion, 2) discernment, 3) integrity, 4) trustworthiness, and 5) conscientiousness; moreover, they must be so ingrained in the personality of the medical professional that implicitly guide all aspects of interaction with patients. Cabot learned from experience that simply dressing wounds and distributing antibiotics alone was insufficient in medical practice. Just as Cabot was convinced that to be efficacious all treatment and healthcare must be fundamentally humanistic and holistic, so too Beauchamp and Childress insist that for a patient to recuperate, he or she must be able to trust in his or her doctor's compassion as much as in the doctor's knowledge and skills, their need and want to be assured that their physician is trustworthy and compassionate rather than judgmental and condemning. The physician must have these characteristics so internalized that the patient senses them and responses with trust and a level of candor that reveals all the insignificant, yet relevant behavioral, psychological, and emotional aspects of the patient's perspective, which will in turn guide the physician toward optimal treatment.52 It goes without saying that such levels of trust and such a doctor-patient relationship entails full and immediate disclosure

of any adverse turns of event, including in particular medical errors, along with corrective action as soon as possible given other circumstance of the patient's condition.

While the bioethical standards that these authors have propounded have been in circulation in the field for decades, these scholars' ideas have been slow to gain traction.53 Even though as early as the 1970's a significant study of medical errors in California hospital admissions found errors in 4.6% of cases, the concern generated by this rate was strong but limited in gaining public attention.54 It took another 20 years before a Harvard Medical Practice Study (1984) backed up the impact of its finding of a 3.7% rate of medical errors by judging 58% of those to have been preventable, Moreover, this study involved 51 hospitals throughout the state of New York and included over 30,000 patients selected at random, all features which bolstered the significance of the study.55 Subsequently, research into the occurrence of medical errors became more frequent, and included a 1992 study of facilities in Utah and Colorado, 56 which found that, out of errors involving 3% of admitted of which 54% were preventable, a full 5.6% of these errors led to fatality, Furthermore, in this study medical errors related to surgery errors led to permanent disability or death in 15% of cases, while fatalities from surgery accounted for 12.2% of all hospital deaths.57 Projecting the finding from the Utah-Colorado study to a nationwide scale gives an estimate of 44,000 deaths in-hospital annually due to the consequences of medical error; estimating from the Harvard study would suggest well over twice that number.58 Nor is this strictly a problem in the United States; all developed English nations including Great Britain, Canada, Australia, and New Zealand, along with others such as Denmark have reported equally serious problems with medical errors leading to significant rates of injury and death.59 Before the decade was

over, the Institute of Medicine (IOM) issued a report, entitled *To Err is Human: Building a Safer Health System*, which not only confirmed the projections of the Harvard and Utah-Colorado studies concerning deaths due to medical errors, but also provided dollar estimates of the costs of dealing with these errors at between \$17 and \$29 billion annually.⁶⁰ The report judged this state of affairs to constitute a major ongoing danger to society and to the fields of medicine and healthcare. In making so bold a conclusion, the IOM report brought widespread public attention to the problem, while revealing it to be systemic in nature, and pervasive in U.S. healthcare.

Throughout the first decade of the 21st century, proposals to stem the tide of medical errors flooded the literature of the field and included establishing procedures for error disclosure, removing barriers to apology, legally mandating apologies, improving organizational team, dismantling the culture of infallibility in the profession, enhancing the transparency of medical information, increasing effective communication, enforcing full and timely disclosure, and developing measures to enhance patient safety.61 As the problem of medical errors persisted despite these efforts, scholars and practitioners in the field came to the realization that at the core of the problem lay the tremendous, systemic obstacles to full disclosure. Rather than any lack of recognition or understanding of either the error's occurrence or the professional ethics and duties involved, the problem appeared to be the lack of will, spurred in part by the natural human tendencies of medical professional, to make full disclosure when medical error occur. The problem was in fact a lack of willpower or ability to empathize with the patient's situation, enough to take the ethically mandated course of action in the face of any and all complex ramifications or negative consequences, which inevitable arise, in other words, to act in

the virtuous manner that Cabot advocates.⁶² Fulfilling the ethical obligation to disclose medical error depends on the personal commitment to do what is morally right, no matter what consequences it entails; this type of behavior demands being proactive, honest, candid, and transparent.⁶³

Before the University of Michigan Health System (UMHS)'s policy shift described above regarding disclosure of medical errors, they had followed a "deny and defend" strategy rooted in the fear that any admission of a mistake would open the figurative legal floodgates of negligence, malpractice, and the ruination of their professional reputation.64 So institutionalized was this policy that legal counsel for the system admonished all doctors and medical staff against any mention of errors to patients, relatives, or friends regardless of the severity of the error's consequences or even the lack of any harm it had caused. Thus, the UMHS community was estimated to have disclosed merely one fourth of all the medical errors that had occurred there, 65 even though statistically fewer than 2% of all errors lead to malpractice litigation and even in those cases, compensation, beyond restoring the patient to his or her health status prior to the error, has been infrequent.66 It was in fact the 1999 Institute of Medicine report which prompted the UMHS policy reassessment, particularly the high frequency of medical errors leading, often indirectly and when not dealt with, to fatality. The chief of staff at the time, Darrel Campbell Jr, set a goal for the institution to become the safest hospital in the nation.67 Campbell made the deny and defend policy his primary target, in that it was inimical to any effort to anticipate and forestall errors by setting up fear of legal, economic (both on the part of the institution and of individual employees), and reputational ramifications as the dominant motivational force, in turn throttling

communication between stakeholders seen as potential adversaries in the aftermath of a medical error, and ultimately actually fostering litigation by creating a climate of misinformation, suspicion, and predisposition to hostility. In 2001 according to its reversal of policy, UMHS ceased fighting the majority of its claims all the way through the courts, saving that as a final resort and opting instead to work through negotiation toward settlement whenever possible. Under a three principle policy, which came to be known as the Michigan Model,68 UMHS began a system of 1) rapid, equitable compensation for all injury to a patient resulting from medical error; 2) medical restitution whenever reasonable and did not non-disruptive to other patients by distracting clinical caregivers; and 3) proactive efforts to learn from every medical error so as to reduce patient injury and avoid recurrence.69 Boothman et al. note that, through subsequent implementation, the model has come to include seven principles: 1) capturing clinical issues – problems must be known and understood before they can be fixed; 2) identification of medical errors – distinctions must be made between medical errors that deserve compensation and adverse outcomes that did not result from medical errors; 3) communication – clear, exhaustive, careful and compassionate listening must take place among caregivers, patients and families; 4) compensation – sincere, willing, fair, and balanced compensation must be provided for medical errors; 5) learning from mistakes - the occurrence of medical errors are valuable opportunities to protect future patients from harm; 6) measurement – exhaustive data collection is an important tool in providing evidence of effective action; and 7) resources – deploy defense counsel and others in more appropriate roles than litigation and cover-up efforts.70

The Michigan Model lead to major improvements in University of Michigan's health system over the following twelve years, significantly changing institutional culture, increasing patient safety, and reducing the financial burden of defending against malpractice claims. As evidence, the average rate of new claims alleging medical error dropped from 7.03 claims monthly per 100,000 patient encounters to 4.52; meanwhile, the average rate of lawsuits filed fell from 2.13 per month to 0.75, again for every 100,000 patient encounters. As part of this same shift, interval of time between reporting and resolving a claim fell significantly.71 By consensus, UMHS's greatest accomplishment has been the progress toward its goal of becoming the safest medical institution in the U.S, which has been largely due to prioritizing patient safety without exception. In the process, the system has overcome obstacles to disclosure from fear of exposure to legal action on down to the worries and psychological barriers in the minds of staff members, living up to fundamental principles of medical ethics, namely patient autonomy, non-maleficence, beneficence, and justice.72

Chapter 4.B. What Patients Desire in the Wake of Medical Errors in the Hospital ICU

This section of the Chapter is divided into two subsections, the first of which focuses the motivations that prompt patients' expectations and demands, including identifying who or what was at fault as the primary driving force and monetary compensation as a secondary motivator. The remaining subsection of the Chapter discusses the patients' need for medical support and how it strengthen the necessity of full disclosure of all medical errors.

Chapter 4.B.1. Motivations on the Part of Patients

The multiplicity of potential sources of any given medical error makes it quite difficult first to document and report and second to explain clearly as part of the disclosure process. The source may be an individual, a group, a technological component, a system, or a procedure, and moreover may be an error of omission, something needed but not done, or of commission, something done that should not have been. The error may have occurred as the result of any or any combination of the following components of treatment failing to perform as intended: 1) the diagnosis, 2) knowledge of any aspect of the case, 3) judgment on any part of the situation, 4) any protocols followed, 5) timing of any part of treatment, 6) medication, 7) labeling, 8) administration of treatment such as an injection, 9) record keeping, 10) any medical device or technology, or even 11) the electrical power.73 While disclosure and corrective measure need to occur promptly, uncovering the sequence of events that triggered a medical error is typically, and especially in the ICU, a time consuming drawn out process require in-depth reconstruction and analysis of actions and circumstances. Furthermore, ultimately gaps in medical and scientific knowledge or in the sequence of events may render understanding incomplete and cause or causes of the error will be unknowable.74

Having surveyed a variety of research in the literature, Robbenolt contends that the primary motivation between much of the legal action in response to medical errors is to authoritatively determine who or what was at fault and to prevent any recurrence. Obviously, monetary compensation for physical injury and emotional trauma may well be an important secondary motivation.75 Anticipating these consequences, many hospitals have already adopted policies and procedures, attempting to forestall formal litigation in the court through negotiated settlement while maintaining goodwill in the form of a reputation for acting morally and ethically in the face of medical errors. Ultimately, the civil court system still exists to ensure that patients and families have their rights protected.⁷⁶

Chapter 4.B.2. The Patient's Need for Medical Support

Beyond and probably before the desire or need for financial compensation, injured patients and their relatives are normally concerned with knowing that they will have medical support and a clear plan for correcting, to the fullest extent possible, whatever harm the error inflicted. Even when future treatment is not affected by the occurrence of the error and no corrective measures are needed, full disclosure is still the duty of attending physicians and institutions involved. Disclosure then becomes necessary are a matter of maintaining trust within the doctor-patient relationship, a basic purpose behind the ethical standards of conduct espoused by the American Medical Association and similar professional medical organizations. According to Wolf and Hughes, the ethical implications of reporting and disclosing medical errors and adverse events reveal respect for patient autonomy and enable healthcare professionals to do their best to prevent any harm being done to the patient to begin with. In the case of a medical error, the ethical principles of fidelity, beneficence and non-maleficence, if complied with, guarantee that any harmful consequences will be minimized.77

As part of the starting foundation of any physician-patient relationship with

any medical institution or practitioners, one expectation is that the medical professional bears the responsibility for the well being of the one in his or her care. Such a relationship assumes trust, including accurate and honest disclosure should a medical error occur for any reason. Whether consciously or not, the public expects healthcare providers to put the interest of the patient, being the one in need of special care, before the medical professional's own. Despite the obvious discomfort in reporting medical errors, along with the fear of legal consequences, Gallagher et al. assert a compelling rationale, which necessitates disclosure as a prerequisite to complying with the ethical mandate of gaining informed consent from patients and their families in the context of correcting the effects of a medical error. Alternatively, rules of medical governing bodies and state laws are available as unassailable arguments reporting medical errors.⁷⁸

Chapter 4.C. The Concepts of Disclosure and Apology

This section of Chapter 4 will outline the definitions and characteristics of the concepts disclosure and apology, highlighting their differences and unique features from the standpoint of biomedical ethics in the context medical errors, though not exclusively in the hospital ICU. The discussion will set the stage for analysis of the effects of nondisclosure versus disclosure on both patients and physicians.

Chapter 4.C.1. Disclosure

At its simplest, full disclosure means providing all relevant details about the illness or injury quick the patient suffers from along with possible and recommended

treatment options, prognosis under their implementation, side effects, and so forth. In the case of medical errors, the same concept applies with the error as injury. In all circumstances, however, full disclosure is a necessary prerequisite for the patient to give informed consent. Between bioethical standards calling for informed consent and full disclosure, only under very rare circumstances, equivalent to literally lifesaving emergency procedures, can medical professionals justify presuming that a patient unable to give consent would choose to accept a particular treatment.⁷⁹ Far from simply being in a hospital intensive care unit, in order for such consent to an emergency intervention to be presumed, the patient would have to be unconscious or delirious and have no surrogate present or available.⁸⁰ The only justifiable motive for doing so would have to be that the sole alternative would be disability or death. Thus, as will be discussed in depth in subsequent section, full disclosure in the case of medical errors is virtually an absolute according to bio-ethical and professional standards.⁸¹

Chapter 4.C.2. Apology

In the context of medical errors, the concept of apology goes beyond a statement of regret or remorse, depending on whether the medical professional conveying bears responsibility for causing the error. Rather, in this context it includes an attempt to clearly present the nature and circumstances leading to the error, the proposal for correcting its consequences and how that will be paid for, along with steps being taken to prevent similar occurrences and answers any unresolved questions about the error.82

Because of the many facets in the context of an apology for a medical error, the communication is neither easy to plan for nor to conduct.⁸³ Many questions surround

who among the medical facility's staff is most appropriate to convey the apology; depending on the patient's circumstances, equally complicated is the question of who the apology should be made to. Also open to debate is the timing, with possibly conflicting argument for immediacy versus waiting for more complete information and the importance of timing the revelation to minimize psychologically disturbing the patient. The setting and manner of communication must also be decided, and even then issues of administrative policy, contractual obligations with insurance providers, and the advice of legal counsel must be taken into consideration. Consequently, conducting an apology is significantly more complex than is providing full disclosure.84

Chapter 4.C.3. Effects of Non-Disclosure on Patients and Physicians

The following sub-section of this chapter of the dissertation considers specifically the negative effects of either selectively withholding relevant information or avoiding disclosure altogether after the occurrence of a medical error in contrast with the duty and the positive consequences of full disclosure.

Chapter 4.C.3.a. Effects of Non-Disclosure on Patients

In terms of negative reactions to discovering a medical error, researcher have reported typical reactions of "anger, bitterness, betrayal, a sense of humiliation, loss of trust, and suspicion of a cover-up" on the part of patients who have discovered themselves to be victims of a medical error for which the attending physician offered neither apology nor explanation. Patients who react this way, clearly consider full, detailed, and candid disclosure receiving a detailed full and open disclosure as the fiduciary, not to mention moral, duty of the medical professional heading up their care and treatment. The attending physician, whether personally responsible for the error or not, is ultimately in the best position to alleviate a patient's anxiety over real or potential adverse consequences and the general unknown surrounding the aftermath of the error. Whereas, full disclosure is liberating in that it enables the doctor to focus on more pressing needs, withholding information and explanations compounds problems in terms of patient distrust and uncooperativeness, which might hinder efforts to undo the damage caused by the initial error.85

Despite these findings and the concomitant reasoning, not all withheld information inevitably lead to negative consequences, nor do all those who feel the effects of the error want to know every detail. Even outside the scope of medical errors, "Not all patients want to know everything about their medical care".86 The full circumstances surrounding many of the afflictions patients suffer are quite complicated; too much information can be confusing and stressful to many individuals, requiring a filtering of the facts and predictions tailored to the specific patient's desire for and ability to deal with the information in a psychologically healthy manner. The ethics manual of the American College of Physicians Ethics acknowledges the risk of harm from overdisclosure. Manual has recognized this negative potential. The term "therapeutic privilege" refers to the concept that a physician should at times stop short of full disclosure to the extent that providing all information is reasonably likely to cause further injury to the patient.87

Chapter 4.C.3.b. Effects of Non-Disclosure on Physicians

The psychological dynamics on the part of physicians in particular toward responsibility for medical errors, such as feeling of embarrassment, remorse, or guilt form a major barrier to disclosure as they show up in the form of denial, concealment, finger pointing at others, and general refusal to accept responsibility.88 Doctors, in particular, have an on-going duty to follow through in treating the patient, often in the context of a longer term relationship, all of which is jeopardized by the error.89 Under these circumstances, perceived consequences easily override the call to honest integrity in following standards of ethical conduct.90

In addition, medical professional at all levels fear that any misstep in disclosing an error could create otherwise nonexistent problems like harmful added stress on the patient or avoidable malpractice litigation. If these disincentive are ignored or not challenged, the consequence is the development of a culture of concealing medical errors, which will obstruct any and all efforts to avoid or reduce the further occurrence of errors. Once such as culture is in place, the common impulse is mutual defense whereby medical professionals assist colleagues by concealment and will even actively impede any attempt to investigate and discipline anyone responsible for the error.91

If the question is posed hypothetically, nearly everyone in the healthcare field will avow, despite the costs or consequences, the necessity for full disclosure of medical errors, not only in order to effectively correct problems created by the error, but also to prevent recurrence.⁹² Counter to the presuppositions of those in the field, research has established that full disclosure can often diminish the probability that a given error will

lead to civil litigation. Far less surprisingly, the chance that a given medical error is disclosed correlates well with the extent of negative consequences and their being attributed to the error. This latter point goes against the expressed fears of some healthcare professionals who think that knowledge of the error automatically creates additional suffering through stress to the patient. On one hand, the above "concern" can be an excuse for avoiding disclosure; on the other, there do exist rare circumstances in which not being informed would indeed be in the best interest of the patient.93 Although full disclosure is no definitive protection against litigation, the discovery of any attempt at concealment or distortion of the facts in the case will increase the probability of a lawsuit, strengthen its claims, and possibly raise the demanded compensation. More fully rebutting the argument for concealment is the finding of multiple research studies that what patients primarily want in such a situation is disclosure of the error and a sincere apology, along with a concerted effort to reverse or mitigate the harm caused.94 To most physicians' credit, some research have concluded that aside from worries of ensuing problems with institutional administrators, health insurance providers, and legal professionals, these medical professional would overcome their internal psychological deterrents and opt for complete disclosure and an apology rather than concealing the occurrence.95

Even though physicians and hospital continue to claim the danger of psychological damage or incapacitation of certain patients, such concerns lack research based support. Furthermore, according to Edwin, it is far more preferable for patients and their relatives to find out about medical errors from an admission by the physicians and hospitals than from any other source; the author cites various studies correlating honest

and timely disclosure with lower levels of disturbance and stress in patients.96 Hammami, Attalah and Al-Qadire, report similar evidence supporting the advisability of medical errors being revealed by culpable physicians.97

If a patient learns of an error from anyone other those who are responsible, he or she will probably have to deal with feeling of humiliation, deception, and betrayal of trust in addition to the trauma and uncertainty of having incomplete information. Moreover, this element of mistrust can lead patients and their families to suspicions of even greater errors being covered up, motivating them toward legal advice from those all too ready to initiate litigation against hospitals and physicians. According to Mazor et al, "Full disclosure results in a more positive response on the part of the patient or family member in terms of satisfaction and trust, and reduces the likelihood of changing physicians. The impact of disclosure on seeking legal advice varied across the error conditions; full disclosure reduced the likelihood of seeking legal advice in the missed allergy error situation, but had no detectable impact in the inadequate monitoring error situation".98

While the rigor and thoroughness of medical school, internship, and residency is legendary, one of the neglected elements of training is communication with patients, relatives, and other stakeholders when the subject to be discussed is difficult, for example in the wake of a medical error. Not only is the situation emotionally charged, but the causes, the consequences, and the positions and interests of the various stakeholders, such as colleagues and staff, institution administrators, medical societies, insurance providers, legal counsel, and government regulators, are not aligned and potentially at odds with each other. This complexity is exacerbated by the varied contextual characteristics of the

situation that must be handled in terms of communicating so that the patient is not confused or left with unnecessary fears and uncertainties concerning the known or anticipated consequences of the medical error. The absence of training or preparation for such a scenario adds to the tension and the chances for compounding the problem through miscommunicate, the consequences of which can include ruining a career or increasing financial costs exponentially.99 While the majority of doctors both in practice and in training understand the gravity of the potential ramifications and the need to know how to handle the aftermath of medical errors, few if any find time to get the help to be prepared ahead of time.100

Depending on the consequences and how they are handled, one medical error has the potential wipe out a career based on years or decades of medical training; the anticipation of this eventually is motivation enough to propel many into avoiding disclosure. While losing one's medical license or being assessed a major malpractice judgment would be the most salient repercussions, losing the trust and respect of colleagues, patients, and others in the healthcare community could be equally devastating.101

Nonetheless, the physician, as much as any other professional, is duty-bound to take responsibility for his or her mistakes, their patients to be held accountable for their mistakes; this stems from unparalleled level of trust patients place in them, creating a fiduciary duty that transcends other considerations. This duty includes doing everything possible to minimize the emotional and psychological trauma of the error revealed,¹⁰² which follows from the ethical principle of non-maleficence, the duty to not harm the

patient in any way that is avoidable.¹⁰³ Both the American Medical Association (AMA) and the American College of Emergency Physicians (ACEP) make the physician's responsibility to be truthful with patients an explicit part of their professional standards. The ethical principle of beneficence further admonishes doctors to invariably act in the best interests of their patients' health even to the detriment of the their own financial or professional best interest. This ideal has already settled the question of whether and how much should to be disclosed after a medical error has occurred. It is the physician's responsibility to mitigate or reverse the mistake to remedy in every respect possible the harm that was caused by the medical error.¹⁰⁴

The concern over possible legal ramification, especially civil litigation, more than any other single factor, may impede the fulfilling of professional expectation concerning disclosure of medical errors.¹⁰⁵ That fear combined with the forces of medical insurance concerning doctors, patients themselves, and medical care institutions, create formidable barriers to achieving professional standards of behavior.¹⁰⁶

Chapter 4.C.4. Effects of Disclosure on Physicians and Patients

From the dominant perspective in Biomedical ethics, the disclosing of medical errors, in the hospital ICU as in any other care setting, is a necessity, regardless of the consequences to medical personnel or the facility and with few possible exceptions, to the patient as well.

Chapter 4.C.4.a. Effects of Disclosure on Physicians

While explicitly taking an oath to do nothing that would harm the patient, medical students and physicians are not typically instructed that this implicitly includes the duty to disclose any medical errors or missteps that could result in unintended harm or additional injury. While both doctors and patients, along with their relatives, would explicitly acknowledge this ideal as an obligation if directly prompted, the full disclosure called for is unfortunately uncommon.¹⁰⁷

Full disclosure is considered to a complete acknowledgement of the occurrence of an error, accounting of the chronology and contributing circumstances, along with a thorough explanation of definite and possible consequences. Accomplishing this task requires full communication between the responsible medical professional, possibly along with a representative of the institution and the patient, relatives, and/or proxy. In the broader context of biomedical ethics, patients have the right to full explanations of their treatment, both proposed and ongoing. This includes understandably communicated assessments of potential adverse outcomes, regardless of cause, and prospects for preventing any negative occurrences.108 Nonetheless, in general, many studies indicate that far too many patients remain inadequately informed of their condition and overall health status, even in the absence of medical errors or stays in the ICU.109 Compounding this problem, close to 33 percent of interns and residents at teaching hospitals say they had not received information specifically concerning the institution's policies and procedures for handling and disclosing medical errors. Understanding what to do was even less widespread, with only about half of the fully licensed doctors at these same

institutions claiming to know how to report an error and fewer that 40 percent feeling that they could determine whether a particular occurrence constituted a medical error that needed reporting.110

Considering how varied human beings are in their character, personality, and reactions to stressful situations juxtaposed with the uncertainty concerning the long-term effects of many medical errors and the possible disparity between a seemingly insignificant contributing misstep and consequences as severe as fatality, reactions to errors can be extreme and dramatic. These factor are inherently amplified in the context of the hospital ICU, where as much as in any other setting, eventual reconciliation between patients and relatives on one hand physicians and the institution is far from guaranteed regardless of how handled. Dramatic emotional responses to learning of a medical error can go as far as widely circulating public accusations of incompetence and murder, which can in turn have the significant impact of inhibiting full disclosure of future errors.

As referred to previously, in disclosing an error, the medical professional must communicate and inform the patient and family members in a way that is optimally conducive to minimizing their distress and maximizing their well being. According to Gallagher et al, an illustrative hypothetical example could consist of an error in the operating room, leading to a six month instead of one week in hospital recuperation for the patient who must work to support his or her family.111 A disclosure statement by the physician worded, "I'm sorry. We made a small mistake in your care, but don't worry, you'll be fine in 6 months," can be expected to have a decidedly different impact as heard

by the patient than would the alternative, "I'm very sorry that we made this mistake. We are going to do what it takes to make you better and make sure the same thing does not happen again".¹¹² Such statement though probably factually similar highlight the care which must be taken in handling disclosure, in order to relieve rather than compound the mental or psychological stress of the patient and his or her relatives who may respond in any number of unforeseen ways, except possibly in the unusual case in which the physician has a long standing relationship of mutual understanding with the patient.¹¹³

According to Edwin, the doctor-patient relationship is inherently fiduciary by nature, rather than transactional, and therefore, the good faith and trust involve rely on candor.114 Only through such a relationship can both parties to be autonomous, nonmaleficent, beneficent and just to each other at all times.115 In addition to fiduciary requirements, Among others, Finkelstein et al., assert that following the standards of biomedical ethics in and of itself requires disclosing all pertinent aspects of an error's occurrence, and not just restoration (to the extent possible) and monetary compensation. The simple yet fundamental ethical premise behind informed consent, that patients are entitled to all relevant information in making decisions about their care and treatment, by clear implication extends to the decisions in the wake of being victim to a medical error, thus mandating full disclosure.116

Consensus is universal as to the reality and significance of professionally and psychologically difficult internal ramifications on physicians personally involved in medical errors, every bit as much as for the patients experiencing the effects of the error. Given this reality, substantial therapeutic benefits exist, beyond the mandates of

professional ethics, for doctors to disclose and admit responsibility for medical errors. Relieving the emotional encumbrance of carrying around the knowledge of responsibility compounded by concealment frees the professional to forgive him or herself and perform professional tasks better. Furthermore, relief comes from healing the injured doctorpatient relationship, which being a reciprocal process requires the doctor's full participation, should lead to regaining his or her sense of self-identity as a healers.117 Admitting mistakes, whether responsible or not, promotes an understanding of the patient's perspective and enables the commencement of corrective measures. Despite a degree of risk and even when the error has resulted in little or no injury, prompt and adequate disclosure has positive consequences for both the physician and the patient, beyond reducing further liability.

In order to prepare physicians to transcend the psychological obstacles to disclosing medical errors, the process of doing so and in the broader scope handling the occurrence of errors needs to become a standard part of medical school curriculum. One factor that could assist with the many cases in which the disclosing physician, normally the primary attending physician, is not individually culpable, is emphasizing the distinction between the 'apology expressing sympathy' and the 'apology admitting responsibility.' Unfortunately, just as was believed true at one point in the history of the UMH system, some jurisdictions do legally equate any formal apology with an admission of liability, prompting medical institutions and their legal counsel to steer physicians away from disclosing at all, or at least apologizing without institutional approval. Obviously, the remedy to this obstacle lies in changing the legal system, which is beyond the scope of this discussion. In the interim, the administration of hospitals and other

medical facilities must actively create and foster a culture for their respective institutions that encourage and promotes prompt, candid disclosure of errors by medical staff, regardless of culpability, along with the appropriate expression of apology. Ultimately, identification and formal investigation of the medical error, multidisciplinary team involvement, in addition to appropriate communication with patients and their families, are all prerequisites to formal disclosure, but must also be followed up by resolution of the specific situation and improvement in the standards of care so as to prevent future occurrences.¹¹⁸ Regardless of the situation, if an error is not covered up entirely or successfully, an option which would be totally unjustifiable ethically, any subsequent apology will appear devoid of candor, complete disclosure, and sincerity, leaving the patient suspicious or dissatisfied.¹¹⁹

In terms of the positive consequences of full disclosure, research indicates that it helps the patient to recuperate both physically and psychologically, in part by reaffirming the efficacy of relationship with the physician and the medical facility. This form of disclosure including apology demonstrates that the error has been identified and acknowledged, that corrective measures including compensation and counseling services are underway, and that steps to prevent recurrence are in the works. According to Berlinger and Wu, "Providing fair compensation prevents malpractice suits not only because patients receive adequate financial settlements, but also because maintaining a caregiving relationship with patients and families "diminishes the anger and desire for revenge that often motivates patients' litigation".120

Chapter 4.C.4.b. Effects of Disclosure on Patients

As will be explained in detail subsequently in this chapter, procedures for disclosing medical errors are involved, requiring preplanning to address the needs and positions of the numerous stakeholders who play either direct or indirect roles in the event. Beyond arrangements to counteract any negative effects of the error and reestablish the patient's progress toward optimal health and well being, the next step is to ensure that the patient is protected from any possible recurrence of the error.121 Hence, it is essential that all staff involved with the patient's care are promptly apprised of the circumstances of the error so as to insure that it is not repeated and that all are vigilant concerning any negative effects of the error which may appear after some delay.122 The patient and those close to him or her need to receive a sincere expression of regret for the error, ideally from the physician in charge of the patient's care and anyone else directly responsible for the occurrence. In order for the patient and those others involved to feel as comfortable as possible in the situation, the healthcare staff need to be sensitive as to when and how much emotion to express, as well as when to keep quiet and wait for questions.123 The disclosure needs to avoid all but the most essential Medical professional need to avoid technical terminology, as it can convey superiority, or lack of concern or empathy.

In medicine, there is often a fine line between simply unanticipated complications in treatment and the medical errors that are distinguished as preventable when all is working as intended; however, patients and relatives may not appreciate the difference, given that both lead to stressful situations. To avoid exacerbating emotional stakes in the

situation, health care provider should avoid apologizing for that which could not have been prevented. Medical professionals must always show empathy is a central to healthcare, but must also not be perceived as confessing their culpability, unless they were indeed at fault.¹²⁴ Such misunderstanding when clarified will tend to leave patients and relatives suspicious, either by the medical professional or by the patient and his or her relatives.

Furthermore, the patients and family assume with good reason that the hospital is ethically by committed to providing any auxiliary care required by the error, including chaplaincy, social work, or even palliative care. In many cases, the disclosure requires a both a formal (written) and a verbal apology, the former of which needs to be presented by the patient safety officer. At the heart of the disclosure process in the wake of a medical error is the goal of maintaining or rebuilding the medical provider-patient relationship, as far as is feasible, given what has occurred and, in particularly the case of errors in the hospital ICU, the fact that family and relatives are almost always an integral part of that relationship.¹²⁵

A clear disconnect in perceptions exists between physician and patients in terms of expectations in relation to revealing medical errors. Doctors and some other medical professional will see errors in a more narrow scope, which exclude 'near misses' and possibly any medical errors that do not have any significant negative impact, and therefore will neglect to inform the patient or couch the information in very innocuous language.126 For the patient, however, anything that was not intended or might have

caused problems is an assault on his or her peace of mind, calling for explanation and reassurance at minimum.

If the consequences of the medical error are significant, additional or extended care and treatment may prove necessary; in these cases, full disclosure aids considerably in preserving the patient's trust and gaining his or her consent to the proposed remediative care. In the large majority of situations, the continuity of care is best for recuperation from the patient's initial injury or illness.127 Typically, as family members communicate among themselves, any suspicions of caregivers being less than forthright and completely candid can easily escalate into demands for a change of doctor any possibly legal action, even at times against the wishes of the patient him or herself. Thus, it is important that the physician communicate all the particulars of how the incident transpired with members of the patient's family if they are involved in any way. Illustrating the factors which need to be explained, Sandars and Aneez, share the hypothetical example of a man who receives an appendectomy instead of the operation for a colon infection that he was scheduled for as the result of paperwork being misfiled by a resident, going unnoticed by the patient's nurse in spite the name being incorrect on the charts. As to be anticipated, the patient's family were unsatisfied with anything less than a full explanation of what had led up to the mistake.128

Unless attending physicians are forthright in all regards. the patient or family will see their perspective as being trivialized or ignored and are likely to demand or pursue engaging a alternate doctor to corrected the effects of the error, as well as possibly seek legal redress. On the other hand, if the attending physician was not the cause through

inexperience or incompetence, he or she is the best situated to oversee corrective measures. Thus, the patient and his or her family need full details in order to be assured especially if the case was an honest mistake in spite of due diligence or if the medical professional involved was not negligent. In the regrettable circumstance in which consequences of the medical error leave the patient unable to give informed consent, the patient's designated representative will need full details in order to give permission for (or deny) corrective treatment. These circumstances illustrate the importance of maintaining trust with the patient and family, which can only happen in the context of full disclosure of all medical errors. In accepting responsibility, the attending physician and the hospital affirm their trustworthiness as prepared to do everything required both to fix the situation and to repair the relationship.129

Chapter 4.D. The Gap between the Acknowledged Need for and the Incidence of Disclosure and Apology

This section of the Chapter explores reasons behind the disparity between duty to disclose medical errors as acknowledged in theory by almost all medical professionals and the reality, according to best estimates, that less than a third of all errors are reported and dealt with openly and candidly. Three subsections focus on this gap in terms of: 1) the differing perspectives of physicians and patients, 2) additional impediments to disclosure in hospital ICUs, and 3) obstacles to disclosure grounded in sources other than physicians themselves.

Being human, all physicians make mistakes, which in medical practice are asserted to be "common, expected, and understandable".130 While the majority of

physicians claim that patients need to be informed of any medical errors, statistic indicate that no more than 30% are followed by disclosure and apology.131 Probably no group has found this circumstance to be more frustrating than the patients who have experienced the effects of these errors, having discovered the fact from someone other than their attending physician. While such distress is entirely understandable, circumstances surrounding a medical error and its consequences can be extremely complicated, beginning with the fact that some medical errors are in no way the result of either negligence or conduct that was improper or unethical.132 Beyond causes, many real and potential medical, ethical, social, interpersonal, business, and legal ramifications must be anticipated and dealt with. Beyond merely the patient and medical professional directly involved, are potentially numerous key stakeholders in any specific case, such as the medical facility, the insurance provider(s), professional medical associations, the medical technology manufacturer, the pharmaceutical industry, as well as government regulators, politicians, the press, religious institutions, universities, the legal system, and a predominantly well-educated public in terms of the broader issue of medical errors and the field of healthcare.133 Any of these stakeholders can wield significant influence over or impinge on decisions concerning disclosure in various ways, six of which are analyzed briefly in the next part of the discussion.

Chapter 4.D.1. The Gap between Physician and Patient Perspectives

Undoubtedly, discrepancy exists between the perspectives of medical professionals on one hand, and patients and their families, on the other with regard to disclosure. If physicians come the conclusion that the risks of disclosure are greater that the benefits, they will suppress the occurrence or at least certain circumstances connected to it, a position obviously at odds with patients' desire for full details in every instance.

In spite of the needs and wishes of patients to be fully current with the status of their conditions, when medical errors occur, full disclosure with apologies appears to happen no more than 30% of the time.134 Scholars and researchers point to a disconnect between the perceptions of physicians and patients in terms of disclosure of medical errors in relation to the possibilities and consequences of various projected outcomes. From the medical professional's perspective, revealing mistakes and apologizing for them is difficult in the face of expectations of superior knowledge, skills, and expertise. In contrast, medical errors frequently involve complicated, interacting contributing factors strongly suggesting mandatory disclosure. Such disclosure is all the more difficult to achieve when the errors in question lead to very limited or no injury to the patient's short-terms recovery or long-term wellbeing. Fein et al. assert that, "Disclosure of errors that have not caused significant harm or about which patients are unaware pose even more complex targets for intervention. These are the errors likely to inform qualityimprovement interventions because they are more common and less frequently revealed. Disclosure of such errors requires provider knowledge of the patient's desire for information and may require disclosure of information to the institution that is not revealed to the patient".135 Yet another circumstance in which exceptions are made to the standards involves patients who are suffering with chronic conditions and the effects of the error will not alter their prognosis. Beyond these reasons for not fully disclosing medical errors, medical staff and physicians are prone to shielding colleagues who are culpable, and may even offer a justification for avoiding disclosure by claiming a conflict

of interest, citing the possibility of harming the wellbeing of other healthcare professionals.136

Chapter 4.D.2. Obstacles to Disclosure of Errors in the ICU

In the ICU in particular, a variety of obstacles inhibit doctors and other the staff from disclosing medical errors, concern over potential malpractice litigation probably being the most formidable among them. More fundamentally, medical training creates an inherent barrier in that it dealing explicitly and extensively with the avoidance of making mistakes, yet pays little or no attention to how to handle medical errors when they occur. This imbalance in turn, instills a psychological predisposition to avoid acknowledging errors and to see them as a personal indictment of professional competence and character, all of which makes it discomforting to disclose errors in the first place. As a result of all these disincentives, those at fault even tangentially for a medical error are more likely to provide an implicit, statement deflecting of any culpability, or to avoid disclosure all together, attempting to hide the error as an unforeseen medical complication.137

Chapter 4.D.3. Other Institutional Barriers to Disclosure

Barriers to fully disclosure of medical errors are not limited to the choices of individual medical practitioners; medical facilities and institutions normally neither foster nor reward efforts to identify and disclose medical errors. Moskep et al, contend that various structural or institutional factors, such as the high levels of patient volume and 'turnover,' due to the acute, episodic characteristics what prompts the need for hospital care have the effect of increasing the chance of medical errors occurring while at the

same time reducing the likelihood that they will be identified, reported, or disclosed to the patient.¹³⁸ Due to system, physician-related, patients related and other legal barriers, the gap between patients' expectation regarding disclosure of medical errors and actual disclosures continues to exist.¹³⁹

Chapter 4.E. The Process for Disclosure of Medical Error in the Hospital ICU

This section of the Chapter outlines the process which needs to be followed in order to prepare for and properly disclose the occurrence of, anticipated consequences of, and plan for dealing with a medical error in the ICU. The first subsection deals with the preparations which must be made in order to prevent or minimize any problems that might otherwise complicate the disclosure process. The second subsection addresses what needs to happen during the disclosure meeting itself.

There are many elements to consider in establishing a process by which physicians and hospitals will fully disclose medical errors by compliance with all principles of bioethics while minimizing additional psychological trauma to the ICU patient whose health has been jeopardized. The process begins with the planning of a face-to-face meeting including the attending physician, other involved medical professionals, the patient and his or her 'supporting' individuals. The goals of this meeting are to disclose the medical error if not previously known to the patient, to apologize, and to lay out proposed corrective treatment and compensation plans, along with measure to be taken to prevent any recurrence of similar errors. 140

Chapter 4.E.1. Preparations for the Disclosure Meeting

The first phase of the process involves preparation for meeting with the patient and those relatives or others affected by the error, during which phase the doctors and hospital authorities must make sure that various actions have been complete and organized. The following tasks need to be accomplished: 1) All the relevant facts need to be assembled and organized; 2) These facts need to be documented, with substantiating independent expert medical opinion; 3) All system related contributions to the error should be identified and acknowledged; 4) Corrective measures already underway need to be documented and available for presentation; 5) Information, documentation, and paperwork involving liability needs to be assembled and available at the meeting; 6) Patient and family questions and concerns should be anticipated with answers and explanations prepared; 7) The wording of potentially confusing or difficult explanations need to be worked out so as to avoid unintended or unnecessary misunderstanding, alarm, or provocation; 8) Acknowledgements, apologies, and explanations need to be reviewed to insure that they are comprehensible for the layperson, i.e, the patient and those connected to him or her; 9) The previous statements must also reviewed to insure that they and complete, conveying full candor absent of any dissembling, prevaricating, or concealing information; 10) The patient's ethnic, religious, and cultural background must be considered so that medical professionals involved do not take any action that would inadvertently offend or cause additional distress; 11) A specific contingency plan needs to be created if not already in place, to assure the patient of the institution's sincere commitment to preventing any recurrence; and 12) All connected parties need to be notified of the time and place of the meeting, whether attending on not.141

Beyond these steps in preparation, hospital administration must support any physicians who are or see themselves as at fault in dealing with their feelings of incompetence, failure and guilt, and self deprecation, so that they are ready to handle their responsibilities when time for the disclosure meeting arrives.¹⁴² Certain parties not directly involved in the occurrence of the error need to be included, such as risk management experts, and leaders of relevant departments should be consulted in planning for the disclosure meeting, but should not attend so as to protect the patient's confidentiality and privacy, as well as not to create a meeting dynamic in which the patient or supporters feel outnumbered by medical professionals representing the 'other side'.¹⁴³ On the other hand, patients should be invited to have in attendance whomever they feel they need for psychological and/or legal support.

Chapter 4.E.2. The Actual Disclosure Meeting

The second phase of the process is the meeting itself. In setting up the meeting, having a convenient private location away from potential interruptions and scheduling well in advance to allow for adequate preparations are important considerations. For example, while the attending physician's making hand-to-hand (or lower arm) physical contact with the patient prior to the meeting may be a reassuring gesture, it must be carefully judged in terms of the cultural backgrounds and the emotional states of all those present, as it could also do considerable harm to the process if not appropriate in the given situation. Throughout the interaction, various considerations need to be observed, including: 1) keeping descriptions and explanation in terms understandable to the layperson, 2) keeping things focused clearly and narrow in scope concerning what went

wrong, 3) adapting to what the patient does and doesn't already know, as well as to how much detail or background the patient wants, 4) giving the listeners time to process information and not confusing by overloading with detail,144 5) giving time for questions, clarifications, and processing implications, 6) maintaining open, i.e, both non-threatening and non-defensive, body language, generally engaging in appropriate non-verbal communication. The apology itself must be explicit, completely truthful, and indicate explicitly any responsible parties without vagueness or shifting of blame, as dictated by principles of biomedical ethics.

The final steps in the disclosure should be a detailed explanation of a prepared, proposed course of secondary corrective treatment, including how it will integrate with ongoing care and treatment for the patient's underlying condition. This proposal is to be accompanied by financial details, specifically how any additional expenses will be covered (presumably not by burdening the patient).145 Alternative options may also be presented, which might involve obtaining second opinions from specialists or transfer to the care of a facility or medical professional better equipped to handle to changed circumstances. Finally, the physician needs to be silent, giving the patient an opportunity to process the information, respond, and ask questions. The meeting needs to conclude not with any air of finality, but rather with the sincere encouragement by the attending physician and institution representatives to continue meeting as necessary until all is resolved.146

Chapter 4.F. Proper Notification and Documentation Processes in the Hospital ICU

This final major section of this Chapter focuses on procedures which need to

be in place and implemented prior to the occurrence of a medical error so as to facilitate the disclosure and apology process when the inevitable error happens.

Chapter 4.F.1. Policies and Procedures

The success of the disclosure process described above relies on the effectiveness of efforts to promptly and accurately identify medical errors as they occur, as well as to completely document all the relevant circumstances surrounding them. The first step to ensuring that this occurs is to have strong hospital or institutional policies and procedures in place and to have all staff familiar with them. Furthermore, the mechanisms for gathering the information that will reveal the errors in the first place and then collect the relevant data essential to analyzing the circumstances is crucial. This is necessary in order to pinpoint the source or sources of what went wrong, only secondarily to affix culpability, but first and foremost to find ways to prevent its recurrence. Nevertheless, certain other obstacles have to be overcome in order for the disclosure process to achieve it goals, one of which is that the details needed for such reports to be complete and most useful must come from those who were closest the specific events, decisions, and actions that triggered the error. These may well be medical professionals or staff who bear "atfault" responsibility, and they may be well aware of the fact or psychological unable to handle the knowledge.147 These individuals may be unwilling or unable provide the information required to achieve full documentation. Given that at-fault doctors or other staff members are not ideal sources of information concerning adverse events, hospitals, facilities, and institutions need to develop multiple sourced methods of medical error detection to either corroborate, fill in gaps, or question the objectivity or spin or less
prone to be reliable sources of information. Rather than isolating those whose objectivity might be more open to doubt, these multi-source mechanisms should serve to bring doctors and staff together with risk management specialists, heads of related agencies, and patient safety specialists, in which all function as a team to investigate, document, and analyze the event with an eye to making sure that no similar medical error occurs in the future.148 Beyond the post hoc documentation of the serious repercussions of medical errors, hospital staff need to watch for and keep records of 'near misses,' as well as actual errors which do not appear to have had any ill effects. Given that such incidents are not subject to mandatory disclosure, reporting becomes voluntary and rarely is reported if the reporter has something to lose by doing so. On the other hand, documentation of 'near misses' and incidents with no harmful effects helps to identify vulnerabilities which may be in the system and, by being pinpointed, may lead to the prevention of a more serious and damaging error. This is especially true in the hospital ICU, considering the enhanced vulnerability of its patients.

Chapter 4.F.2. Other Factors and Issues to Consider

While designing a disclosure mechanism, it is also important that hospitals consider impact of factors like provider issues, as well as patient, error, and organizational culture factors. Fein et al., define *provider issues* to constitute how medical professionals see their responsibility, their fears in the aftermath of a medical error, and their training in how to conduct themselves in such situations. By *patient factors*, the authors mean what the patient wants to see and understand based on his or her desire for information, degree of sophistication regarding medical and health care,

and rapport with his or her primary care provider and other medical staff. *Error factors*, for these researchers, designates the degree of injury sustained specifically as the result of the error and whether patients and others were cognizant of its having occurred or of the damage done. In the findings of these authors, *institutional factors* consisted of a perceived tolerance for error and in the presence of a supportive infrastructure fostered disclosure.149

Chapter 4.G. Conclusion

The values and morals of Western and possibly the majority, if not all, of the world's cultures and religious belief systems dictate that any individual or group, whose actions cause injury to another person or his or her property, are morally obligated to take responsibility and in most cases make some form of restitution. In the field of medicine, including the hospital intensive care unit, this translates into an ethical responsibility to make full disclosure of the circumstances leading up or contributing to any medical error, along with a full confession and apology (to borrow Western cultural/religious terminology), and both a proposal for corrective or ameliorative action including financial compensation and plans for adjustments in policies or procedures to prevent any further recurrence of the same or similar errors. All these component of full disclosure and apology are expected by society at large, and agree with the priorities of patients and their relatives or family members (especially significant in the context of the ICU) upon finding themselves the victims of a medical error. This latter group of individuals are most primarily concerned with being informed of the detail of how the error occurred, what the consequences are or are likely to be, how these negative effects will be managed

and corrected, and what is being done to prevent this from happening again to themselves or to anybody else. Nevertheless, in spite of the pressure of cultural norms, moral imperatives, ethical standards, professional codes of conduct, institutional policies, and legal requirements, the disincentives medical professionals experience prompting them to hide all or critical parts or else distort the circumstances of errors is formidable. Aside from feeling of guilt and shame, not the least of these forces is the fear of damage to professional reputation, loss of employment and legal action in terms of civil litigation. Regardless of the motivators to denial and defense, the consequence of failure to fully disclose a medical error leave the victim, in this case the ICU patient, open to further psychological and physical trauma, especially when the error is revealed through sources other than those appropriately responsible for informing. Ironically, any effort to hide fault or responsibility can cause the very result, the fear of which had prompted the effort at concealment. Any action directed away from full disclosure as described in this chapter leads to patient dissatisfaction, which significantly increases the likelihood of lawsuits.

The disclosure process in hospitals and similar institutions involve significant preparation as a first step, including the gathering and analyzing of all relevant information; documenting the same; identifying any of those among the physicians and medical staff bear responsibility in terms of having taken actions that directly contributed to the error; preparing to present the facts of the case, the apology, the plan for correcting or at least mitigating the effects of the error, and the steps being taken to see that such errors do not occur again. The meeting itself constitutes the second step in the disclosure process and includes many details concerning time, place, attendees, and who is speak, when, and how during the meeting; all of these are specifically thought in an attempt to

maximize communication and understanding while minimizing discomfort and stress for the patient and supporters at the meeting. However, possibly because this thorough plan for disclosure is most often not fully or carefully implemented, estimates of patient satisfaction in the aftermath of a medical error suggest that, approximately 70% of the time, patients and family members leave with their expectations of what would be done in the wake of the error unmet. This finding call for a fundamental reexamination of restructuring of the institutional disclosure process in the wake of medical errors, beginning with upgrading the notification and documentation components.

Endnotes

1 Nau, Konrad C., "Disclosing Medical Error to Patients," PHIL1364g

. Slide 23, accessed, December, 6, 2015.

2 Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u> Slide 23, accessed, December, 6, 2015.

³ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 524.

⁴ Beauchamp, Tom L., and James F. Childress, *Principles of Biomedical Ethics*. (New York, NY: Oxford University Press, 2001), 38-39.

⁵ Gabbard, G. O., and C. Nadelson, "Professional boundaries in the physicianpatient relation." JAMA, 273 (1995): 1445-1449.

⁶ Brock, D. W., "Informed Consent" In *Health Care Ethics*, eds., D. Van De Veer, and T. Regan (Philadelphia, PA: Temple University Press, 1987), 98-116.

7 Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 524.

⁸ Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 106.

9 Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 106.

¹⁰ Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 107.

¹¹ Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 107-108.

¹² Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 106-107.

¹³ Robbennolt, Jennifer K., "Apologies and medical errors." *Clinical Orthopaedics and Related Research* 467, no. 2 (2009): 378.

¹⁴ Robbennolt, Jennifer K., "Apologies and medical errors." *Clinical Orthopaedics and Related Research* 467, no. 2 (2009): 378.

¹⁵ U.S. Census Bureau, "Our Diverse Population" Retrieved from <u>https://www.census.gov/population/pop-profile/2000/chap16.pdf</u>. 1-4, accessed Feb, 4. 2016. ¹⁶ U.S. Census Bureau, "2010 Census Shows America's Diversity" Retrieved from <u>http://www.census.gov/newsroom/releases/archives/2010_census/cb11-cn125.html</u> Geographic Distribution, accessed Feb, 4, 2016.

¹⁷ Aplin, Greg, "Once is sometimes too much: Cultural competence can reduce medical errors, increase patient satisfaction." *MGMA Connex* 7 no. 1 (2007), 21-22; Shannon, Diane, "Cultural Competency in Health Care Organizations: Why and How?" *Physician Executive* 36 no. 5 (2010): 18-22.

¹⁸ Levine, Cynthia S., and Nalani Ambady, "The role of non-verbal behavior in racial disparities in health care: Implications and Solutions." *Medical Education* 47 no. 9 (2013): 867-876.

¹⁹ U.S. Department of Health and Human Services, Retrieved from <u>https://cccm.thinkculturalhealth.hhs.gov/</u>. A Physician's Practical Guide to Culturally Competent Care. Accessed Feb, 7, 2016.

²⁰ Good, Mary-Jo Delvecchio and Seth, D. Hannah, "Shattering culture": Perspectives on cultural competence and evidence-based practice in mental health services." *Transcultural Psychiatry* 52 no. 2 (2015): 198-221.

²¹ Goodale, Mark, *Surrendering to utopia: An anthropology of human right* (Stanford, CA: Stanford University Press, 2009), 65-90.

²² Gone, Joseph P, "Reconciling evidence-based practice and cultural competence in mental health services: Introduction to a special issue." *Transcultural Psychiatry* 52 no. 2 (2015): 139-149; Good, Mary-Jo Delvecchio, and Seth, D. Hannah, "Shattering culture": Perspectives on cultural competence and evidence-based practice in mental health services." *Transcultural Psychiatry* 52 no. 2 (2015): 212.

²³ Matusitz, Jonathan, and Jennifer Spear, "Effective Doctor-Patient Communication: An Updated Examination." *Social Work in Public Health* 29 no. 3 (2014): 252-266.

²⁴ McLaren Margaret C., *Interpreting cultural differences: The challenge of intercultural communication* (Norfolk, VA: Peter Francis, 1998), 40-45.

25 Charon, R., "Narrative medicine as witness for the self-telling body." *Journal of Applied Communication Research* 37 no. 2. (2009): 118-131.

²⁶ Matusitz, Jonathan, and Jennifer Spear, "Effective Doctor-Patient Communication: An Updated Examination." *Social Work in Public Health* 29 no. 3 (2014): 252-266.

27 Matusitz, Jonathan, and Jennifer Spear, "Effective Doctor-Patient Communication: An Updated Examination." *Social Work in Public Health* 29 no. 3 (2014): 252-266; Bertakis Klea D., and Rahman Azari, "Patient gender and physician practice style." *Journal of Women's Health* 16 no. 6 (2007): 859-868.

28 Bertakis Klea D., and Rahman Azari, "Patient gender and physician practice style." *Journal of Women's Health* 16 no. 6 (2007): 859-868.

²⁹ Gao, Ge, et al., "Considering culture in physician-patient communication during colorectal cancer screening." *Qualitative Health Research* 19 no. 6 (2009): 778-789.

30 Hofstede, Geert, Culture's consequences (Thousand Oaks: Sage, 2001), 1-31.

³¹ Gao, Ge, et al., "Considering culture in physician-patient communication during colorectal cancer screening." *Qualitative Health Research* 19 no. 6 (2009): 778-789.

³² Gao, Ge, et al., "Considering culture in physician-patient communication during colorectal cancer screening." *Qualitative Health Research* 19 no. 6 (2009): 778-789.

³³ Pasick, Rena, et al., "Similarities and differences across cultures: Questions to inform a third generation for health promotion research." *Health Education Quarterly*, 23 no. 1 (1996): 142-161.

³⁴ Bensing, Jozien, et al., " Communication in context: New directions in communication research." *Patient Education and Counseling* 50 no. 1 (2003): 27-32; Dasinger, Lisa K., et al., "Doctor proactive communication, return-to-workrecommendation and duration of disability after a workers' compensation low back injury." *Journal of Occupational and Environmental Medicine* 43 no. 6 (2001): 515-525; Dibbelt, Susanne, et al., "Patient-doctor interaction in rehabilitation: The relationship between perceived interaction quality and long-term treatment results." *Patient Education and Counseling* 76 no. 3 (2009): 328-335; Griffin, Simon J., et al., "Effect on healthrelated outcomes of interventions to alter the interaction between patients and practitioners: A systematic review of trials." *Annals of Family Medicine* 2 no. 6 (2004): 595- 608; Matusitz, Jonathan, and Jennifer Spear, "Effective Doctor-Patient Communication: An Updated Examination." *Social Work in Public Health* 29 no. 3 (2014): 253; Stewart, A. L., et al., "Interpersonal processes of care in diverse populations." *Milbank Quarterly* 77 no. 3 (1999): 305-339.

³⁵ Gao, Ge, et al., "Considering culture in physician-patient communication during colorectal cancer screening." *Qualitative Health Research* 19 no. 6 (2009): 778-789.

³⁶ Cole, Steven A., and Julian Bird, *The medical interview: The three-function approach* (Philadelphia, PA: Elsevier Sauders, 2013), 233-234; Makoul, G., "Essential elements of communication in medical encounters: The Kalamazoo consensus statement." *Academic Medicine* 76 no. 4 (2001): 390:393.

³⁷ Dasinger, Lisa K., et al., "Doctor proactive communication, return-to-workrecommendation and duration of disability after a workers' compensation low back injury." *Journal of Occupational and Environmental Medicine* 43 no. 6 (2001): 515.

³⁸ Schenker, Yael, et al. "Depressive symptoms and perceived doctor-patient communication in the heart and soul study." *Journal of General Internal Medicine* 24 no. 5 (2009): 550-556.

³⁹ Breen, Gerald-Mark, et al., "Improving doctor-patient communication: Examining innovative modalities vis-à-vis effective patient-centric care management technology." *Journal of Medical Systems* 33 no. 2 (2009): 155-162.

⁴⁰ Stewart, Anna L., et al., "Interpersonal processes of care survey: Patientreported of care in diverse groups." *Health Services Research* 42 no. 4 (2007): 1235-1256.

⁴¹ Gao, Ge, et al., "Considering culture in physician-patient communication during colorectal cancer screening." *Qualitative Health Research* 19 no. 6 (2009): 778-789.

⁴² Bensing Jozieno, "Bridging the Gap. The separate worlds of evidence-based medicine and patient-centered medicine." *Patient Education and Counseling* 39 no. 1 (2000): 17-25; Oliffe, John, and Sally Thorne, "Men, masculinity, and prostate cancer: Australian and Canadian patient perspectives of communication with male physicians." *Qualitative Health Research* 17 no. 2 (2007): 149-161; Simpson, Michael, et al., "Doctor-patient communication: The Toronto consensus statement." *British Medical Journal* 303 no. 6814 (1991): 1385-1387.

⁴³ Maguire, Peter, et al., "Consultation skills of young doctors: Benefits of feedback training in interviewing as students persist." *British Medical journal* 292 no. 6535 (1986): 1573-1576.

⁴⁴ Griffith, C H., et al., "House staff nonverbal communication skills and standardized patient satisfaction." *Journal of General Internal Medicine* 18 no. 3 (2003): 170-174; Riccardi, Vincent M., and Suzanne M. Kurtz, *Communication and counseling in healthcare* (Springfield, IL: Charles C. Thomas, 1983), 99-101.

⁴⁵ Aitini, Enrico, et al., "Communication Models for Doctor-Patient Relationships," *Journal of Cancer Education* 30 no. 2 (2014): 211-212.

⁴⁶ Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions," *Frontiers of Health Services Management* 28 no. 3 (2012): 13-28.

⁴⁷ Cravens, Catherine, and Jo Anne L. Earp, "Disclosure and Apology," *North Carolina Medical Journal 70* no. 2 (2009): 140-146.

⁴⁸ Hannawa, Annegret F., "Principles of medical ethics: implications of the disclosure of medical errors," *Medicolegal and Bioethics* 2 (2012): 1-11.

⁴⁹ Garchar, Kimberly, and John Kaag, "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot," *Transactions of the Charles S. Pierce Society* 49 no. 4 (2013): 553-574.

⁵⁰ Garchar, Kimberly, and John Kaag, "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot," *Transactions of the Charles S. Pierce Society* 49 no. 4 (2013): 555. ⁵¹ Garchar, Kimberly, and John Kaag, "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot," *Transactions of the Charles S. Pierce Society* 49 no. 4 (2013): 564.

⁵² Beauchamp, Tom L., and James F. Childress, *Principles of Biomedical Ethics* (New York, NY: Oxford University Press, 2001), 567.

⁵³ Garchar, Kimberly, and John Kaag, "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot," *Transactions of the Charles S. Pierce Society* 49 no. 4 (2013): 553.

⁵⁴ Mills, Don Harper, "Medical Insurance Feasibility Study A Technical Summary," *West Journal of medicine* 128 no. 4 (1978): 360-365.

55 Brennan, Troyen A., et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study 1," *New England Journal of Medicine* 324 no. 6 (1991): 370-376.

⁵⁶ Gawande, Atul A., et al., "The incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992." *Surgery* 126 no. 1 (1999): 66-75.

57 Gawande, Atul A., et al., "The incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992." *Surgery* 126 no. 1 (1999): 70.

58 Gawande, Atul A., et al., "The incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992." *Surgery* 126 no. 1 (1999): 70.

⁵⁹ Waite, Michael, "To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error." *Health Law Journal* 13 no. 1 (2005): 1-33.

⁶⁰ Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy, 2000), 1-2.

⁶¹ Cravens, Catherine, and Jo Anne L. Earp, "Disclosure and Apology: Patient-Centered Approaches to the Public Health Problem" North Carolina Medical Journal 70 no. 2 (2009): 140.

⁶² Garchar, Kimberly, and John Kaag, "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot," *Transactions of the Charles S. Pierce Society* 49 no. 4 (2013): 571.

⁶³ Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions." *Frontiers of Health Services Management* 28 no. 3 (2012): 13.

⁶⁴ Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions." *Frontiers of Health Services Management* 28 no. 3 (2012): 14.

65 Blendon, Robert J., et al., "Views of Practicing Physicians and the Public on Medical Errors," *New England Journal of Medicine* 347 no. 24 (2002): 1933-1940; Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1001-1007; Kaldjian, Lauris C., et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals." *Archives of Internal Medicine* 168 no. 1 (2008): 40-46; Kronman, Andrea C., et al., "Factors Associated with Disclosure of Medical Errors by Housestaff." *BMJ Quality and Safety* 21 no. 4 (2011): 271-278; Lamb, Rae M., et al., "Hospital Disclosure Practices: Results of a National Survey," *Health Affairs* 22 no. 2 (2003): 73-83; Wu, Albert W., et al., "How House Officers Cope with Their Mistakes," *Western Journal of Medicine* 159 no. 5 (1993): 565-559.

⁶⁶ Meyers, Allan R., "Lumping It: The Hidden Denominator of the Medical Malpractice Crisis." *American Journal of Public Health* 77 no. 12 (1987): 1544-1548; Localio, A Russell, et al., "Relation Between medical malpractice Claims and Adverse Events Due to Negligence: Results of a Harvard Medical Practice Study III." *New England Journal of Medicine* 325 no. 4 (1991): 245-251.

⁶⁷ Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions." *Frontiers of Health Services Management* 28 no. 3 (2012): 16.

68 Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions." *Frontiers of Health Services Management* 28 no. 3 (2012): 17.

⁶⁹ Boothman, Richard C., et al., "A Better Approach to Medical Malpractice Claims? The University of Michigan Experience." *Journal of Health and Life Sciences Law* 2 no. 2 (2009): 125-159.

⁷⁰ Boothman, Richard C., et al., "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions" *Frontiers of Health Services Management* 28 no. 3 (2012): 20-22.

⁷¹ Kachalia, Allen, et al., "Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program." *Annals of Internal Medicine* 153 no. 4 (2010): 213-221.

⁷² Hannawa, Annegret F., "Principles of medical ethics: implications for the disclosure of medical errors," *Medicolegal and Bioethics* 2 (2012): 1-11.

⁷³ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients" *Journal of General Internal Medicine* 12 no. 12 (1997): 770.

⁷⁴ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients" *Journal of General Internal Medicine* 12 no. 12 (1997): 771.

⁷⁵ Robbennolt, Jennifer K., "Apologies and medical errors" *Clinical Orthopaedics and Related Research* 467 no. 2 (2009): 378.

⁷⁶ Mazor, Kathleen M., et al., "Health plan members' view about disclosure of medical errors." *Annals of Internal Medicine* 140, no. 6 (2004): 410.

77 Wolf, Zane, and Ronda G. Hughes, "Error reporting and disclosure," *Agency for Healthcare Research and Quality*, Retrieved from: <u>http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurs</u> eshdbk/WolfZ ERED.pdf. 3-4, Accessed Feb 2015.

⁷⁸ Gallagher, T.H., et al., "Patients' and physicians' attitudes regarding the disclosure of medical errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1001-1007.

79 Steinbrook, R., "Protecting Research Subjects - The Crisis at John Hopkins." *New England Journal of Medicine* 346 no. 9 (2012): 716-720.

⁸⁰ Taylor, K. M., "Telling Bad News: Physicians and the Disclosure of Undesirable Information." *Sociology of Health and Illness* 10 (1998): 109-120.

⁸¹ Taylor, K. M., "Telling Bad News: Physicians and the Disclosure of Undesirable Information" *Sociology of Health and Illness* 10 (2008): 125-132.

⁸² Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u>, Slide 31-32, accessed, December, 6, 2015.

83 Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients" *Journal of General Internal Medicine* 12, no. 12 (1997): 773; Banja, John D., "Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause?." In *Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues)*, eds, Kerm Henriksen, James B Battles, Eric S Marks, and David I Lewin. Rockville (MD): Agency for Healthcare Research and Quality; 2005 Feb.) Retrieved from: http://www.ncbi.nlm.nih.gov/books/NBK20549/. Ethical reflections on the cooperation clause, 7, Feb, 2016,

⁸⁴ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients" *Journal of General Internal Medicine* 12, no. 12 (1997): 773; Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/.</u> Slide 31-32, accessed, December, 6, 2015.

85 Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u>. Slide 29, accessed, December, 6, 2015.

⁸⁶ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine* 12 no. 12 (1997): 771.

⁸⁷ Maynard, Edwin P., Karen Coblens, Errol D. Crook, Lee Dunn, Arthur W. Feinberg, Lloyd W. Kitchens, Bernard Lo et al. "American college of physicians ethics manual." *Annals of Internal Medicine* 117, no. 11 (1992): 947-960.

⁸⁸ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1003-1005.

⁸⁹ Matlow, A., et al., "Disclosure of medical errors." *Pediatric Clinics of North America* 53 no. 6 (2006): 1094-1095.

90 Wolf, Zane, and Ronda G. Hughes, "Error reporting and disclosure," *Agency for Healthcare Research and Quality*, Retrieved from: <u>http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nu</u> <u>rseshdbk/WolfZ_ERED.pdf</u> 2-5, Accessed Feb 2015.

⁹¹ Fein, Stephanie, et al., "A Conceptual Model for Disclosure of Medical Errors" *Advances in Patient Safety* 2 (2005). Available from: http://www.ahrq.gov/downloads/pub/advances/vol2/Fein.pdf.

⁹² Hobgood, Cherri, et al., "Medical error identification, disclosure, and reporting: do emergency medicine provider groups differ?" *Academic Emergency Medicine* 13 no. 4 (2006): 444.

⁹³ Mazor, K., et al., "Health plan members' views about disclosure of medical errors" *Annals of Internal Medicine* 140:6 (2004): 410.

94 Banja, J., "Problematic medical errors and their implications for disclosure." *HEC forum* 20 no. 3 (2008): 202-205.

95 Annas, A., "The patient's right to safety-improving the quality of care through litigation against hospitals." *New England Journal of Medicine* 354 no.19 (2006): 2066.

⁹⁶ Edwin, A.K., "Non-disclosure of medical errors an egregious violation of ethical principles." *Ghana Medical Journal* 43, no.1 (2009): 34-39.

⁹⁷ Hammami, Muhammad M., et al., "Which medical error to disclose to patients and by whom? Public preference and perceptions of norm and current practice." *BMC Medical Ethics* 11, no. 1 (2010): 17.

⁹⁸ Mazor, Kathleen M., et al., "Disclosure of medical errors: What factors influence how patients respond." *Journal of Internal Medicine* 21 no. 7 (2006): 708.

⁹⁹ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 527.

100 Kaldjian, Lauris C., et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals" *Archives of Internal Medicine* 168 no. 1(2008): 40-46.

101 Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine* 12 no. 12 (1997): 774.

¹⁰² Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine* 12 no. 12 (1997): 773.

103Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u>. Slide 23, accessed, December, 6, 2015.

104 Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 524.

105 Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/. Slide 33, accessed, December, 6, 2015.

¹⁰⁶Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 526.

¹⁰⁷ Leape, L., et al., "Promoting patient safety by preventing medical error." *Jama* 280 no. 16 (1998): 1445-1447.

¹⁰⁸ Mazor, K., et al., "Communicating with patients about medical errors: a review of the literature" *Archives of internal medicine* 164 no. 15 (2004): 1692.

109 Hebert, P., et al., "Bioethics for clinicians: 23. Disclosure of medical error." *Canadian Medical Association Journal* 164 no. 4 (2001): 509.

110 Kaldjian, L., et al., "Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals" *Archives of internal medicine* 168 no.1 (2008): 48.

¹¹¹ Gallagher, T., et al., "Disclosing harmful medical errors to patients," *New England Journal of Medicine* 356 no. 26 (2007): 2715.

112 Kachalia Allen, "Disclosure of Medical Error," Retrieved from: <u>https://psnet.ahrq.gov/perspectives/perspective/70</u> Perspective, accessed, Dec, 6, 2015.

¹¹³ Wu, A., "Medical error: the second victim." *Bmj* 320 no. 7237 (2000): 727.

114 Edwin, A.K., "Non-disclosure of medical errors an egregious violation of ethical principles," *Ghana Medical Journal* 43, no.1 (2009): 34-39.

¹¹⁵ Hannawa, Annegret F., "Principles of medical ethics: implications for the disclosure of medical errors," *Medicolegal and Bioethics* 2 (2012): 1-11.

¹¹⁶ Finkelstein, D., et al., "When a physician harms a patient by a medical error: ethical, legal, and risk-management considerations." *the Journal of Clinical Ethics* 8, no. 4 (1996): 333.

117 Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors," *Journal of Medical Ethics* 31 (2005): 107.

118 Agency for Healthcare Research and Quality, "Full Disclosure of Medical Errors Reduces Malpractice Claims and Claim Costs for Health System," <u>https://innovations.ahrq.gov/profiles/full-disclosure-medical-errors-reduces-malpracticeclaims-and-claim-costs-health-system</u> Problem Addressed, accessed, 7, Feb, 2016.

¹¹⁹ Kalra, Jawaher, K., et al., "Disclosure of medical error: policies and practice." *Journal of the Royal Society of Medicine* 98 no. 7 (2005): 307.

120 Berlinger, N., and A.W. Wu, "Subtracting insult from injury: Addressing cultural expectations in the disclosure of medical errors." *Journal of Medical Ethics* 31 (2005): 108.

¹²¹ Blendon, R., et al., "Views of practicing physicians and the public on medical errors," *New England Journal of Medicine* 347 no. 24 (2002): 1937.

122 Shanafelt, T., et al., "Burnout and medical errors among American surgeons." *Annals of surgery* 251 no. 6 (2010): 998.

¹²³ Clinton, Hillary, and Obama Barack, "Making patient safety the centerpiece of medical liability reform." *New England Journal of Medicine* 354 no. 21 (2006): 2205-2208.

124 Butcher, L., "Lawyers say 'sorry' may sink you in court." *Physician Exec* 32 (2006): 23.

¹²⁵ Chan, D., et al., "How surgeons disclose medical errors to patients: a study using standardized patients." *Surgery* 138 no. 5 (2005): 854.

126 Bates, D., and Gawande Atul. A., "Error in medicine: what have we learned?" *Annals of Internal Medicine* 132 no. 9 (2000): 764.

127 Schwappach, D., and Koeck Christian, "What makes an error unacceptable? A factorial survey on the disclosure of medical errors." *International Journal for Quality in Health Care* 16 no. 4 (2004): 321.

¹²⁸ Sandars, John, and Esmail Aneez, "The frequency and nature of medical error in primary care: understanding the diversity across studies." *Family practice* 20 no. 3 (2003): 233.

129 Wachter, R., "Patient safety at ten: unmistakable progress, troubling gaps." *Health affairs* 29 no. 1 (2010): 166.

¹³⁰ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients. *Journal of General Internal Medicine* 12 no. 12 (1997): 771.

131 Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/. Slide 30, accessed, December, 6, 2015.

132 Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/. Slide 18, accessed, December, 6, 2015.

133 Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/. Slide 20, accessed, December, 6, 2015.

¹³⁴ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1003. 135 Fein S., et al., "A Conceptual Model for Disclosure of Medical Errors" *Advances in Patient Safety* 2 (2005). Available from: http://www.ahrq.gov/downloads/pub/advances/vol2/Fein.pdf.

¹³⁶ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1003.

¹³⁷ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289 no. 8 (2003): 1003.

¹³⁸ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 523-531.

139 Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine*, 48, no. 5 (2006): 524.

140 Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/. Slide 37, accessed, December, 6, 2015.

141 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies," *The American Association of Physicists in Medicine*. Retrieved from: <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error</u> <u>%20NEAAPM.pdf</u> 34, accessed Feb, 2015.

142 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies," *The American Association of Physicists in Medicine*. Retrieved from: <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error</u> <u>%20NEAAPM.pdf</u>. 31, accessed Feb, 2015.

143 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies," *The American Association of Physicists in Medicine*. Retrieved from: http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error %20NEAAPM.pdf. 33-35, accessed Feb, 2015; Nau, Konrad C., "Disclosing Medical Error to Patients," http://slideplayer.com/slide/7041421/, accessed, December, 6, 2015.

144 Evans, Sue, "After the Error: Disclosure Responsibilities and Controversies," *The American Association of Physicists in Medicine*. Retrieved from: <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%20error</u> <u>%20NEAAPM.pdf</u>. 38, Accessed, February, 2015.

145Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u>. Slide 37, accessed, December, 6, 2015.

146 Nau, Konrad C., "Disclosing Medical Error to Patients," <u>http://slideplayer.com/slide/7041421/</u>. Slide 33-42, accessed, December, 6, 2015.

147 Wolf, Zane, and Ronda G. Hughes, "Error reporting and disclosure," *Agency for Healthcare Research and Quality*, Retrieved from: <u>http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurs</u> <u>eshdbk/WolfZ_ERED.pdf</u>. 3, accessed, February, 2016. 148 Wolf, Zane, and Ronda G. Hughes, "Error reporting and disclosure," *Agency for Healthcare Research and Quality*, Retrieved from: <u>http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurs</u> <u>eshdbk/WolfZ_ERED.pdf</u>. 4, accessed, February, 2016.

149 Fein S., et al., "A Conceptual Model for Disclosure of Medical Errors" *Advances in Patient Safety* 2 (2005). Available from: http://www.ahrq.gov/downloads/pub/advances/vol2/Fein.pdf.

Chapter 5. Medical Error Disclosure Protocols in the Hospital ICU Introduction

This chapter of the dissertation discusses eight key issues involved in establishing and implementing protocols applicable to disclosing any type of medical error that may occur in the intensive care unit whenever it may occur. These eight include: 1) the scope and scale of the error, 2) the ethical criteria for accepting responsibility, 3) measures to correct the impact of the error and the prognosis for the patient, 4) strategies to manage anticipated risks, 5) the timing of disclosure, 6) the various stakeholders and their interests in the case, 7) the informal and formal acknowledgement of the error and apologies for it, and 8) the compensation to be offered. Used together in the planning and implementation of policies and procedure for the disclosure of medical errors, the issues described in this listing comprise a comprehensive approach which satisfies all principles of biomedical ethics. Each one of these points represents an issue of substantial breadth and depth in its scope.

As its name suggests, the first issue in this list, the *scope and scale of the error*, involves determining breadth and depth of the various impacts of the error, whether it involves just one or, less frequently, multiple patients and where the consequences fall in the range of severity from essentially minor inconveniences all the way to irreversible calamities such as extreme permanent disability or even fatality. Additionally, this category of issues covers determinations as to: 1) whether responsibility for the medical error rest fully with a single individual or is shared by multiple caregivers, such as any combination of doctors, nurses, aides, therapists, or technicians; 2) whether the nature of

the error is latent or systemic; 3) whether the error in question falls into one or several categories of medical errors and which types of error it represents; for example, a drug dosage error in the ICU can also be the result of an error in communication during the transfer of a palliative care patient from the emergency room to the ICU; and 4) whether the medical error under consideration was one of omission, commission, or some combination of both.

Numerous *ethical criteria* exist and form a foundation *for accepting responsibility* in accord with fiduciary expectations incumbent on all medical professionals and healthcare institutions, given the nature of the physician-patient relationship. These expectations in turn rest on the foundations of the principles of bioethics, namely nonmaleficence, beneficence, patient autonomy, and justice. Protocols have been formulated to guide doctors and medical facilities as to when and to what extent medical errors must be disclosed, as well as how to handle potential conflicts between these different ethical principles when their prescriptions contradict each other.² Nevertheless, evidence from multiple sources corroborates the notion that, faced with the situation of being the victim of a medical error, patients uniformly expect full disclosure of the details surrounding the occurrence, regardless of how major or minor.

Determining the scope and scale of the medical error or errors in question functions as a prerequisite and cornerstone for developing *measures to correct the impact of the error*, as well as for assessing the *prognosis for the patient* in terms of recovering from any negative effects of the error and their impact on the patient's original illness or injury. Because it will be based or a least strongly influenced by all of the previously

outlined considerations, determining *the anticipated risk management strategy* that involved doctors, hospital administrators, and other stakeholders will or should adopt becomes an equally complex issue, in particular because it will greatly affect *the timing of disclosure*, which in turn can potentially exert a major negative impact on the patient's condition including his or her vulnerability to further harm from other sources.

One factor complicating resolution of issues arising in the wake of a medical error is the nature of the complex, interrelated, and sometimes contradictory *interests of the various stakeholders in the case*. Besides the patient him or herself, who by virtue of being in the ICU may not be capable of autonomously exercising informed consent, stakeholders will typically include: 1) family members, 2) surrogates empowered to make legally binding decisions for the patient, 3) the medical professionals involved in the case, both those involved with the error and those otherwise involved in caring for the patient, 3) the hospital itself as an institution, 4) the medical insurance providers for the patient, which may extend to the Centers for Medicare and Medicaid Services (CMS), 5) the insurers for the medical professionals, facilities, and institutions involved, and 6) any relevant government regulators.

From the perspective of what the patient observes, the *acknowledgement of the error and the apology for it*, along with, whatever *compensation is being offered* are the most visible and critical issues in the wake of any medical error. A virtually unassailable number of patient surveys concur that the respondents are deeply interested in learning and expect complete answers to what happened, who was responsible, how it came about, and why. The answers to these questions are every bit as important to the patient as are what the consequences will be, how they will be corrected, and how similar errors will be prevented going forward.3

Chapter 5.A. Medical Error Disclosure Protocols Based on the Scope and Scale of the Medical Error in the Hospital ICU

The planning and implementation of disclosure protocols must take into account the full range of severity of the potential consequences from being undetectable or having no effect on the prognosis of the patient's original illness or injury through a spectrum of severity to permanent disability or even death. Minor medical errors are defined as those that may go unnoticed, produce no ill-effects, are minimally disconcerting, or cause only minor discomfort.4 The continuum reaches its other end with major medical errors which leave the patient in far worse condition with additional infirmities or disabilities, with chronic ailments, with life threatening conditions, or which prove to be the cause of death. Throughout the spectrum of effects of the medical error, the causes may fall into either the category of those of commission or those of omission. Errors of commission signify actions that are unwarranted or executed either incorrectly or in the wrong manner, at the wrong time or to the wrong patient, which at least potentially have unwanted outcomes. Conversely, errors of omission refer to those warranted actions, which went unexecuted and thereby lead to unwanted outcomes, whether because of ignorance of the need in the situation, distraction, neglect, or deliberate choice to refrain from taking action.5 According to such a broad point of view, any medical error disrupts and potential inhibits the course of treatment for the patient's original medical problem, requiring additional corrective measures or adaptations in the original treatment plan.

Despite the extremely disruptive sound of these characterizations, a wide latitude exists in the degree to which a particular level of response or action is called for.6

This section of Chapter 5 is divided into three subsections covering: 1) The Severity, Disruption, and Cost of Medical Errors; 2) Handoffs and Black Swan, along with Postoperative Handovers; and 3) Errors of Commission.

Chapter 5.A.1. The Severity, Disruption, and Cost of Medical Errors

The process of developing disclosure procedures needs to take into account the level of severity, the degree and complexity of the disruption, and costs of medical errors, all of which could be measured in number of ways. However, the possibly most revealing of measurements, that of patient outcomes, has been neglected in what body of research exists on the subject. Instead, the literature tends to focus on costs in terms of the more easily quantifiable dollar figures as they relate to the hospitals as institutions or the health insurance providers, and to the costs of compensation or litigation. Errors of omission, by their nature more difficult to quantify or even unambiguously attribute, are often ignored in calculations.7 One notable exception to this trend is the Institute of Medicine's report from 2000, entitled To Err is Human: Building a Safer Health System; it projects approximately 44,000 to 98,000 deaths per year among patients admitted to the hospital from both types of errors.8 Estimating the frequency of all severity levels of medical errors becomes even more difficult although research based on data from 2009 came up with a nationwide extrapolation that one out of 4 million visits to U.S. hospitals for treatment of injuries that year resulted in independent medical errors, costing over a billion dollars. At this average rate, including medical errors of the most minor

consequences, each would have an average cost of nearly a thousand dollars. Moreover, such a statistic fails to capture the most expensive of negative effects, such as disability and fatality, which are inherently almost impossible to quantify with any precision. Other major limitations on this study's findings include: 1) exclusion of levels of care other than inpatient and outpatient at hospitals, 2) exclusion of costs of dealing with medical errors outside the hospital setting, 3) deliberate underestimating in the interest of avoiding double counting, and 4) exclusion of any estimates of costs related to lost work or litigation.9

Chapter 5.A.2. Handoffs, 'Black Swan' Errors, and Postoperative Handovers

Beyond formulating procedures and protocols for disclosing medical errors based on the severity or type of error, specific protocols are needed for errors that happen in environments with unique features, populations of patients, or activities, such as errors involving medications, hospital ICU patients, or during the transfer of patients from one care setting to another, which is referred to as a *handoff*. In each of these cases, the risk of medical error is significantly elevated. Specific populations of patients fitting this categorization would include: 1) those isolated within or outside the health care system, 2) those with limited English proficiency, 3) those with little health literacy, patients who are members of 4) members of racial and ethnic minorities, and patients 5) those nearing the end of their lives, including residents of long-term care facilities.¹⁰ Such patients will have difficulty communicating and interacting with medical staff and therefore are more likely to fail to notice and ask about any irregularities in their care, which might indicate a medical error.¹¹ Yet another group of special cases, are labelled "Black swan" errors, referring to those that don't fit into any classification scheme for typically occurring or foreseeable errors. For example, A new technique or procedure for addressing a subgroup within this category deals with medical errors, discovered and prevented at the last moment, also known as near misses or recovered medical errors. This procedure involves four steps, namely surveillance, identification, interruption, and correction.12

Unlike the structure of individuals or small group practice, physicians working for hospitals in the ICU unit are serving private patients function semi-independently in their own private practices, responsibility for medical errors within the context of a hospital ICU principally resides with a healthcare delivery system that is governed and operated by a complex of rules, protocols, procedures, contracts, regulations, machinery and specialized subsystems. Even if a private or primary care physician has hospital standing and privileges, which allows him or her to provide some of the care of a patient in the ICU, the reality is that a large number of other specialist and medical support personnel will be involved in the overall care and treatment given the complexity and bureaucracy of the healthcare delivery system. Even that single physician must rely on a tremendous amount of communication with and among a wide range of medical practitioners, for example anesthesiologists, neurologists, osteopathic physicians, pathologists, pharmacists, nurses, aides, therapists, and technicians, who arguably provide a substantial part of patient services. These realities make the private physician in question one subsystem within a complex system of connecting subsystems, all of which must communicate effectively if they are to prevent medical errors.13

The complexity of the system which any seriously ill or injured patient finds him or herself in makes it probable that any occurring medical error or adverse event, if not detected and counteracted, will be compounded by subsequent treatment lead to further errors or both. For instance, a considerable body of research indicates that communication errors occur with some frequency during *postoperative handovers*, as a patient is moved from the surgical unit of the hospital to the ICU and all the various components of the patient's background and history of treatment, including the anesthesia administered, the surgical procedures done, medications the patient is currently taking, the patient's treatment plan, and the responsible physician responsible for care.14 Among the various technical errors which can cause delays in accurate diagnostic and effective therapy are gaps in the patient's record as transferred, faulty coordination between teams at each end of the handoff, the absence of essential staff member at critical periods, the overburdening of staff with excessive concurrent responsibilities leading to inadequate attention to task, and the lack of continuity in procedures between departments.¹⁵ Various research studies have correlated the effectiveness of postoperative handoffs to prognosis of patient outcomes. 16 On the other hand, in spite of finding over 500 published studies, 31 of which focused specifically on postoperative turnovers, one meta-study's investigators concluded that research into the effects of such transfers is in its early stages and lacking in clear findings.17 Given the obviously variation in procedures and standards so many aspects both within and between the multidisciplinary teams involved in a patient's transfer, the potential for miscommunication leading to a medical error is great.18 This ramifications of such circumstances are like those of a patient with concurrent illnesses or injuries such as bipolar disorder and drug addiction who are

vulnerable if their care for the several conditions is fragmented, such that the different treatments are contraindicated by each other and receiving both exacerbates both conditions.¹⁹

Chapter 5.A.3. Errors of Commission versus Omission

Errors of commission, by their very nature, are more obvious and consequently less prone to be ignored or glossed over than are error of omission. For instance, if a doctor misinterprets symptoms and diagnoses the wrong affliction, the treatment prescribed whether therapy or medication will result in a noticeably inappropriate patient outcome, with the significant probability of a discernable unexpected negative effect. In contrast, errors of omission, because they stem from inaction whether or not intentional may go unnoticed with their negative effects interpreted simply has the patient's failure to respond to treatment.²⁰ As a result, research into the frequency and causes of errors of omission is distinctly and lamentably lacking; they are, moreover, more susceptible targets of intentional nondisclosure. Yet another circumstance which can camouflage this latter type of medical error is any lack of medical knowledge or consensus of opinion among healthcare professionals in relation to the patient's original condition, the scientific diagnosis of its symptoms, or the treatment procedures that are effective in dealing with it.

While precise statistics are unavailable, it is likely that medication errors constitute the greatest share, possibly as much as two thirds, of medical errors of commission in U.S. hospitals.²¹ Supporting this estimation is the complexity of standard procedures which must be followed individually for every medication administered to

each patient in the hospital ICU. This five-step protocol involves: 1) prescription, 2) transcription, 3) preparation, 4) dispensation, and 5) administration; while seeming simple, each step may be subdivided into hundreds sub-procedures. Every sub-procedure compounds the risk error, whether by a single individual involved or through miscommunication between several staff members. Viewed from this perspective, it is remarkable that medication errors are not significantly more frequent and damaging, in all fairness a credit of the staff of most hospital ICUs.22 Nonetheless, the negative impact of any error can be especially severe in the ICU, therefore warranting a thorough understanding of their causes as the first step to their prevention or at least minimization. Using the aforementioned five-step process as a framework, one research study that ranked medication errors by frequency in relation to the process, revealing that the majority of errors happened at some point in the final step, the administration (53%) followed by errors occurring prescription (17%), during preparation (14%), and lastly during transcription (11%).23 One contributing factor in the frequency of errors during administration may have occurred in relation to the process known as postoperative handovers.

Chapter 5.B. Medical Error Disclosure Protocols Based on the Ethical Acceptance of Responsibility in the Hospital ICU

This section of Chapter 5 is broken into two major subsections; the first focuses on Medical Standards, while the second covers the Responsibilities of Physicians and Medical Providers.

Chapter 5.B.1. Medical Standards

In order to fulfill the fiduciary duties which physicians and others working in hospitals incur by virtue of the trust which their patients place in these medical professionals, the disclosure protocols which medical practitioners adopt need to be grounded in the acceptance of responsibility as it accords with the principles of biomedical ethics, which in turn grows out of the traditional teachings of Judeo-Christian ethics concerning confession, repentance, and forgiveness. In theory, this system of ethics entails the notions that the medical practitioner must: 1) accept responsibility for the medical error, 2) disclose all the circumstances surrounding the error, as well as its consequences both realized and potential, 3) sincerely apologize for the error, and 4) be accountable for the consequences of the error. This last point implies that the medical practitioner will do his or her utmost to correct or if not possible least mitigate any negative effects of the error, while preventing any recurrence of the same or similar medical errors.24 All the following professional medical institutions have explicitly endorsed these principles as the cornerstone of the medical standards which they promulgate- the American Medical Association (AMA), American Nurses Association (ANA), American College of Physicians (ACP), the American College of Emergency Physicians (ACEP) and the National Medical Association (NMA) – It should be noted that this group constitutes the majority of most respected organizations of medical professionals in the United State; moreover their memberships include the large majority of medical professional current working in the field of health and medicine. These behavior guidelines and expectations are in complete harmony with the fundamental ethical principles universally acknowledged in the field of bioethics as pertaining to all

the physician-patient relationships, namely non-maleficence, beneficence, patient autonomy, and justice.

While, for medical professionals, following these standards is a fundamentally a matter of what is owed to the patient, it is equally beneficial to the medical professional, who thereby is able to experience an absolution of guilt which allows one to begin the process of self-forgiveness and thereby enables the medical professional to continued effectively delivering medical care and treatment to the injured patient, as well as to subsequent patients.25 Arguably, this process promotes psychologically healthier attitudes toward medical care, specifically attitudes more in tune with the realities of an imprecise field, in which errors are ultimately inevitable, even predictable. In the final analysis, such realistic perspectives promote increased trust as a strengthening foundation of the physician-patient relationship and ultimately more effective care, treatment, and ideally recuperation. Contrary to the fears which inhibit some in the profession from following these principles, their practice can lead to a less adversarial relationship in the wake of a medical error and actually reduce the propensity to engage in malpractice litigation, which would have the predictable consequence of reductions in the costs of medical liability insurance and of overall medical treatment in the long run. Other positive results from medical practitioners' accepting their ethical responsibility as describe here include: 1) an increased degree of patient safety; 2) significant progress toward reducing the incidence of medical errors, both individually triggered and systemic; 3) improved monitoring of active failures, enabling targeted efforts to prevent recurrence; 4) the revealing of latent or inherent risks for medical errors within the healthcare delivery

system; and 5) a psychologically healthier set of attitudes within medical culture, fostering appropriate handling of expected medical errors.²⁶

Chapter 5.B.2. Physician and Medical Provider Responsibilities

Considerable evidence exists to support the assertion that the majority of physicians are reluctant to operate according to these standards of medical conduct when faced with an actual medical error situation.27 Reasons for such attitudes and behavior include the obvious concerns, including: 1) triggering malpractice lawsuits; 2) incurring some form of punishment, even as severe as incarceration; 3) losing one's professional reputation, one's hospital privileges, or even one's licensure; 4) as a result of any of the previous eventualities, losing one's livelihood; 5) being made the 'scapegoat' by being held responsible for a medical errors the ultimate cause of which was primarily systemic or cumulative due to the inherent inter-connectivity of complicated delivery of multidisciplinary medicine; 6) feelings guilty over having harmed a patient; 7) being ambivalent about the degree of severity of the error and whether the details should be reported; and 8) being shamed by an unforgiving culture which holds unrealistic expectations of perfection and omnipotence on the part of medicine and its practitioners.28 With all these inhibitory factors, it should be of little surprise to discover that while 70 to 80% of physicians pay lip service to the need for full disclosure of medical errors, merely an estimated 24 to 54% actually do so when the occasion presents itself.29

In reality, it is not just the physicians who are reluctant. Beyond the imposing list of factors causing doctors reluctance to fully disclose the errors they discover, a very significant number of hospitals and other healthcare facilities have administrations and institutional cultures which are ill prepared and equipped to monitor for, investigate, handle, or reward and promote the reporting of medical errors.³⁰ More egregious still, a very significant number of institutions even actively discourage the identifying and disclosing of errors.

This reluctance on the part of the medical establishment stands in complete contrast to the attitudes of patients themselves, their relatives, and advocates, all of whom generally expect full disclosure and official reporting of errors, regardless of severity of consequences, candidly and descriptively with complete transparency. Among concurring research findings, one health maintenance organization (HMO) based in New England recently polled residents concerning hypothetical cases of medical error and found that 91% of those whom they surveyed felt that each and every one should be disclosed, even if it never caused any injury or harm.³¹ In a similar study, a mere 12% considered it acceptable to neglect or intentionally avoid disclosing a medical error to the affected patient even when the error had no effect on the patient's health.32 In related studies, this predominant opinion has been substantiated using focus groups. This position is unanimously and unequivocally insisted upon in biomedical ethics and through professional codes of conduct; full disclosure of major medical errors is obligatory, given the potential, if not already realized, danger these errors patients, the consequences of which can range as severe as fatality or if not, at minimum, serious physical or psychological injury. Harm of this significance demands immediate corrective, preventative, or mitigating action in response. This the minimum effort that society will morally tolerate, and to do so effectively requires full disclosure.33

This disparity between what medical standards and bioethics demand, for which physicians pledge support on one hand and what physicians actually think and do on the other hand, along with the contrast between the doctors' thinking and that of patients and other affected by the error, causes great difficulty; specifically, it complicates and hinders any effort to establish disclosure protocols which deal appropriately with the ethical duty to accept responsibility. An understanding and acceptance of these ethical standards is apparently controlling the survey responses of medical providers when situations are described hypothetically in more abstract terms, but not so when questions are put into contexts of individual cases and elaborated in terms that presuppose personal involvement in the situation. Research has demonstrated that doctors and other medical professionals when asked about what should be done, their responses will exhibit a clear belief in and unqualified ethical acceptance of responsibility. On the other hand, the very physicians and medical providers, who responded as described above, will shift to hesitant, highly qualified, or even blatantly contradictory evaluations of their duties to disclosure, in the face of legal, cultural, and other practical considerations, especially when they perceived themselves to be involved in the situation.³⁴ For instance, according to the "Principles of Medical Ethics" of the American Medical Association, all medical professionals must exhibit unflinching trustworthiness in every aspect of professional interactions with patients.35 The American College of Emergency Physicians, in its "Code of Ethics for Emergency Physicians," demands the same standard of absolute truthfulness.36 The same standards are asserted, without stated or implied exception, by the American Nurses Association, the American College of Physicians, and the National Medical Association. On the other hand, when considering the When the concrete details

and circumstances of a particular scenario are introduced, however, numerous medical providers begin to disagree over what limits exist in their duty to be completely truthful. The distinction between dealing with the patient's medical status and treatment plan and the personal relationship as human beings is a boundary that has become blurred, partly by trends toward good medical practice, in the modern physician-patient relationship.37 Nonetheless, the rightful complexity of this relationship complicates the development of medical error disclosure protocols, in as much as these the relationships can vary significantly in character.38 Beyond these considerations, inherent limitations exist in communicating technical minutia and professionally significant nuances in information concerning the medical error that are not describable in language the patient can grasp, if only because he or she lacks the medical training to interpret the ideas.39 Even after these distinctions are delineated, many issues of interpretation and evaluation of specific, 'real,' cases remain to be resolved. Consequently, establishing an implementable disclosure protocol in practice requires careful attention to illuminating and considering the specifics of each individual case as part of arriving at decisions of how to proceed.

A possible solution to the challenge of achieving more detail in carrying out disclosure protocols is to incorporate the legal definition of informed consent, which dictates the presentation of all information whether positive or negative, including the occurrence of a medical error by physicians so that the patient or his or her representative can make reasoned and informed decisions about treatment options that might fix or counter the effects of the error. Another possibility for ensuring more frequent and complete disclosure in practice would be for the protocol to explicitly stipulate scenarios necessitating detailed disclosure in terms concrete enough not to be open to

interpretation. For instance, disclosure to patients to be part of this mandate could include any accidental error that has a high likelihood of compromising the patient's safety in the future, which would require full, detailed disclosure. Similarly, any error that necessitates adjustment to the patient's original treatment plan would qualify for required disclosure on the grounds of preserving informed consent. By contrast certain types of errors the disclosure of which might remain optional could include those latent or potential errors that were discovered and prevented before they had caused any harm, as well as errors that have a more than a 50% chance of occurring and are thus the subject of assiduous monitoring. More rare and debatable in the interpretation of when to use its rationale would the choice not to disclose errors to an excessively excitable or worrying patient if the stress related damage from knowledge of the error would significantly exceed any damage that the error itself has caused. Other concrete grounds might be set for delaying disclosure, such as when a patient is being prepared for imminent surgery, or the health care organization is under legal investigation, or the institution is ordered to refrain from doing so during the process of litigation, or the cause of the error is not yet known and investigation is underway.40

Chapter 5.C. Medical Error Disclosure Protocols Based on Type of Information

This section of Chapter 5 is divided into three subsections, which will discuss respectively: 1) Better Communication, 2) Communicative Competency, and 3) Barriers to Communication

Patient outcome, as opposed to accuracy in conveying all the complexities of the situation, must be the principal focus when formulating procedures or protocols and

overseeing their implementation in communicating with affected parties in the wake of a medical error.⁴¹ Disclosure of the error and its consequences needs to be guided by three major considerations: 1) the patient and any other involved layperson must be able to fully understand grammar and vocabulary of the language used by medical professionals at all points in the communications process; 2) the focus of the explanation should consistently be on the impact of the medical error, in particular any negative effects, damage, or risks incurred as opposed to an 'cut-and-dry' iteration of the antecedents, events leading up to, and characteristics of the error; and 3) the patient must receive a clear and thorough explanation of steps being taken to mitigate any negative impact, real or potential, options for correcting any damages that have ensued or may develop in the future, together with their prognosis for success.42

Chapter 5.C.1. Better Communication

There is research which demonstrates that an ongoing supportive attitude promoting patient autonomy in the ICU to the maximum extent possible in conjunction with concerted efforts toward facilitating communication between physicians and medical staff on one side and patients, surrogates, and family members on the other can and has fostered a collaboration in shared decision-making.43 This model envisions the doctor, the patient, and involved relatives or surrogates discussing and identifying the values, goals and priorities of the patient and family. Subsequent to this meeting as a consensus is achieved as to these general guiding consideration, the physician will explain the patient's prognosis and will present options and recommendations how to move forward with treatment based on the evidence at hand concerning the patient's

condition.44 Studies have further revealed that this collaborative decision-making model can be especially effective and advantageous in case no advanced directive exists, there is no proxy for healthcare, or medical certainty or clarity as to the clinical status of the patient is limited.45

In meetings such as these between medical professionals and family or surrogates, at which the patient is unable to independently and constructively participate as is common in the hospital ICU setting, the patient's prognosis becomes critical information. After it has been presented, it becomes important in the course of the conversation that time is allocated for dispelling any confusion or uncertainty, as well as for potential psychological, logistical, or emotional reactions, and any form of bereavement that can be anticipated.46 Depending on the ramifications of the medical error, consideration of any number of life-support therapies (LSTs), issues, or decisions, such as palliative, hospice, or end-of-life care, possibly focusing on a priority to manage pain or undesirable symptoms. Concurrently, withdrawal options such as do-not-resuscitate (DNR) orders need to be addresses, along with the natural feelings many surrogates are prone to expressing concerning their doubt or reluctance to accept the accuracy of doctor's prognosis; under these circumstances, the time to reconcile with the inevitable and the option of being able to decide for oneself will ultimately be appreciated.47 Studies have also shown a correlation between communication improvements between physicians and surrogates and improvement in clinical outcomes which include. According to a variety of research, the results of the enhanced communication envisioned with this model include: 1) ICU stays of shorter duration, 2) increased in referrals for hospice care and support, 3) earlier and less agonizing decisions concerning DNR orders and withdrawal

of other LSTs, and ultimately 4) a lowering of the frequency and incidence of medical errors.48

Chapter 5.C.2. Communicative Competency

Possibly one of the most indispensable facilitators of improved patient outcomes is increasing the level of doctors' communicative competency in the following three areas: 1) expressing empathy, 2) sharing the patient's prognosis with all involved parties, and 3) aligning the shared decision-making model with the habitual and preferred communicative norms and preferences, especially in terms of the pacing of interaction and communication.49 An established correlation exists in the research literature between empathy as expressed by the medical professional and the comfort level of both patients and family members. In particular, the physician's acknowledging the family's stress, difficulties in arriving at momentous decisions, and fears over the impending death of a loved one.50 This diverges significantly from historical precedent, according to which doctors actively restrained themselves from even appearing to become involved in the patterns of elevated emotion and levels of stress, which patients and relatives were experiencing.51 In the past, only in unusual circumstances did doctors into the family's readiness much less willingness to discuss candidly the patient's prognosis, let alone decisions concerning the employing versus withholding or withdrawing of life-support options in the ICU.52 Even today, many physicians are dubious about frank discussions of the uncertainties of prognosis, fearing that a realistic understanding of the lack of certainty will contribute to excessive stress and crush any hope the patient's family has.53 Research has demonstrated that contrary to these misgivings, relatives of patients report
more positive attitudes, i.e, are more optimistic when they feel they are receiving accurate information and candid appraisals even though that candor reveals how much is unknown or unknowable.⁵⁴ A reason for this admittedly counterintuitive situation may lie in the time that a realistic assessment of the uncertainty gives psychologically preparing for the inevitability of the patient's demise. Whatever the mechanism, family members, relatives, and surrogates reject the notion of concealing either the negativity or the uncertainty of the prognosis as ultimately causing greater stress and possibly unwarranted or false hopes, which will prove to be such in the end. Moreover, the individuals responding to the research investigation were clear that they did not expect omniscience or infallibility from physicians in charge of the case.⁵⁵

With the frequency of cases in which the patient as an individual is not capable of personal exercising autonomy, the focus of decision making in the hospital ICU has in recent years migrated toward the model of shared or collaborative decision-making between physicians and the principal stakeholders, such as next of kin or surrogates.⁵⁶ Research findings would indicate that disclosure protocols should be grounded in the goals of determining optimal outcomes for the patient and corrective measures to achieve these outcomes, rather than dwelling on the antecedents of the error and causes of the current negative impact or the details of ameliorating procedures and implementation.⁵⁷ As enumerated above, the three principles of communication that need to guide disclosure are: 1) layperson-friendly terminology, 2) a focus of consequences in terms of risks or negative impacts, rather than simply a description of the error and its antecedents, and 3) a clear elaboration of options for correcting, mitigating, and preventing further negative consequences.⁵⁸ Though far easier to describe than to implement, these

principles form a foundation for physicians and patients, along with other interested parties to agree upon an efficacious course of action for dealing with the ramifications of the error without getting bogged down in the complexities of detail.

One of the inherent obstacles to this approach is the diversity of background which the different interested parties bring to the process in terms of motivations and interests, education and understanding of the medical aspects of the situation, perceptions and concerns, as well as stress levels and emotional states. Furthermore, any lack of preparation for such eventualities, such as advanced directives or powers of attorney will complicate the task of decision-making. In order for such communication processes to be effective, parties on all sides need to utilize the following interpersonal, problem solving skills: 1) openness and flexibility in exploring a variety of options, 2) willingness to maintain a sense of compatibility and cohesion while discussing and deliberating over options, 3) the basic willingness to actively listen to other points of view, 4) the ability to withhold premature judgment. Aside from the lack of these skills among the participants, potentially working against these requirements for effective deliberation are: 1) the need for taking immediate action and consequently rapid decision making decisions rapidly if not instantaneously, 2) the elevated levels of tension and anxiety, exacerbated by the high levels of uncertainty, and 3) the high levels of drama and urgency emanating from the ICU environment itself. Moreover, some aspects of the discussion are inherently complex and difficult to communicate, such as how a prognosis was formulated, has been quantified and qualified, has evolved for significantly and radically altered over time, as well as how and why uncertainties have arisen or evaporated. Given that making decisions, setting goals, and clarifying expectations are inextricably intertwined, the

assumptions by all parties underlying the communications process can be the source of obstacles and areas of potential conflict between the medical staff and the patient's family members in particular.59

Chapter 5.C.3. Barriers to Communication

A considerable variety of obstacles at a number of different levels together form a series of barriers, each individually functioning to inhibit effective communication. For instance, the population of those residing in the U.S. continues to include a significant portion of potential patients who do not have the functional fluency to understand spoken, and something even written English, especially its idioms, making language a major barrier in all facets of negotiating the healthcare system.60 Even for the native speaker of English, communication can be opaque as medical practitioners, like all specialized professionals speak a "language of the field" all of their own, with frequently used terminology and jargon that is poorly understood if at all by the educated layperson, let alone those whose education is not as advanced. Numerous terms consistently used within the ICU can cloud physician-layperson communication, thus impairing the decision making and treatment process, including abbreviations and terms such as DNR, AD, CPR, and *intubation*.61 Moreover, superficially comprehensible phrases such as *poor* prognosis, unlikely to work, withdrawal of care or withdrawal of life-sustaining treatment can be imprecise, context dependent, or misleading, easily confusing or even causing unwarranted anxiety for the layperson.62 Some euphemisms such as letting nature take its course or do everything may so context dependent or used differently by different

professionals that even the medical practitioners themselves are vulnerable to misinterpreting the precise intent being conveyed.₆₃

Beyond language and vocabulary in the strictest sense, cultural and religious differences may also play a role with concepts such as *patient autonomy* that is not practiced in many countries that depend on relatives to make decisions of the patient or the patriarchal dictates of medical practitioners.⁶⁴ Values will differ, impeding communication, with such seeming innocuous phrases as *truth telling*, in which the candor valued in U.S. majority culture may come across as cruel and offensive to those raised in societies with sharply differing attitudes toward what is polite. Ideas matter; for example, there is the globally somewhat widespread superstition that even discussing death elevates the likelihood that it will indeed occur.⁶⁵

Among the greatest challenges in cross-cultural medical communication is clearly explain of corrective treatment options, given that some outcomes and courses of treatment such those which are futile or inappropriate from the standpoint of Western medical practice, may even be fully expected by others related to the patient, who grew up with contrary beliefs or cultural traditions.⁶⁶ Despite the best efforts to surmount other barriers to communication, these impasses involving futile or inappropriate treatment tend to be unresolvable. Such impasses usually involve the physician refusing to take futile measures that family or relatives insist upon, which because the measures have been deemed useless, are unfundable through medical insurance, Medicare, or Medicaid; or even prohibited by institutions, professional medical associations, HMOs, or government agencies who deem these measures unethical to pursue. Furthermore, these

futile treatment are many practitioners to be unethical because of their cost, certainty of no beneficial outcome, and their diverting of resources from efforts with more positive prognoses.⁶⁷ Simple though emotionally harsh as this type of situation sounds, it is vastly more complex because of the difficulty of qualitatively or quantitatively characterizing the specific situation and reliably identifying which case are indeed futile.⁶⁸ Even when the complexities of a patient's condition can be spelled out, there may be little chance of resolving a debate as to whether some treatments or all of the treatments under consideration will prove futile. Demonstrating this phenomenon, a recent study of hospital in Europe revealed that almost 75% of their ICUs had given admission to patients without no chance of survival even in the short term.⁶⁹ As document in other research, in the U.S, almost 5% of Medicare patients received ICU care in terms of grossly expensive yet foreseeably futile treatment measures immediately before dying.⁷⁰

Chapter 5.D. Protocols for Medical Error Disclosure Based on the Anticipated Risk Management Strategy in the Hospital ICU

This section of Chapter 5 is divided into three subsections, which will discuss the following aspects in relation to the disclosure of medical errors, respectively: 1) the Global Trigger Tool (GTT) of the Institute for Healthcare Improvement; 2) the Conditions for Informed Consent; 3) the Role of Surrogates.

Chapter 5.D.1. The Global Trigger Tool (GTT)

Although possibly intuitively self-evident, a body of research has emerged illuminating the intrinsically hazardous nature of being treated in a hospital's intensive

care unit (ICU). Among these studies, one from 2011 focused on 3 hospitals in the United States, examining 795 patient records and identified 393 adverse events; such analysis suggests that these adverse events may prove to be more frequent by a measure of tenfold in hospitals than had been previously assessed on the basis of an earlier review of medical records using the Global Trigger Tool (GTT) of the Massachusetts based Institute for Healthcare Improvement. Backing up the 2011 research, the National Coordinating Council for Medication Error Reporting and its Prevention Index for Categorizing Errors revealed a nearly identical frequency and patterning in the distribution of severity of errors it studied. These findings represent events at least a decade subsequent to those of the Institute of Medicine's 1999 report suggesting that medical errors or adverse events are still as much as if not more than a problem for patients in hospitals today.71

Further revealing, the 2011 study's findings placed medication errors, adverse events connected to surgery and other procedures, along with hospital-related infections at the top of their medical error frequency rankings – a situation similar that shown in earlier previously described research. Related to this study, using the same GTT methodology that identifies more patient injuries that are a result of adverse events, Internationally and even more currently, in 2012 researchers studying average sized Swedish hospitals and their ICUs that various forms of adverse events were surprising common given that they had never previously been reported or documented as occurring in the ICU. Of greatest concern, over a two years interval, 128 patients fatalities were recorded as having been the results of some 41 different adverse events such as healthcare-related infections, hypoglycemia, pressure sores and procedural complications.

Distressingly, a full 54% of these medical errors, termed 'adverse events' were judged to have been avoidable.72

Starting in 1991 with the Patient Self Determination Act, disclosure protocols began to be established in U. S. law, as part of the larger goal of promulgating policies and procedures to spur the use of advanced directives among medical institutions.73 Subsequently, informed consent has come to include the notion of permission given by the patient to the medical practitioner to carrying out a regimen of medical treatment for a specific condition, on the foundation of knowledgeable decision made ultimately by the patient to subscribe to that treatment. The circumstances surrounding surgery as treatment provide a clear-cut illustration of the specifics of informed consent. In this context, it refers to the physician-patient process of communication, possibly involving educational dialogue, definitely including an elaboration and mutual evaluation of 1) benefits and risks, 2) feasible alternative courses of action, and 3) characterization of and rationales for the various procedure options. In this context, the span of event during which informed consent is operative runs from the initial consideration of surgery as an option, all the way through subsequent recovery and includes any postoperative complications.74 By the same token and closely related, informed consent has also been characterized as the collaborative decision-making process shared and mutually reinforced by the doctor and the patient or the latter's surrogate.

Chapter 5.D.2. Conditions for Informed Consent

The conditions required of providing consent are four-fold. The first condition is that patients must be capable of making a decision about their healthcare. According to bioethics in healthcare, four conditions are prerequisite to the patient's giving true informed consent: 1) that he or she clearly sees his or her condition as being in need of medical treatment, whether because of injury or illness; 2) that he or she is aware of and understands each of the therapeutic options which the physician has offered as feasible or at least possible courses of treatment, and moreover comprehends the advantages and potential drawbacks or negative consequences of each option; 3) that he or she can assimilate the information provided concerning the various options in order to resolve conflicting points of view and arrive at a decision consistent with his or her beliefs and goals, and finally 4) that he or she can clearly articulate the choice once made.75

In order for the patient to demonstrate the second required condition in order to exhibit informed consent, he or she must have ready access to enough information about all options in order to deliberate and arrived at an informed choice. Although creating a precise measure of what constitutes sufficient information is elusive, a widely accepted criterion is that which a reasonable individual would need to have at hand in order to make a rational choice. In practice, such a standard necessitates the patient having a working comprehension of both the potential advantages and the risks of all options the doctor presents for consideration, a standard given legal precedent in the appeal of *Canterbury v. Spence* 1972.76 An alternative disclosure standard has been stated in terms of the patient receiving sufficient information so that a patient could not objectively claim surprised by any foreseeable outcome that might follow treatment.77

Implicit in the third conditional requirement of consent is the notion that the patient gives it free of any coercion or undue influence provides consent without coercion

from any source, whether the physician, relatives, or others. Obviously, this requirement does not exclude recommendations and reasons offered in support thereof. Rather, coercion is something that a reasonable person would have to struggle to resist; broadly defined, it can include decisions based deceptive misinformation or exaggeration. In order to prevent any accusations of coercion having been involved in a treatment decision, the physician needs to notes into the patient's file summarizing any verbal conversations along with decisions made by patients and physicians as opposed to merely relying on standard consent forms.⁷⁸

The informed consent principle in biomedical ethics is especially applicable to care in the hospital ICU given the foreseeable, heightened risks of medical errors leading to serious additional injury or even fatality. Protocols need to incorporate both written permission and verbal (i.e, spoken communication) discussion of the risks, as well as the potential benefits; this dual approach helps to guarantee that the patient or surrogate completely understands the course of treatment being prescribed.⁷⁹ Informed consent documents always need to comply with the principles of communication previously discussed in this dissertation; furthermore, they need to be compatible with subsequent communication which would be generated by the occurrence of a medical error. To facilitate this second goal, the informed consent document may even include anticipated remedial procedures for dealing with both foreseeable and unexpected occurrences, such as but not limited to medical errors.⁸⁰

There is no standardization of hospitals consent forms, just as facility operating procedures can vary as greatly as do medical and surgical procedures. Some forms

contain information about risks involved; others include space document patients' reasons for declining a recommended procedure. With this degree of variation, any assumption that most or all patients understand what they are consenting to would be a gross error as at least one body of research has demonstrated.⁸¹ Particularly with surgery, consent for unanticipated eventualities becomes a complicated medical issue; therefore, as much prior discussion with the patient as possible is warranted and should cover realistic hypothetical scenarios such as the need for extended mechanical ventilation arising in mid-operation.⁸² Other procedures that can be anticipated as highly likely might also be considered ahead of time as well such as Postoperative procedures in the ICU are one of various foreseeable needs to be discussed in advance and ideally to have a surrogate designated for, should the patient not be able to give informed consent for the unexpected.⁸³

Chapter 5.D.3. The Surrogate

Across the country, numerous state agencies advocate bringing a surrogate into any extended consent discussion between the doctor and the patient, along with having involved discussions between the patient and the designated surrogate. State level authorized surrogates acting on behalf of incapacitated patients fall under various nomenclature, such as healthcare agents, healthcare proxies, and designees having durable powers of attorney for healthcare. Given the serious complications which the absence of a surrogate can present, various states have further set out procedures through which a surrogate may be designated if needed and not already done. Other states that default provisions for spouses or nearest of kin. Regardless of the arrangements in the jurisdiction, the doctor needs to engage in prior consent discussions with the surrogate whenever possible.84

The concept that, with medical advice, a surrogate can effectively provide guidance for an incapacitated patient needing surgery has considerable ethical and legal precedent. Whenever possible, having and following the patient's written desires and instructions as nearly as the circumstances dictate is the best practice in this regard. When this ideal is not achievable given the unpredictability of foreseeing most eventualities, the surrogate needs to rely on a standard of substitute judgment, taking the patient's known priorities and values into account. Thus, as extensive previous contact between patient and proposed surrogate as is possible is to be sought. In the absence of the knowledge and understanding that comes from interaction, the surrogate must rely on the standard of what is in the best interest of the patient, often necessary when the patient is a minor or has had long term mental incapacity. If surrogate and physician disagree, more likely in these latter circumstances, a professional ethicist may be consulted. The physician's reason for disagreeing should has ethical merit, such as an honest conviction that the surrogate; 1) insufficiently understands the choices from a medical or ethical perspective, 2) has a conflict of interest, 3) is making a decision which the physician has evidence that the patient would have rejected, or 4) has not followed the available and appropriate standards in arriving at the decision.85

Chapter 5.E. Medical Error Disclosure Protocols Based on the Timing of Disclosure

This section of Chapter 5 is separated into two subsections, the first discussing the advanced directive; (AD) and the second examining issues connected with verbal instructions.

Faced with the possibility of either danger or harm, human beings as a species are apparently innately prone to finding discomfort in and avoiding uncertainty, which is course, inherent in medicine's treatment of illness or injury.86 Consequently, any protocol disclosing ahead of time what can or should be anticipated throughout the course of a treatment regimen will relieve concern, stress, and worry, circumstances that will help reduce the chance of medical errors while providing a framework for contextualized understanding of any errors that might occur.87 While not always feasible in various ICU settings and circumstances, pretreatment disclosure brings the patient into the care and treatment decision-making process, laying the groundwork understanding the potential for medical error before one arises.88

Chapter 5.E.1. Advanced Directives

Advanced directives (ADs) allow patients to give a written account of their decisions concerning care and treatment, along with their choice of surrogate, all prior to any situation in which the need for decision making arises.⁸⁹ Various research studies support the contention that individuals who have created ADs are more able to exercise individual autonomy, significantly increasing the likelihood their wishes will be followed. Further to their benefit, those with ADs can receive decision-making assistance

from the surrogates they have chosen, and are ultimately less likely to die in a hospital setting, where medical professionals might attempt "heroic' measures that the future patient would not want and which would cost family members unnecessary trauma and expense at the end of the patient's life.⁹⁰ Despite the obvious benefits of advanced directives, along with the closely related living wills and powers of attorney, and in some case legal requirement that hospitals obtain ADs before admitting a patient, the majority of people have failed to create an AD. Furthermore, some recent studies have suggested that advanced directives are failing to achieve many if any of the goals for which they were developed, such as guiding the care provided by medical practitioners in settings like the hospital ICU and ultimately reducing the uncertainty, pain, and expenses of critical and end-of-life hospital.⁹¹

The typical timing of the disclosure of a patient's condition and prognosis in the ICU illustrates one failing in the use of advanced directives. Physicians make the decision of when to communicate a patient's condition and prognosis to the appropriate persons, and tend to hold off on doing so when the prognosis is not good, ultimately shortening the time families or surrogates have to prepare themselves psychologically and to make decisions.⁹² The research on the phenomenon suggests that doctors are primarily motivated to delay informing those involved out of a desire reach greater certainty with less reliance on judgment or intuition. However, this attitude places a higher value on scientific accuracy than on the emotional and logistical needs of those close to the patient to prepare for what is inevitable.⁹³ The stress in this situation is compounded if the physician gives the negative prognosis and immediately asks the surrogate and family to begin making end-of-life decisions. In this situation, loved ones will tend to feel

emotionally and cognitively pressured by the lack of time to resolve outstanding issues and to say farewell to the dying patient, all of which can lead to a subconscious sense of resentment should a medical error be discovered to have been involved. The body of relevant research clearly indicates that patients and family members want the earliest practical disclosure of prognosis, as soon as feasible after initial diagnosis and if possible before the patient is admitted to the ICU, all of which is decidedly before the doctor has a strong degree of certainty.94 Among the negative impacts of delaying disclosure is that in its absence, physicians and even other hospital staff are distracted by persistent queries from family members about the patient's prognosis in terms of ascertaining some idea of his or her chance of survival.95 Furthermore, reducing the interval between a negative prognosis and the actual end-of-life reduces or possible eliminates the options of hospice or palliative treatment, which would have assisted the patient in managing pain while affording the family and the patient more time and a more comfortable environment than the ICU to prepare themselves emotionally and to deal with any unresolved issues or practical matters prior to the patient's death.96 While there have been few studies attempting to delineate precise time preferences for disclosure, at least one has found that an average of 36 hours passed between initial communication and prognosis or a combination of prognosis with a negative conclusions of physicians in the ICU; in 19% of the cases sampled, no prognosis had even been communicated.97

Chapter 5.E.2. Verbal Instructions

Enhancing the process of disclosing a patient's prognosis is not merely an issue of the attending physician intuitively prognosticating based on empirical evidence from vital signs and communicating such prognosis to those involved with the patient's treatment. From the perspective of the medical professional, envisioning ways to improve prognosis disclosure in relation to advanced directives once the patient is admitted to the ICU is difficult in large part because of the behavioral reluctance of most patients to specify in written or often even in spoken detail their wishes for advanced directive, living wills, powers of attorney; this is true even in the context of direct communication between, physicians, patients, and relatives or surrogates. The absence of advanced directives, or their lack of specificity when present, compound the uncertainties with which the physician must contend. One revealing body of research, conducted at a major teaching hospital in Illinois over a number of years and involving over 2,000 patients to the neurological and intensive care units, involved the collection of empirical evidence in both written and oral form of patient advanced directives.98

Those patients or their surrogates and family members who stated that they had created an advanced directive, either previous or at the hospital amounted to only a third of those polled; even significantly fewer reported having it documented on the patient's medical chart where it would be readily accessible if the situation arose for consulting it. While the study under consideration represents data from a single hospital, it give some impression as to the frequency and types of ADs which may exist. What is clearly the norm is a patient arriving at the hospital ICU unable to articulate personal wishes with family or a surrogate, if present, only able to reconstruct from memory any discussions relating to ADs, and no written documentation to be had. Incomplete proxy statements are common, as are those deemed legally invalid for lack of being properly signed and witnessed. Patient directives which actually were documented in hospital charts were also lacking in the specificity of their instructions.99

Lastly, the research study provided some record of the types of instructions and directives which arise out of the long-term spoken interactions and communication between doctors, patients, and relatives over the course of lifetimes of treatment. Being self-reporting of data as remembered, they may well represent inaccurate, distorted, or selective remembrance, and may prove incomplete, no longer current, or even complete fiction. Nevertheless, this body of data reveals that patients frequently want medical intervention to be limited and dependent on a reasonable prospect for recovery or maintaining a certain quality of life. Patients with such perspectives were much more numerous than those who wanted every measure of care or treatment at all costs. The data reveals an interesting mix of detail or lack thereof, juxtaposed against a clear, general absence of specific temporal directives.¹⁰⁰

Chapter 5.F. Medical Error Disclosure Protocols Based on the Stakeholders of Interest

This section of Chapter 5 is divided into three subsections, which will cover: 1) communication failures; 2) the disclosure of information concerning the medical error; and 3) the transfer of patients, also known as handoffs.

Chapter 5.F.1. Communication Failures

Treatment of a patient in the ICU always involves stakeholders beyond the physician, the patient and close relatives; rather it involves the hospital, everyone serving on the care and treatment team, the patient's insurance provider, manufacturers of the ICU equipment used in care and treatment, pharmaceutical companies whose medication is part of treatment, and any relevant government regulators (as representatives of the Centers for Medicare and Medicaid Services). Proactive disclosure to stakeholders of any foreseeable medical errors, possibly as part of informed consent documentation, could facilitate disclosure protocols should an error indeed occur. Such disclosure becomes a natural outgrowth of enumerating and describing the risks involved with anticipated interventions, outcomes, and contingencies to undo or mitigate the damage from a major medical error.101

According to several research studies, a full 85% of patients deemed part of sentinel populations, and therefore at elevated risk of experiencing harm from a medical error had a communication failure linked to their particular case; among these ICU surgical patients experienced the greatest risk from such breakdown in communication.102 While the patients themselves have the most significant stake in ensuring accurate conveyance and understanding of information, it is most often between the medical staff and family member that the breakdowns occur. As described earlier in this chapter, difficulties with and barriers to communication are complex, multifaceted, and bidirectional. In the ICU and for the patient, barriers to communication can further include: 1) ventilators, 2) intubation, 3) a tenuous grip on consciousness owing to sedation, 4) coma, and 5) physical and psychological distractions such as fatigue, distress, alienation, disorientation, pain, depression, or frustration. For medical staff of the ICU, despite their substantial knowledge, skills, and experience, they face barriers including: 1) the inability to read lips or to communicate with sign language, formal or impromptu; 2) the inability to decipher what patients try to say during brief moments when the latter

are conscious or thinking rationally, or 3) a lack of understanding of the patient's particular that would be necessary for decipherment of abbreviated messages. The complexity of these barriers predicts that neither technological breakthroughs nor specialized training would be likely to overcome these obstacles in any simple or highly effective manner.¹⁰³

Chapter 5.F.2. Disclosure of Medical Error Information

In the process of disclosure for a medical error, certain individuals and groups need to be considered in detail, given their roles as stakeholders. This subsection is further broken down into discussions of three of these: 1) the family of the patient, 2) the medical staff of the ICU, and 3) those involved in transfers or 'handoffs' of the patient.

Chapter 5.F.2.a. The Family

Aside from the patient and the required documentation, him or herself, the group of stakeholders with the next strongest interest in disclosure of medical error information is the patient's family. Multiple studies have concluded that patients' family members are frequently dissatisfied with and disapproving of the timeliness and the manner in which they receive medical information from ICU staff and the hospital in general. Close relatives cite the inadequacy of communication, as well as its unpredictability and inconsistency. Many inherent characteristics of the circumstances create barriers to clear and adequate communication, such as the dynamics or lack of internal organization or cohesion in the family itself, severe time constraints and the lack of doctors and nurses to attend to the immediate demands of the ICU. In the past, ICU staff have not observed a tradition of engaging families in critical decision-making processes whether or not an AD has been created, and despite the shift in the field of medicine to collaborative family centered decision making, this trend has been slow to take hold.104 The result is the family's heightened psychological worries and stress concerning invasive treatments without patient or family consent and the awkwardness of interactions among the ICU staff as a multidisciplinary team.105 Various research surveys have revealed the deeply felt need and desire on the part of families of patients to be an active, informed part of the process of ICU care and treatment of their loved one, particularly in relation to end-of-life care and decision making.106

Chapter 5.F.2.b. The Medical Staff of the ICU

The medical staff of the ICU in which the error occurred constitute only part of larger group of professional involved in dealing with the error. Insofar as the patient's family members have been actively involved in decision making for the patient with regard to treatment of the original condition, they might conceptually be considered members of the staff. In fact, the medical staff itself may also regard the patient and family as part of their group, particularly in light of the current emphasis on patient autonomy and collaborative decision-making. However, this merging of categories further complicates disclosure protocols. Thus, the medical staff should be thought of as the professional team within the hospital ICU and thus faced with the challenge of providing expert medical care in this high-pressure setting.¹⁰⁷ The degree to which the ICU staff works efficiently and smoothly as a team of highly skilled and specialized experts has the utmost bearing on the degree to which quality care is provided, in turn

determining the safety and probability of survival and recovery for the ICU patients.¹⁰⁸ Various studies have shown positive correlation between the quality of this teamwork in practice and a wide range of efficient operations in the department, while conversely a negative correlation with errors rates, medical difficulties, and fatalities. Coupled with the 32 to 37% portion of documented medical errors related to verbal miscommunications between doctors and nurses, the need for the type of teamwork that incorporates efficient reliable communication becomes obvious, made all the more significant given these verbal miscommunications arise from a mere 2% of the doctors' and nurses' work activities.¹⁰⁹ However, research studies also offer the promise of benefits from teamwork that includes effective communication; productive interaction between ICU caregivers has been found to lead to shorter ICU stays by fostering effective leadership, conflict resolution, and colleague sensitive cooperation.¹¹⁰

Chapter 5.F.3. Those Involved in Transfers or Handoffs of the Patient

Transferring patients, also referred to as a *handoff*, whether in either direction between the ICU and another part of the hospital or alternatively between two hospitals or even simply between the care of different physicians, constitutes among the most complex, challenging, and high risk activities for the medical staff.111 During such transitions, the patient in in a position of increased vulnerability, and it is at this point that all sorts of medical errors are prone to occur and more likely than other times to go unnoticed. The risks include the heightened opportunity for lapses in essential communication and confusion about responsibilities related to patient data involving the patient's medication, diagnosis, tests results, ongoing treatment, special needs and circumstances, as well as the overall goals of the patient's care.112 There is substantial research findings to correlate the occurrence of medical errors and adverse outcomes directly with such transfers, in addition to which, patients tends to report more dissatisfaction with the quality of their care during these periods.113 As many as an estimated 18% of the reported adverse events affecting ICU patients are connected with their discharge from that hospital unit.114

The benefits of accurate and timely handing off of critical patient information include: 1) reducing risks or eliminating sources of errors, 2) avoiding unnecessary duplication of diagnostics and laboratory testing, 3) minimizing the likelihood of needed re-hospitalization, and 4) overall, boosting the patient's quality of life. Optimal patient outcomes are highly correlated with communication that is exhibits not just quantity and frequency, but also clarity in its content.¹¹⁵ In contrast, studies on the subject have found that inter-site communication and coordination of care and treatment has been noticeably absent; this phenomenon has been particularly evident between acute care providers in the ICU and the patients' primary care providers (PCPs) to the distress of the patients themselves.¹¹⁶ In 2011, it was estimated that somewhere between \$25 and \$45 billion U.S. dollars could have been saved through better communications during patient transfers.¹¹⁷

There is no indication at present that any country has established a uniform hospital discharge protocol, in spite of research indicating the advantage of such standardization.¹¹⁸ The complexity and considerable degree of variation in practice among discharge processes creates added risk of the occurrence of medical errors.¹¹⁹ For example, a transfer to the ICU from the operating room (OR) involves inherent risk in that the patient is in a particularly fragile state physically, yet must be moved between environments; meanwhile the patient's data, which can change rapidly and dramatically during this time must be passed between various medical professionals of differing specialties in different locations. In such a scenario, obviously the patient will not be in a condition to help monitor the process; all of these factors create an elevated potential for medical error.120

Chapter 5.G. Medical Error Disclosure Protocols Based on the Formal and Informal Acknowledgement of Medical Errors and Apologies

This section of Chapter 5 is separated into two subsections, namely Informal and Formal Apologies; 2) Apology Laws.

Chapter 5.G.1. Informal and Formal Apologies

While minor medical errors, i.e, those whose consequences do not materially or adversely affect the patient's original prognosis or cause separate damage can ethically be handled through informal apology protocols involving only those closely, formal procedures and policies for apologies must be adopted in advance of occurrence of any error with major consequences.¹²¹ This latter, admittedly broad, category will involve various parties or stakeholders who are secondarily connected to the event and have differing, possibly conflicting interests. Since this type of situation always includes the potential for communication problems to compound issues, having a well drafted formal apology at least in outline form is a wise precaution, although various researchers have

concluded that such pre-formulated apology statement can have mixed results in terms of successful resolution.122

Given that informal apologies generally occur within the person-to-person context of the physician-patient relationship, the four cornerstone characteristics of successful informal apologies for medical errors are that: 1) the doctor acknowledges that an error has occurred, revealing who or whatever is responsible and the specifics of what has happened; 2) the doctor accepts responsibility and describes the effect it is having or will have on the victim; 3) the doctor *expresses regret* by admitting culpability, personally or on behalf of the institution and those responsible, along with showing humiliation, sincere contrition, and compassion; and 4) the doctor offers mitigation and compensation for the damage caused by the error.123 Informal apologies such as this constitute typical moral behavior in reconciliation between individuals in their interpersonal relationships. Absent from this scenario, in contrast to formal apologies in the wake of medical errors, are any involvement of any government agencies and regulators, legal institutions, or enforcement officers and mechanisms. Moreover, an informal apology can be more or less spontaneous and immediate, without need for forethought concerning its ramification in situations for which the stakes are small because the error was minor.124

By contrast, formal apology for a medical error as is much more common in the ICU, is normally an affairs bringing in at minimum a number of doctors, other medical staff, and hospital administrators institutions, in addition to those experiencing the effects of the error. Furthermore, apology protocols may very well involve secondary stakeholders such as medical insurance providers and legal counsel, as well as the

eventualities of malpractice litigation, major consequences in terms of damage, serious injury, death, and extensive financial burdens. Because of all the legal considerations involved, the formal apology process is inextricably linked to the legal processes of adjudication, objective determination of culpability, and compensation, as opposed to any face to face expression of responsibility.125 Thus, in the majority of cases in which formal apology protocols are needed, spontaneous admissions of responsibility or even regret are strenuously discouraged and avoided.

Intrinsic differences in circumstances can logically account for differences between informal and formal apology protocols. On the interpersonal level, medical apologies can involve merely the simple, immediately implementable actions described earlier in accord with the religiously based, cultural expectations for apologies. By contrast, formal apologies involve institutions, bureaucracies with complicated procedures, multiple actors, all of which can delay the protocol weeks or months, possibly years if litigation ensues. Moreover, formal apologies correlate with medical errors occurring at large facilities, where determining causation as due to a single act of omission or commission, as opposed to a complex systemic failure, or anything in between, is an involved time consuming endeavor. Thus, in cases such as those in the ICU, the medical staff may face various constraints in communicating to patients details about the incident, details which the patient and family members are anxious to learn. Unfortunately, given society's tendency to overestimate the certainty of medicine and the omnipotence of physicians, patients can be prone to confusing tragic outcomes of medical procedures that are high-risk or have a small chance of succeeding with those of a medical error involving culpability.126

Chapter 5.G.2. Apology Laws

In an effort to promote timely apologies for medical errors partly as a means of enhancing patient safety, several countries including the United States, New Zealand, Finland, Denmark, and Sweden, have adopted apology laws intended in part to remove the fear of legal action from suppressing explanations of errors, expressions of regret, and apologies.127 Prompting this change in perspective, the Institute of Medicine report of 1999,128 had documented the following disturbing trends: 1) a rapid increase in the rates of medical errors, 2) commensurate rises in the costs of medical care and malpractice litigation, 3) rapid technological change as contributing factor, and 4) significant decline in the public reputation of physicians stemming from conflicts over medical error and the lack of patient involvement in the process of making decisions about care and treatment. It is important to note that the Although the 1999 report did not address the issue of changes to how apologies are treated in legal contexts, it did advocate for adjusting the imbalance of power dynamics in the doctor-patient relationship, in which patients lacked both knowledge of medical healthcare and technology and a lack of decision-making power that was a long established tradition in medicine.129

The apology laws which resulted from this shift in thinking did make the use of some aspects apologies by doctors inadmissible in court, but were weak at best, lead to half-hearted expressions of sympathy rather than apology that failed to assuage patients' concerns and fears, and in the end did little or nothing to improve the physician-patient relationship.130 While over two-thirds of the states in the U.S. passed into law some form of these statutes, Colorado's apology law was the only that unequivocally barred all

statements of apology by doctors from being admitted in court proceedings. One of the problems was that From the point of view of many victims of error-related adverse outcomes, the type of apologies without admission of fault, which these new laws engendered lacked and sense of self-examination on the part of the physician and thus lacked honesty and sincerity.131 Research finding are clear in that patients want explanations aside from any compensation, and if they sense insensitivity and a lack of honest remorse they will resort to legal action, in part to prevent others from suffering a similar fate.132

The intent of apology laws was to remove the barrier that the threat of legal action had on candor and apology in the wake of a medical error so that other benefits would accrue; whether these laws did anything to foster better doctor-patient communication, facilitate more patient control in treatment decisions, or even reduce the rate of medical errors, improving patient safety in the process is still undecided by the research community.133 As a case in point, Minnesota and Florida have similar apology statutes. While the former has no cap on medical malpractice awards, physician-patient apologies and medical error disclosures are quite frequent, and along with those circumstances, the rates of medical errors, malpractice litigation, and concomitant insurance rates are near the bottom ranked among the 50 states. More to its credit, Minnesota's payouts for awards are only marginally above the nationwide average despite the absence of any cap on judgments. On the other hand, Florida's ranking in the same categories are among the highest in the nation, in some cases 19 times as high as those of Minnesota.134 All these statistics call into question whether state apology laws aimed at fostering disclosure protocols have had any inhibitory effect on either malpractice litigation or medical costs.

In the final analysis, the incidence of medicals errors is high and on the rise, apologies for errors remain strikingly infrequent, physicians still are typically vulnerable to having an apology used against them in court, and medical costs continue to rise far faster than inflation.135

Minnesota's overall approach to dealing with errors in healthcare is notable in several ways; the state has had since 1999, its Adverse Health Care Events Law, which mandates the reporting of adverse events, categorized into one or more of 28 groupings, documented to the Minnesota Medical Practice Board, including an determination of root causes and a plan for corrective action.136 Some of the categories match those of the National Quality Forum, such as surgical, product or device, patient protection, care management, environmental, and criminal events.137 Fundamentally, this policy is an outgrowth the state's prioritizing public safety in medical practice over punishment through the legal system. Five years after implementation, 90% of all hospitals in the state had adopted policies of disclosing adverse events to all patients and family member victims.138 Even earlier, the Children's Hospitals and Clinics of Minnesota (CHCM) had created and instituted its own patient safety program, which included disclosure to all families whenever an adverse event had occurred or might foreseeably occur in the future, along with the steps being done to remedy the effects of the adverse event and prevent any reoccurrence. The Board explicitly declared when adopted these policies that they believed it was the right thing to do, even in the face of liability to medical malpractice litigation.139 Ironically, Minnesota's patient apology law actually resembles the U.S. Supreme Court's famous Miranda ruling in its statement everything said by the apologizers can potentially be used against them in a court of law. In the final analysis,

Minnesota's success have resulted primarily from its creation of a 'culture of safety' founded on the principle of doing what is ethically right.140

Chapter 5.H. Medical Error Disclosure Protocols Based on Compensation

This section of Chapter 5 is divided into two subsections, the first of which is entitled Medical Error Disclosure Protocols and Compensation, with an implied focus only financial reimbursement for damages, harm, or loss. As its name implies, the second subsection, entitled Non-Monetary Compensation, covers other forms of restitution.

Both the principles of biomedical ethics and legal statutes concur in requiring just and sufficient compensation for any harm done, moreover, the legal systems presupposes at least the potential for adjudication between adversarial parties and the need for enforcement. By contrast, if agreement concerning fair compensation is possible without formal legal action, all parties involved may reap the benefits the cost saving in the form of time and resources expended, in the avoidance of distraction from other priorities and responsibilities such as doctors focusing on other patients and patients concentrating on recovery, and finally in the substantial reduction of emotional duress. Specific disclosure protocols as related to detailed procedures and criteria for arriving at equitable compensation promise to significantly increase the likelihood of an amicable settlement with all the advantages that it would entail.141

Chapter 5.H.1. Medical Error Disclosure Protocols and Compensation

From the patient's point of view as well as that of those who support him or her, any disclosure of a medical error will inevitably lead to a discussion of compensation, and thus any procedure or protocol developed for the purpose of disclosure must take this factor into account. However, the minute, disclosure and compensation are broadened in scope this way, the issue is no longer simply an ICU matter, but becomes system wide matter for the institution as a whole, engaging new stakeholders with concern and policies related to apologies in relation to the potential for lawsuits, insurance coverage for medical errors, opportunities for mediation, and binding arbitration versus nonbinding arbitration.142 From this broader perspective compensation includes not only financial remuneration for loss and damages, but also: 1) apologies, 2) sincere expressions of regret and contrition, 3) admissions of guilt by those culpable, 4) an explanation of the series of events leading up to the error, 5) expressions of compassion and empathy, and 6) outlining of procedures being or to be taken to prevent any repeat of the same or similar errors in the future.143 The broad view towards disclosure and compensation would enable medical error disclosure to be conceptualized as a process encompassing the error, and its reverberations, aftermath, and ultimate outcome. The 1999 publication of the report entitled To Err is Human by the Institute of Medicine laid a conceptual foundation for this broader notion of compensation. Following in the same vein, a 2009 Canadian research team gathered data concerning of 64 malpractice cases and found that 59% of medical error victims instigating lawsuits over medical errors were primarily motivated by the desire to force the medical practitioners involved to acknowledge their culpability in the matter, as well as to force these professionals and

facilities to take measure that would ensure there would no be repeating of the error.144 Despite the differences between the Canadian and U.S. healthcare and legal systems, the findings of this study are generalizable given that they concern patient attitudes, expectations, and dissatisfaction with behaviors among physicians which are not specific to either country.145According to the Canadian study, 53% of respondents claimed their main goal was to obtain explanations for what had happened to them. While 41% did admit to wanting to enable some form of punishment, a nearly equal number, 40%, were focused on forcing an apology as their primary goal. By contrast, a mere 18% stated that obtaining monetary compensation was their first priority as a goal. Another 35% of respondents relegated obtaining money to the status of secondary goal, and scarcely 6% declared that financial compensation was their sole goal. Most tellingly, a full 41% of the participants in the Canadian study did not cite money as their purpose at all, let alone as either as their primary or secondary goal. Revealing of the disparity in perspectives between the medical establishment and of patients and family members affected by medical errors, the same Canadian study found that surveyed members of the professional medical and legal communities were strikingly out of touch with the feelings of their legal opponents. Perhaps less surprisingly, over 90 % of the defense attorneys representing the doctors involved contended that the sole purpose of patient-victims lawsuits over medical errors was to get money; compounding this misperception, 65% percent of the hospital administrators who were themselves or had their facilities named in the suits, along with the attorneys for the latter group of defendants, thought that monetary compensation had been the victims' primary goal although this latter group admitted the possibility of other secondary goals such as receiving an explanation,

justice, the acceptance of responsibility, or insuring corrective measures to forestall recurrences.146

Chapter 5.H.2. Non-Monetary Compensation

The findings of the research presented above imply that desired non-monetary forms of compensation, as mitigation for medical errors could may be viewed by patients in a substantially divergent manner than do medical professionals and their legal counsel. While the results of this study suggest that attorneys, insurers and many hospitals, view lawsuits as appropriate disclosure protocol in cases of significant medical errors, the response of plaintiffs in these cases, the injured patients and their representatives, indicate that much of the need for litigation could be avoided to the advantage of all parties, with the possible exception of legal counsel. Further supporting this notion, researchers for the Pew Charitable Trust conducted a series of studies in New York state and Pennsylvania, which compared the mediation efforts made by medical practitioners and institutions to resolve issues in the wake of errors with subsequent litigation when it developed. Their findings indicate that the more doctors and hospitals showed sincere remorse and made specific, good faith efforts to improve in the aftermath of a medical error, the more willing the patients became to resolving the case through mediation rather than pursuing a lawsuit.147

However, in line the attitudes suggested by the Canadian study, physicians and hospital administrators supported with advice from their defense lawyers attempt to forestall legal proceedings by engaging in legal delay maneuvers, fighting to maintain secrecy, dispute any suggestion or responsibility for the error. The result is invariably long protracted court battles with increasing animosity, when the patient or family member initiated the malpractice suits out of confusion, anger, and frustrated at doctors' and hospitals' unwillingness to candidly reveal what had occurred, admit to their mistakes, and apologize for them.¹⁴⁸ Putting all this into perspective and casting further doubt on the wisdom of the medical practitioners' and institutions' strategies, studies has shown that the clear majority of patients who are victims of medical error do not pursue litigation.¹⁴⁹ One practical reason for this hesitancy on the part of those injured through medical errors is the long delays which are likely and the fact that such a large portion, 54% of the compensation eventually paid out according to one well regarded study, was consumed in prosecuting costs and legal fees.¹⁵⁰

Even though there is clear evidence that forms of non-monetary compensation are the primary concern and motivating force behind patients' initiating legal action, monetary compensation does play a role in their decision to pursue litigation. Isolating the monetary aspects of the legal cases, one major research endeavor focused on 1452 closed malpractice litigation claims and brought to light insights concerning the nature of the claims being made, as well as and the final settlement or judgment figures.151

A sizeable body of research, focusing on the Northeast, Mid-Atlantic, Southwest, and West of the U.S, investigate the workings of 5 malpractice insurance providers companies operating in the target areas. This data pool amounted to 33,000 physicians work in 61 acute care hospitals, of which 35 were academic and 26 were non-academic; added to this pool were 428 outpatient facilities. Significant subgroups of plaintiffs included 60% females with a median age of 38; 19% newborns and infants, and 12%

seniors, age 65 and above. Given that the study concentrated on four clinical categories, namely obstetrics, surgery, missed or delayed diagnosis, and medication errors which comprised that 80% of claims investigated, predictably the classes of medical professionals most frequently the defendants in lawsuits were obstetrician-gynecologists (OBGYNs) at 19% and general surgeons at 17%, followed closely by primary care physicians at 16%. Adverse impacts motivated a substantial amount of the lawsuits; 39% were cases of those whose injury resulted in significant disability, 15% were those whose resulting disability was classified as major, and 26% were on behalf of those who died as a result of the error. Less frequently at 4% were those who had experienced emotional or psychological trauma, 1% who claimed their informed consent has been violated, and 3% who pursued cases despite there being on adverse outcome.152

In terms of time and money, the average period from initiation to settlement was five years, for an average monetary award of approximately \$485,000 in 1995–2004 dollars, this latter average representing 56% of the applicable cases. While just 15% of the lawsuits went as far as a trial verdict, the chances of winning were much lower with plaintiffs winning only 21% of their cases, as opposed to 61% of litigants who won settlements out of court. However, of those who did win at trial the average award was approximately \$799,000 in contrast to settlements averaging about \$462,000. The mean administrative costs for claims decided by trial was On the other hand, at an average of around \$113,000, administrative costs for cases that went to trial was nearly triple that of out of court settlements, at about \$42,000. In the final analysis, the investigators in this study found these costs to be exorbitant and unwarranted.153

Among the large number of cases included in the study, medical error was the sole or significant partial cause in 63%; of these, in 73% of the cases, the plaintiffs received compensation. In contrast, of all the lawsuits in which errors did not play a role, 72% of the plaintiffs failed to receive damages; among the claims in this group, 84% failed to receive compensation if no injury was sustained. Based on the corpus of cases studied, the investigators in study concluded that: 1) from a legal perspective, the concepts of medical error and negligence are not easily disentangled, 2) contrary to the charges of a vocal body of critics, many lawsuits are not frivolous and inherently without merit, and 3) the proportion of legal actions which are initiated by victims of medical errors is, as other researchers have puzzled over, surprisingly small given the frequency at which errors are documented or believed to have occurred.154

Recently, in addition to researchers, academic hospitals, medical professionals, and some state agencies and entities have been discussing initiatives and making efforts to and implement disclosure and compensation protocols that would replace the traditional litigation, arbitration, and mediation model for resolving cases of medical error. With some limited success, protocols for offering formal apologies, fully disclosing medical errors, and offering immediate compensation have been implemented, such as 1) the "disclosure-and-offer approach" in operation specifically at the Veterans Affairs Hospital in Lexington, Kentucky; 2) the "reimbursement model" in which the institution automatically offers compensation to the patient for any losses in time, wages, and expenses incurred due to the medical error; 3) the "early settlement model" as implemented by the University of Michigan Health System, which sets no cap on compensation, which is dispersed when the facility has confirmed that a medical error has

occurred; and 4) the "avoidability standard" model, in which an panel of experts determines whether the same error would have still occurred if the patient were being care for and treated at the a top quality healthcare system or by the leading specialist in the field. Under this last model, upon the panel's ruling that the medical error would not have occurred under these ideal conditions, the patient or his or her representative receives remuneration for both economic and noneconomic losses corresponding to the seriousness of the harm or damages.155 Despite substantial savings in terms of time and money some of these initiatives have achieved in terms of enhancing disclosure and involving patients in the process, these models still have flaws and inefficiencies, which a small number of researchers are quick to point out.156

Chapter 5.J. Conclusion

In the final analysis, a critical step in improving ethical behavior involves establishing and implementing protocols for disclosing medical errors when they occur in the ICU. Protocols need to be commensurate with the scope and scale of errors and proactively address the acceptance of responsibility, considerations involving risk to patient outcomes and loss, management of the risk to the medical institution, anticipation of consequences, identification and involvement of stakeholders, and disclosure timing, apologies, and compensation.

This chapter has analyzed in detail eight aspects of disclosure protocols for dealing with medical errors in the hospital ICU whenever it may occur, specifically, the scope and scale of the error, the ethical criteria supporting the acceptance of responsibility, measures to correct the impact of the error and establish the prognosis of the patient, strategies for managing anticipated risks, the timing of disclosure, the various stakeholders in the apology process and their interests in the case, informal and formal acknowledgement of the error and apologies for it, and the compensation, in both its monetary and non-monetary forms. Specific facets of the issue of medical errors have been explored, leading to the following insights, among others, into where protocols will have special needs in their development and implementation: 1) biomedical ethics, along with most professional medical associations, takes a clear stand advocating full and detailed disclosure, 2) transfers and handoffs of patients in and out of the ICU are particularly prone to the occurrence of medical errors, 3) barriers to communication in all their forms need to be addressed proactively, 4)great differences exist between acceptable protocols for informal versus formal apologies, and 5) apology laws while well intentioned have had mixed results.

Among the themes that cut across the various sections of this chapter are that: 1) medical professionals acknowledge ethical obligations for disclosure in concept, but live up to these duties in practice, 2) patients and those close to them expect answers, explanations, and apologies stemming from sincerely felt contrition, 3) physicians severely misunderstand the perspectives and motivations of patients as victims.

Patients and family member harmed by a medical error are neither solely nor primarily interested in gaining money as compensation, as the 2009 Canadian study indicates. Further supporting this, the Pew research study of mediation and litigation described above is one of numerous studies suggesting the tendency of victims of medical errors to avoid resorting to going to court if they receive what they most want,
namely a sincere admission of fault, apologies, and efforts to prevent errors in the future. Despite this tendency, physicians throughout the medical establishment, including the ICU, remain distinctly reluctant to admit their culpability in cases of medical errors based on their concerns about potential negative impacts on their reputations, careers, and even livelihoods. From a myriad of research, it is clear that medical professionals, facilities, and institutions are very far out of touch with the feeling and priorities of victims or medical errors, real or potential.

One possible solution has been exemplified by the experiences of the medical establishment in Minnesota, where they have achieved lower rates of errors, litigation, and malpractice insurance rates, not so much by shielding physicians from legal consequences of admitting fault or apologizing for errors, but rather by proactively committing to take the ethical course of action, i.e, by 'doing the right thing,' despite possible ramifications. Endnote

¹ The Joint Commission, "TJC Sentinel Events and Alerts,"Retrieved from: <u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf</u>, Accessed, May 15,2015; Wu, Albert W. et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine*, 12, no. 12 (1997): 770-773; Segall, Noa, et al., "Can We Make Postoperative Patient Handovers Safer? A Systematic Review of the Literature," *Anesthesia & Analgesia*, 115, no. 1 (2012): 102.

² Wu, Albert W. et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine*, 12, no. 12 (1997): 772-774.

³ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289, no. 8 (2003): 1001-1002.

4 Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of Emergency Medicine*, 48, no. 5 (2006): 524-525.

⁵ Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse*, 30, no. 2 (2010): 61-70.

⁶ The Joint Commission, "TJC Sentinel Events and Alerts,"Retrieved from: <u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf</u>, Accessed, May 15, 2016.

7 Kaplan, Robert S., and Mary L. Witkowski, "Better Accounting Transforms Health Care Delivery," *Accounting Horizons*, 28, no. 2 (2014): 365-383.

⁸ Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy, 2000), 26.

9 David, Guy, et al., "Economic Measurement of Medical Errors in a Hospital Data Claims Database," *Value in Health*, 16, no. 2 (2013): 305-310.

¹⁰ Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse*, 30, no. 2 (2010): 61.

¹¹ Mattox, Elizabeth Andersson, "Identifying Vulnerable Patients at Heightened Risk for Medical Error," *Critical Care Nurse*, 30, no. 2 (2010): 67.

¹² Dykes, Patricia, et al., "Recovered Medical Error Inventory," *Journal of Nursing Scholarship*, 42, no. 3 (2010): 314-318; Henneman, E. A., and A. Gawlinski, "A 'near miss' model for describing the nurse's role in the recovery of medical errors," *Journal of Professional Nursing*, 20, no. 3 (2004): 196-201; Hurley, Ann C., et al., "A model of recovering medical errors in the coronary care unit," *Heart & Lung: Journal of Acute & Critical Care*, 37, no. 1 (2008): 219-226.

¹³ Wu, Albert W. et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 770-771.

¹⁴ Borowitz, S. M., et al., "Adequacy of information transferred at resident signout (in hospital handover of care): a prospective survey," *Quality and Safety in Health Care*, 17, no. 1 (2008), 6-10; Clancy, Carolyn M., "The importance of simulation: preventing handoff mistakes," *AORN Journal*, 88, no. 4 (2008), 625-627.

¹⁵ de Leval, Marc R., et al., "Human factors and cardiac surgery: a multicenter study," *Journal of Thoracic Cardiovascular Surgery*, 119, no. 4 (2000), 661-672; Arora, V., et al., "Communication failures in patient sign-out and suggestions for improvement: a critical incident analysis," *Quality and Safety in Health Care*, 14, no. 6 (2005), 401-407; Mazzocco, Karen., et al., "Surgical team behaviors and patient outcomes," *American Journal of Surgery*, 197, no. 5 (2009), 678-685; Mistry, Kshitij, et al., "Communication error during pot-operative patient hand off iin the pediatric intensive care unit," *Critical Care Medicine*, 33, no. 12 (2005), A12; Segall, Noa, et al., "Can we make postoperative patient handovers safer? A systematic review of the literature," *Anesthesia & Analgesia*, 115, no. 1 (2012): 110.

¹⁶ Mistry, Kshitij, et al., "Communication error during pot-operative patient hand off iin the pediatric intensive care unit," Critical Care Medicine, 33, no. 12 (2005), A12; Nagpal, Kamal A., et al., "Evaluation of postoperative handover using a tool to assess information transfer and teamwork," *Annals of Surgery*, 253, no. 4 (2011), 831-837; Catchpole, Ken. R., et al., "Patient handover from surgery to intensive care: using Formula 1 pit-stop and aviation models to improve safety and quality," *Paediatric Anaestheisa*, 17, no. 5 (2007), 470-478.

¹⁷ Segall, Noa, et al., "Can we make postoperative patient handovers safer? A systematic review of the literature," *Anesthesia & Analgesia*, 115, no. 1 (2012): 107.

18 Segall, Noa, et al., "Can we make postoperative patient handovers safer? A systematic review of the literature," *Anesthesia & Analgesia*, 115, no. 1 (2012): 102.

¹⁹ Chow, Clifton M.,et al., "Mission impossible: Treating serious mental illness and substance use co-occurring disorder with integrated treatment: a meta-analysis," *Mental Health & Substance Use: Dual Diagnosis,* 6, no. 2 (2013): 150-168.

²⁰ Wu, Albert W. et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 770.

²¹ Rothschild, Jeffrey M., et al., "The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care," *Critical care medicine*, 33, no. 8 (2005): 1694-700.

²² Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal*, 180, no. 9 (2009): 936-937.

²³ Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care," *Critical Care*, 12, no. 2 (2008): 1-2.

²⁴ Segall, Noa, et al., "Can we make postoperative patient handovers safer? A systematic review of the literature," *Anesthesia & Analgesia*, 115, no. 1 (2012): 102-115.

25 Berlinger, N. and A.W. Wu, "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Errors." *Journal of Medical Ethics*, 31, no 2 (2005): 107-108; Penson, Richard T. et al., "Medical Mistakes: a Workshop on Personal Perspectives," *The Oncologist*, 6 no. 1(2001): 92-93.

²⁶ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of emergency medicine*, 48, no. 5 (2006): 527-529; Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care," *Critical Care*, 12, no. 2 (2008): 1-5.

²⁷ Gallagher, Thomas H., et al., "Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients," *Archives of Internal Medicine*, 166, no. 15 (2006), 1585-1593.

²⁸ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Jama*, 289, no. 8 (2003): 1004; Berlinger, N. and A.W. Wu, "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Errors," *Journal of Medical Ethics*, 31, no 2 (2005): 106; Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of emergency medicine*, 48, no. 5 (2006): 525.

²⁹ Rosner, Fred, et al., "Disclosure and Prevention of Medical Errors," *JAMA Internal Medicine*, 160, no. 14 (2000): 2089-2092. Wu, Albert W., et al., "Do house officers learn from their mistakes?," *JAMA*, 265, no. 16 (1991): 2089-2094; Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Jama*, 289, no. 8 (2003): 1001-1007; Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of emergency medicine*, 48, no. 5 (2006): 523-531; Sorokin, Rachel, et al., "Attitudes about patient safety: a survey of physicians-in-training," *American Journal of Medical Quality*, 20, no. 2 (2005), 70-77.

³⁰ Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of emergency medicine*, 48, no. 5 (2006): 523-531.

³¹ Hobgood, Cherri, et al., "Medical errors: what and when: what do patients want to know? *Academic Emergency Medicine*, 9, no. 11 (2002): 1156-1161; Mazor, Kathleen. M., et al., "Health plan members' views about disclosure of medical errors," *Annals of Internal Medicine*, 140, no. 6 (2004): 409-418.

³² Hobgood, Cherri, et al., "Medical errors: what and when: what do patients want to know? *Academic Emergency Medicine*, 9, no. 11 (2002): 1156-1161.

³³ Nau, Konrad, "Disclosing Medical Error to Patients," Retrieved from: <u>http://slideplayer.com/slide/7041421/</u>. Slide7, Accessed July, 2014; Moskop, John C. et al., "Emergency Physicians and Disclosure of Medical Errors," Annals of Emergency Medicine, 48, no. 5 (2006): 524-525.

³⁴ Hobgood, Cherri, and Armando Hevia, "Disclosing Medical Error: A Professional Standard," *Hospital Physician*, 40, no. 5 (2004): 41-52.

³⁵ American Medical Association, "Principles of Medical Ethics" from <u>http://www.ama-assn.org/ama/pub/ physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page.</u> Accessed February 5, 2016.

³⁶ American College of Emergency Physicians, "Code of Ethics for Emergency Physicians" from http://www.emcongress.org/barcelona03/handouts/larkin_2.pdf. Accessed February 5, 2016.

³⁷ Moskop, John C. et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of Emergency Medicine*, 48, no. 5 (2006): 524.

³⁸ Gabbard, Glen. O., and Carol Nadelson, "Professional boundaries in the physician-patient relationship," *JAMA*, 273, no. 18 (1995): 1445-1449.

³⁹ Brock, D. W., "Informed Consent," In *Health Care Ethics*, eds. D. VanDeVeer, and T. Regan (Philadelphia, PA: Temple University Press, 1987), 98-116.

⁴⁰ Delany, C., "Making a difference: incorporating theories of autonomy into models of informed consent," *Journal of Medical Ethics*, 34, no. 9 (2008): 1-5; Gabbard, Glen. O., and Carol Nadelson, "Professional boundaries in the physician-patient relationship," *JAMA*, 273, no. 18 (1995): 1445-1449.

⁴¹ Marchev, Mimi, et al., "How States Report Medical Errors to the Public: Issues and Barriers," *Onceinaweil.org*. Retrieved from: <u>http://www.nashp.org/sites/default/files/reporting_medical_errors.pdf</u>. 22-25, Accessed Mar 13, 2016.

⁴² Schaefer, Kristen G, and Susan D Block, "Physician Communication with Families in the ICU: Evidence-Based Strategies for Improvement," *Current opinion in critical care*, 15, no. 6 (2009): 569-77; Furrow, Barry R., "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction," *Widener L. Rev*, 12 (2005): 28-31; Massachusetts Coalition for the Prevention of Medical Errors, "When Things for Wrong: Responding to Adverse Events, "Retrieved from:

http://www.macoalition.org/documents/respondingToAdverseEvents.pdf .11-15, Accessed Mar 15, 2016.

⁴³ Nelson, Judith E., et al., "Communication About Chronic Critical Illness," *Archives of Internal Medicine*, 167, no. 22 (2007): 2509-2515; Siegel, Mark D., "End-of-Life Decision Making in the ICU," *Clinics in Chest Medicine*, 30, no. 1 (2009): 181-194.

⁴⁴ Schaefer, Kristen G. and Susan D. Block, "Physician communication with families in the ICU: evidence-based strategies for improvement," *Current Opinion in Critical Care*, 557, no. 6 (2009): 569-577.

⁴⁵ Torke, Alexia M., et al., "Substituted Judgment: The Limitations in Surrogate Decision Making," *Journal of General Internal Medicine*, 23, no. 9 (2008): 1514-1517; Levy, Mitchell. M. "Shared decision-making in the ICU: Entering a new era," *Critical Care Medicine*, 32, no. 9 (2004): 1966-1968.

⁴⁶ Schaefer, Kristen G. and Susan D. Block, "Physician communication with families in the ICU: evidence-based strategies for improvement," *Current Opinion in Critical Care*, 557, no. 6 (2009): 574.

⁴⁷ Zier, Lucas S., et al., "Surrogate Decision Makers' Responses to Physicians' Predictions of Medical Futility," *Chest Journal*, 136, no. 1 (2009): 110-117.

⁴⁸ Norton, Sally A., et al., "Proactive palliative care in the medical intensive care unit: effects on length of stay for selected high-risk patients," *Critical Care Medicine*, 35, no. 6 (2007): 1530–1535; Lilly, Craig, M., et al., "An intensive communication intervention for the critically ill," *American Journal of Medicine*, 109, no. 6 (2000): 469-475; Curtis, J. Randall and Douglas B. White, "Practical guidance for evidence-based ICU family conferences," *Chest*, 134, no. 4 (2008): 835-843.

⁴⁹ Schaefer, Kristen G. and Susan D. Block, "Physician communication with families in the ICU: evidence-based strategies for improvement," *Current Opinion in Critical Care*, 557, no. 6 (2009): 570.

⁵⁰ Selph, R. Brac, et al., "Empathy and Life Support Decisions in Intensive Care," *Journal of General Internal Medicine*, 23, no. 9 (2008): 1311-1317.

⁵¹ Schaufel, Margrethe Aase, et al., "So you think I'll survive?": A qualitative study about doctor-patient dialogues preceding high-risk cardiac surgery or intervention," *Heart*, 95, no. 15 (2009): 1245-1249.

52 White, Douglas, M., et al., "The Language of Prognostication in Intensive Care Units," *Medical Decision Making*, 30, no. 1 (2010): 76-83.

⁵³ Christakis, Nicholas A., and Theodore J. Iwashyna, "Attitude and Self-reported Practice Regarding Prognostication in a National Sample of Internists," *Archives of Internal Medicine*, 158, no. 21 (1998): 2389-2395; Wenrich, Marjorie D., et al., "Communicating with dying patients within the spectrum of medical care from terminal diagnosis to death," *Archives of Internal Medicine*, 161, no. 6 (2001): 868-874.

⁵⁴ Mack, Jennifer W., et al., "Hope and Prognostic Disclosure," *Journal of Clinical Oncology*, 25, no. 35 (2008): 5636-5642.

55 Apatira, Latifat, et al., "Hope, Truth, and Preparing for Death: Perspectives of Surrogate Decision Makers," *Annals of Internal Medicine*, 149, no. 12 (2008): 861-868.

⁵⁶ Siegel, Mark D., "End-of-Life Decision Making in the ICU," *Clinics in Chest Medicine*, 30, no. 1 (2009): 181-194; Heyland, Daren K., et al., "Dying in the ICU: perspectives of family members" *Chest Journal*, 124, no. 1 (2003): 392-397.

57 Marchev, Mimi, et al., "How States Report Medical Errors to the Public: Issues and Barriers," *Onceinaweil.org*. Retrieved from: <u>http://www.nashp.org/sites/default/files/reporting_medical_errors.pdf</u>. 22-25, Accessed Mar 13, 2016.

⁵⁸ Schaefer, Kristen G. and Susan D. Block, "Physician communication with families in the ICU: evidence-based strategies for improvement," *Current Opinion in Critical Care*, 557, no. 6 (2009): 569-577; Furrow, Barry R., "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction," *Widener L. Rev*, 12 (2005): 28-31; Massachusetts Coalition for the Prevention of Medical Errors, "When Things for Wrong: Responding to Adverse Events," Retrieved from:

http://www.macoalition.org/documents/respondingToAdverseEvents.pdf 11-15,

Accessed Mar 15, 2016.

59 Siegel, Mark D., "End-of-Life Decision Making in the ICU," *Clinics in Chest Medicine*, 30, no. 1 (2009): 181-194.

⁶⁰ Kagawa-Singer, Marjorie and Leslie J. Blackhall. "Negotiating cross-cultural issues at the end of life: 'you got to go where he lives,'" *JAMA*, 286, no. 23 (2001): 2993-3001.

⁶¹ Curtis, J. Randall and Douglas B. White, "Practical guidance for evidencebased ICU family conferences," *Chest*, 134, no. 4 (2008): 835-843.

⁶² Truog, Robert D., et al., "Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American College of Critical Care Medicine," *Critical Care Medicine*, 36, no. 3 (2008): 953-963.

⁶³ Civetta, Joseph M., "Futile care or caregiver frustration? A Practical Approach," *Critical Care Medicine*, 24, no. 2 (1996): 346-351.

⁶⁴ Berger, Jeffrey T., et al., "Surrogate decision making: Reconciling ethical theory and clinical practice," *Annals of Internal Medicine*, 149, no. 1 (2008): 49-53.

65 Kagawa-Singer, Marjorie and Leslie J. Blackhall. "Negotiating cross-cultural issues at the end of life: 'you got to go where he lives,'" *JAMA*, 286, no. 23 (2001): 2993-3001.

66 Shanawani, Hasan., et al., "Meeting physicians' responsibilities in proving endof-life care," *Chest*, 133, no. 3 (2008): 775-786.

67 Atkinson, Simon, et al., "Identification of futility in intensive care," *Lancet*, 344, no. 8931 (1994): 1203-1206.

⁶⁸ Curtis, J. Randall, et al., "The attitudes of patients with advanced AIDS toward use of the medical futility rationale in decisions to forgo mechanical ventilation," *Archives of Internal Medicine*, 160 no. 11 (2000): 1597-1601.

⁶⁹ Vincent, Jean-Louis, "Forgoing life support in west European intensive care units: the results of an ethical questionnaire," *Critical Care Medicine*, 27, no. 8 (1999): 1626-1633.

⁷⁰ Cher, Daniel J. and Leslie A. Lenert. "Method of Medicare reimbursement and the rate of potentially ineffective care of critically ill patients," *JAMA*, 278, no. 12 (1997): 1001-1007.

⁷¹ Classen, David C., et al., "Global Trigger Tool Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured," *Health Affairs*, 30, no. 4 (2011): 581-589.

⁷² Nilsson. Lena, et al., "Adverse events are common on the intensive care unit: Results from a structured record review," *Acta Anaesthesiologica Scanddinavica*, 56, no. 8 (2012): 959-965. ⁷³ Thomasson, Joseph, et al., "Quality of Documented Consent for the Deescalation of Care on a General and Truma Surgery Service," *The American Surgeon*, 77 no. 7 (2011): 883-887.

⁷⁴ Bernat, James L. and Lynn M. Peterson, "Patient-Centered Informed Consent in Surgical Practice," *Archives of JAMA Surgery*, 141 no. 1 (2006): 86-92.

75 Appelbaum, Paul S. and Thomas Grissso, "Assessing patients' capacities to consent to treatment," *New England Journal of Medicine*, 319, no. 25 (1988): 1635-1638; Piper Jr., August. "Truce on the battlefield: A proposal for a different approach to medical informed consent," *Journal of Law and Medical Ethics*, 22, no. 4 (1994): 301-317.

⁷⁶ Canterbury v Spence, 464 F2d 772 (DC Cir 1972), cert denied, 409 Us 1064 (1972).

77 Gert, Heather J., "Avoiding Surprises: A model for informing patients," *Hastings Center Report*, 32, no. 5 (2002): 23-32.

78 Bernat, James L. and Lynn M. Peterson, "Patient-Centered Informed Consent in Surgical Practice," *Archives of JAMA Surgery* 141 no. 1 (2006): 86-92.

⁷⁹ Abaunza, Hernando and Klaus Romero, "Elements for Adequate Informed Consent in the Surgical Context," *World Journal of Surgery*, 38, no. 7 (2014): 1594-1604.

⁸⁰ Gluck, Eric H. and Daniel O. Dugan, "Informed Consent in the Intensive Care Unit," *Critical Care Medicine*, 6, no. 2 (2001): 1-12.

⁸¹ Hopper, Kenneth D., et al., "The readability of currently used surgical/procedure consent forms in the United States," *Surgery, 123*, no. 5 (1998): 496-503.

⁸² Vodinh, J., et al., "Risk factors of postoperative pulmonary complications after vascular surgery," *Surgery*, 109, no. 3 (1989): 360-365.

⁸³ Bernat, James L. and Lynn M. Peterson, "Patient-Centered Informed Consent in Surgical Practice," *Archives of JAMA Surgery*, 141 no. 1 (2006): 86-88.

⁸⁴ Bernat, James L. and Lynn M. Peterson, "Patient-Centered Informed Consent in Surgical Practice," *Archives of JAMA Surgery*, 141 no. 1 (2006): 86.

85 Bernat, James L. and Lynn M. Peterson, "Patient-Centered Informed Consent in Surgical Practice," *Archives of JAMA Surgery*, 141 no. 1 (2006): 86-92; Wikler, Daniel, "Patient interests: clinical implications of philosophical distinctions," *Journal of the American Geriatric Society*, 36, no. 10 (1988): 951-958.

⁸⁶ Gallagher, Thomas H., et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," *Journal of the American Medical Association* 289, no. 8 (2003): 1001-1002. ⁸⁷ Wu, Albert W. et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," *Journal of General Internal Medicine* 12, no. 12 (1997): 770-773.

88 Sayeed, Sadath A. and Robert D. Troug. "Malpractice and Disclosure of Errors," *America Academy of Pediatrics*. Retrieved from: <u>https://www2.aap.org/sections/bioethics/PDFs/ Curriculum_Session8.pdf</u>, 51-56, <u>Accessed Mar, 2015.</u>

⁸⁹ Silveira, Maria J., et al., "Advance Directive Completion by Elderly Americans: A Decade of Change," *Journal of the American Geriatrics Society*, 62 no. 4 (2014): 706-710.

⁹⁰ Nicholas, Lauren Hersch, et al., "Regional Variation in the Association Between Advance Directives and End-of-Life Medicare Expenditures," *Journal of the American Medical Association*, 306 no. 13 (2011): 1447-1453; Teno, Joan M., et al., "Association Between Advance Directives and Quality of End-of-Life Care: A National Study," *Journal of the American Geriatrics Society*, 55 no. 2 (2007): 189-194; White, Douglas B., and Robert M. Arnold, "The evolution of advance directives," *Journal of the American Medical Association*, 306 no. 13 (2011): 1485-1486.

⁹¹ Shapiro, Susan P. "Advance Directives: The Elusive Goal of Having the Last Word, "*Journal of the National Academy of Elder Law Attorneys*, 8 no. 2 (2012): 205-232; Ditto, Peter H., et al., "Advance Directives as Acts of Communication; A Randomized Controlled Trial," *Archives of Internal Medicine*, 161, no 3 (2001): 421-430; Fonk, James, et al., "The Effect of Advance Directives on End-of-Life Cost Experience," *Journal of Health Care for the Poor and Underserved*, 23, no. 3 (2012): 1137–56.

⁹² Gutierrez, Karen, M., "Prognostic categories and timing of negative prognostic communication from critical care physicians to family members at end-of-life in an intensive care unit," *Nursing Inquiry*, 20 no. 3 (2013): 232-244.

⁹³ Daugherty, Christoher K. and Fay J. Hlubocky., "What are terminally ill cancer patients told about their expected deaths? A study of cancer physicians' self-reports of prognosis disclosure," *Journal of Clinical Oncology*, 26, no. 36 (2008): 988-993.

⁹⁴ Curtis J. Randall, "Communicating about end-of-life care with patients and families in the intensive care unit," *Critical Care Clinics*, 20, no. 3 (2004): 363–80; Russ, Ann J. and Sharon R. Kaufman, "Family perceptions of prognosis, silence and the 'suddenness' of death," *Culture, Medicine and Psychiatry*, 29, no. 1 (2005): 103–23; Parker Sharon M., et al., "A systematic review of prognostic end-of-life communication with adults in the advanced stages of a life- limiting illness: Patient-caregiver preferences for the content, style, and timing of Information," *Journal of Pain and Symptom Management*, 34, no. 1, (2007): 81–93.

⁹⁵ Gutierrez, Karen, M., "Prognostic categories and timing of negative prognostic communication from critical care physicians to family members at end-of-life in an intensive care unit," *Nursing Inquiry*, 20 no. 3 (2013): 232-244.

⁹⁶ Schulman-Green, et al., "Nurses' communication of prognosis and implications for hospice referral: A study of nurses caring for terminally ill hospitalized patients," *American Journal of Critical Care*, 14 no. 1 (2005): 64–70.

97 LeClaire Michelle M., et al., "Communication of prognostic information for critically ill patients," *Chest*, 128, no. 3 (2005): 1728–35.

⁹⁸ Shapiro, Susan P. "Advance Directives: The Elusive Goal of Having the Last Word, " *Journal of the National Academy of Elder Law Attorneys*, 8 no. 2 (2012): 205-232.

⁹⁹ Shapiro, Susan P. "Advance Directives: The Elusive Goal of Having the Last Word, " *Journal of the National Academy of Elder Law Attorneys*, 8 no. 2 (2012): 205-232.

100 Shapiro, Susan P. "Advance Directives: The Elusive Goal of Having the Last Word," *Journal of the National Academy of Elder Law Attorneys*, 8 no. 2 (2012): 205-232.

¹⁰¹ Jenicek, Milos, *Medical Error and Harm: Understanding, Prevention and Control* (New York, NY: CRC Press, 2011), 1-5.

¹⁰² The Joint Commission, "TJC Sentinel Events and Alerts". Retrieved from: <u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf</u>, Accessed, May 15,2015; Williams, Mallory, et al., "Measuring Communication in the Surgical ICU: Better Communication Equals Better Care," *Journal of the American College of Surgeons*, 210, no. 1 (2010): 17-22.

103 Menzel, Linda K., "Factors related to the emotional responses of intubated patients to being unable to speak," *Heart Lung: The Journal of Acute and Critical Care*, 27, no. 4 (1998): 819-826; Magnus, Victoria S., and Leisa Turkington, "Communication interaction in ICU- Patient and staff experiences and perceptions," *Intensive and Critical Care Nursing*, 22, no. 3 (2006): 167-180.

104 Cox, Christopher E., et al., "Expectations and outcomes of prolonged mechanical ventilation," *Critical Care Medicine*, 35, no. 2 (2009): 2888-2894; Milic, Michelle M., et al., "Communicating with Patients' Families and Physicians About Prognosis and Goals of Care," *American Journal of Critical Care*, 24, no. 4 (2015): e56-e64; White, Douglas B., et al., "Prognostication during physician-family discussions about limiting life support in intensive care units," *Critical Care Medicine*, 35, no. 2 (2007): 442-448.

¹⁰⁵ Anderson, Wendy G., et al., "Posttraumatic stress and complicated grief in family members of patients in the intensive care unit," *Journal of General Internal Medicine*, 23, no. 11 (2008): 1871-1876; McAdam, Jennifer L., and Kathleen Puntillo, "Symptoms experienced by family members of patients in intensive care units," *American Journal of Critical Care*, 18, no. 3 (2009): 200-209; Azoulay, Elie, et al., "Half the families of intensive care units patients experience inadequate communication with physicians," *Critical Care Medicine*, 28, no. 8 (2000): 3044-3049; Heyland, Daren K., et al., "Family satisfaction with care in the intensive care unit: Results of a multiple center study," *Critical Care Medicine*, 30, no. 7 (2002): 1413-1418. ¹⁰⁶ Truog, Robert D., et al., "Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American Academy of Critical Care Medicine," *Critical Care Medicine*, 36, no. 3 (2008): 953-963.

¹⁰⁷ Collins, Sarah A., et al., "Model development for EHR interdisciplinary information exchange of ICU common goals," *International Journal of Medical Informatics*, 80, no. 8 (2011): e141-e149; Douglas, Stephen, et al., "The work of adult and pediatric intensive care unit nurses," *Nursing Research*, 62, no. 1 (2013): 50-58.

¹⁰⁸ Mardon, Russell E., et al., "Exploring relationships between hospital patient safety culture and adverse events," *Journal of Patient Safety*, 6, no. 4 (2010): 226-232.

109 Donchin, Yoel., et al., "A look into the nature and causes of human errors in the intensive care unit," *Critical Care Medicine*, 23, no. 2 (1995): 294-300; Pronovost, Peter. J., et al., "Toward learning from patient safety reporting systems," *Journal of Critical Care*, 21, no. 4 (2006): 305-315.

110 Baggs, Judith G., et al., "Association between nurse-physician collaboration and patient outcomes in three intensive care units," *Critical Care Medicine*, 27, no. 9 (1999): 1991-1998

111 Li, Pin, Jamie M. et al., "Stakeholder views regarding patient discharge from intensive care: Suboptimal quality and opportunities for improvement," *Canadian Respiratory Journal*, 22, no. 2 (2015): 109-118.

¹¹² Ong, Mei Sing, and Enrico Coiera, "A systematic review of failures in handoff communication during intrahospital transfers," *Joint Commission Journal on Quality and Patient Safety*, 37, no. 6 (2011): 274-284.

113 Bell, Chaim M., et al., "Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases," *Journal of the American Medical Association*, 306, *no.* 8 (2011): 840-847.

114 Halasyamani, Lakshmi, et al., "Transition of care for hospitalized elderly patients – development of a discharge checklist for hospitalists," *Journal of Hospital Medicine*, 1, no. 6 (2006): 354-360.

¹¹⁵ Arora, Vaneet M., et al., "Problems after discharge and understanding of communication with their primary care physicians among hospitalized seniors: A mixed methods study," *Journal of Hospital Medicine*, 5, no. 7 (2010): 385-391; Ellis, Kerri, A., et al., "Standardizing communication from acute care providers to primary care providers on critically ill adults," *American Journal of Critical Care*, 24, no. 6 (2015): 496-500.

116 Bell, Chaim. M., et al., "Association of communication between hospital-based physicians and primary care providers with patient outcomes," *Journal of General Internal Medicine 24*, no. 3 (2009): 381-386; Ellis, Kerri, A., et al., "Standardizing communication from acute care providers to primary care providers on critically ill adults," *American Journal of Critical Care*, 24, no. 6 (2015): 496-500.

117 Burton, R., et al., "Improving Care Transitions," Retrieved from: http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=76, What's the issue?, Accessed Feb 26, 2016. 118 Watts, R., J. Pierson, and H. Gardner, "Co-ordination of the discharge planning process in critical care," *Journal of Clinical Nursing*, 16, no. 1 (2007): 201-205; Kaufman, Jon., et al., "A handoff protocol from the cardiovascular operating room to cardiac ICU is associated with improvements in care beyond the immediate postoperative period," *Joint Commission Journal on Quality and Patient Safety*, 39, no. 7 (2013): 306– 311.

119 Li, Pin, Jamie M. et al., "Stakeholder views regarding patient discharge from intensive care: Suboptimal quality and opportunities for improvement," *Canadian Respiratory Journal*, 22, no. 2 (2015): 109-118.

120 Bonifacio, Alberto S., et al., "Handovers from the OR to the ICU," *International Anesthesiology Clinics*, 51, no. 1 (2013): 43-61; Lane-Fall, et al., "Handoffs and transitions in critical care (HATRICC): Protocol for a mixed methods study of operating room to intensive care unit handoffs," Retrieved from: <u>http://www.biomedcentral.com/1471-2482/14/96</u>, Accessed Feb 25, 2016.

121 Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of Emergency Medicine*, 48, no. 5 (2006): 524-525.

122 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal*, 180, no. 9 (2009): 937-938; Alberstein, Mical, and Nadav Davidovitch, "Apologies in the Healthcare System: From Clinical Medicine to Public Health," *Law and Contemporary Problems*, 74, no. 3 (2011): 151-175.

123 Lazare, Aaron, "Apology in Medical Practice: An emerging clinical skill," *Journal of the American Medical Association*, 296, no. 11 (2006): 1401-1404.

124 Alberstein, Mical, and Nadav Davidovitch, "Apologies in the Healthcare System: From Clinical Medicine to Public Health," *Law and Contemporary Problems*, 74, no. 3 (2011): 151-175.

125 Alberstein, Mical, and Nadav Davidovitch, "Apologies in the Healthcare System: From Clinical Medicine to Public Health," *Law and Contemporary Problems*, 74, no. 3 (2011): 151-175; Taft, Lee, "Apology and Medical Mistake: Opportunity of Foil?," *Annals of Health Law*, 14, no. 1 (2005), 55-94.

126 Fallowfield, Lesley, "Communication with patients after errors," *Journal of Health Services Research & Policy*, 15, no. 1 (2010): 56-59; Lazare, Aaron, "Apology in Medical Practice: An emerging clinical skill," *Journal of the American Medical Association*, 296, no. 11 (2006): 1401-1404.

127 Alberstein, Mical, and Nadav Davidovitch, "Apologies in the Healthcare System: From Clinical Medicine to Public Health," *Law and Contemporary Problems*, 74, no. 3 (2011): 151-175.

128 Kohn, Linda T., et al., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy, 2000), 1-2.

129 Alberstein, Mical, and Nadav Davidovitch, "Apologies in the Healthcare System: From Clinical Medicine to Public Health," *Law and Contemporary Problems*, 74, no. 3 (2011): 151-175.

130 Robbennolt, Jennifer K., "Apologies and Legal Settlement: An empirical examination," *Michigan Law Review*, 102, no. 3 (2003): 460-465.

131 Jesson, Lucinda E., and Peter B. Knapp, "My lawyer told me to say I'm sorry: Lawyers, Doctors, and Medical Apologies," *William Mitchell Law Review*, 35, no. 2 (2009): 1410-1452; Gailey, Lauren, "I'm Sorry" as Evidence? Why the Federal Rules of Evidence Should Include a New Specialized Relevance Rule to Protect Physicians," *Defense Council Journal*, 82, no. 2 (2015): 172-184.

¹³² Hickson, Gerald B., et al., "Factors that Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries," *Journal of the American Medical Association*, 267, no. 10 (1992): 1359-1363.

¹³³ Gailey, Lauren, "I'm Sorry" as Evidence? Why the Federal Rules of Evidence Should Include a New Specialized Relevance Rule to Protect Physicians," *Defense Council Journal*, 82, no. 2 (2015): 172-184.

134 Jesson, Lucinda E., and Peter B. Knapp, "My lawyer told me to say I'm sorry: Lawyers, Doctors, and Medical Apologies," *William Mitchell Law Review*, 35, no. 2 (2009): 1410-1452.

¹³⁵ Mastroianni, Anna C., et al., "The Flaws in State 'Apology' and 'Disclosure' Laws Dilute Their Intended Impact on Malpractice Suits," *Health Affairs*, 29, no. 9 (2010): 1611-1619.

136 Jesson, Lucinda E., and Peter B. Knapp, "My lawyer told me to say I'm sorry: Lawyers, Doctors, and Medical Apologies," *William Mitchell Law Review*, 35, no. 2 (2009): 1410-1452.

137 Minnesota Hospital Association, "Adverse Health Event Report System: Indicates Care is More Transparent," Safer. Retrieved from: <u>http://www.health.state.mn.us/patientsafety/ae/09ahereportLpdf</u>. Accessed Mach 5, 2016.

138 Minnesota Department of Health, "Adverse Healthcare Events Reporting System: What Have We Learned?," Retrieved from:

http://www.health.state.mn.us/patientsafety/publications/09aheeval.pdf. Accessed March 5, 2016.

139 Children's Hospitals and Clinics of Minnesota, "What we've learned: Stories and milestones from the patient safety journey," Retrieved from: http://www.childrensmn.org/web/aboutus/072550.pdf. Accessed March 5, 2016.

¹⁴⁰ Jesson, Lucinda E., and Peter B. Knapp, "My lawyer told me to say I'm sorry: Lawyers, Doctors, and Medical Apologies," *William Mitchell Law Review*, 35, no. 2 (2009): 1410-1452. 141 Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032.

¹⁴² Moskop, John C., et al., "Emergency Physicians and Disclosure of Medical Errors," *Annals of Emergency Medicine*, 48, no. 5 (2006): 524-525.

143 Camiré, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure," *Canadian Medical Association Journal*, 180, no. 9 (2009): 937-938.

144 Relis, Tamara, *Perceptions in Litigation and Mediation: Lawyers, Defendants Plainiffs, and Gendered Parties*, (New York, NY: Cambridge University Press, 2009).

145 Liebman, Carol B., and Chris Stern Hyman, "Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania," Retrieved from:

http://www.pewtrusts.0rg/~/media/legacy/uploadedfiles/wwwpewtmstsorg/reports/ medical_liability/LiebmanReportpdf.pdf. Accessed March 5, 2016; Metzloff, Thomas, et al., "Empirical Perspectives on Mediation and Malpractice," *Law and Contemporary Problems*, 60, no. 1 (1997): 107-152.

146 Relis, Tamara, *Perceptions in Litigation and Mediation: Lawyers, Defendants Plainiffs, and Gendered Parties*, (New York, NY: Cambridge University Press, 2009).

¹⁴⁷ Morreim, E. Haavi, "Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank," *Ohio State Journal on Dispute Resolution*, 27, no. 1 (2012): 109-177; Liebman, Carol B., and Chris Stern Hyman, "Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania," Retrieved from:

http://www.pewtrusts.0rg/~/media/legacy/uploadedfiles/wwwpewtmstsorg/reports/ medical liability/LiebmanReportpdf.pdf. Accessed March 5, 2016.

148 Garbutt, Jane, et al., "Lost Opportunities: How Physicians Communicate About Medical Errors," *Health Affairs*, 27, no. 1 (2008): 246-255; Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032; Metzloff, Thomas, et al., "Empirical Perspectives on Mediation and Malpractice," *Law and Contemporary Problems*, 60, no. 1 (1997): 107-152.

149 Localio, A. Russell, et al., "Relation between malpractice claims and adverse events due to negligence: Results of the Harvard Medical Practice Study III," *New England Journal of Medicine*, 325, no. 4 (1991): 245-251.

¹⁵⁰ Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032.

¹⁵¹ Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032. 152 Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032.

153 Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032.

154 Morreim, E. Haavi, "Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank," *Ohio State Journal on Dispute Resolution*, 27, no. 1 (2012): 109-177; Studdert, David M., et al., "Claims, Errors and Compensation Payments in Medical Malpractice Litigation," *The New England Journal of Medicine*, 354, no. 19 (2006): 2029-2032.

155 Reddy, Bhavani S., "Apology and Medical Error Full Disclosure Programs: Is Saying 'I'm Sorry' the Answer to Reducing Hospital Legal Costs?," *University of Houston Law Center Health Law Perspectives* (2006). Retrieved from: http://www.law.uh.edu/healthlaw/perspectives/2006\(BR) ApologiesFinal.pdf. Accessed March 5, 2016; Mello, Michelle M. and Thomas H. Gallagher, "Malpractice Reform – Opportunities for Leadership by Health Care Institutions and Liability Insurers," New England Journal of Medicine, 362, (2010): 1353-1356

¹⁵⁶ Morreim, E. Haavi, "Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank," *Ohio State Journal on Dispute Resolution*, 27, no. 1 (2012): 109-177

Chapter 6. Systemic Endeavors to Diminish Medical Errors in the Hospital ICU Introduction

The previous chapter focused on protocols relating to the disclosure of medical errors once they have occurred; this chapter of the dissertation, its sections, and subsections together with the protocols and recommendations they describe concentrate on efforts and procedures to prevent medical errors before they happen to the extent humanly possible, or when not, to lessen the severity of and mitigate the harm caused by medical errors. These protocols include prevention planning, communication, administering medication, as well as preventing and managing equipment failure and system failure. Subsequently, the chapter's analysis will consider the history of tort reform in the U.S., describing the direction that such reforms need to take in order to ensure justice for all parties and to discourage medical errors. Further recommendations concern the educational system for training future physicians and other healthcare professionals, which along with legal reforms, are aimed at getting the medical professional, as well as the administration of medical facilities and institutions to handle medical errors with the high standards of biomedical ethics which they claim in theory to espouse.

Chapter 6 is divided into six sections, which will cover respectively; 1) Prevention planning protocols, 2) Communication protocols, 3) Medication protocols, 4) Equipment failure protocols, 5) System failure protocols, and 6) Tort and medical education reform.

The first section discusses organized effort to minimize if not preempt the occurrence of adverse events, considering the role and potential of information technology. Since, they have long been a practical cornerstone in forestalling adverse events, cleaning and decontamination techniques are analyzed here in detail. The potential of teamwork to reduce errors is described in parts of this chapter; in conjunction with this emphasis, the second section analyzes how effective communication, both internally and external to the medical institution should function. The section concerning medication protocols highlights three innovations that promise to significantly reduce, or in some cases eliminate specific causes or sources of this very common classes of medical errors. In terms of technology, computerized physician order entry in particular does away with a number of causes of medication error that have plagued the traditional prescription and treatment process. While the benefits of eliminating the overworking of physicians and other involved personnel are understood, if difficult to get facilities to commit to, an innovative approach, feasible at least for the ICU is to include pharmacists in patient rounds. After these sections, the two subsequent one will focus on the need for and obstacles to creating effective protocols for the prevention of equipment failure and system failure, respectively. In both areas, complexity as well as other features common to the two make preparing to identify risks for and the occurrence of, to avoid or minimize them, and to deal with them once they have been discovered, uniquely difficult among the various root causes of errors and adverse events.

While recommendations for improving the prevention or minimization of

medical errors, the hospital ICU and elsewhere are incorporated wherever appropriate, the final section of this chapter is devoted to badly needed changes in both the legal foundations for handling claims of negligence and malpractice and the system of educating future medical professionals.

Chapter 6.A. Prevention Planning Protocols in the Hospital ICU

The prevention, or at least to the extent possible, the minimization of medical errors in the hospital ICU or elsewhere in medicine is the primary aim behind planning; furthermore the achievement of this goal necessitates anticipating foreseeable risks and tendencies toward error, which in turn requires that planners know the circumstances that foster the occurrence of errors comprehend the characteristics of these events and be able to realistically assess the likelihood of their happening.1

This section on planning protocols is divided into two major parts, with the latter containing a further four subdivisions. As presented, they include 1) Prophylaxis and Monitoring Procedures and 2) Steps to Avoid Adverse Events. This second part is segmented into subsections dealing with: a) The Role of Information Technology, b) Cleaning, Disinfection, and Sterilization Procedures, c) Investigative and Evaluative Procedures, and d) Reorganization of Medical Team Operations in the ICU. Chapter 6.A.1. Prophylaxis and Monitoring Procedures

Chapter 6.A.1.i. Prophylaxis Procedures

The term *prophylaxis procedures* refers to tangible actions taken in the course of the diagnosis and treatment of a patient that are aimed at error prevention, implying that such must be a priority for hospitals in general and ICU departments specifically. Accurately assessing the probability of medical errors in advance enables the medical staff to take two preemptive measures- first, increasing vigilance in high risk places and procedures, and second, developing strategies and protocols ahead of time to forestall the anticipated type of error. The ultimate benefit of such efforts is more effective and accurate patient care. The majority of these prophylactic activities and strategies have been incorporated into established and widely available procedural checklists for all sorts of medical professionals from attending physicians and specialists such as cardiologists, anesthesiologists, and laboratory technicians to nurses and other care staff to follow in carrying out their respective duties.² The principle goal of this standardized approach is to guarantee that all procedures are not forgotten but are conducted, yet not repeated in so much as unnecessary duplication is not only a waste of resources, but could constitute a medical error causing harm in and of itself. The natural next step beyond the use of such checklists is the development of contingency plans to correct any omissions or consequences of repetitions. On a broader scale, such detailed understanding of the dayto-day functioning of the ICU enable more efficient general administration of the unit through sufficient staffing and supervision.3

The body of research literature available specifically focusing on medical errors points to the effectiveness of dividing errors for the sake of prevention into two types: 1) those which can be forestalled through improved medical management, typically relating to planning and implementation; and 2) those which typically can be prevented through appropriate interventions in course of diagnosis, treatment, or specifically the administration of medication. A significant portion of the potential advantages of these checklist lies in their timely and continuous documentation of any and all occurrences, in turn reducing liability in the form of alleged negligence while assisting in prevention of future errors by enabling the regular improvement of prophylactic protocols.4

Chapter 6.A.1.ii. Monitoring Procedures

As typically employed, the general term *monitoring procedures* is not restricted in scope to overseeing the treatment plan of the patient and its progress, but rather includes the overview of standard procedures for administration of all routine activities of departments such as the ICU and for specific categories of treatment such as surgical interventions. As an integrated component of general monitoring, procedural checklists have been proven to contribute to noticeable decreases the rate of medical errors, as well as reducing the level of harm caused by those errors that did occur.⁵ The hospital ICU in particular is a unit in which the routine use of checklist program is not a foreign concept and is most essential, given the complexity of activities in the unit. At minimum, this list needs to be employed daily and must include: 1) the patient's status, in terms of code; 2) the patient's degree of sedation; 3) the patient's GI and DVT Prophylaxis, 4) the patient's levels of fluids, electrolytes, and nutrition; and 5) an assessment of the patient's

disposition. Beyond this minimal level of monitoring and data collection, it is important to frequently and regularly assess and record: 1) the I/O for each patient, recorded with daily cumulative totals; 2) each patient's IV access, with ready access to the dates and times at which the central lines were installed; and 3) for each patient, the occurrence and length of any administration of steroids for shock purposes. There are additional checklist items for any and all patient receiving mechanical ventilation, namely: 1) the date of initial intubation; 2) the gage of the tube; 3) the settings for the vent, specifically the mode, the rate, the volume, the pressure, the PEEP, and the FiO2); and 4) the peak/plateau pressure.6

A mnemonic device which serves as an additional monitoring reminder in numerous ICUs is termed FAST HUG, which stands for: 1) feeding, 2) analgesia, 3) sedation, 4) thromboembolic prophylaxis, 5) head of bed elevation, 6) stress ulcer prevention, and 7) glucose control. According to Vincent, "The concept of the Fast Hug, a simple, short mnemonic to highlight some key aspects in the general care of all critically ill patients, which should be considered at least once a day during rounds and, ideally, every time the patient is seen by any member of the care team. This approach helps involve all members of the critical care team, including nurses, physiotherapists, and respiratory therapists."⁷ The goal of all these checklist style monitoring measures is the comprehensive and systematic overseeing of the status of the patient's condition, his or her response to the prescribed course of treatments, adding up to an accurate prognosis for recovery or improvement.

A study conducted by Carless et al., investigated two procedures aimed at

enhancing quality of care in the ICU, namely facilitated incident monitoring (FIM) and medical chart review (MCR), looking at both comparatively as implemented by ICU staffs. In order to observe the FIM in practice, the researchers trained the participating ICU staff in the course of the latter group's ICU orientation. Subsequently, staff members were asked to recall incidents of medical errors they had been witness to or a part of; they were then asked to document each occurrence an incident report form. Meanwhile, as a component of more established quality control procedures, the investigators had MCR used as a part of peer review. In the final analysis, Carless et al. concluded that in an ICU setting, FIM was more effective at potential and real problem identification and alert than was MCR. Explaining their analysis, these researchers noted that FIM was superior to MCR in 1) yielding more contextualized data, revealing both more problems overall and specifically more, as well as a higher percentage of those deemed preventable, and 2) being easier to integrate with existing ICU clinical routines.s

Chapter 6.A.2. Steps to Avoid Adverse Events

The first step toward systematically planning and implementing medical errors prevention is to create a classification scheme for medical errors in order to properly identify them and investigate their causes. One widely used categorization scheme labels them as: 1) adverse events, 2) near misses, 3) slips, 4) lapses, 5) mistakes, 6) errors of omission, and 7) errors of commission although these last two categories may be argued to overlap with some of the others. To clarify, in order to be labelled an *adverse event*, the harm or damage must be the result of a flaw in the medical management rather a negative development in the patient's condition through a progression of the injury or

illness in spite of appropriate treatment. Even excluding these unfortunate setbacks in the face of efficacious, diligent treatment, Brennan et al. assert that, "There is a substantial amount of injury to patients from medical management, and many injuries are the result of substandard care."9 As any system designed to aid in preventing medical errors must include those events that did not cause harm in the case in question, but could well have done so in other circumstances, in other words, *near misses*. For example, any error in the creation of a treatment plan is a mistake if it could have led to harm, even though it actually didn't. Medical errors categorized as *mistakes* are most clearly defined by precipitating circumstance occur when anyone involved in care or treatment of a patient must perform a non-routine action, often a novel undertaking for the caregiver; the task will necessitate concentration and possibly judgment or problem-solving skills.¹⁰ Any deviation from a set of standard procedures for treatment and care can increase the danger and probability of errors or adverse events although even the deviations themselves may be hard to document. One difficulty with assessing and analyzing medical errors on a scale beyond that of the individual institution is that various facilities have their own schema for identifying and classifying errors, as well as determining the likelihood of their occurrence which nevertheless may be very useful to doctors and other medical staff in adhering to standards and formulating corrective measures when errors arise.11

Chapter 6.A.2.i. The Role of Information Technology

Two obvious methods of medical error detection typical come to mind first, namely spontaneous reporting by those involved and manual review by disconnected observers; however, both are impractical for accurately revealing the broader picture of the situation in that the former methods elucidates only a small fraction of occurrences and a glimpse of the situation that enables them while the latter is prohibitively labor intensive to be cost effective, except as targeted sampling in the context of a broadly based research investigation.¹² Originally brought into hospitals and similar facilities for billing and payment processing, as well as for other high-volume, time-sensitive needs such as lab tests, computer and electronically facilitated technologies are increasingly being employed to monitor, evaluate, and enhance the quality of patient care which hospitals and outpatient facilities deliver.¹³

The use of information technology can eliminate the drawbacks mentioned above that make strictly human monitoring unfeasible, yet has its limitations in that coded data only will not reveal all forms of medical error. Thus data from a variety of sources, both quantitative and qualitative, such as clinical narratives, must be synthesized in order to identify a truly broad range of adverse events that have or could occur.

Given the promise of gaining a more complete picture of error generation, investigation needs to move toward understanding the process by which it occurs. To date, the focus of research has been reactive, identifying the occurrence and analyzing the causes of errors, and not on developing adverse event detection systems or effective procedures for prevention. Advances in the thoroughness of medical error detection should enable the study of the effectiveness of various approaches to enhancing patient safety through adverse event prevention. This progress will be of significant benefit in that the unpredictability of most medical errors coupled with the high costs of interventions makes definitively determining their effectiveness very difficult.14

Chapter 6.A.2.ii. Cleaning, Disinfecting, and Sterilization Procedures

Chapter 6.A.2.ii.a. Cleaning Procedures

The term *decontamination* is refers to a variety of activities, the goal of which alone or in combination, is to eradicate or at least render innocuous any pathogen or other dilatory substance enabling the reuse of anything coming in contact with multiple patients. Decontamination can take the form of: 1) cleaning, the physical removal of infectious agents and the organic matter that supports them, typically without destroy them; 2) disinfection, the killing or rendering harmless of most but not all microorganisms; and 3) sterilization, the complete eradication of anything living or potentially so, such as bacterial spores, whether or not deemed harmful.15

Sharbaugh asserts that cleaning is the first and most critical step in preventing adverse events caused by contamination, in addition to being a prerequisite to disinfection and sterilization. Significantly advances in preventing infection within hospital settings, including rigid cleaning and reprocessing standards along with the rise of one-time use equipment, have made infectious complications during hospitalization attention getting exception, as opposed to the norm of centuries past. Cleaning may need to be either a manual or automated task, depending on the features of the equipment or implement to be cleaned; alternatively, it may require a combination of both methods, the operative factors being preserving the proper performance of the device while insuring the safety of the one doing the cleaning. Depending on the task, acceptable cleaning methods, as provided by the manufacturer of the article to be cleaned, include: 1) simply applying soap and water, 2) applying another specified chemical agent, 3) manual

scrubbing, i.e, by human hands, 4) ultrasonic cleaning, and either 5) washer disinfecting or washer sterilizing, i.e, by placement in a machine.¹⁶

For cleaning to be effective, it must involve the complete removal of foreign material; otherwise, any subsequent disinfection or sterilization will be more time and energy intensive and possibly ineffective in the end. It consists of washing an item with a detergent or a disinfectant detergent and water, rinsing the item, and thoroughly drying the item. Multiple research endeavors concerning endoscopes, surgical instruments, and other equipment have document exponential and logarithmic scale reductions in microorganisms from cleaning alone. As alluded to above, a direct correlation exists between the level of biological material present at the inception of disinfection or sterilization and the time delay needed to effectively accomplish those processes. Reducing what is referred to as *bioburden* reduces time and costs while increasing effectiveness and safety, including that of employees who undertake subsequent equipment handling. Sufficient, effective cleaning further prevents of release of potentially harmful endotoxins, removes barriers that would otherwise shield microorganisms from contact with liquid disinfectants or sterilizing agents, while preventing any deactivation of the latter two groups of agents.17

Chapter 6.A.2.ii.b. Disinfecting Procedures

Crucial to preventing adverse events proximally caused by harmful microorganisms coming into contact with the patient under treatment is *disinfection*, which by definition kills or renders innocuous pathogenic organisms other than bacterial spores.18 Immersing medical equipment in liquid chemicals for sufficient periods of time and processing them through wet pasteurization are the two most common ways of handling the non-living objects and surfaces with which the patient comes into contact.¹⁹ Obviously, disinfectants cannot be used directly on the patient or with items such as eating utensils by means of which the disinfectant could be ingested.²⁰

Sharbaugh classifies disinfectants into three categories, namely; 1) the high-level ones, which eradicate all microorganisms other than some types of bacterial spores; 2) the intermediate-level ones, which kill off vegetative bacteria, the majority of viruses and fungi, along with (of special importance) the organism Mycobacterium tuberculosis, but not bacterial spores; and finally 3) the low-level ones, which kill most bacteria, as well as a number of virus and fungi types, yet are ineffective against M. tuberculosis or bacterial spores. Outside Sharbaugh's scheme is sterilization, defined as the killing of absolutely all microorganisms without exception.²¹

Reporting on research by Rutala, and Weber highlighted the former's conclusion concerning the efficacy of classifying the sterilization of equipment for patient care as being either critical, semicritical, or noncritical, with the criterion for categorization being the level of the danger of infection. Two policy guidelines, namely the "Guidelines for Environmental Infection Control in HealthCare Facilities" and the "Guideline for Disinfection and Sterilization in Healthcare Facilities" both published by the U.S. Centers for Disease Control, the (CDC), incorporate this three-fold system of classification. Those instruments considered critical items include anything subjected to potential microorganism or bacterial spore contamination and a correspondingly high risk level. Semicritical items, including everything from diaphragm-fitting rings to respiratory

therapy and anesthesia equipment, may come into contact with a patient's mucous membranes or nonintact skin. By contrast, equipment and instruments that come in contact only with intact skin and no moist tissue, such as mucous membranes, are designated as non-critical, inasmuch as the large majority of microorganisms cannot penetrate the unbreached epidermis. Such noncritical equipment would include, the ICU surroundings consisting of furniture, curtains, bed rails, linens, and floors, as well as those items the come into bodily contact in the way that crutches, blood-pressure cuffs, and bedpan do.22

Chapter 6.A.2.ii.c. Sterilization Procedures

Sufficient heat, frequently by means of steam, is the most efficient method of sterilization for healthcare institutions, given the heat tolerance and stability of most equipment in need of the process. On the other hand, cost saving and other trends over the last six or seven decades have led to a growing segment of the medical device and instrument arsenal that cannot tolerate high-temperature sterilization and therefore necessitates a low-temperature equivalent. One such alternative is ethylene oxide gas, effective for medical devices sensitive to both heat and moisture. More recently, the following processes: 1) hydrogen peroxide gas plasma, 2) peracetic acid immersion, and 3) ozone have been engineered and proven effective in the sterilization of medical devices. The following portion of this sub-section analyzes various procedures for sterilization as currently used in the fields of medicine and healthcare with the goal of identifying their optimum usage in the effort to forestall the contamination of medical devices leading to medical errors.23

The purpose of sterilization is to eradicate all living organisms from the treated implement or surface, among the most dangerous of which are staph infections.²⁴ Sterilization destroys all microorganisms on the surface of an article or in a fluid with the goal of eliminating any risk of disease transmission through the use of the sterilized item in treating a patient. Although common sense dictates that inadequate sterilization creates a decisive risk of pathogenic infection, the documentation of such occurrences is extremely sparse. While a wide variety sterilization methods are in use, the present discussion focuses on the two most common, namely steam sterilization and ethylene oxide or "gas" sterilization (ETO).²⁵

As a form of moist heat, saturated pressurized has a multiplicity of advantages, leading to its frequency and recommendation as the first choice for sterilization wherever feasible; these advantages include: 1) dependability, 2) low cost, 3) nontoxicity, 4) rapid and thorough killing of microorganisms and spores, and 5) rapid heating and penetration of fabric. These properties make sterilization by steam advisable for treating anything that tolerates high temperatures and moisture, such as respiratory therapy and anesthesia equipment, even when doing so would not be strictly necessary for preventing pathogen transmission. This process, over a longer time frame, can even be used in the decontamination of microbiological waste. Four parameters are required for steam sterilization to be effective, namely sufficient steam, pressure, temperature, and time of exposure.26

The other widely utilized sterilization technique is ethylene oxide "gas" sterilization (ETO). Inasmuch as this gas is a colorless gas, as well as both flammable

and explosive, its use by hospitals and other healthcare institutions is generally confined to sterilizing moisture or heat sensitive equipment and implements the complete decontamination of which is semi-critical or critical.27

One of the innovations within the medical field in recent decades has been the inception of single-use medical implements, which substitute the costs, problems, and risks of waste disposal for those of disinfection or sterilization and reuse; these should, however, be utilized whenever appropriate. Infections fall within the scope of medical errors as unintended and largely preventable harmful consequences, constituting a foreseeable adverse event of elevated consequences in the hospital ICU and a legal responsibility to prevent to the extent possible. Just as any medical device or piece of equipment may become recontaminated as easily as it became contaminated before sterilization, infection control and prevention must be a coordinated endeavor by the entire medical facility, rather than merely the task of the sterilization processing unit or staff. Comprehensive guidance for cleaning, disinfecting, and sterilizing of medical devices and equipment is contained in the *MAC Manual* of the Medicines and Healthcare Products Regulatory Agency.28

Chapter 6.A.2.iii. Investigative and Evaluative Procedures

Chapter 6.A.2.iii.a. The Basic Concept of Checklists

Like airline pilots, doctors must work with sophisticated equipment under circumstances that can evolve rapidly in terms of the source of the threat and the degree of the hazard. While safety in both professions is an absolute, cost containment is always

a potentially conflicting priority.29 In recent years, a number of medical institutions have been able to reduce error rates noticeably by imitating the adopting investigative and evaluative procedures comparable with those used by the Federal Aviation Administration's policies and procedures for monitoring prior to and investigating in the wake of adverse incidents. A powerful tool for error reduction or elimination, developed in the fields of aviation, aeronautics, and product manufacturing, now becoming increasingly utilized in the field of medicine is the checklist. Its spread as a tool is predictable in that just as in the other fields safety and precision are uncompromising standards in the delivery of services, and given that lives are at stake, errors are unacceptable even when unavoidable.30 Conceptually, checklists may assume the format of a list of: 1) factors, properties, or aspects to consider; 2) components or dimensions of tasks; or 3) criteria or decision trees for decision-making.31 Checklists are distinct from cognitive aids in that they lack the informality and ambiguity of a posted note or the proverbial string around one's finger; they differ from the protocol in that they normally do not mandate the completion of specified tasks leading to predetermined outcomes. Thus, checklists give guidance, organizing sub-tasks and routines, providing verification of completion, but not specifying the end result. According to Hales and Pronovost, "Checklists can have several objectives, including memory recall, standardization and regulation of processes or methodologies, providing a framework for evaluations or as a diagnostic tool."32 Checklists are designed with the goal of preventing potential errors which would otherwise occur due to oversight or omission of necessary procedure or action by preventing or else catching the omission and rectifying it prior to any damage or injury.33 The routine use of checklists facilitates and preserves the qualities of

precision, focus, clarity, and memory recall in the performance of tasks whether routine or otherwise and by those on all levels of medical staff; their use has proved particularly effective in preventing errors under conditions of elevated stress.³⁴

Chapter 6.A.2.iii.b. The Effects of Checklists in the ICU

Yet another area in which healthcare institutions are adopting successful practices in aviation is in the organization and deployment of crews or, in the case of medical facilities such as ICUs, teams. Promising as this apparently analogous situation seems, the theories and approaches of checklist implementation and error management have to date been incompletely adapted or implemented at best, and not without reason. Unlike flight processes which deal with the operation of machines, inherent factors in healthcare and medicine, such as the unpredictability of the human body in the course of illness, injury, and recuperation, make the rigid standardization in the use of checklist unfeasible.35 Nonetheless, there has been some slow movement toward the adoption of checklists in the critical care branch of medicine, albeit adapted to fit the complexities and uniqueness of this environment, with moreover, some indication of beneficial outcomes. One investigation involving the medical-surgical ICU tertiary care units at two teaching hospitals report that some 80% of the nurses felt that the adoption of checklist procedures had enhanced the quality of patient end-of-life care, including when it involved the withdrawal of life support. More objectively, the study found that a significantly smaller number of patients were subjected to inappropriate resuscitation or comfort medications during the final 12-hour period of their lives.36

Chapter 6.A.2.iv. Reorganizing the Medical Team in the Hospital ICU

By fundamentally rethinking their medical staffing and task allocation approaches, various hospital ICU departments have implemented creative and effective models of staffing, with the result being an increase in teamwork and a corresponding decrease in the dependence on isolated individual specialist to independently select and implement steps in the treatment process.37

Chapter 6.A.2.iv.a. The Effects of Teamwork in the Hospital ICU

Manser defines teams as consisting of "Two or more individuals who work together to achieve specified and shared goals, have task-specific competencies and specialized work roles, use shared resources, and communicate to coordinate and to adapt to change. Compared with teams in other industries, medical teams especially in the dynamic domains of healthcare such as operating rooms, intensive care, emergency medicine, or trauma and resuscitation teams."₃₈ These changes in conceptualization have increased the responsibilities of professional medical staff members at all levels, have reduced the clarity of boundaries between professionals, and have increased the interdependence and correspondingly the collaboration among the medical professionals, as well as that of others in support and managerial position. On the other hand, all of these theoretically positive outcomes are inherently linked to an increased risk of interdisciplinary communication failure, often leading to consequences potentially more disastrous than with the previous paradigm. While surgeons had been at the forefront of this teamwork approach and touted it as quite effective, their teams were invariably strictly hierarchical with themselves as the individual authoritative leaders, such would and could not be the structure of the multidisciplinary team.39

Wheelan et al. assert that physicians, nurses, and even support personnel do not receive anything close to adequate training in team building and teamwork skills although doing so would be extremely beneficial to healthcare facilities and to patients alike, even if accomplished in the form of in-service training. Furthermore, access to assistance from professional consultants would be very useful when problems arise, yet only a small fraction of facilities have this resource available. Improved patient outcomes and higher quality work environments for healthcare staff are inherently connected, explicit goals of the healthcare industry, and achievable through the development and fostering of supportive, productive healthcare teams.⁴⁰ Among the benefits claimed for teamwork from an administration perspective better teamwork: 1) reduces costs, 2) reduced staff turnover and absenteeism, 3) diminishes interstaff conflict, 4) increases the level of quality care, 5) bolsters staff motivation, and 6) improves patient outcomes. All these benefits stem from improving the psychological health and well being of the healthcare staff. Concomitantly, stress decreases while greater effectiveness and innovation bloom wherever a team of healthcare professionals are working harmoniously.41

The first step in evaluating the quality and effectiveness of teamwork i n specific situations is to identify, in general, behaviors and characteristics which form the foundation of efficacious teamwork, interrelate to constitute successful clinical performance, and finally manifest themselves in positives outcomes for the patient. Measuring tools or instruments for the assessment of teamwork competencies and

processes are neither new nor unique to the field of medicine, and has been promulgated throughout the research literature. As in other fields, in this process of measuring and assessing teamwork in the care and treatment of patients, attention must be devoted to ascertaining the degree to which these skills and processes must be adapted or individually prioritized in defining what is effective teamwork in individual circumstances, such as a hospital ICU.42 Asserting that potential performance indicators in the ICU include level of available technology, case mix, nurse staffing and patient ratios, and caregiver interaction, Rafferty et al. proceeded to test the hypothesis that each was related directly to quality of care. In order to do so, the author further defines *caregiver interaction* as being an amalgamation of five different aspects, namely: 1) culture, in its manifestations as the shared norms, beliefs and expectations of a particular group; 2) leadership, as displayed by the medical practitioners involved with the case; 3) coordination, not only ICU internal, but also with other acute care units of the hospital; 4) communication between all of the aforementioned parties; and 5) management of the conflicts that inevitably arise. Given the complexities of the ICU setting, Rafferty singled out communication for special in-depth analysis.43

Chapter 6.A.2.iv.b. Teamwork and Patient Outcomes in the Hospital ICU

The value of proper teamwork in promoting productivity has been established in many in the work environment is universally recognized throughout the public and private sectors, whether for profit or nonprofit. Despite this conclusion, to date the relationship between teamwork among healthcare professionals and patient outcomes remains unclear. Wheelan et al. report the existence of apparently contradictory finding from various studies as to whether patient outcomes were impacted positively or not at all by how well the staff members attending the patients worked as a team.44 One recently published study does conclude that the lack of or poorly coordinated management of staff likely contributes to a dominant percentage of adverse events experienced by patients.45 In many hospital ICUs, effective communication and teamwork between doctors and other healthcare staff members is advocated as a means of enhancing the care that patients receive. Ideally, such coordination and teamwork lead to more complete information which becomes the foundation of better decision-making. The collaboration needed to achieve this was defined as physicians and nurses sharing the task of problem solving in making decisions in selecting the optimal plan for patient treatment and care, as well as implementing that plan.46

Chapter 6.B. Communication Protocols in the Hospital ICU

Just as communication which is clear, accurate, and timely is a necessity in preempting the occurrence of a medical error, it is equally essential in dealing with and minimizing the harmful consequences of an error.47 Although physicians must prepare themselves to be medical experts through rigorous education, extensive both in scope and depth, all this training includes scant attention to the development of communications skills.48 In spite of this omission, the physician in clinical practice is faced with the near constant demand to utilize these skills at an extremely high level of proficiency in dealing with not just colleagues, other medical professionals, and staff members, but also with patients and family members, not to mention facility administrators, insurance representatives, and government agency bureaucrats. All of these interactions take on
heightened requirements for communicative proficiency when a medical error is involved.49 The consequences of mistakes in communicating, not only yet particularly in the ICU, but also throughout the medical institution and its dealing with outside entities, can be catastrophic to the point of irreparably harming or end careers or exponentially increasing the costs of dealing with a medical error.50 To their credit, the large majority of physicians comprehend the dangers of ineffective or inappropriate communication, yet with equal frequency, they lack the time or the motivation to take action to improve their communication skills.51 At its most simplistic description, effective communication means assuring that the substance of the message being sent equals that of one being received; nonetheless, many factors can impede this ideal.52 Bypassing a theoretical analysis of these impediments and bringing the discussion to a practical level, hospital administrations must focus their efforts on fundamentally revising both external and internal communications protocols, well beyond measures such as extending the use of informed consent paperwork or building more extensive networks of internal communication between the medical professionals, administrators, and support personnel.53 The following section will divide the topic of communication into two parts, namely internal communications and external communications.

Chapter 6.B.1. Internal Communication

Adverse events, whether on not properly classified as medical errors, are often discovered to have had faulty communication among those medical professionals involved in critical care as a contributing factor. Research is now being directed toward the goal of isolating those features of effective communication, which will assist in protecting against and preventing medical errors.54 Poor communication is a multidimensional problem, one of the most fundamental aspects of which is the divergence of the way doctors and nurses communicate according to their respective medical training regimens.55 Baggs et al. reports on several studies as conducted by Knaus et al, on one hand and Shortell et al on the other compared 13 ICUs and established differences in the ratio of actual to predicted mortality, after controlling for severity of illness. The former group of researchers developed an instrument they named the Acute Physiology and Chronic Health Evaluation (APACHE) and used it to measure differences in the ICUs of 13 hospitals between the proportions of predicted fatalities and those which actually occurred. Kraus et al found that the interaction and coordination among staff members, basically measuring the same phenomenon the other investigators have labelled *collaboration*, proved to be the crucial determinant in the cases studies. Subsequently, the latter group of researchers, Shortell et al, expanded the study to include data from some 42 hospital ICUs analyzing the influences of a collection of variables related to communication and coordination, which these investigators conflated in a collective group which they labelled, "caregiver interaction." While this group of researchers could not make definitive conclusions concerning their chosen variable and long term or overall risk-adjusted survival, they did uncover a positive correlation between caregiver interaction and the shorter risk-adjusted duration of a patient's stay in the ICU. Moreover, Shortell et al. determined based on this study that positive organizational characteristics, such as communication and collaborative problem solving, lead to better ICU care.56

The characteristics and components of team communications which facilitate or

inhibit effective teamwork have been the subject of significant research, not only for the purpose of analysis, but also for the development of training in the appropriate skills. Specifically focusing on the ICU, a number of studies have identified neglect or misunderstandings in inter-team communication as a frequent causal contributor to medical errors; nonetheless, this relationship has been far less explored, analyzed, or understood in comparison to the work that has been accomplished in other equally highrisk field of endeavor where stress levels can be intense, the pace fast and the course of activity rapidly and unpredictably changing, the stakes high, and safety paramount.57 Ironically, while the need for effective, error-free communication and teamwork would be universally acknowledged, systematic efforts to provide formal training and to evaluate their quality in practice have been severely lacking.58 In one of the most extensive human factors investigations of error in the ICU, According to Donchin et al. in possibly the most thorough studies to date of human factors which precipitate medical errors, the communications between doctors and nurses in the ICU constituted merely 2% of the activities which each were engaged in during the course of their work in the unit; on the other hand, this 2% was involved in approximately 33% of medical errors detected. Undoubtedly, communication skills in the ICU are an integral part of ensuring safety and quality patient care. Other research has demonstrated a correlation between greater degrees of collaboration between doctors and nurses and decreases in both patient mortality and average length of stay in the ICU.59

A clear prerequisite to creating training and assessment mechanisms for enhancing teamwork in the ICU is an in-depth understanding of the process and an identification of the precise communication skills critical to preserving patient safety.60 Crew resource management (CRM) is an example of one such communications tool, which since its adoption in the aviation industry in 1979 has experienced success in reducing the frequency of accidents caused at least in part by human factors, especially in time-sensitive critical situations similar to those involving interdisciplinary teams in the ICU. The CRM approach concentrates on upgrading the safety of systems, eschewing individual culpability while employing standardized communication tools to ensure safety. Despite the similar challenges faced in the fields of aviation and medicine, CRM has yet to prove its effectiveness in terms of patient safety and outcomes. Although some earlier thorough surveys of the published literature had failed to demonstrate any significant relationship, some more recent research into the use of CRM and improved patient outcomes is beginning to suggest a positive correlation.61

Chapter 6.B.2. External Communication

While modern medicine, with its technological advances and multidisciplinary focus, has improved patients' health and extended their lives, it has typically done so at a cost to their psychological well-being. In contrast the traditional doctor-patient relationship, many a patient today senses that medical professionals see him or her as merely as set of data based on test results, rather that taking an interest in him or her as a human being.⁶² In this environment, the National Patient Safety Foundation exhorts medical professionals on all levels to be forthright, candid, and compassionate disclosing and explaining medical errors to patients and family members.⁶³ Each doctor-patient relationship is unique; time and effort are needed to build it, in part because of physical and psychological influence its character will have when injury or illness impacts the patient's life.64

While circumstances requiring the conveyance of unpleasant or negative information occurs throughout the field of medicine, sensitivity or lack thereof in sharing such news can all the difference in how it is handled by receiving patients and family members. Increased psychological trauma, inhibited coping mechanisms, denial, anger, and the elevated tendency to pursue legal redress are all predictable responses. Contributing to the problem, the situation is typically stressful for many physicians themselves, as they lack effective training in how to handle such situations, and may thereby do or say something that aggravates the situation.65 Even from the point of preliminary diagnosis, the patient must deal with the stress of uncertainty.66 In recent years, an acknowledgement of the significance and gravity of such communication has grown, and with it an understanding of the need to incorporate appropriate skills into undergraduate and postgraduate medical education curriculum. Bad news poorly communicated stimulates confusion, extended stress, and ultimately resentment; in contrast to the understanding, acceptance, and adjustment fostered by handling the same information with sensitivity. To be effective, communications training for medical professionals must adhere to sound educational approaches and be evidence-based, as well as supported by adequate monitoring, coaching, and practice.67 In conveying unpleasant information, the physician must be aware of current aspects of the cultural climate, such as the predominance of and comfort level with electronic communication, which among other things constantly surrounds people with one report after another of suffering and death.68

Chapter 6.C. Medication Protocols in the Hospital ICU

One of the most significant categories of medical error, in the ICU as in other hospital departments, is that of medication errors.69 In the ICU environment, medication errors are most common at the stage of finally administering the substance prescribed, outnumbering all other types of errors and adverse events.70 Implied by investigations of their root causes is the conclusion that systemic flaws in the training, communications, monitoring, and implementation of protocols by staff members are core contributing factors.71 Further complicating the process of analyzing and combating these systemic errors is their possible source in the sequential accumulation of various individual errors, each with a distinct ultimate cause.72 In order to have any prospect for prevention or minimization, the analysis and evaluation must sort out and as far as possible isolate all these causes which may trace back to the initial diagnosis of the original illness or injury, likely involving environments outside the ICU.73 The subsequent section endeavors to explain strategies recently promulgated in an effort to prevent medication errors in the ICU; these include 1) the implementation of computerized physician order entry; 2) the elimination of extended work by individual physicians; and 3) the participation of pharmacists in hospital rounds.

Chapter 6.C.1. Computerized Physician Order Entry

Estimates by the Institute of Medicine suggest a rate of medication errors in hospital setting as high as one error per patient per day, based on their 1999 report, which documented 7,000 fatalities connected to medication errors. Since then, electronic prescription, such as Computerized Physician Order Entry (CPOE) systems, have come into wide use and are endorsed by the British Department of Health as having proven to reduce the likelihood of medication errors.⁷⁴ The CPOE functions as the cornerstone for clinical information systems; by permitting doctors to input their prescriptions electronically, the system saves the professional's time, reduces the potential for misreading handwriting, and allows the computerized system to provide real-time recommendations to the physician concerning dosage, potential multiple drug interactions, and any duplication of medication, all in time to catch medication errors before administration of the drug.⁷⁵

While these systems have frequently been successfully incorporated into the routine of healthcare institutions, just as many have failed or caused enormous problems, including: 1) significant implementation delays, 2) chaotic transitions, 3) cost overruns, and 4) threatened work actions by staff members or groups hostile to the systems. This last problem of human opposition can be explained in part by: 1) changes in work routines necessitated by implementation of the system, 2) shifts in roles among of the members of the care team, 3) the need for retraining, and 4) conflicts with institutional policies.76 Despite the negative experiences many institutions have had, benefits from successful implementation of CPOE are unassailable, and include the virtual elimination of lost, delayed, overdue, and ambiguous orders, all by directly inputting the initial prescription order into a computer database. The automation inherent in a CPOE system ensure automatic: 1) orders for routine procedures, such as heparin-flush orders for intermittent injection sites; 2) stop orders, such as for prophylactic antibiotic treatments; 3) monitoring to prevent order duplication; and 4) reduction in time lapses in filling drug orders.77

Camire et al. report on a study done by Shulman, et al. which analyzed, "The rate of medication errors before and after institution of computerized physician order entry without decision support in their 22-bed multisystem ICU. A pharmacist prospectively identified medication errors during prescription review over 26 days of data collection. Following the introduction of computerized physician order entry, the proportion of prescriptions with errors decreased from 6.7% to 4.8%."78

Chapter 6.C.2. Elimination of Extended Physician Work

As with all other human beings, physicians, nurses, and all other care staff feel the effects of excessive workloads and long working shifts, resulting in fatigue and sleep deprivation and leading to vulnerability to making mistakes. Though often thought of as unavoidable in healthcare, such administrative staffing is not a necessity but rather a short-sighted mistake with negative consequences for the safety of medical professionals and patients alike.⁷⁹ Medical professionals in this country, regardless of level of training and expertise, are typically required to work longer both by hours per week and by length of shift than considered safe or allowed by law in equally hazardous environments such as transportation or nuclear power. Similarly mandated limits in the fields medicine and healthcare would reduce the dangerously high risk to patients, given that institution and facilities are highly motivated to contain soaring medical costs by scheduling long shifts and much overtime.⁸⁰

Among the sparse efforts to date to curb the practice of overworking staff at medical facilities, New York is the sole state to mandate a limit on working hours during residency, along with increased residency supervision. Among its 27 committees

overseeing residency program review, the Accreditation Council for Graduate Medical Education (ACGME) has a mixed record in terms of setting standards for work hours, oncall rotations, and time off; moreover, from one specialization to another, the variation in these standards is great vary widely among specialties. For instance, while strict limits of 60 hours per week hold for emergency medicine, no such limits or even recommendations exist for pediatrics, or for obstetrics and gynecology, the former of which can be as unpredictable, critical, and stress inducing as can emergency medicine.81

Landrighn et al. found a positive correlation between hospital interns regularly working shifts equal to or in excess of 24 hours and a substantially higher rate of behaviors leading to serious medical errors, as opposed to period of time when these interns were responsible for significantly shorter shifts. Clearly, the authors conclude, abolishing these shifts of extended duration, along with reducing the total number of hours that any given intern works in a week has the potential to precipitate a noticeable decrease in serious medical errors occurring in the hospital ICU.82 Moreover, Camire, et al. report on a recent study comparing the clinical work schedules of interns with their propensity for making medication errors. The research compared two groups of interns, one of which averaged 77–81 hours a week, a traditional clinical schedule, while the other averaged a lesser 60–63 hours a week, which furthermore, capped the number of hours that could be worked at a stretch to 16. The results for the group of interns whose hours were limited was a 17.3% lower rate of serious medication errors, specifically a rate of 82.5 errors per 1000 patient-days, rather than the 99.7 errors reported by those working a more traditional schedule. Nor was this reduction limited to interns in the ICU, but was similarly seen across hospital units.83

Chapter 6.C.3. Participation of Pharmacists in ICU Rounds

One of the root causes of medication errors is the absence of critical information, both about the drug and about the patient, at the point of selecting a particular medication as treatment. Given that the pharmacist is the professional whose expertise includes knowing what information is needed to accurately evaluate a proposed regimen of medicine, having that individual on hand as a part of the team conducting patient rounds can forestall many adverse drug events (ADEs).84 Research data documents cases of pharmacists preventing medication errors which would otherwise have occurred in the hospital ICU, as well as giving advice that lead to lowering medication costs. Traditionally, due to the accepted communications paradigm, pharmacists merely responded to prescriptions made by physicians without interaction and without critical knowledge of the patient and in the ICU, unlike in outpatient circumstances, without the opportunity to at least meet the patient and ask crucial questions. Ideally, the pharmacist's expertise would prove most efficient and error preventing if it were available at the point of decision-making.85

Supporting the value of immediate input from pharmacists, one of the studies mentioned above, demonstrated a 66% reduction in the occurrence of adverse drug events when a pharmacist participated directly in ICU medical rounds.⁸⁶ Camire, et al. also report on another study, which investigated the effects of having pharmacists participate in ICU hospital rounds. In this study, the author gathered data on the incidence of adverse drug events in an ICU prior and subsequent to having pharmacists involved, using a coronary care unit of the hospital in which no pharmacists were involved as a control for the comparison. While the control unit reported the rate of adverse drug events statistically unchanged, the group into which pharmacists were incorporated saw a 66% decrease in the rate, dropping from 10.4 to 3.5 events per 1000 patient-days. Supporting the contention that such collaboration between medical professionals is feasible, the researchers documented a 99% acceptance rate of pharmacists' advice by attending physicians over the course of the nine month study. Such participation is not a unique innovation of this study; both the Society of Critical Care Medicine and the American College of Clinical Pharmacy have been advocated just such pharmacist participation in hospital rounds as part of multidisciplinary teams for some years.87

Chapter 6.D. Equipment Failure Protocols in the Hospital ICU

As medical technology and its capabilities have increased exponentially in recent decades, the hospital ICU has become ever more reliant on complex and sophisticated systems and equipment for the monitoring of patients, alerting of medical staff, and even the automatic delivery of treatment. Exacerbating the potential for medical errors due to equipment failure is the disconnect between the understanding and perspectives of onsite ICU staff and higher levels of institutional administration, along with an across-the-board lack of understanding of the vulnerabilities of these system and their associated risks. Inherently, the ICU is a transcendently complex environment to start with, and the advances in medical technology only make it more so, necessitating the absolutely highest standards of continual vigilance.88 As a significant portion of this technology and associated equipment is devoted to supporting the patient's life functions so as to permit recuperation, flawless functioning of these systems is crucial.89 The next section includes two subsections, both focusing on errors in relation to medical equipment and technology, namely: 1) Equipment Failure in the ICU, and 2) Medical Equipment Maintenance in the ICU.

Chapter 6.D.1. Equipment Failure in the ICU

Inasmuch as all these sophisticated equipment and systems require expertise to understand, maintain, and repair, equipment failure is intrinsically elusive both to diagnose as the source of a medical error and to repair so as to prevent recurrence. It would be stating the obvious, but needs to be emphasized, that the entire spectrum of medical staff, supervisors, and administrators alike are far from being competent to diagnose the causes of mechanical or electronic malfunctions beyond identifying what errors have been produced. The resulting conundrum is that while manufacturers and technicians have initial responsibility for control of systems so as to prevent errors before the equipment and systems are actually in use, once they are in operation and errors can actually occur, the technologically untrained healthcare provider has become proximately responsible for preventing any errors from the poorly understood technology.90 Shirley and Bion note that, "From a total of 7525 incident reports collected over the course of approximately 6 years, they identified 176 reports of 191 incidents relating to intrahospital transportation from 37 ICUs. Clinical management errors accounted for 61% of the problems, and equipment failure for the remainder."91 The speed at which medical technology and equipment is becoming ever more complex and sophisticated only exacerbates this trend. Paradoxically, even as medical facilities and staff grow more and more reliant on the proper functioning of the technology, they become less and less able

to monitor its performance or identify and fix its malfunctioning.⁹² Two potentially effective measures for dealing with this problem of equipment failure and the errors it creates, albeit at a significant additional cost, would include either having available a sufficient quantity of backup equipment or integrating representative of the equipment manufacturers into all stages of planning for and using the equipment.⁹³ The growing capability and sophistication of technology in modern healthcare, along with its ever increasing role, necessitate that maintenance and management issues be given ever higher priority.⁹⁴

Chapter 6.D.2. Medical Equipment Maintenance in the ICU

Obviously, any use of equipment in the ICU requires prior testing out on site.95 Subsequently, proper maintenance is essential to continued delivery of quality, error free patient care, given that poor maintenance, planning, and management are the most likely root causes of adverse events involving equipment. One remedy consists of employing computerized maintenance management systems (CMMS), which can provide an abundance of relevant data for both maintenance, analysis, and long term planning. Utilizing CMMS can be crucial for managers and engineers, who must both respond quickly to issues and plan in order to forestall future problems.96

According to Taghipour et al., "The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a Medical Equipment Management Program (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. As fundamental aspects of this program inspection, preventive maintenance, and testing of medical equipment should be reviewed continuously to keep up with today's technological improvements and the increasing expectations of healthcare organizations."97 The authors further describe the World Health Organization's (WHO) four-category classification system for essential medical equipment, based on delivery of specific types of health services, namely: 1) diagnostic imaging equipment, 2) laboratory equipment, 3) general electro-medical equipment, and 4) other support equipment.98 Recently, the clinical engineering departments of hospital as far apart as the entire United States, Australia, and Canada have come to view simply adhering to the recommendations of medical equipment manufacturers as insufficient and have pursued a variety of maintenance strategies aimed not only at reducing errors, but also at being simultaneously more efficient and costeffective.99 According to Taghipour "Ridgway provide concise guidelines for maintenance management of medical equipment and address methods which have been used for a long time in other industry segments, such as Reliability Centered Maintenance (RCM). RCM is a structured methodology for determining the maintenance requirement of a physical asset in its operating context through a thorough and rigorous decision process."100

Chapter 6.E. System Failure Protocols in the Hospital ICU

Indisputably, areas of overlap between or among various systems whether human, technological, or both are juncture at which the propensity for errors is elevated, and yet is more difficult to identify and prevent or fix, given that with their complexity comes a degree of uniqueness, frustrating attempts to create standard protocols.¹⁰¹ Among hospital departments, the ICU represents perhaps the greatest confluence of interacting systems, possibly accounting in part for the prevalence of this type of medical error in this part of the institution.¹⁰² System failures can either be the immediate cause of a medical error or just as frequently the root cause; moreover, they can be due to problems as simple as neglected maintenance of equipment or as complex as issues of ergonomics or institutional culture of an institution.¹⁰³ The following subsection will discuss: 1) improvements in the quality of healthcare in the ICU; and 2) analysis of the causes of errors in this department of the hospital.

Chapter 6.E.1. Improvement in Healthcare Quality in the ICU

Although quality improvement is universally acknowledged as one of the highest priorities for healthcare institutions and facilities and has been studies regularly for over twenty years, ascertaining which approaches are likely to prove effective is still a mystery to be solved.¹⁰⁴ Some trends even suggest that it is becoming more elusive. Al-Doghaither contends that the shared responsibility among different doctors for individual patient care and treatment inherently creates a propensity for disagreements based on sincerely held professional beliefs and judgments.¹⁰⁵ Batalden and Davidoff define *quality improvement* as "the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators — to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development."¹⁰⁶ Al-Ahmadi and Roland assert that both internal and external forces are capable of stimulating enhancements in the quality of care, the internal ones on the basis of systematic efforts within the system while the external ones on the basis of public pressure.¹⁰⁷ Groene, et al., take this

specification further, labeling these forces in terms of healthcare industry-wide actions aimed at improving quality and safety, including: 1) aligning organizational processes with external pressure, 2) elevating the quality of service delivery to highest priority, 3) developing and implementing quality support mechanisms across the organization, 4) building teamwork throughout the institution with clear responsibilities and general expertise in team building, 5) creating and utilizing experientially based 'care pathways' that focus on safety and quality of patient care, 6) restructuring information systems according to a pathway focus, and 7) integrating feedback focused evaluation and recommendation into routine operations.¹⁰⁸

Given the complex interaction of the wide range of diverse and hard to quantify variables that make up healthcare delivery, evaluating its quality in any given setting is inherently extremely difficult. Patient satisfaction may be the best parameter for evaluating specific aspects of healthcare. From the perspective of commerce, the degree of patient satisfaction predicts the use of services and market share, but this assumes the patient's continuing need and ability to choose between providers.¹⁰⁹ Nevertheless, levels of patient's satisfaction with their treatment and care have proven measurable to an extent such that the extent to which care is patient-centered can demonstrably be identified as a crucial component in how satisfied the patient ultimately feels. Moreover, two distinct assessable circumstances that undermine patient satisfaction are, first, insufficient instruction prior to hospital admission, and second, communication difficulties with the care-giving staff. Conversely, other research has identified two factors for doctors which lead to the greatest satisfaction, namely incorporating the patient's opinions and wishes into treatment and care decisions, and maintaining the highest possible levels of privacy for the patient. Ironically, satisfaction ratings were at their lowest when doctors explicitly asked patients for feedback on the quality of their care and treatment, as well as about what difficulties they were having.¹¹⁰ Focusing more generally on their satisfaction, Al-Doghaither found that those hospital patients who receive regular checkins and updates from their attending physicians rated their level of satisfaction twice as high on average compared to those who did not and thus lacked a clear idea of how their treatment was progressing.¹¹¹

A related component of this sense of satisfaction is the timeliness of responses by medical professionals and support staff to questions and concerns expressed by the patient. The Al-Doghaither investigation reinforces this conclusion, finding a significant correlation between how promptly requests were dealt with by doctors and whether the patient gave a significantly higher satisfaction rating.112

In one of the more specifically focused studies, Mokhtar et al., recommend better education of diabetic patients as part of improving the quality of their care.113 A research investigation involving that same specific medical condition but focusing more tangentially on satisfaction as a measure of quality in inpatient diabetic care in relation to early hospital readmission documented the predictable correlation, namely higher quality care and lower chances of early readmission. Although groups with strong reputations, such as the American Diabetes Association, have promulgated guidelines for measures known to reduce the likelihood of readmission, medical practitioners and the facilities in which they work have been reluctant to embrace the guidelines in practice, undercutting the effectiveness of diabetes care. As an antidote to this Hussein recommends prioritizing

and emphasizing team building among physicians and healthcare professionals of various specialties.114

Other indications of barriers to improving quality in patient care residing within the perceptions, attitudes, and beliefs, and practices of medical professionals and hospital staff have been documented in a number of research studies, Among these investigations the use of clinical practice guidelines (CPG) ran up against resistance in the form of survey responses among healthcare professionals indicating that only a minority agreed with the idea that scientific evidence ought be utilized as the priority consideration selecting a patient's course treatment, which reveals a definite reluctance to trust and adopt the practices of evidence-based medicine. Along the same lines of thought, a separate study reported that both doctors and nurses, by their own admission were dubious or skeptical of the value and importance of patient-centered care as a determinant of the quality of medical care and treatment; in fact, fewer than 60% of respondents thought of the concept as important to any degree. It has been hypothesized that a failure of administrative and institutional leadership is the root cause of these attitudes. Were the leadership in understanding of and promoting the patient-centered approach, it should translate into commitment and support from the policy making and planning stage onward. In contrast to these negative or discouraging attitudes, within the same surveyed population, 97% of respondents acknowledged that CPGs are a valuable educational tool; moreover, in excess of 90% claimed that the CPGs have value in the quest to coordinate, standardize, and improve the quality of healthcare for patients.115

According to Hussein, the perception of doctors and nurses differ substantially in terms of patient safety in a given environment, with physicians giving higher ratings of 62.9 compared to that of the nurses at 56.6, which Hussein interprets as possibly a sign of poor leadership in facilitating a culture of safety in the hospital.116 Speculating on Hussein's finding, Hughes notes the heavier burden of workload nurses are faced with involving extended contact delivering patient care, frequently round the clock, and involving more routine tasks, all of which leads to greater fatigue, and thereby the difference in perceptions.117 According to El-Jardali et al. based on their work, and inverse correlation exists between disclosure and communication in the wake of a medical error, and how routine the normal activity related to the error is or how frequently it is performed. In such cases, the authors hypothesize, the fear of repercussions from committing an error in the context of a routine activity add to the reluctance to report it.118 Van Geest and Cummins contend that healthcare professionals fail in their ethics-grounded obligation to report medical errors and adverse incidents because they experience fear, shame, or guilt, anticipating punitive measures and a readiness on the part of administration to label someone, anyone as culpable. On a more hopeful note, the most recent reaccreditation process for hospitals documented some significant improvement in the way in which medical professionals communicated with their patients with regard to safety concerns.119

Chapter 6.E.2. Root Causes Analysis

With the increasing prioritization of patient safety, analysts in the healthcare industry have been searching for tools which will aid in uncovering system vulnerabilities

so that they may be strengthened and monitored.120 Root cause analysis (RCA), first promulgated in the field of psychology, and systems engineering are among those being applied to the field of medicine and healthcare in the attempt to uncover fundamental causal factors which account for variations in the quality of performance with regard to healthcare delivery. Such tools have already proved successful in fields as disparate as aviation and nuclear power by enabling systematic post hoc analysis of errors, identifying latent potential for errors in the process.121 So far, these tools are already in use by the healthcare services of the US Department of Veterans Affairs (VA).122 Root cause analysis is rapidly becoming a well understood approach in many hospitals and healthcare facilities and anecdotally has had success identifying various problems and in point to potential solutions.123 In the process of addressing a medical error, the RCA team meets on three times, first to identify known versus unknown facets of the case, second to document established facts and to prepare to investigate those that are unknown, a flow chart of events is developed, and third to determine the ultimate or root causes and to make recommendations for response and future prevention, focusing on addressing systemic weaknesses rather than individual blame.124 The three goals of the RCA are embodied in the following fundamental questions: 1) What happened? 2) Why did it happen? and 3) What can be done to prevent it from happening again? Root cause analysis is quite adaptable in healthcare, useful in environments as diverse as inpatient, outpatient, long term, acute, and even home care.125

Root cause analysis has been embraced by both the Veterans' Administration and the Joint Commission; the latter currently mandates an analysis of every adverse event while the former facilities the submission of RCA reports on significant adverse events to the National Center for Patient Safety. As for other governmental bodies, 25 of the states mandate that adverse events, which are intended to include medical errors, be documented with the information forwarded to the health department of the state in question. Both among and within organizations, the required or implemented parts of a root cause analysis and its report may vary; for instance the VA mandates that each RCA include recommendations as to corrective measures and a plan to monitor and ascertain that the action taken produces its intended results. However, the follow-up to these corrective action plans is entirely in the hands of the individual facilities. Alternatively, the Joint Commission's handling of the RCA involves commissioning healthcare institutions to develop their independent criteria for what constitutes a sentinel event and to voluntarily report any such events they uncover to the commission. Here, too, an action plan with measurement strategy is required; moreover, in some instances, the Joint Commission has been known to follow up on how the plan has worked out. Although, one fifth of the states in the U.S. require root cause analysis including the development of a plan for remedial action, the follow-up on compliance with these regulation is spotty at best on these plans, given that the regulations vary significantly to begin with.126

Chapter 6.F. Needed Reforms and the Disclosure of Medical Error in the Hospital ICU

Under current conditions, inherent institutional barriers to the disclosure of medical errors exist in the areas medical educational, administration, and legislation; therefore reforms in all three of these areas are necessary to combat the rising incidence, harms, and costs of errors. The next two subsections will discuss areas in which reforms are needed as part of the larger quest to reduce and effectively deal with the consequences of medical errors in the hospital ICU. They are: 1) tort reform, in conjunction with legislation reform, and 2) medical education reform.

Tort law refers to the body of legislation and the process it establishes for injured patients or those acting on their behalf to pursue whatever restitution for their injury is not already forthcoming whether in the form of "repairing" damages, to the extent possible, or compensating for physical, emotional, and other damages or loss. Within this legally based approach, medical errors are seen as a matter of negligence for civil jurisprudence to handle with the goal being correcting an injustice to the victims of the medical error. However, the increasing preponderance of opinion in the field is that the current system fails far more than succeeds at either adequately redressing injustice or preventing future occurrences of harm to patients.127

Chapter 6.F.1. Tort Reform

While historically, the individual doctor or attending physician was the predominant focus of care for the patient and thereby uniquely accountable any harm done through negligence, today health care has become an affair involving whole systems of medical professionals and support staff, with accountability becoming an institutional responsibility. Emblematic of this shift are the increasing numbers of physicians working as professionals yet as employees of medical facilities, established systems of institutional quality control, In particular, more physicians are employed, quality and outcomes are routinely measured, and reimbursement increasing being handled according to the consumer model of a value-based purchase.¹²⁸ Tort reform has become an expensive aggressively fought battle over the last twenty years, focusing increasingly on

the issues of physician liability and the costs of an already exorbitantly expensive health care system.¹²⁹ To its discredit, the current system; 1) elevates administrative costs, 2) actually discourages legitimately injured patients from using civil action to seek compensation, 3) sets up an adversarial process with unreasonable delays and a low probability of winning, and 4) rewards attorneys and others with no directly hand in the initial adverse event with a more than fair share of whatever compensation is forthcoming.¹³⁰

In order to understand calls for reform, one must first understand the legal foundations invoked when a medical error leads to litigation. Medical malpractice is classified under tort law, civil wrongs which do not involve explicit legal contracts, and negligence, an alleged wrongful act of commission or omission leading to injury of another person or damage to his or her property, which the accused presumably should have been able to avoid. In recent years, the chances of any given doctor, regardless of specialty or practice, having an open malpractice claim against him or her was recently reported to be 7.4%, of which 1.6% had claims resulting to a payment to the plaintiff. Over the course of a career, by the traditional retirement age of 65, 75% of physicians in low-risk specialties and 99% of physicians in high-risk specialties can anticipate having faced a malpractice claim, irrespective of resolution.131 Conceptually, malpractice liability exists in the legal system to ensure that quality healthcare and especially treatment is equally and mutually in the interests of both health care providers and patients by creating penalties and disincentives for poor performance leading to harm. Thus any effort to limit liability or excessive judgments for compensation can be opposed as reducing incentives to provide proper care and ultimately harming patients

outcomes.¹³² Nonetheless, both of the two most recent U.S. presidents, Bush in 2004 and Obama in 2009, have recommended placing limits medical malpractice liability with the ostensible goal of keeping healthcare costs in check, thus making health insurance more affordable and thereby raising coverage rates.¹³³

There has been a disconnect between to stated aims of reform in terms of curbing negligence and the ulterior motives of reducing malpractice liability premiums as opposed to increasing patient safety.134 Unfortunately, rather than promoting ethical behavior in reporting, disclosing, and dealing with the consequences of medical errors, the cumulative effect of repeated rounds of tort reform has been to create and enhance a 'conspiracy of silence' throughout the institutional hierarchy, including the ICU.135

By contrast, the thrust of currently proposed reform measures must foster a nonpunitive atmosphere, which in turn will facilitate complete and timely reporting of and learning from medical errors without sacrificing organizational accountability or fair redress for those who have been harmed.¹³⁶ The currently advocated tort reforms if achieved would constitute a fourth round, subsequent to major reforms in each of the last three decades of the 20th century.¹³⁷ Legitimate tort reform has the potential to lower excessive monetary awards, as well as curb the practice of defensive medicine. In theory, any change that, on balance, lowers healthcare costs should raise the rates of health insurance coverage rates, further reducing healthcare costs in general. Even before the Affordable care act, from 1981 and 2007 reforms capping damage awards, along with redefining collateral sources and joint-and-several liability were documented to increase health insurance coverage by those most sensitive to the rising cost of insurance from a half to a whole percentage point for each such group.138

The goal and focus of legislative reform needs to be ensuring patient safety rather than suppressing medical liability. Measures now in place which: 1) limit non-economic damages, 2) set statutes of limitations, and 3) redefine the concept of joint and several liability are all are due for reevaluation from the perspective of prioritizing patient safety. In addition, upgrading the standards for qualification as an *expert witness* in litigation and ongoing oversight of trends in health insurance industry should help to preserve justice and ethical treatment for side involved in litigation in the wake of a medical error.¹³⁹ Other supportive steps of reform to be recommended include: 1) further revision of payfor-performance incentives, which will ultimately support litigation reform, 2) revising the Medicare system for greater efficiency and effectiveness, which will help avoid medical errors while rapidly, comprehensively, and compassionately responding whenever preventable errors have occurred.¹⁴⁰

Avraham and Schanzenbach report on a 2002 conclusion by the Department of Health and Human Services, which argues for curbing unreasonably high monetary judgments for non-economic damages in civil suits, claiming that doing so would create a savings of between 5%–9% of nationwide healthcare costs, thereby enabling somewhere between 2.4 and 4.3 million Americans who could not at the time afford to do so to obtain health insurance. A number of interest groups, such as the national association of health insurance providers, working under the name, America's Health Insurance Plans (AHIP), have been advocating for tort reform, on a platform asserting that defensive

medicine and litigation costs add approximately 9% to the growing costs of health insurance premiums. Furthermore, despite the obvious increase in availability and affordability subsequently brought about through the Affordable Care Act of 2010, the potential savings and benefits of tort reform remain unchanged.¹⁴¹

Other studies on the consequences of tort reforms have concentrated on how reforms have influences award payments. This body of literature supports the conclusion that capping the award levels for noneconomic damages has led to a reduction in the amounts of payments to plaintiffs in cases for which juries had exceeded such limits in determining the value of non-economic damages. Although predictable, these findings confirm that caps can be effectively established and adhered to in trial law.142

Furthermore, Gilmour reports that tort reform has typically included, in addition to capping damage awards: 1) offsetting payments from collateral sources, 2) placing limits on legal fees for plaintiff representation, 3) setting periodic payments of damages either on a discretionary or mandatory basis, 4) restricting the manner in which damages are labelled in relation to joint and several liability, and 5) raising the criteria for qualification as an expert witness.¹⁴³ Looking back historically, Stamm et al. classify reforms into two generations, namely first-generation measures, which aim by direct means to decrease the number of malpractice claims and to reduce the levels of settlements, and second-generation malpractice reforms which are currently being experimented with in pilot programs at individual health care facilities and systems and whose measures are more varied and less direct. The former group have resorted to: 1) monetary caps on malpractice awards, 2) shortening of the statutes of limitation, 3)

pretrial screening, and 4) eliminating rules concerning joint and several liability. Such reforms have been in effect long enough for significant research literature to document their impact, albeit inconclusively. For example, according to Stamm et al., "There is also good evidence that noneconomic caps reduce malpractice claim volume and payment amounts by 20%-30%. 11 Much less literature is available describing the impact of these early measures on patient-centered outcomes, such as access to care and patient safety."144 The latter group, Stamm et al's second generation of malpractice reforms, tends to employ concepts such as schedules of noneconomic damages, health courts, along with mandated or voluntary communication procedures and resolution programs, among other ideas.

All such attempts tort reform share two common characteristics; first, their primary aim is reduce the costs of malpractice litigation and in particular the amounts of monetary awards, and second, they have unfortunately created a significant impediments to the ability of injured patients, along with their families, to establish which parties were negligent and thus liable, making rightful compensation harder to obtain.145

Chapter 6.F.2. Education Reform

The first step in educational reform is to integrate explicit training in preventing, minimizing the effects of, and handling medical errors into the curricula of medicine and nursing schools, a primary educational objective of which must be instilling a commitment to behaving in accordance with the principles of biomedical ethics in dealing with all types of errors.146

The call for adding to the curriculum of professional medical training is not at all a new phenomenon. At various points in its history, medical education in the United States has expanded from a pre-World War I undergraduate medical education, specifically at a medical school leading to the MD degree to a post-war realization that the rapid increase of knowledge, techniques, and practices necessitated further clinical training in the form of the internship and later the residency before commencing general practice. Further expansion of medical education was called for at that time to prepare individuals who wished to pursue a clinical specialty or take up medical research.147 Thus, the call for various extensions of medical education made in this analysis, are not without precedent.

Subsequent to the 1999 report by the Institute of Medicine (IOM), the body of professional literature concerning medical errors and patient safety in general has expanded exponentially; however, while frequently advocated in these publications, reports on efforts to educate future medical professionals in this regard are not to be found.148 Among the IOM recommendations for improving patient safety were the following: 1) voluntary error reporting, 2) re-evaluating the design of safety systems, 3) revising and implementing these enhanced designs, and 4) setting out clear standards for healthcare professionals with regard to safety, many aspects of which specifically focus on both preparatory and continuing education of medical and health care professionals. The report implies that these avenues of improvement have a profound ability to beneficially alter the flaws in current practice and advocates the creation of broadly focus programs promoting patient safety in order to accomplish this. Overall, the IOM report advocated coordinated efforts to raise both standards and expectations in terms of prioritizing, monitoring, and ensuring patient safety.149

According to Halbach, while legislators and agencies at various levels of government, along with NGOs, such as the National Patient Safety Goals of the Joint Commission on Accreditation of Healthcare Organizations and the Leapfrog Group relating to the field of healthcare have exerted considerable effort toward reforms aimed at curbing unsafe practices at healthcare institutions and the medical errors they lead to, the research literature appears to indicate a distinct lack of attention being paid to educating medical students and other healthcare professionals in best practices for prioritizing and maintaining the safety of patients. Reports on any efforts to incorporate this aspect of medical care into the curriculum were conspicuously absent.150 According to Dr. Dennis O'Leary, who at the time in 2003 served as President of the Joint Commission on Accreditation of Healthcare Organizations, in testimony held by the U.S. Senate Subcommittee on Government Affairs, "I would finally suggest that consideration be given to a government commissioned study of the content of professional education as it relates to patient safety. Such a report could create pressure for sufficient reforms of medical and nursing education to permit appropriate allocations of time to systems learning, education about the contribution of human factors to patient safety, and interprofessional team training."151

What reform has been achieved in medical education has been restricted nearly exclusively to the preclinical phase of training.152 The type of reform that will positively and significantly affect patient safety requires that provide future physicians be provided

with the opportunity and time for meaningful interaction with patients in clinical settings, including the in-depth study of and critical reflection on their cases.¹⁵³ The results of any effective reforms in the training of healthcare professionals must be doctors who are prepared more that solely as experts in the theory and practice of biomedical science, but are moreover adept at the skills of human interaction as taught in the social science disciplines, especially when dealing with difficult situations such as medical errors.¹⁵⁴

Halbach contends that explicit instruction in the principles and practices of patient safety is to be mandated for many reasons, with medical error prevention quality of care enhancement topping the list. Beyond these two reasons for integrating patient safety into the medical school and residency curriculum, another five include: 1) the enormous effects of medical errors on society, 2) the lagging attention of academic medicine to patient safety issues in comparison to others in the field and in government, 3) the need of medical schools to instill in future physicians attitudes toward disclosing and handling errors, which align with the expectations of patients and the public, 4) the assessment of many physicians themselves that such training in dealing with medical errors is sorely needed, in particular with how the medical professional can cope and recover from the psychological impact of being responsible for an error, and 5) the need to reduce the emotional and cultural barriers in medicine to handling medical errors. Creating barriers against these reasons for change are various attitudes and motivations, including: 1) fear of encouraging malpractice litigation, 2) perceived threats to professional autonomy, 3) discomfort with and reluctance to engage in practical applications of systems theory, 4) a lack of faculty with the expertise to train in these matters, and 5) the crowded field of worthwhile topics and needs all in competition for the attention of medical practitioners

and educators. 155 Sales asserts that three integrally related aspects of effective reform include: 1) Medical school admissions policies, 2) academic and intellectual preparation, and 3) professional and clinical training. Reform in the first aspect involves shifting admissions criteria away from it over-reliance on the ability memorize facts in the natural science as assessed in the likes of standardized test. The second aspect refers to the need to more fully and extensively incorporate the social science framework and skills needed for best practices in medicine into the existing preclinical medical school curricula. The third and final aspect deals with the need, in the course of professional and clinical training, for rising medical professionals to learn to integrate administrative, policy, management, and research, components of clinical practice with direct patient treatment and care. The aim here is to integrate these parts of the job in order to serve goal of quality improvement in healthcare delivery, and not to view those activities that are not a direct part of the physician-patient relationship as unwelcome, but unavoidable intrusions on the care and treatment of patients.156

Overall, the U.S. system of medical education has been quite successful, adapting to a rapidly advancing field throughout the last century. Still, the system has always lagged behind its own ideals in terms of adequately preparing students for the rising standards of the profession. Inasmuch as the field of modern medicine has become incredibly complex, rapidly changing, and unprecedentedly demanding on current and future practitioners, the need to reform medical education has taken on a corresponding urgency.157

Chapter 6.H. Conclusion

The topic of protocols covers a much wider scope that simply the response to adverse events or medical errors, as dealt with in the previous chapter under the heading of disclosure and apology. In contrast, the primary goal behind the process of establishing protocols, from their conception, creation, and development to their implementation and monitoring, is to eliminate wherever possible errors and adverse events. Moreover, as complete prevention in the broader sense is not feasible, the implementation protocols is essentially proactive seeking to decrease the frequency with which medical errors occur, to mitigate their severity, and to undo or at least ameliorate any harm or damage they may have caused.

The process of establishing and using protocols for the prevention of medical errors, in the hospital intensive care unit or elsewhere, commences with prevention planning starting with prophylaxis, which focuses on anticipating vulnerabilities to error so as to strengthen against them and monitoring, which inherently can never be absolute but which is becoming feasible to a much greater extent through the aid of information technology. The avoidance of medical errors and potential adverse events necessitates the teamwork by and increasingly larger group of medical professionals who must work efficiently together, needing enhanced communications skill, not just in terms of the traditional doctor-patient relationship, which requires special effort at personalization, given the trends toward impersonalization in modern medicine. For the medical professional, the imperative of better communication does not stop with the patient; accurate mutual understood communication must occur with the patient's family and

relatives, as well as internally with other staff member, facility administrators, insurers, and government regulators. As one of the major routine components of the care and treatment of most patient, particularly in the hospital ICU, the process of providing medication from prescription through administration, is uniquely vulnerable to the occurrence of adverse events and medical errors. In general, improvements in the administration of medication in terms of better training for and communications among staff members, more effective monitoring, and protocols will help to significantly reduce this vulnerability. Two promising innovations described here to combat medication errors are computerized physician order entry (CPOE) and, specifically in the ICU, the practice of having a pharmacist participate in patient rounds. Yet another means of preventing or minimizing the occurrence of medical errors the root cause of which is equipment failure; the obvious, solution is ensuring access to backup equipment although in many cases it is not financially feasible and requires that the malfunction be detected prior to its leading to and adverse event. A more practical solution would be to keep a representative of the equipment's manufacturer in touch for advice and monitoring.

Finally, this chapter has discussed at length and made recommendations concerning three areas in which it would be possible with the correct approach to substantially reduce the occurrence of adverse events and medical errors. These three include 1) adopting measures to prevent system failures; 2) instituting the type of tort reform in the judicial system through legislation that would promote adherence to the principles of ethics and provide justice, rather than create protracted adversarial proceedings; and 3) restructuring the system of medical education, so as to prepare future physicians and other medical professional to be more effective communicators and to handle medical errors, whenever they happen, according to the highest standards and principles of biomedical ethics. Reforms in these areas, while they cannot be accomplished through protocols per se, will significantly assist in lowering the rate of medical errors across the board in the field of medicine, not just in the ICU, all of which ultimately is the purpose behind this chapter. Endnotes

1 Gawande, Atul, "The Save," in *The Checklist Manifesto: How to Get Things Right* (New York: Metropolitan Books, 2009), 187-190; Steyrer, Johannes, et al., "Attitude is everything?: The impact of workload, safety climate, and safety tools on medical errors: A study of intensive care units." *Health Care Management Review* 38, no. 4 (2013): 307.

2 World Health Organization, *Implementation manual: Who surgical safety Checklist.* Retrieved from: <u>http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.</u> pdf, 9-13, Accessed, Mar 28, 2016.

³ Royal Adelaide Hospital, *Intensive Care Unit Manual*. Retrieved from: http://www.icuadelaide.com.au/manual/manual icu.pdf, Accessed, April 5 2016.

⁴ Kaprielian, Victoria, et al., *A system to describe and reduce medical Errors in primary care.* Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK43616/</u>, Accessed, April 5, 2016.

⁵ World Health Organization, *Implementation Manual: Who Surgical Safety Checklist.* Retrieved from: <u>http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.</u> pdf, 9-13, Accessed, Mar 28, 2016.

⁶ University of Illinois, *Online ICU Guidebook*. Retrieved from: <u>http://chicago.medicine.uic.edu/UserFiles/Servers/Server_442934/Image/1.1/residentguid</u> <u>es/final/icuguidebook.pdf</u>, <u>Accessed</u>, April 5, 2016.

7 Vincent, Jean-Louis, "Give your patient a fast hug (at least) once a day." *Critical care medicine*, 33, no. 6 (2005): 1225-1229.

⁸ Carless, Ruth, et al., "Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review." *Crit Care Med* 31, no. 4 (2003): 1006-1011.

⁹ Brennan, Troyen A., et al., "Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I." *New England journal of medicine* 324, no. 6 (1991): 370.

¹⁰ McDowell, Sarah E., et al., "The pathophysiology of medication errors: how and where they arise" *British Journal of Clinical Pharmacology* 67, no. 6 (2009): 606.

11 World Health Organization, *WHO Draft guidelines for Adverse Event Reporting and Learning Syste*. Retrieved from: <u>http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf</u>, Accessed April 7, 2016.

¹² Murff, Harvey J., et al., "Detecting adverse events for patient safety research: a review of current methodologies." *Journal of biomedical informatics* 36, no. 1 (2003): 131-143.

¹³ Honigman, Benjamin, et al., "A computerized method for identifying incidents associated with adverse drug events in outpatients." *International journal of medical informatics* 61, no. 1 (2001): 21-32.

¹⁴ Murff, Harvey J., et al., "Detecting adverse events for patient safety research: a review of current methodologies." *Journal of biomedical informatics* 36, no. 1 (2003): 131-143.

¹⁵ Veerabadran, Sethu, and Ian M. Parkinson, "Cleaning, disinfection and sterilization of equipment." *Anaesthesia & intensive care medicine* 11, no. 11 (2010): 451-454.

¹⁶ Sharbaugh, Robert J., "Cleaning reusable equipment in the ICU." *Critical care nursing quarterly* 24, no. 2 (2001): 48-52.

17 Sharbaugh, Robert J., "Cleaning reusable equipment in the ICU." *Critical care nursing quarterly* 24, no. 2 (2001): 51.

¹⁸ Veerabadran, Sethu, and Ian M. Parkinson, "Cleaning, disinfection and sterilization of equipment." *Anaesthesia & intensive care medicine* 11, no. 11 (2010): 451-454.

¹⁹ Rutala, W. A., and D. J. Weber, "Infection control: the role of disinfection and sterilization." *Journal of Hospital Infection* 43 (1999): 377-384.

²⁰ Sharbaugh, Robert J, "Cleaning reusable equipment in the ICU." *Critical care nursing quarterly* 24, no. 2 (2001): 49.

²¹ Sharbaugh, Robert J, "Cleaning reusable equipment in the ICU." *Critical care nursing quarterly* 24, no. 2 (2001): 49-50.

²² Rutala, William A., and David J. Weber, "Disinfection and sterilization in health care facilities: what clinicians need to know." *Clinical infectious diseases* 39, no. 5 (2004): 702-705.

23 Rutala, William A., and David J. Weber, *Guideline for disinfection and sterilization in healthcare facilities,* Centers for Disease Control (US). From: http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf, Sterilization, accessed, April 19, 2016.

²⁴ Veerabadran, Sethu, and Ian M. Parkinson, "Cleaning, disinfection and sterilization of equipment." *Anaesthesia & intensive care medicine* 11, no. 11 (2010): 451-454; Gawande, Atul, *Better: A Surgeon's Notes on Performance* (New Your: Metropolitan Books, 2007), 14 - 17.

25 Rutala, William A., and David J. Weber, *Guideline for disinfection and sterilization in healthcare facilities*, Centers for Disease Control (US). From: http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf, Sterilization, accessed, April 19, 2016.

²⁶ Rutala, William A., and David J. Weber, *Guideline for disinfection and sterilization in healthcare facilities,* Centers for Disease Control (US). From:
http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf, Sterilization, accessed, April 19, 2016.

27 Rutala, William A., and David J. Weber, *Guideline for disinfection and sterilization in healthcare facilities*, Centers for Disease Control (US). From: http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf, Sterilization, accessed, April 19, 2016; Herwaldt, Loreen A., and William A. Rutala, "Disinfection and sterilization of patient-care items." *Infection Control & Hospital Epidemiology* 17, no. 06 (1996): 382.

²⁸ Veerabadran, Sethu, and Ian M. Parkinson, "Cleaning, disinfection and sterilization of equipment." *Anaesthesia and intensive care medicine* 11, no. 11 (2010): 451-454.

29 Helmreich, Robert L. "On error management: lessons from aviation." *British Medical Journal* 320, no. 7237 (2000): 781.

³⁰ Hales, Brigette M., and Peter J Pronovost, "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 231-233.

³¹ Scriven, Michael, *The logic and methodology of checklists*. Retrieved from: https://www.wmich.edu/sites/default/files/attachments/u350/2014/logic%26methodology _dec07.pdf. Basic concepts, Accessed 21, April, 2016.

³² Hales, Brigette M., and Peter J Pronovost, "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 231.

³³ World Health Organization, *Patient safety checklists*. Retrieved from: <u>http://www.who.int/patientsafety/implementation/checklists/en/</u>, Patient safety checklists, accessed, April, 21, 2016.

³⁴ Hales, Brigette M., and Peter J Pronovost, "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 233.

³⁵ Hales, Brigette M., and Peter J Pronovost, "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 233.

³⁶ Hall, Richard I., et al., "Simple changes can improve conduct of end-of-life care in the intensive care unit." *Canadian Journal of Anesthesia* 51, no. 6 (2004): 631-636; Hales, Brigette M., and Peter J Pronovost, "The Checklist--a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 234.

37 Gawande, Atul, "The Save," in *The Checklist Manifesto: How to Get Things Right*. (New York: Metropolitan Books, 2009), 187-190.

³⁸ Manser, T., "Teamwork and Patient Safety in Dynamic Domains of Healthcare: A Review of the Literature." *Acta Anaesthesiologica Scandinavica* 53, no. 2 (2009): 143.

³⁹ Rafferty, Anne-Marie, et al., "Are Teamwork and Professional Autonomy Compatible, and Do They Result in Improved Hospital Care?" *Quality in Health care*, 10, no. 2 (2001): ii32.

⁴⁰ Wheelan, Susan A, et al., "The Link between Teamwork and Patients' Outcomes in Intensive Care Units." *American Journal of Critical Care* 12, no. 6 (2003): 533.

⁴¹ Rafferty, Anne-Marie, et al., "Are Teamwork and Professional Autonomy Compatible, and Do They Result in Improved Hospital Care?" *Quality in Health care* 10, no. 2 (2001): ii33.

⁴² Manser, T., "Teamwork and Patient Safety in Dynamic Domains of Healthcare: A Review of the Literature." *Acta Anaesthesiologica Scandinavica* 53, no. 2 (2009): 149.

⁴³ Rafferty, Anne-Marie, et al., "Are Teamwork and Professional Autonomy Compatible, and Do They Result in Improved Hospital Care?" *Quality in Health care*, 10, no. 2 (2001): ii33.

⁴⁴ Wheelan, Susan A, et al., "The Link between Teamwork and Patients' Outcomes in Intensive Care Units." *American Journal of Critical Care* 12, no. 6 (2003): 527.

⁴⁵ Young, Gary, et al., "Patterns of coordination and clinical outcomes: a study of surgical services." *Health Service Res* 33, no.5 (1998): 1212.

⁴⁶ Baggs, Judith Gedney, et al., "Association between nurse-physician collaboration and patient outcomes in three intensive care units." *Critical care medicine* 27, no.9 (1999): 1991-1998.

⁴⁷ Arora, Vineet, and Julie Johnson, "A Model for Building a Standardized Hand-Off Protocol." *Joint Commission journal on quality and patient safety* 32, no.11 (2006): 646-655.

⁴⁸ Schaefer, Kristen G., and Susan D. Block, "Physician Communication with Families in the ICU: Evidence-Based Strategies for Improvement." *Current opinion in critical care* 15, no.6 (2009): 569-577.

49 The Joint Commission, Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals. Retrieved from:

http://www.jointcommission.org/assets/1/6/aroadmapforhospitalsfinalversion727.pdf 4-5. Accessed, Mar, 2015.

⁵⁰ U.S. Department of Health & Human Services. *Effective Communication in Hospitals*. Retrieved from: <u>http://www.hhs.gov/civil-rights/for-individuals/special-topics/hospitals-effective-communication/index.html</u>. Effective Communication in Hospitals, Accessed Mar, 2015.

⁵¹ Moskop, John C. et al., "Emergency Physicians and Disclosure of Medical Errors." *Annals of Emergency Medicine* 48, no. 5 (2006): 527-531.

⁵² Shannon, Claude Elwood, "A mathematical theory of communication." *ACM SIGMOBILE Mobile Computing and Communications Review* 5, no. 1 (2001): 5.

⁵³ Kaldjian, Lauris C., et al., "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals." *Archives of Internal Medicine* 168, no.1 (2008): 44-46.

⁵⁴ Reader, Tom W, et al., "Communication Skills and Error in the Intensive Care Unit." *Current opinion in critical care* 13, no. 6 (2007): 732.

⁵⁵ Leonard, Michael, et al., "The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care." *Quality and Safety in Health Care* 13, no.1 (2004): i85.

⁵⁶ Baggs, Judith Gedney, et al., "Association between Nurse-Physician Collaboration and Patient Outcomes in Three Intensive Care Units." *Critical care medicine* 27, no. 9 (1999): 1991-98.

⁵⁷ Reader, Tom W, et al., "Communication Skills and Error in the Intensive Care Unit." *Current opinion in critical care* 13, no. 6 (2007): 732.

⁵⁸ Leonard, Michael, et al., "The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care." *Quality and Safety in Health Care* 13, no.1 (2004): i85.

⁵⁹ Donchin Y, Gopher D, Olin M, et al. "A look into the nature and causes of human errors in the intensive care unit." *Crit Care Med* 23 (1995): 294-300; Reader, Tom W, et al., "Communication Skills and Error in the Intensive Care Unit." *Current opinion in critical care*, 13, no. 6 (2007): 734.

⁶⁰ Reader, Tom W, et al., "Communication Skills and Error in the Intensive Care Unit." *Current opinion in critical care* 13, no. 6 (2007): 732.

⁶¹ MacDonald, Russell D., "Articles That May Change Your Practice: Crew Resource Management." *Air medical journal* 35, no. 2 (2016): 65.

62 Aitini, E., et al., "Communication Models for Doctor-Patient Relationships." J Cancer Educ 29, no. 2 (2014): 211.

⁶³ Mazor, K. M., et al., "Communicating with Patients About Medical Errors: A Review of the Literature." *Arch Intern Med* 164, no. 15 (2004): 1690.

⁶⁴ Aitini, E., et al., "Communication Models for Doctor-Patient Relationships." *J Cancer Educ* 29, no. 2 (2014): 212.

65 Fallowfield, Lesley, and Valerie Jenkins, "Communicating sad, bad, and difficult news in medicine." *The Lancet* 363, no. 9405 (2004): 312.

⁶⁶ Aitini, E., et al., "Communication Models for Doctor-Patient Relationships." *J Cancer Educ* 29, no. 2 (2014): 212.

67 Fallowfield, Lesley, and Valerie Jenkins, "Communicating sad, bad, and difficult news in medicine." *The Lancet* 363, no. 9405 (2004): 317-18.

⁶⁸ Aitini, E., et al., "Communication Models for Doctor-Patient Relationships." *J Cancer Educ* 29, no. 2 (2014): 212.

69 Ammenwerth, Elske, et al., "The effect of electronic prescribing on medication errors and adverse drug events: a systematic review." *Journal of the American Medical Informatics Association* 15, no. 5 (2008): 585.

⁷⁰ Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care." *Critical Care* 12, no. 2 (2008): 210-214.

71 California HealthCare Foundation, "*Addressing medication errors in hospitals: ten tools.*" Retrieved from: <u>http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF%20A/PDF%20</u> addressingmederrorstentools.pdf. Accessed, Mar 20, 2016.

72 DeJohn, P., "Follow Protocols When Using Medications from Compounding Pharmacies." *OR Manager* 29, no. 8 (2013): 28-30.

⁷³ Wu, Albert W., et al., "To Tell the Truth. Ethical and Practical Issues in Disclosing Medical Mistakes to Patients." *Journal of General Internal Medicine* 12, no. 12 (1997): 773-775.

⁷⁴ Ammenwerth, Elske, et al., "The effect of electronic prescribing on medication errors and adverse drug events: a systematic review." *Journal of the American Medical Informatics Association* 15, no. 5 (2008): 585.

⁷⁵ Camire, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *CMAJ* 180, no. 9 (2009): 939.

⁷⁶ Sittig, Dean F., and William W Stead, "Computer-Based Physician Order Entry: The State of the Art." *Journal of the American Medical Informatics Association* 1, no. 2 (1994): 111-112.

⁷⁷ Sittig, Dean F., and William W Stead, "Computer-Based Physician Order Entry: The State of the Art." *Journal of the American Medical Informatics Association* 1, no. 2 (1994): 111-112.

⁷⁸ Camire, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *CMAJ* 180, no. 9 (2009): 939.

⁷⁹ Valentin, Andreas, and Julian Bion, "How safe is my intensive care unit? An overview of error causation and prevention." *Current opinion in critical care* 13, no. 6 (2007): 699-700.

⁸⁰ Gaba, David M., and Steven K. Howard, "Fatigue among clinicians and the safety of patients." *New England Journal of Medicine* 347, no. 16 (2002): 1249-1255.

⁸¹ Gaba, David M., and Steven K. Howard, "Fatigue among clinicians and the safety of patients." *New England Journal of Medicine* 347, no. 16 (2002): 1250.

⁸² Landrigan, Christopher P., et al., "Effect of reducing interns' work hours on serious medical errors in intensive care units." *New England Journal of Medicine* 351, no. 18 (2004): 1838. ⁸³ Camire, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *CMAJ* 180, no. 9 (2009): 939.

⁸⁴ Kucukarslan, Suzan N., et al., "Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units." *Archives of Internal Medicine* 163, no. 17 (2003): 2014.

85 Leape, Lucian L., et al., "Pharmacist participation on physician rounds and adverse drug events in the intensive care unit." *Jama* 282, no. 3 (1999): 267-270.

⁸⁶ Kucukarslan, Suzan N., et al., "Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units." *Archives of Internal Medicine* 163, no. 17 (2003): 2014-2018.

⁸⁷ Camire, Eric, et al., "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *CMAJ* 180, no. 9 (2009): 939.

⁸⁸ Moyen, Eric, et al., "Clinical Review: Medication Errors in Critical Care." *Critical Care* 12, no.2 (2008): 208-215; David, Guy, et al., "Economic Measurement of Medical Errors Using a Hospital Claims Database." *Value In Health* 16, no. 2 (2013): 309.

⁸⁹ Donchin, Yoel, and F Jacob Seagull, "The hostile environment of the intensive care unit." *Current opinion in critical care* 8, no. 4 (2002): 316-320; Graf, J, A Von den Driesch, et al., "Identification and characterization of errors and incidents in a medical intensive care unit." *Acta Anaesthesiologica Scandinavica* 49, no. 7 (2005): 935.

90 Agency of Healthcare Research and Quality, *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk.* Retrieved from: <u>http://www.ahrq.gov/research/findings/final-reports/pscongrpt/psini2.html</u> Most Common Root Causes of Medical Errors, Accessed Mar 2015.

⁹¹ Shirley, Peter J., and Julian F. Bion, "Intra-hospital transport of critically ill patients: minimising risk." *Intensive care medicine* 30, no. 8 (2004): 1508.

92 Van Beuzekom, et al., "Patient safety: Latent Risk Factors." *British journal of anaesthesia* 105, no.1 (2010): 52-59.

⁹³ Cooper, Jeffrey B., et al., "An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for Prevention and Detection." *Anesthesiology* 60, no.1 (1984): 37-41.

⁹⁴ Hamdi, Naser, et al., "An intelligent healthcare management system: A new approach in work-order prioritization for medical equipment maintenance requests." *Journal of medical systems* 36, no. 2 (2012): 557-567.

95 Shirley, Peter J., and Julian F. Bion, "Intra-hospital transport of critically ill patients: minimising risk." *Intensive care medicine* 30, no. 8 (2004): 1509.

⁹⁶ Hamdi, Naser, et al., "An intelligent healthcare management system: A new approach in work-order prioritization for medical equipment maintenance requests." *Journal of medical systems* 36, no. 2 (2012): 557-567.

97 Taghipour, Sharareh, et al., "Prioritization of medical equipment for maintenance decisions." *Journal of the Operational Research Society* 62, no. 9 (2011): 1666.

98 Taghipour, Sharareh, "Reliability and maintenance of medical devices." PhD diss., University of Toronto. Retrieved from:

https://tspace.library.utoronto.ca/bitstream/1807/29886/6/Taghipour_Sharareh_201106_P hD_thesis.pdf. 6-8. Accessed May 16, 2016.

99 Ridgway, Malcolm, "Optimizing our PM programs." *Biomedical Instrumentation & Technology* 43, no. 3 (2009): 244-254.

100 Taghipour, Sharareh, et al., "Prioritization of medical equipment for maintenance decisions." *Journal of the Operational Research Society* 62, no. 9 (2011): 1666.

¹⁰¹ Van den Bemt, et al., "Frequency and determinants of drug administration errors in the intensive care unit." *Critical care medicine* 30, no. 4 (2002): 846-850; Tucker, Anita L., and Amy C. Edmondson, "Why hospitals don't learn from failures: organizational and psychological dynamics that inhibit system change." *California management review* 45, no. 2 (2003): 55-72.

102 World Health Organization, *Hospital Emergency Response Checklist*. Retrieved fromhttp://www.euro.who.int/__data/assets/pdf_file/0008/268766/Hospitalemergency-response-checklist-Eng.pdf. <u>5</u>, Accessed Mar 2015.

103 Valentin, Andreas, and Julian Bion, "How safe is my intensive care unit? An overview of error causation and prevention." *Current opinion in critical care* 13, no. 6 (2007): 698.

104 Pope, Catherine, et al., "Qualitative methods in research on healthcare quality." *Quality and Safety in Health Care* 11, no. 2 (2002): 151.

¹⁰⁵ Al-Doghaither, A., "Inpatient satisfaction with physician services at King Khalid University Hospital, Riyadh, Saudi Arabia." East Mediterr Health J. 10, no. 3 (2004): 358–364.

106 Batalden, Paul B., and Frank Davidoff, "What is "quality improvement" and how can it transform healthcare?" *Quality and safety in health care* 16, no. 1 (2007): 2-3.

¹⁰⁷ Hanan, AL-Ahmadi, and Martin Roland, "Quality of primary health care in Saudi Arabia: a comprehensive review." *International Journal for Quality in Health Care* 17, no. 4 (2005): 331-346.

108 Groene, O., et al., Seven ways to improve quality and safety in hospitals: An evidence-based guide. Retrieved from: http://www.duque.eu/uploads/DUQuE_Seven_Ways_To_Improve_Quality_And_Safety_2014.pdf. Accessed Mar 25, 2016.

109 Naidu, Aditi, "Factors affecting patient satisfaction and healthcare quality." *International journal of health care quality assurance* 22, no. 4 (2009): 366-7.

110 Mokhtar, S. A., et al., "Study of the relation between quality of inpatient care and early readmission for diabetic patients at a hospital in the Eastern province of Saudi Arabia." *Eastern Mediterranean health journal* 18, no. 5 (2012): 474.

111 Al-Doghaither, A., "Inpatient satisfaction with physician services at King Khalid University Hospital, Riyadh, Saudi Arabia." East Mediterr Health J. 10, no. 3 (2004): 358–364.

¹¹² Al-Doghaither, A., "Inpatient satisfaction with physician services at King Khalid University Hospital, Riyadh, Saudi Arabia." East Mediterr Health J. 10, no. 3 (2004): 358–364.

113 Mokhtar, S. A., et al., "Study of the relation between quality of inpatient care and early readmission for diabetic patients at a hospital in the Eastern province of Saudi Arabia." *Eastern Mediterranean health journal* 18, no. 5 (2012): 474.

114 Hussein, A. H. M., "Relationship between nurses' and physicians' perceptions of organizational health and quality of patient care." *Eastern Mediterranean Health Journal* 20, no. 10 (2014): 634-42.

¹¹⁵ Boyd, Cynthia M., et al., "Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases: implications for pay for performance." *Jama* 294, no. 6 (2005): 716-724.

¹¹⁶ Hussein, A. H. M., "Relationship between nurses' and physicians' perceptions of organizational health and quality of patient care." *Eastern Mediterranean Health Journal* 20, no. 10 (2014): 634-42.

117 Hughes, R G., "Nurses at the "Sharp End" of patient care, in *Patient safety and quality: An evidence based handbook for nurses.*" Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK2672/</u>. Accessed May 20, 2016.

118 El-Jardali, Fadi, et al., "Patient safety culture in a large teaching hospital in Riyadh: baseline assessment, comparative analysis and opportunities for improvement." *BMC health services research* 14, no. 1 (2014): 1-10.

¹¹⁹ Van Geest, J B., and Cummins, D S., "An educational needs assessment for improving patient safety." *White Paper Report* 3, (2003): 1-28.

¹²⁰ Tutorial, Tool, "Using aggregate root cause analysis to improve patient safety." *Joint Commission Journal on Quality and Safety* 29, no 8 (2003): 434.

121 Wu, Albert W., et al., "Effectiveness and efficiency of root cause analysis in medicine." *Jama* 299, no. 6 (2008): 685.

122 Braithwaite, Jeffrey, et al., "Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme." *Quality and Safety in Health Care* 15, no. 6 (2006): 393.

123 Wu, Albert W., et al., "Effectiveness and efficiency of root cause analysis in medicine." *Jama* 299, no. 6 (2008): 685.

124 Braithwaite, Jeffrey, et al., "Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme." *Quality and Safety in Health Care* 15, no. 6 (2006): 393.

125 Pham, Julius Cuong, et al., "Recasting the RCA: an improved model for performing root cause analyses." *American Journal of Medical Quality* 25, no. 3 (2010): 186; Wu, Albert W., et al., "Effectiveness and efficiency of root cause analysis in medicine." *Jama* 299, no. 6 (2008): 685; Tutorial, Tool, "Using aggregate root cause analysis to improve patient safety." *Joint Commission Journal on Quality and Safety* 29, no 8 (2003): 434.

126 Wu, Albert W., et al., "Effectiveness and efficiency of root cause analysis in medicine." *Jama* 299, no. 6 (2008): 685.

127 Commonwealth of Australia, "Reform of Liability Insurance Law in Australia." Retrieved from: <u>http://archive.treasury.gov.au/documents/799/PDF/complete.pdf</u>. 3-4. Accessed Mar, 2015.

128 Stamm, Jason A., et al., "Medical Malpractice: Reform for Today's Patients and Clinicians." *The American journal of medicine* 129, no. 1 (2016): 20.

129 Avraham, Ronen, and Max Schanzenbach, "The Impact of Tort Reform on Private Health Insurance Coverage, February 2010." *American law and economics review* (2010): 319-355.

¹³⁰ Schoenbaum, Stephen C., and Randall R. Bovbjerg, "Malpractice Reform must Include Steps to Prevent Medical Injury." *Annals of Internal Medicine* 140, no. 1 (2004): 51-53.

¹³¹ Stamm, Jason A., et al., "Medical Malpractice: Reform for Today's Patients and Clinicians." *The American journal of medicine* 129, no. 1 (2016): 20-21.

¹³² Avraham, Ronen, and Max Schanzenbach, "The impact of tort reform on intensity of treatment: Evidence from heart patients." *Journal of health economics* 39 (2015): 274.

133 Avraham, Ronen, and Max Schanzenbach, "The Impact of Tort Reform on Private Health Insurance Coverage, February 2010." *American law and economics review* (2010): 319-355.

¹³⁴ Schoenbaum, Stephen C., and Randall R. Bovbjerg, "Malpractice Reform must Include Steps to Prevent Medical Injury." *Annals of Internal Medicine* 140, no. 1 (2004): 53.

135 American College of Physicians, "Medical Liability Reform: Innovative Solutions for a New Health Care System," Retrieved from: <u>https://www.acponline.org/acp_policy/policies/medical_liability_reform_2014.pdf</u>.15-22. Accessed Mar, 2015. ¹³⁶ MacCourt, Duncan and Joseph Bernstein, "Medical Error Reduction and Tort Reform through Private, Contractually Based Quality Medicine Societies." *American Journal of Law and Medicine* 35, no. 4 (2009): 558-561.

¹³⁷ Born, Patricia, W., et al., "The effects of tort reform on medical malpractice insurers' ultimate losses." *Journal of Risk and Insurance* 76, no. 1 (2009): 197-219.

¹³⁸ Avraham, Ronen, and Max Schanzenbach, "The Impact of Tort Reform on Private Health Insurance Coverage, February 2010." *American law and economics review* (2010): 319-355.

139 American College of Physicians, "Medical Liability Reform: Innovative Solutions for a New Health Care System," Retrieved from: <u>https://www.acponline.org/acp_policy/policies/medical_liability_reform_2014.pdf</u>.15-22. Accessed Mar, 2015.

140 Harris, Lee, "Tort Reforms as Carrot and Sticks." *Harvard Journal on Legislation* 46 (2009): 204-206; Sage, William M., "The Role of Medicare in Medical Malpractice." *Journal of Health Care Law and Policy* 9, no. 2 (2009): 233-234.

141 Avraham, Ronen, and Max Schanzenbach, "The Impact of Tort Reform on Private Health Insurance Coverage, February 2010." *American law and economics review* (2010): 320.

¹⁴² Born, Patricia, W., et al., "The effects of tort reform on medical malpractice insurers' ultimate losses." *Journal of Risk and Insurance*. 76, no. 1 (2009): 197-219.

143 Gilmour, Joan M., *Patient Safety, Medical Error and Tort Law: An International Comparison.* Retrieved from: <u>https://apps.osgoode.yorku.ca/osgmedia.nsf/0/094676DE3FAD06A5852572330059253C</u> /\$FILE/FinalReport Full.pdf. 20-21. Accessed Mar, 2015.

144 Stamm, Jason A., et al., "Medical Malpractice: Reform for Today's Patients and Clinicians." *The American journal of medicine* 129, no. 1 (2016): 21.

145 Gilmour, Joan M., Patient Safety, Medical Error and Tort Law: An International Comparison. Retrieved from: https://apps.osgoode.yorku.ca/osgmedia.nsf/0/094676DE3FAD06A5852572330059253C /\$FILE/FinalReport Full.pdf. 20-21. Accessed Mar, 2015.

146 Furrow, Barry R., "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction." *Widener L. Rev.* 12, no. 1 (2005): 7-8.

147 Ludmerer, Kenneth M., and Michael ME Johns, "Reforming graduate medical education." *Jama* 294, no. 9 (2005): 1083.

¹⁴⁸ Halbach, Joseph L., and Laurie L. Sullivan, "Teaching medical students about medical errors and patient safety: evaluation of a required curriculum." *Academic Medicine* 80, no. 6 (2005): 600.

149 Baker, David P., et al., "The role of teamwork in the professional education of physicians: current status and assessment recommendations." *The Joint Commission Journal on Quality and Patient Safety* 31, no. 4 (2005): 185.

¹⁵⁰ Halbach, Joseph L., and Laurie L. Sullivan, "Teaching medical students about medical errors and patient safety: evaluation of a required curriculum." *Academic Medicine* 80, no. 6 (2005): 600.

¹⁵¹ Baker, David P., et al., "The role of teamwork in the professional education of physicians: current status and assessment recommendations." *The Joint Commission Journal on Quality and Patient Safety* 31, no. 4 (2005): 185-186.

¹⁵² Sales, Christopher S., and Anthony L. Schlaff, "Reforming medical education: a review and synthesis of five critiques of medical practice." *Social Science & Medicine* 70, no. 11 (2010): 1667.

153 Ludmerer, Kenneth M., and Michael ME Johns, "Reforming graduate medical education." *Jama* 294, no. 9 (2005): 1085.

¹⁵⁴ Sales, Christopher S., and Anthony L. Schlaff, "Reforming medical education: a review and synthesis of five critiques of medical practice." *Social Science & Medicine* 70, no. 11 (2010): 1667.

155 Halbach, Joseph L., and Laurie L. Sullivan, "Teaching medical students about medical errors and patient safety: evaluation of a required curriculum." *Academic Medicine* 80, no. 6 (2005): 600-601.

¹⁵⁶ Sales, Christopher S., and Anthony L. Schlaff, "Reforming medical education: a review and synthesis of five critiques of medical practice." *Social Science & Medicine* 70, no. 11 (2010): 1667.

157 Ludmerer, Kenneth M., and Michael ME Johns, "Reforming graduate medical education." *Jama* 294, no. 9 (2005): 1087.

Chapter 7. Conclusion

The very facts that humans are fallible and that they are integrally involved in the delivery of healthcare and medical treatment guarantee that medical errors will occur despite the best of training, skills and vigilance, precautions, or preventive procedures. The analysis presented in this dissertation makes this conclusion clear and that, furthermore, the fast paced development of innovative medical techniques and procedures, along with evermore sophisticated technology only intensifies the risks and multiplies the opportunities for adverse medical events.

While medical errors occur across the spectrum of care and treatment, the propensity for their occurrence and the severity of the damage they are likely to inflict are undeniably greatest in the hospital intensive care unit (ICU). Through the chapters of this dissertation, the research and analysis has provided the following: 1) a detailed account, to the extent that it has been documented, of the high frequency of errors occurring in the U.S. in general and specifically in hospital intensive care units, as well as the range and extent of the harm done to patients and family members, both physically and financially; 2) a classification and analysis of the proximate, intermediate and ultimate causes of and contributing factors to medical errors, which in addition to identifying causation has formed the basis for this dissertation's recommendations aimed at developing procedures and protocols to effectively reduce errors to the greatest degree possible while minimizing their harmful impact; 3) an in-depth analysis of expectations, grounded in biomedical ethics, for dealing with the consequences of medical errors including disclosure and communication, the expectations of patients and family members, the

attitudes and concerns of medical professionals, the disconnect between these two groups, and recommendations for procedures and protocols to ensure prompt, complete, and just handling of all consequences of the error; 4) an in-depth framework, based on Western religious and cultural foundations, for both those responsible for and those injured by medical errors to interact in handling the consequences of the error, as well as all of the communication which it engenders; and 5) proposals for numerous procedures and protocols, both for lessening the vulnerability of hospital ICU patients to suffering the effects of an error and for addressing and counteracting the variety of systemic problems which create or heighten the propensity for the occurrence of medical errors.

It is the contention of this dissertation that biomedical ethics, no matter what philosophical foundation serves as its basis, demands that nothing less than continual vigilance to anticipate and forestall the occurrence of even the most minor or errors, be justifiable. This stand insists on every effort being made to plan for prevention, including training, monitoring, procedures and protocols, along with the incorporation of technology directed at prevention and the prior establishment of protocols for dealing with errors once they are discovered. Furthermore, in the event of a medical error, the only acceptable course of action is complete and honest disclosure to the patient and all other relevant stakeholders of the error and its consequences, both real and potential. In keeping with the principles of biomedical ethics, the key necessities for such disclosure include: 1) explaining the circumstances leading to the error in layperson's terms, 2) describing both the real and potential consequences of the error, 3) accepting responsibility for the error, either personally or on behalf of the institution and individuals responsible, as appropriate 4) presenting a proposed course of action and

alternatives if appropriate to ameliorate, and to the extent possible, to reverse the negative effects of the error; and 5) proposing equitable arrangements to compensate the patient for any and all negative consequences of the error.

As part of the overall conclusions and recommendations provided by this dissertation, the greatly elevated tendency of medical errors occurring in the ICU. Such is to be anticipated, given the weakened and thus vulnerable physical condition of ICU patients, the large number of medical professionals and staff members who must coordinate their care, the complexity of both the patients' treatment plans and the communication involved in implementing them successfully, and the ever increasing reliance on sophisticated equipment and other technological support. Therefore, every hospital ICU must engage in the development, implementation, and periodic review of system wide, as well as individual staff member and action specific, protocols designed to prevent medical errors to the absolute minimum that is possible. All of these efforts must be developed on a foundation consistent with the highest standards of biomedical ethics, acknowledging that medical errors will inevitably occur and that when they do, principles of ethics must take precedence over other considerations, whether financial, reputational, or other. The last two chapter of this dissertation address the need for, barriers to, and specifics of creating and implementing protocols and proposals both to prevent and to deal equitably with medical errors in the hospital ICU, with applicability to the rest of the field of healthcare.

Chapter 2 of this dissertation presented an overview of the extensive scope of medical errors, in terms of their severity from 'near misses' that lead to no negative

consequences all the way on the scale up to errors that cause fatalities. The analysis in this chapter has further classified typical medical errors and adverse events in the hospital ICU as either errors of commission or omission; errors of commission are those events that should not have happened potentially causing damage because they did, while errors of omission are planned and intended actions in the treatment process that failed to occur at all or within the necessary timeframe potentially causing harm by their absence. The unifying characteristic of both types of error, and indeed of anything that all discussions of medical errors agree on, is that to be classified an error the event must not have been caused by the disease, injury, or ailment for which the patient is already being treated, except in those cases in which the error precipitated a negative progression in the original affliction which would not otherwise have occurred as swiftly or severely.

Among the forms that errors of commission may take are: 1) improper execution of treatment or of treatment not called for, 2) incorrect diagnosis or selection of and planning for treatment, 3) any delay in correct administration of treatment including medication, 4) the failure of sophisticated technology or equipment, and 5) miscommunication between any of the various medical practitioners involved with the patient's care. Errors of omission usually fall under specific descriptors, such as the failure to administer some preventative treatment, such as neglecting decontamination or sterilization procedures, a lapse in monitoring, and the omission or poor implementation of a scheduled step in the patient's treatment regimen, implementation of medical management.

This chapter has further documented the specifics of medical errors within the context of the hospital intensive care unit (ICU). While the ICU constitutes an environment with an inherently and extremely elevated risk of medical error, which moreover will involve patients for whom any error can be of greater severity than in other areas of the facility, the ramifications of a medical error in the ICU can range as widely as its cause, from virtually no effect at one end of the continuum to irreparable damage or even fatality at the other. Despite this variety, one clear trend among the types of errors occurring frequently in the ICU is the preponderance of errors involving medication. All the above factors point to the hospital ICU as likely to be one of the most, if not the most, medical error prone environments in the field of medicine. Furthermore, the harm caused by an error is likely to be more severe than in most other environments, considering the following circumstances: 1) patients in this unit already are dealing with life threatening illness or injuries, 2) they are in a weakened physical state as a result, often with compromised or suppressed natural immune systems, 3) they are frequently sedated, 4) they require constant monitoring and are under the care of many different medical and healthcare personnel, and 5) they are being cared for according to complicated treatment plans, typically involving multiple medications.

The statistics on preventable medical errors in the hospital ICU are grim, with preventable fatalities estimated to range between 44,000 and 98,000, in addition to economic costs of 17 to 29 billion dollars. Thus, it should come as no surprise that the ICU is the setting for more than an estimated one third of all the medical errors in any particular medical facility; this estimate hold for both the number and frequency of incidents, as well as the percentage of the hospital's annual budget devoted to ICU in an effort to prevent even greater error costs and consequences.

In this dissertation, Chapter 3 focused on the principles of biomedical ethics, which have been espoused and publicized by the American College of Physicians, the American Medical Association, and other professional medicals groups based in the United States, which have indicated that these standards are mandated foundations and guiding principles for both preventing and dealing with medical errors occurring in the ICU or elsewhere within professional practice. Central to these principles is the complete and candid disclosure of every medical error or adverse event, including all relevant details and the informing of all stakeholders. Aside from legal duties, which have been addressed in later chapters of this dissertation, by virtue of professional oaths and codes of conduct, every medical practitioner, institution, facility, and organization is bound to these standards.

The discussion in this chapter addressed the foundations of these ethical principles in consequentialism, teleological theory, and utilitarianism. The first two of these are focused on promoting and ensuring optimal outcomes in medical treatment and healthcare; the last focuses on providing the greatest degree of positive benefit to the largest segment of the population. The discussion has further considered the premises and claims of deontology and principlism, which are in many ways in distinct opposition to the aforementioned ethical schools of thought. Nevertheless, despite fundamental differences, all the theories of bioethics agree that the principles of autonomy, justice, beneficence and non-maleficence are necessary cornerstones in dealing with medical

errors.

Regardless of the philosophical foundations of these approaches to bioethics, they are unanimous in insisting that medical errors be fully disclosed to all involved parties; they come into disagreement over questions such as how to deal with patients who lack the capacity to provide informed consent or are in futile circumstances, as are those receiving end-of-life care, both situations more common in a hospital ICU. Ethical dilemmas, such as the conflict between family members agitating for every attempt to prolong the life of a loved one against the medical professional's judgment of futility and the violation of professional ethical standards that continued or extreme measures would entail, are situations which complicate the determination of and handling of medical errors, real or perceived.

Among the inherent characteristics of medical services in the ICU, which bring many ethical issues and dilemmas to the forefront, are the limitations on its resources compounded with the unpredictability, intensity, immediacy of the services required at any given point in time. To begin with, a high proportion of the Unit's patients are experiencing terminal illness, which means that they need extensive resources that even though expended may do little to extend let alone improve the quality of life. Thus, acting in each patient's best interest simultaneously becomes an impossible ideal. These realities require painful, ethically charged decision making frequently with foreseeably fatal outcomes. Having discussed and assessed various ethical foundation principles for allocating treatment resources, this dissertation has concluded that no single strategy, such as: 1) treating each patient thoroughly in order of he or she presents, 2) favoring

those patients whose conditions are more life threatening, 3) seeking to treat the greatest number of patients to the greatest extent possible in other words, utilitarianism, or 4) prioritizing those patients deemed to have the most social usefulness, can be considered completely satisfactory or even fully ethical in the practical circumstances of the ICU. Integrating multiple ethical principles can better achieve equity and adherence to standards, but at a cost of increased complexity and thus, difficulty with implementation. The chapter has concluded by examining the issues surrounding the withholding and withdrawing of life-saving treatment and the ethical or legal distinction which may exist between the two treatment decisions, particularly within the ICU. Medical errors and adverse events occur in the hospital ICU in the climate of all these already complex ethical circumstances and must be dealt with accordingly.

Chapter 4 began with an overview of those precepts with which most Western and other cultures and religions across the globe concur in relation to the responsibilities of those involved in the aftermath of a medical error, regardless of how minor or devastating. These moral traditions require that any person, group, or organization that is responsible for causing harm or damage to another individual or group, explicitly acknowledge that responsibility to all those affected by its consequences and offer some appropriate form of restitution or compensation to the extent possible. From the point of view of the hospital ICU, what is demanded by ethics is full disclosure of the error, including: 1) all relevant contributing conditions and circumstances; 2) all already manifested impacts- typically negative; 3) all those consequences which can be anticipated; 4) a sincere confession and apology; 5) proposed courses of action to alleviate any suffering caused by the error, to rectify or undo any damage caused; 6)

proposed steps to prevent further occurrence of the same or similar; and 7) proposals for rectifying the error and compensating the victim.

The ultimate conclusion of all these ethical considerations is that it is the undeniable responsibility of those in the ICU to completely communicate the circumstances leading up or contributing to all errors, together with explicit acknowledgements of responsibility and apologies from those responsible. Society as a whole expects all these elements; moreover, they are the priorities desired by those experiencing the effects of the error. This group of affected individuals indicate, both in hypothetical scenarios and as experiencers of the situation in reality, that receiving the details of how the error occurred, what its consequences are or can be anticipated to arise, how these consequences of the error will be managed and corrected, and what will be changed to forestall future occurrences.

Despite the combined force of cultural norms, moral dictates, principles of biomedical ethics, codes of conduct from professional medical associations, policies of the more enlightened medical facilities and institutions, and even legal mandates, the norm among medical professionals is either to conceal part or all of the circumstances surrounding a medical error or to distort the situation in an attempt to hide fallibility or culpability. The pressure to follow the route of concealment is formidable. The list of fears counteracting the sense of professional obligation in the minds of medical practitioners includes: 1) feeling of guilt and shame, 2) lasting impairment to professional reputations, 3) fear of loss of employment and permanent damage to one's career, and 4) civil litigation for malpractice with the accompanying publicity. From the perspective of

biomedical ethics, motivations to deny or otherwise avoid responsibility are ultimately irrelevant in that such actions expose patient, in the ICU or elsewhere, to additional trauma both psychologically and physically.

As the analysis in this chapter concludes, contrary to the intended results of concealing fault and culpability, such behaviors or measures readily produce the very results medical professional had wished to avoid, namely patient dissatisfaction, harm to professional reputations, and litigation.

The chapter goes on to describe the procedures necessary in dealing with a medical error. The first step in the disclosure process involves collecting and reviewing all pertinent data; documenting it; identifying all those whose actions contributed directly to the error; creating a presentation of all that is known and surmised in the case, as well as preparing the apology, the plan for dealing with the effects of the error, and taking measures to ensure that there will be no recurrence. The second step is planning for the disclosure meeting itself constitutes the second step in the disclosure process and includes many details concerning time, place, attendees, and who is speak, when, and how during the meeting; all aspects of which must be considered in order to optimize clarity of communication and understanding and at the same time minimize the concern and stress felt by the patient and others. Research has shown that the lack of careful implementation of this process is the likely cause of approximately 70% of patients and others involved reporting unmet expectations in the wake of the disclosure process. This chapter of the dissertation concludes that a reevaluation of the institutional disclosure process is called for, the goal of which needs to be no less than a fundamental restructuring of the process.

The initial step in achieving this goal needs to accomplish significant improvements in notification and documentation in the wake of any medical error.

Chapter 5 of this dissertation rests on the premise that the high standards of biomedical ethics inherently cannot be upheld, complied with, or achieved in the absence of the prior development and implementation of a comprehensive systems of protocols for the disclosure and handling of every medical error in the ICU, from the most minor to the most severe. Given that medical errors vary widely in the scope and scale of their causes and consequences, protocols must be equally flexible, not only to ensure adherence to ethical standards, but also to be consistently commensurate with the intensity and severity of the error in question. These protocols must also be designed flexibly enough to: 1) handle issues of accepting responsibility before errors occur, 2) proactively manage risks to patients from errors, 3) deal with risk to the medical facility, 4) anticipate the consequences of an error, 5) identify and deal with all the stakeholders in the event according to their individual relationship to it, and 6) coordinate the timing and execution of disclosure, apologies, and compensation.

This chapter has described eight essentials of designing disclosure protocols including: 1) uncovering the scope of the error, 2) adhering to the ethical principles in acknowledging responsibility, 3) accurately assessing patient prognosis and planning to correct the consequences of the error, 4) managing foreseeable risks arising from the error, 5) coordinating the timing of disclosure to various stakeholders, 6) incorporating these stakeholders into the process of disclosure and apology, 7) informal and formal acknowledging the error and providing apologies, formally and informally as appropriate, and 8) handling compensation, in all the forms it will take. Moreover, this chapter's analysis has clearly established a number of basic factors which must be taken into account when creating protocols and other efforts to combat medical errors in the hospital ICU: 1) both the principles of ethics and those of professional medical associations insist on full disclosure, 2) transfers and handoffs of patients are an especially vulnerable activity, 3) a pressing need exists to work proactively to overcome barriers to communication, 4) the differences in what is appropriate protocol in formal as opposed to informal apology is considerable, and 5) current apology laws in many jurisdictions do not achieve the positive results that were intended.

The various sections of Chapter 5 converge in establishing four distinct and contrasting attitudes among those involved in adverse medical events and medical errors in particular. First, medical professionals unanimously, or nearly so, concur in principle when confronted with the issue hypothetically, that standards of biomedical ethics oblige them to provide full disclosure and apologies. Second, these same physicians and administrators consistently behave in directly the opposite fashion when confronted with a medical error and its ramifications, involving them personally. Third, the clear priorities of patients, as well as their relatives and friends are to receive answers, explanations, and apologies from the medical professionals responsible, all of which should be motivated by sincere regret and contrition. Fourth and possibly forming the greatest obstacle to satisfactorily resolving the consequences and problems created by a medical error, medical professionals fundamentally misjudge the attitudes and motivations of these patients who have been exposed to a medical error, as well as the desires and feelings of those concerned for these victims.

Contrary to the presupposition of many medical professional, and even more so their legal counsels, the primary aims of those patients who have been victims of medical errors or their relatives and who subsequently pursue legal redress is not the pursuit of financial compensation, as documented by a Canadian study from 2009. Findings of the Pew research group, looking into research on mediation and litigation in the wake of adverse medical events document the results of various studies concurring on the point that victims of medical errors first and foremost desire a candid acknowledgement of culpability, a sincere apology, and a demonstrable commitment prevent similar mistake in the future. As this dissertation as discussed at length, all these findings starkly contradict the presumptions of the majority of doctors and administrators in all segments of the medical establishment, including the ICU, who see all legal recourse as motivated by greed or the desire to inflict financial punishment, and thus, out of fear for their reputations, careers, and finances remain distinctly reluctant to admit anything hinting of negligence or responsibility. One major conclusion that the analysis of this dissertation establishes is the extreme degree to which professionals in the medical community misunderstand and misinterpret the feeling and priorities of patients who experience and suffer the consequences of medical errors and their family members.

The experience of the medical institutions in the state of Minnesota provides an example of the positive outcomes or proactive measures to combat medical errors, in terms of significantly reducing the frequency and severity of errors, which has been accompanied by declines in the frequency of lawsuits and concomitantly a significant drop in the rates of malpractice insurance premiums. These impressive goals have been achieved by doing the opposite of what has been the instinctive inclination of the medical

community, in particular physicians, along with the thrust of the legal reforms of recent decade. Those predominant attitudes, which Minnesota has eschewed, have been realized in efforts to either hide medical errors, to make circumstances extremely difficult for patients to successfully pursue redress in the courts, or to protect doctors from legal ramifications they may engender by acknowledging medical errors and apologizing for them. To the contrary, the professional medical community in Minnesota dedicated itself to adhering proactively to the standards of biomedical ethics, in other words to 'do the right thing,' without regard for possible consequences.

The final chapter of this dissertation, Chapter 6, concentrates on the development of protocols and procedures, both to prevent and to dealing with medical errors occurring particularly in the hospital ICU, but also in the broader scope of the fields of medicine and healthcare. Protocols, as discussed in the previous chapter which were related directly to disclosure and apology, are a vital yet narrowly focused portion of the full scope of developing and implementing a comprehensive approach to the prevention, minimization, and ethical handling of medical errors and adverse events. While, the primary aim of protocols for disclosure and apology is the minimization of harm to and the ensuring of justice for the injured patient and others aggrieved as a result of the error, the broader focus in this chapter has been the prevention and elimination of the occurrence of these errors and adverse events in the first place, along with the blunting of their severity when they do occur, as stipulated at the outset of the investigation of this dissertation. This comprehensive approach to recommending protocols encompasses their conception, creation, and development, implementation and monitoring on an ongoing basis, as well as their invocation once a medical error or its effects have been detected.

Moreover, as complete prevention in the broader sense is not feasible, the implementation Thus, as highlighted in this chapter, protocols are inherently proactive in their goal of reducing both the rate at which medical errors occur and the levels of damage they inflict, just as much as they aim to undo or minimize the ill effects on the patient, to the extent possible.

The beginning of instituting, implementing, and administering the protocols described in this chapter, whether for the hospital ICU in particular or the facility in general is a comprehensive assessment of the institution's specific and distinct vulnerability to medical error as a precursor to the anticipation of definable weaknesses that need to be proactively addressed and targeted with specific measures aimed at correcting conditions that would foster errors, forestalling errors in inherently highly vulnerable and unavoidable activities, and systematic monitoring of all areas and activities prone to the occurrence of medical errors. On a promising note, this final goal of monitoring is being increasingly facilitated by advances in information technology. Just as modern medicine typically brings larger groups of medical professional working together as teams dedicated to the care and treatment of various individual patients, so too must the effort to prevent and counteract the effects of medical errors and adverse medical events. Achieving these goals requires: 1) the efficient cooperation of various professionals with individual specialties, 2) prompt, clear, and accurate, communications between professionals explicitly trained and proficient in such skill, and 3) a concerted effort to retain the personal dimension of the traditional doctor-patient relationship in the face of the impersonalization in which is the natural tendency of the aforementioned trends in modern medicine. The need for more effective communication extents beyond

exchanges between physician and patient to encompass interactions with family and relatives, other medical staff member, institution supervisors and administrators, insurance providers, legal counsel, and government agency representatives. This need is especially true for the error-prone activities surrounding the delivery and administration of medication in the ICU, where training in communication skills, enhanced monitoring, and appropriate protocols promise to significantly reduce errors. As part of these recommendation, computerized physician order entry (CPOE), including pharmacists in patient rounds, and providing access either to backup medical equipment or to expert equipment technicians will each contribute to forestalling many adverse medical events.

Beyond the recommendations for protocols to forestall, minimize the effects of, and deal with the consequences of medical errors, this dissertation calls for three major initiatives in the broader context of the field of healthcare, which will aid in significantly diminishing the frequency and harm caused by adverse events and medical errors while improving the profession in other ways. First, measures need to be devised and implemented to eliminate failures to deliver quality care and treatment resulting from system-wide flaws or inadequacies. Second, tort reform needs to be undertaken throughout the legal system with the expressed aim and which results in fostering adherence to the highest ethical standards and the delivery of timely justice, as opposed to protracted adversarial legal processes. Third, the process of educating future physicians and other medical professionals needs fundamental revision, so as emphasize and thereby prepare medical and healthcare students in effective communications in general and specifically for dealing with medical errors. Since it is not possible to achieve the goals behind these proposals through protocols along, these recommendations will contribute significantly to reducing the incidence of medical errors throughout the field of

medicine, beyond the scope of the hospital ICU.

Bibliography

- Abaunza, Hernando, and Klaus Romero. "Elements for Adequate Informed Consent in the Surgical Context." *World Journal of Surgery* 38, no. 7 (2014): 1594-604.
- Aberegg, Scott K, Edward F Haponik, and Peter B Terry. "Omission Bias and Decision Making in Pulmonary and Critical Care Medicine." *CHEST Journal* 128, no. 3 (2005): 1497-1505.
- Abramson, Norman S., Karen Silvasy Wald, Ake N. A. Grenvik, Deborah Robinson, and James V. Snyder, "Adverse Occurrences in Intensive Care Units," *JAMA* 244, no. 14 (1980): 1582-1584.
- Ackroyd, Rajeena, Lynne Russon, and Rob Newell. "Views of Oncology Patients, Their Relatives and Oncologists on Cardiopulmonary Resuscitation (Cpr): Questionnaire-Based Study." *Palliative medicine* 21, no. 2 (2007): 139-144.
- Aitini, E., G. Martignoni, R. Labianca, and Cancer Italian Group for the study of Digestive Tract. "Communication Models for Doctor-Patient Relationships." J Cancer Educ 29, no. 2 (2014): 211-12.
- Al-Assaf, Al F. et al. "Preventing Errors in Healthcare: A Call for Action". *Hospital Topics.* 81, no 3(2003): 5-12.
- Al-Doghaither, AH. "Inpatient Satisfaction with Physician Services at King Khalid University Hospital, Riyadh, Saudi Arabia." *East Mediterr Health J* 10, no. 3 (2004): 358-64.
- Alberstein, Michal, and Nadav Davidovitch. "Apologies in the Healthcare System: From Clinical Medicine to Public Health." *Law & Contemp. Probs.* 74 (2011): 151.
- American College of Physicians, American College of Physicians Ethics Manual, 6th ed. Annals of Internal Medicine, 156 no. 1 part 2 (2012): 73-104.

- Ammenwerth, Elske, Petra Schnell-Inderst, Christof Machan, and Uwe Siebert. "The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review."*Journal of the American Medical Informatics* Association 15, no. 5 (2008): 585-600.
- Anderson, Wendy G, Robert M Arnold, Derek C Angus, and Cindy L Bryce. "Posttraumatic Stress and Complicated Grief in Family Members of Patients in the Intensive Care Unit." *Journal of general internal medicine* 23, no. 11 (2008): 1871-76.
- Andrews, Lori B, Carol Stocking, Thomas Krizek, Lawrence Gottlieb, Claudette Krizek, Thomas Vargish, and Mark Siegler. "An Alternative Strategy for Studying Adverse Events in Medical Care." *The Lancet* 349, no. 9048 (1997): 309-13.
- Angus, Derek C, and Jean Carlet. "Surviving Intensive Care: A Report from the 2002 Brussels Roundtable." *Intensive care medicine* 29, no. 3 (2003): 368-77.
- Angus, Derek C, Mark A Kelley, Robert J Schmitz, Alan White, and John Popovich Jr. "Current and Projected Workforce Requirements for Care of the Critically Ill and Patients with Pulmonary Disease: Can We Meet the Requirements of an Aging Population?." JAMA 284, no. 21 (2000): 2762-70.
- Annas, George J. "The Patient's Right to Safety-Improving the Quality of Care through Litigation against Hospitals." *New England Journal of Medicine* 354, no. 19 (2006): 2063-66.
- Apatira, Latifat, Elizabeth A Boyd, Grace Malvar, Leah R Evans, John M Luce, Bernard Lo, and Douglas B White. "Hope, Truth, and Preparing for Death: Perspectives of Surrogate Decision Makers." *Annals of Internal Medicine* 149, no. 12 (2008): 861-68.
- Aplin, G. "Once Is Sometimes Too Much. Cultural Competence Can Reduce Medical Errors, Increase Patient Satisfaction." *MGMA connexion/Medical group Management Association* 7, no. 1 (2007): 21-22.
- Appelbaum, Paul S, and Thomas Grisso. "Assessing Patients' Capacities to Consent to Treatment." *New England Journal of Medicine* 319, no. 25 (1988): 1635-38.
- Arora, V., and J. Johnson. "A Model for Building a Standardized Hand-Off Protocol." *Jt Comm J Qual Patient Saf* 32, no. 11 (2006): 646-55.
- Arora, Vineet M, Megan L Prochaska, Jeanne M Farnan, V D'Arcy, J Michael, Korry J Schwanz, Lisa M Vinci, *et al.* "Problems after Discharge and Understanding of Communication with Their Primary Care Physicians among Hospitalized Seniors: A Mixed Methods Study." *Journal of Hospital Medicine* 5, no. 7 (2010): 385-91.

- Arora, Vinett, J Johnson, D Lovinger, HJ Humphrey, and DO Meltzer. "Communication Failures in Patient Sign-out and Suggestions for Improvement: A Critical Incident Analysis." *Quality and Safety in Health Care* 14, no. 6 (2005): 401-07.
- Association, American Medical. "Ethical Responsibility to Study and Prevent Error and Harm." American Medical Association, <u>http://www.ama-</u> <u>assn.org/ama/pub/physician-resources/medical-ethics/code-medical-</u> <u>ethics/opinion8121.page.</u>
- Association, American Medical. "Principles of Medical Ethics." <u>http://www.ama-assn.org/ama/pub/</u> physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page.
- Association, Minnesota Hospital. "Adverse Health Event Report Indicates Care Is More Transparent." <u>http://www.health.state.mn.us/</u> patientsafety/ae/09ahereportLpdf.
- Atkinson, Simon, R Mason, LordI McColl, D Bihari, M Smithies, and K Daly. "Identification of Futility in Intensive Care." *The Lancet* 344, no. 8931 (1994): 1203-06.
- Australia, Commonwealth of. "Reform of Liability Insurance Law in Australia." (2004). Retrieved from: <u>http://archive.treasury.gov.au/documents/799/PDF/complete.pdf</u>.
- Avraham, Ronen, and Max Schanzenbach. "The Impact of Tort Reform on Intensity of Treatment: Evidence from Heart Patients." *Journal of health economics* 39 (2015): 273-88.
- Avraham, Ronen, and Max Schanzenbach. "The Impact of Tort Reform on Private Health Insurance Coverage, February 2010." American law and economics review (2010): 319-55.
- Azoulay, Elie, Sylvie Chevret, Ghislaine Leleu, Frederic Pochard, Michel Barboteu, Christophe Adrie, Pierre Canoui, Jean Roger Le Gall, and Benoît Schlemmer.
 "Half the Families of Intensive Care Unit Patients Experience Inadequate Communication with Physicians." *Critical care medicine* 28, no. 8 (2000): 3044-49.
- Baggs, Judith Gedney, Madeline H Schmitt, Alvin I Mushlin, Pamela H Mitchell, Deborah H Eldredge, David Oakes, and Alan D Hutson. "Association between Nurse-Physician Collaboration and Patient Outcomes in Three Intensive Care Units." *Critical care medicine* 27, no. 9 (1999): 1991-98.
- Baker, David P, Eduardo Salas, Heidi King, James Battles, and Paul Barach. "The Role of Teamwork in the Professional Education of Physicians: Current Status and Assessment Recommendations." *The Joint Commission Journal on Quality and Patient Safety* 31, no. 4 (2005): 185-202.

- Baker, Robert. The American Medical Ethics Revolution: How the Ama's Code of Ethics Has Transformed Physicians' Relationships to Patients, Professionals, and Society. JHU Press, 1999.
- Banja, JD. Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause? In: Henriksen K, Battles JB, Marks ES, et al., editors. Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb. Available from: http://www.ncbi.nlm.nih.gov/books/NBK20549/ accessed, February 7, 2016.
- Banja, John D. "Problematic Medical Errors and Their Implications for Disclosure." HEC forum 20, no. 3 (2008): 201-13.
- Banja, John D. Medical Errors and Medical Narcissism. Jones & Bartlett Learning, 2004.
- Basford, Lynn, and Oliver Slevin. *Theory and Practice of Nursing: An Integrated Approach to Caring Practice*. Nelson Thornes, 2003.
- Batalden, Paul B, and Frank Davidoff. "What Is "Quality Improvement" and How Can It Transform Healthcare?". *Quality and safety in health care* 16, no. 1 (2007): 2-3.
- Bates, David W, and Atul A Gawande. "Error in Medicine: What Have We Learned?" *Annals of Internal Medicine* 132, no. 9 (2000): 763-67.
- Bauman, Kristy A, and Robert C Hyzy. "Icu 2020 Five Interventions to Revolutionize Quality of Care in the Icu." *Journal of intensive care medicine* 29, no. 1 (2014): 13-21.
- Beauchamp, Tom L, and James F Childress. *Principles of Biomedical Ethics*. Oxford university press, 2001.
- Bedevian, Rima. "Medical Errors: How Can You Avoid Them?" <u>http://www.plasticsurgerypractice.com/2010/06/medical-errors-how-can-you-avoid-them/.</u>
- Bell, Chaim M, Jeffrey L Schnipper, Andrew D Auerbach, Peter J Kaboli, Tosha B Wetterneck, David V Gonzales, Vineet M Arora, James X Zhang, and David O Meltzer. "Association of Communication between Hospital-Based Physicians and Primary Care Providers with Patient Outcomes." *Journal of general internal medicine* 24, no. 3 (2009): 381-86.
- Bell, Chaim M, Stacey S Brener, Nadia Gunraj, Cindy Huo, Arlene S Bierman, Damon C Scales, Jana Bajcar, Merrick Zwarenstein, and David R Urbach. "Association of Icu or Hospital Admission with Unintentional Discontinuation of Medications for Chronic Diseases." JAMA 306, no. 8 (2011): 840-47.

- Benoit, E, P Eckert, C Theytaz, M JORIS- FRASSEREN, M Faouzi, and J Beney.
 "Streamlining the Medication Process Improves Safety in the Intensive Care Unit." *Acta anaesthesiologica Scandinavica* 56, no. 8 (2012): 966-75.
- Bensing Jozieno, "Bridging the Gap. The separate worlds of evidence-based medicine and patient-centered medicine." *Patient Education and Counseling* 39 no. 1 (2000): 17-25.
- Bensing, Jozien, et al., "Communication in context: New directions in communication research." *Patient Education and Counseling* 50 no. 1 (2003): 27-32.
- Berger, Jeffrey T, Evan G DeRenzo, and Jack Schwartz. "Surrogate Decision Making: Reconciling Ethical Theory and Clinical Practice." *Annals of Internal Medicine* 149, no. 1 (2008): 48-53.
- Berlinger N. "Avoiding cheap grace. Medical harm, patient safety, and the culture(s) of forgiveness," Hastings Cent Rep 33, no. 6 (2003): 28-36.
- Berlinger, N. *After Harm: Medical Error and the Ethics of Forgiveness*. Baltimore, Maryland: Jhons Hopkins University, 2005.
- Berlinger, Nancy, and Albert W Wu. "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Error." *Journal of medical ethics* 31, no. 2 (2005): 106-08.
- Bernat, James L, and Lynn M Peterson. "Patient-Centered Informed Consent in Surgical Practice." *Archives of Surgery* 141, no. 1 (2006): 86-92.
- Bernat, James L. *Ethical Issues in Neurology*. Lippincott Williams & Wilkins Philadelphia, 2008.
- Bersten, Andrew D, and Neil Soni. *Oh's Intensive Care Manual*. Elsevier Health Sciences, 2013.
- Bertakis Klea D., and Rahman Azari, "Patient gender and physician practice style." *Journal of Women's Health* 16 no. 6 (2007): 859-868.
- Bhat, Vivek, Manikchandra Tiwari, Preeti Chavan, and Rohini Kelkar. "Analysis of laboratory sample rejections in the pre-analytical stage at an oncology center." *Clinica Chimica Acta* 413, no. 15 (2012): 1203-1206.
- Bibler, Trevor M. "Why I No Longer Say "Withdrawal of Care" or "Life Sustaining Technology"." *Journal of palliative medicine* 16, no. 9 (2013): 1146-1147.
- Bigatello, Luca M, Hasan Alam, and Rae M Allain. Critical Care Handbook of the Massachusetts General Hospital. Lippincott Williams & Wilkins, 2010.

- Blendon, Robert J., et al., "Views of Practicing Physicians and the Public on Medical Errors." *New England Journal of Medicine* 347 no. 24 (2002): 1933-40.
- Blot, Stijn, Elsa Afonso, and Sonia Labeau. "Recent Advances in Multidisciplinary Critical Care." *American Journal of Critical Care* 24, no. 1 (2015): 75-86.
- Boettger, Ryan K. "Types of Errors Used in Medical Editing Tests." *Journal of the American Medical Writers Association* 27, no. 3 (2012): 99-104.
- Bohomol, Elena, Lais Helena Ramos, and Maria D'Innocenzo. "Medication Errors in an Intensive Care Unit." *Journal of Advanced Nursing* 65, no. 6 (2009): 1259-67.
- Bonifacio, Alberto S, Noa Segall, Atilio Barbeito, Jeffrey Taekman, Rebecca Schroeder, and Jonathan B Mark. "Handovers from the or to the Icu." *International anesthesiology clinics* 51, no. 1 (2013): 43-61.
- Boothman, R. C., A. C. Blackwell, D. A. Campbell, Jr., E. Commiskey, and S. Anderson.
 "A Better Approach to Medical Malpractice Claims? The University of Michigan Experience." *J Health Life Sci Law* 2, no. 2 (2009): 125-59.
- Boothman, Richard C, Sarah J Imhoff, and Darrell A Campbell Jr. "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Directions." *Frontiers of Health Services Management* 28, no. 3 (2012): 13-28.
- Born, Patricia, W Kip Viscusi, and Tom Baker. "The Effects of Tort Reform on Medical Malpractice Insurers' Ultimate Losses." *Journal of Risk and Insurance* 76, no. 1 (2009): 197-219.
- Borowitz, SM, LA Waggoner-Fountain, EJ Bass, and RM Sledd. "Adequacy of Information Transferred at Resident Sign-out (Inhospital Handover of Care): A Prospective Survey." *Quality and Safety in Health Care* 17, no. 1 (2008): 6-10.
- Bosek, Marcia Sue DeWolf, and Teresa A Savage. *The Ethical Component of Nursing Education: Integrating Ethics into Clinical Experience*. Lippincott Williams & Wilkins, 2007.
- Boyd, Cynthia M, Jonathan Darer, Chad Boult, Linda P Fried, Lisa Boult, and Albert W Wu. "Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Comorbid Diseases: Implications for Pay for Performance." Jama 294, no. 6 (2005): 716-24.
- Bracco, D, Jean-Baptiste Favre, Bruno Bissonnette, Jean-Blaise Wasserfallen, Jean-Pierre Revelly, Patrick Ravussin, and René Chioléro. "Human errors in a multidisciplinary intensive care unit: a 1-year prospective study." *Intensive care medicine* 27, no 1 (2001): 137-145.

- Bradley, Ciarán T, and Karen J Brasel. "Developing Guidelines That Identify Patients Who Would Benefit from Palliative Care Services in the Surgical Intensive Care Unit." *Critical care medicine* 37, no. 3 (2009): 946-950.
- Braithwaite, Jeffrey, Mary T Westbrook, Nadine A Mallock, Joanne F Travaglia, and Rick A Iedema. "Experiences of Health Professionals Who Conducted Root Cause Analyses after Undergoing a Safety Improvement Programme." *Quality* and Safety in Health Care 15, no. 6 (2006): 393-99.
- Breen, G. M., T. T. Wan, N. J. Zhang, S. S. Marathe, B. K. Seblega, and S. C. Paek. "Improving Doctor-Patient Communication: Examining Innovative Modalities Vis-a-Vis Effective Patient-Centric Care Management Technology." *J Med Syst* 33, no. 2 (2009): 155-62.
- Brehmer, Berndt. "Dynamic decision making: Human control of complex systems." *Acta psychologica* 81, no. 3 (1992): 211-241.
- Brendel, David H. "Healing Psychiatry: A Pragmatic Approach to Bridging the Science/Humanism Divide." *Harvard review of psychiatry* 12, no. 3 (2004): 150-157.
- Brennan, Troyen A, Lucian L Leape, Nan M Laird, Liesi Hebert, A Russell Localio, Ann G Lawthers, Joseph P Newhouse, Paul C Weiler, and Howard H Hiatt. "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I." *New England journal of medicine* 324, no. 6 (1991): 370-76.
- Brennan, Troyen A., et al. "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study 1." *New England Journal of Medicine* 324 no. 6 (1991): 370-76.
- Bria, William F, and M Michael Shabot. "The Electronic Medical Record, Safety, and Critical Care." *Critical care clinics* 21, no. 1 (2005): 55-79.
- Brieva, Jorge L, Prashanth Cooray, and Martin Rowley. "Withholding and Withdrawal of Life-Sustaining Therapies in Intensive Care: An Australian Experience." *Clitical Care and Resuscitation* 11, no. 4 (2009): 266-268.
- Brock DM, Quella A, Lipira L, Lu DW, Gallagher TH. "Physician assistants and the disclosure of medical error." *Acad Med* 89, no 6 (2014): 858-862.
- Brock, D. W. "Informed Consent." In *Health Care Ethics*, edited by and T. Regan D. VanDeVeer. PA: Temple University Press: PA: Temple University Press, 1987, 98-116.

- Brown, Samuel M, C Gregory Elliott, and Robert Paine. "Withdrawal of Nonfutile Life Support after Attempted Suicide." *The American Journal of Bioethics* 13, no. 3 (2013): 3-12.
- Bucknall, Tracey K. "Medical Error and Decision Making: Learning from the Past and Present in Intensive Care." *Australian critical care* 23, no. 3 (2010): 150-56.
- Bureau, U.S. Census. "2010 Census Shows America's Diversity."<u>https://www.census.gov/newsroom/releases/archives/2010_census/cb1_1-cn125.html.</u>
- Bureau, U.S. Census. "Our Diverse Population." <u>http://www.census.gov/population/pop-profile/2000/chap16.pdf.</u>
- Burroughs, T., Amy D. Waterman, Thomas H. Gallagher, Brian Waterman, Donna B. Jeffe, William Claiborne Dunagan, Jane Garbutt, Max M. Cohen, Jane Cira, and Victoria J. Fraser. "Medication safety: patients' concerns about medical errors during hospitalization." *Joint Commission Journal on Quality and Patient Safety* 33, no. 1 (2007): 5-14.
- Burton, R., E. Coleman, D. Lipson, T. Agres, A. Schwartz, and S. Dentzer, "Improving Care Transitions," Retrieved from: http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=76, What's the issue?, Accessed Feb 26, 2016.
- Butcher, Lola. "Lawyers Say 'sorry' may Sink You in Court." *Physician Executive* 32, no. 2 (2006): 20-4.
- Butts, Janie B, and Karen L Rich. *Nursing Ethics: Across the Curriculum and into Practice*. Jones & Bartlett Publishers, 2005.
- Calabrese, Andrea D, Brian L Erstad, Katherine Brandl, Jeffrey F Barletta, Sandra L Kane, and Deb S Sherman. "Medication Administration Errors in Adult Patients in the Icu." *Intensive care medicine* 27, no. 10 (2001): 1592-98.
- Camiré, Eric, Eric Moyen, and Henry Thomas Stelfox. "Medication Errors in Critical Care: Risk Factors, Prevention and Disclosure." *Canadian Medical Association Journal* 180, no. 9 (2009): 936-43.
- Campbell, Emily M. Dean F. Sittig, Joan S. Ash, Kenneth P. Guappone, and Richard H. Dykstra, "Types of unintended consequences related to computerized provider order entry," *Journal of American Medical Information Association* 13 no. 5 (2006): 547-556.
- Canterbury v Spence, 464 F2d 772 (DC Cir 1972), cert denied, 409 Us 1064 (1972). (1972).

- Carayon, Pascale, Tosha B. Wetterneck, Bashar Alyousef, Roger L. Brown, Randi S. Cartmill, Kerry McGuire, Peter L. T. Hoonakker, Jason Slagle, Kara S. Van Roy, James M. Walker, Matthew B. Weinger, Anping Xie, and Kenneth E. Wood, "Impact of electronic health record technology on the work and workflow of physicians in the intensive care unit," *International Journal of Medical Informatics* 84 no. 8 (2015): 578:594.
- Carless, Ruth, ICU Cert, PICU Cert, Donna M Gillies, William B Runciman, Albert W Wu, and Peter Pronovost. "Evaluation of Two Methods for Quality Improvement in Intensive Care: Facilitated Incident Monitoring and Retrospective Medical Chart Review." *Crit Care Med* 31, no. 4 (2003).
- Carlson, Erik. "Consequentialism Characterized." In *Consequentialism Reconsidered*. Dordrecht: Kluwer Academic, 1995.
- Casalino, Lawrence, Robin R. Gillies, Stephen M. Shortell, Julie A. Schmittdiel, Thomas Bodenheimer, James C. Robinson, Thomas Rundall, Nancy Oswald, Helen Schauffler, and Margaret C. Wang. "External incentives, information technology, and organized processes to improve health care quality for patients with chronic diseases." Jama 289, no. 4 (2003): 434-441.
- Catchpole, Ken R, Marc R De Leval, Angus Mcewan, Nick Pigott, Martin J Elliott, Annette Mcquillan, Carol Macdonald, and Allan J Goldman. "Patient Handover from Surgery to Intensive Care: Using Formula 1 Pit- Stop and Aviation Models to Improve Safety and Quality." *Pediatric Anesthesia* 17, no. 5 (2007): 470-78.
- Chan, D., et al., "How surgeons disclose medical errors to patients: a study using standardized patients." *Surgery* 138 no. 5 (2005): 851-58.
- Charon, Rita. "Narrative Medicine as Witness for the Self-Telling Body." *Journal of Applied Communication Research* 37, no. 2 (2009): 118-31.
- Cher, Daniel J, and Leslie A Lenert. "Method of Medicare Reimbursement and the Rate of Potentially Ineffective Care of Critically Iii Patients." *Jama* 278, no. 12 (1997): 1001-07.
- Chow, Clifton M, Dow Wieman, Ben Cichocki, Helena Qvicklund, and Dorothy Hiersteiner. "Mission Impossible: Treating Serious Mental Illness and Substance Use Co-Occurring Disorder with Integrated Treatment: A Meta-Analysis." *Mental Health and Substance Use* 6, no. 2 (2013): 150-68.
- Christakis, Nicholas A, and Theodore J Iwashyna. "Attitude and Self-Reported Practice Regarding Prognostication in a National Sample of Internists." *Archives of Internal Medicine* 158, no. 21 (1998): 2389-95.

- Church, Rhonda, and Neil MacKinnon. *Take as Directed: Your Prescription for Safe Health Care in Canada*. ECW Press, 2010.
- Civetta, Joseph M. "Futile Care or Caregiver Frustration? A Practical Approach." *Critical care medicine* 24, no. 2 (1996): 346-51.
- Clancy, Carolyn M. "The Importance of Simulation: Preventing Hand-Off Mistakes." *AORN journal* 88, no. 4 (2008): 625-27.
- Clark, Peter A. "Medication Errors in Family Practice, in Hospitals and after Discharge from the Hospital an Ethical Analysis." *The Journal of Law, Medicine & Ethics* 32, no. 2 (2004): 349-357.
- Classen, David C, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C Whittington, *et al.* "'Global Trigger Tool'shows That Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured." *Health affairs* 30, no. 4 (2011): 581-89.
- Clinton, H. R., and B. Obama. "Making Patient Safety the Centerpiece of Medical Liability Reform." *N Engl J Med* 354, no. 21 (2006): 2205-8.
- Cole, Steven A., and Julian Bird, *The medical interview: The three-function approach* Philadelphia, PA: Elsevier Sauders, 2013.
- Collins, Sarah A, Suzanne Bakken, David K Vawdrey, Enrico Coiera, and Leanne Currie. "Model Development for Ehr Interdisciplinary Information Exchange of Icu Common Goals."*International journal of medical informatics* 80, no. 8 (2011): e141-e49.
- Commission, The Joint. "Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals." 2015, Retrieved from: <u>http://www.jointcommission.org/assets/1/6/aroadmapforhospitalsfinalversion727.</u> <u>pdf</u>.
- Compliance, Report on Medicare. "Chance of Errors with Inpatient-Only List Abound; medical Necessity Still a Question ", 2012.
- Cook, A., and Helena Hoas. "Ethics Conflicts in Rural Communities: Recognizing and Disclosing Medical Errors." *Psychology Faculty Publications* (2009): 231-253.
- Cooper, Jeffrey B, Ronald S Newbower, and Richard J Kitz. "An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations For." *Anesthesiology* 60 (1984): 34-42.
- Cooper, Mary Carolyn. "Principle-Oriented Ethics and the Ethic of Care: A Creative Tension." *Advances in Nursing Science* 14, no. 2 (1991): 22-31.
- Courtright, Katherine R, and Meeta Prasad Kerlin. "Intensive Care Unit Staffing and Quality of Care: Challenges in Times of an Intensivist Shortage." *Revista Brasileira de terapia intensiva* 26, no. 3 (2014): 205-07.
- Cox, Christopher E, Tereza Martinu, Shailaja J Sathy, Alison S Clay, Jessica Chia, Alice L Gray, Maren K Olsen, et al. "Expectations and Outcomes of Prolonged Mechanical Ventilation." Critical care medicine 37, no. 11 (2009): 2888.
- Cravens, Catherine, and Jo Anne L. Earp, "Disclosure and Apology." North Carolina Medical Journal 70 no. 2 (2009): 90-192.
- Crippen, David W. *End-of-Life Communication in the ICU: A Global Perspective*. Springer Science & Business Media, 2007.
- Crippen, David. ICU Resource Allocation in the New Millennium: Will We Say" No"? : Springer Science & Business Media, 2012.
- Cronin, Brian. Value Ethics: A Lonergan Perspective. Nairobi, Kenya: Consolata Institute of Philosophy Press, 2006.
- Croskerry, Pat. "Cognitive Forcing Strategies in Clinical Decisionmaking." Annals of emergency medicine 41, no. 1 (2003): 110-20.
- Croskerry, Pat. "Achieving Quality in Clinical Decision Making: Cognitive Strategies and Detection of Bias." *Academic Emergency Medicine* 9, no. 11 (2002): 1184-204.
- Cullen, David J, Bobbie Jean Sweitzer, David W Bates, Elisabeth Burdick, Amy Edmondson, and Lucian L Leape. "Preventable Adverse Drug Events in Hospitalized Patients: A Comparative Study of Intensive Care and General Care Units." *Critical care medicine* 25, no. 8 (1997): 1289-97.
- Curtis, J Randall, and Douglas B White. "Practical Guidance for Evidence-Based Icu Family Conferences." *Chest journal* 134, no. 4 (2008): 835-43.
- Curtis, J Randall, Donald L Patrick, Ellen S Caldwell, and Ann C Collier. "The Attitudes of Patients with Advanced Aids toward Use of the Medical Futility Rationale in Decisions to Forgo Mechanical Ventilation." *Archives of internal medicine* 160, no. 11 (2000): 1597-601.
- Curtis, J Randall, Ruth A Engelberg, Mark E Bensink, and Scott D Ramsey. "End-of-Life Care in the Intensive Care Unit: Can We Simultaneously Increase Quality and

Reduce Costs?". *American journal of respiratory and critical care medicine* 186, no. 7 (2012): 587-92.

- Curtis, J Randall. "Communicating About End-of-Life Care with Patients and Families in the Intensive Care Unit." *Critical care clinics* 20, no. 3 (2004): 363-80.
- Curtis, J Randall. Managing Death in the Icu: The Transition from Cure to Comfort: The Transition from Cure to Comfort. Oxford University Press, 2000.
- Dasinger, Lisa K, Niklas Krause, Pamela J Thompson, Richard J Brand, and Linda Rudolph. "Doctor Proactive Communication, Return-to-Work Recommendation, and Duration of Disability after a Workers' Compensation Low Back Injury." *Journal of Occupational and Environmental Medicine* 43, no. 6 (2001): 515-25.
- Daugherty, Christopher K, and Fay J Hlubocky. "What Are Terminally Ill Cancer Patients Told About Their Expected Deaths? A Study of Cancer Physicians' Self-Reports of Prognosis Disclosure." *Journal of Clinical Oncology* 26, no. 36 (2008): 5988-93.
- David, Guy, Candace L Gunnarsson, Heidi C Waters, Ruslan Horblyuk, and Harold S Kaplan. "Economic Measurement of Medical Errors Using a Hospital Claims Database." *Value in Health* 16, no. 2 (2013): 305-10.
- de Leval, Marc R, Jane Carthey, David J Wright, Vernon T Farewell, and James T Reason. "Human Factors and Cardiac Surgery: A Multicenter Study." *The Journal* of Thoracic and Cardiovascular Surgery 119, no. 4 (2000): 661-72.
- DeJohn, P. "Follow Protocols When Using Medications from Compounding Pharmacies." *OR manager* 29, no. 8 (2013): 28-30.
- Dekker, Sidney WA, and Nancy G Leveson. "The Bad Apple Theory Won't Work: Response to 'Challenging the Systems Approach: Why Adverse Event Rates Are Not Improving'by Dr Levitt."*BMJ quality & safety* (2014): bmjqs-2014-003585.
- Delany, C. "Making a Difference: Incorporating Theories of Autonomy into Models of Informed Consent." *Journal of Medical Ethics* 34, no. 9 (2008): e3-e3.
- Dhillon, Balbir S. *Human Reliability and Error in Medical System*. Vol. 2: World Scientific Publishing Company Incorporated, 2003.
- Dibbelt, Susanne, Monika Schaidhammer, Christian Fleischer, and Bernhard Greitemann. "Patient–Doctor Interaction in Rehabilitation: The Relationship between Perceived Interaction Quality and Long-Term Treatment Results." *Patient Education and Counseling* 76, no. 3 (2009): 328-35.

- Dietz, Isabel, Gian Domenico Borasio, Dipl Pall Med, Christoph Molnar, Christof Müller-Busch, Anke Plog, Gerhard Schneider, and Ralf J Jox. "Errors in Palliative Care: Kinds, Causes, and Consequences: A Pilot Survey of Experiences and Attitudes of Palliative Care Professionals." *Journal of palliative medicine* 16, no. 1 (2013): 74-81.
- Ditto, Peter H, Joseph H Danks, William D Smucker, Jamila Bookwala, Kristen M Coppola, Rebecca Dresser, Angela Fagerlin, et al. "Advance Directives as Acts of Communication: A Randomized Controlled Trial." Archives of Internal Medicine 161, no. 3 (2001): 421-30.
- Dodek, Peter. "2 or More Medical Errors with Adverse Consequences, Affecting 2.6% of Patients, Increased Mortality in Intensive Care Units." ACP Journal Club 152, no. 5 (2010): JC5-12.
- Doerner, Dietrich. "The logic of failure." *Philosophical Transactions of the Royal Society* of London. Series B, Biological Sciences 327, no. 1241 (1990): 463-473.
- Donchin, Yoel, and F Jacob Seagull. "The Hostile Environment of the Intensive Care Unit." *Current opinion in critical care* 8, no. 4 (2002): 316-20.
- Donchin, Yoel, D Gopher, M Olin, Y Badihi, M Biesky, CL Sprung, R Pizov, and S Cotev. "A Look into the Nature and Causes of Human Errors in the Intensive Care Unit." *Quality and Safety in Health Care* 12, no. 2 (2003): 143-47.
- Donchin, Yoel, Daniel Gopher, Miriam Olin, Yehuda Badihi, Michal RNB Biesky, Charles L Sprung, Ruven Pizov, and Shamay Cotev. "A Look into the Nature and Causes of Human Errors in the Intensive Care Unit." *Critical care medicine* 23, no. 2 (1995): 294-300.
- Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. "Use of a standardized protocol to decrease medication errors and adverse events related to sliding scale insulin," *Qual Saf Health Care* 15, no. 2 (2006): 89-91.
- Douglas, Stephen, Randi Cartmill, Roger Brown, Peter Hoonakker, Jason Slagle, Kara Schultz Van Roy, James M Walker, *et al.* "The Work of Adult and Pediatric Intensive Care Unit Nurses." *Nursing research* 62, no. 1 (2013): 50-58.
- Dreeben, Olga. Patient Education in Rehabilitation. Jones & Bartlett Publishers, 2010.
- Dunn, Edward J., and Paul J. Moga. "Patient misidentification in laboratory medicine: a qualitative analysis of 227 root cause analysis reports in the Veterans Health Administration." Archives of pathology & laboratory medicine 134, no. 2 (2010): 244-255.

- Dunn, Geoffrey P, R Martensen, and D Weissman. "Surgical Palliative Care: A Resident's Guide." *American college of surgeons. Chicago: Cuniff-Dixon Foundation* (2009): 107-132.
- Dykes, Patricia C, Jeffrey M Rothschild, and Ann C Hurley. "Medical Errors Recovered by Critical Care Nurses." *Journal of Nursing Administration* 40, no. 5 (2010): 241-46.
- Dykes, Patricia C, Jeffrey M Rothschild, and Ann C Hurley. "Recovered Medical Error Inventory." *Journal of Nursing Scholarship* 42, no. 3 (2010): 314-18.
- Edwin, AK. "Non-Disclosure of Medical Errors an Egregious Violation of Ethical Principles." *Ghana Medical Journal* 43, no. 1 (2009): 34-39.
- Ehsani, Seyyedeh Roghayeh, Mohammad Ali Cheraghi, Amir Nejati, Amir Salari, Ayeshe Haji Esmaeilpoor, and Esmaeil Mohammad Nejad. "Medication Errors of Nurses in the Emergency Department." *Journal of medical ethics and history of medicine* 6 (2013).
- Eidelman, LA, DJ Jakobson, R Pizov, D Geber, L Leibovitz, and CL Sprung. "Forgoing Life-Sustaining Treatment in an Israeli Icu." *Intensive care medicine* 24, no. 2 (1998): 162-166.
- El-Jardali, Fadi, Farheen Sheikh, Nereo A Garcia, Diana Jamal, and Ayman Abdo.
 "Patient Safety Culture in a Large Teaching Hospital in Riyadh: Baseline Assessment, Comparative Analysis and Opportunities for Improvement." *BMC health services research* 14, no. 1 (2014): 1-10.
- Elliott, Doug, Leanne Aitken, and Wendy Chaboyer. *Accen's Critical Care Nursing*. Elsevier Australia, 2011.
- Ellis, Kerri A, Ann Connolly, Alireza Hosseinnezhad, and Craig M Lilly. "Standardizing Communication from Acute Care Providers to Primary Care Providers on Critically Ill Adults." *American Journal of Critical Care* 24, no. 6 (2015): 496-500.
- Emanuel, Ezekiel J, and Alan Wertheimer. "Who Should Get Influenza Vaccine When Not All Can." *Public Health Ethik* 1 (2010): 191.
- Emanuel, Ezekiel J, Arlene Ash, Wei Yu, Gail Gazelle, Norman G Levinsky, Olga Saynina, Mark McClellan, and Mark Moskowitz. "Managed Care, Hospice Use, Site of Death, and Medical Expenditures in the Last Year of Life." Archives of Internal Medicine 162, no. 15 (2002): 1722-1728.

- Entwistle, Vikki A, Stacy M Carter, Alan Cribb, and Kirsten McCaffery. "Supporting Patient Autonomy: The Importance of Clinician-Patient Relationships." *Journal* of general internal medicine 25, no. 7 (2010): 741-745.
- Erlen JA. "When the family asks, 'what happened?," Orthop Nurs. 19:6 (2000): 68-71.
- Errors, Massachusetts Coalition for the Prevention of Medical. "When Things for Wrong: Responding to Adverse Events." <u>http://www.macoalition.org/documents/respondingToAdverseEvents.pdf</u>
- Evans, Sue. "After the Error: Disclosure Responsibilities and Controversies." *The American association of Physicists in Medicine*. <u>http://chapter.aapm.org/NE/DOCUMENTS/Presentations/2012Summer/medical%</u> <u>20error%20NEAAPM.pdf.</u> accessed, February 7, 2016.
- Fairfield, Conn. "Improving the Safety of Health Care: The Leapfrog Initiative." *Eff Clin Pract* 6 (2000): 313-16.
- Fallowfield, Lesley, and Valerie Jenkins. "Communicating Sad, Bad, and Difficult News in Medicine." *The Lancet* 363, no. 9405 (2004): 312-19.
- Fallowfield, Lesley. "Communication with Patients after Errors." *Journal of health* services research & policy 15, no. suppl 1 (2010): 56-59.
- Fein, Stephanie, Lee Hilborne, Margie Kagawa-Singer, Eugene Spiritus, Craig Keenan, Gregory Seymann, Kaveh Sojania, and Neil Wenger. "A Conceptual Model for Disclosure of Medical Errors." (2005). Available from: http://www.ahrq.gov/downloads/pub/advances/vol2/Fein.pdf. accessed, February 7, 2016.
- Fine, Robert L. "The Texas Advance Directives Act of 1999: Politics and Reality." Paper presented at the HEC Forum, 2001.
- Fink, M. P., P. M. Suter, and William J. Sibbald. *Intensive Care Medicine in 10 Years*. Update in Intensive Care Medicine. Berlin ; New York: Springer, 2006.
- Finkelstein, Daniel, Albert W Wu, Neil A Holtzman, and Melanie K Smith. "When a Physician Harms a Patient by a Medical Error: Ethical, Legal, and Risk-Management Considerations." *The Journal of Clinical Ethics* 8, no. 4 (1996): 330-35.
- Fitzpatrick, Joyce J, and Meredith Wallace. *Encyclopedia of Nursing Research*. Springer Publishing Company, 2006.
- Flaatten, H, and O Hevrøy. "Errors in the Intensive Care Unit (Icu)." Acta anaesthesiologica scandinavica 43, no. 6 (1999): 614-17.

- Fleck, Leonard M. "Just Caring: Health Care Rationing, Terminal Illness, and the Medically Least Well Off." *The Journal of Law, Medicine & Ethics* 39, no. 2 (2011): 156-171.
- Fonk, James, Donna Davidoff, Thomas Lutzow, Noelle Chesley, and Nancy Mathiowetz. "The Effect of Advance Directives on End-of-Life Cost Experience." *Journal of health care for the poor and underserved* 23, no. 3 (2012): 1137-56.
- Foundation, California HealthCare. "Addressing Medication Errors in Hospitals: Ten Tools."<u>http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF</u> %20A/PDF%20addressingmederrorstentools.pdf.
- Francis D., and J. Lahaie, Iatrogenesis. *The Nurse's Role in Preventing Patient Harm*. In Evidence-Based Geriatric Nursing Protocols for Best Practice. Springer Publishing Company, 2012 (4th Edition).
- Frank L. The Great Healthcare Fraud. Nottingham, PA: kimkris publishing, 2012.
- Furrow, Barry R. "Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction." *Widener L. Rev.* 12 (2005): 1.
- Gaba, David M, and Steven K Howard. "Fatigue among Clinicians and the Safety of Patients." *New England Journal of Medicine* 347, no. 16 (2002): 1249-55.
- Gabbard, Glen O, and Carol Nadelson. "Professional Boundaries in the Physician-Patient Relationship." JAMA 273, no. 18 (1995): 1445-49.
- Gailey, Lauren. "I'm Sorry as Evidence: Why the Federal Rules of Evidence Should Include a New Specialized Relevance Rule to Protect Physicians." *Def. Counsel* J. 82 (2015): 172.
- Gallagher, Thomas H, Amy D Waterman, Alison G Ebers, Victoria J Fraser, and Wendy Levinson. "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors." JAMA 289, no. 8 (2003): 1001-07.
- Gallagher, Thomas H, David Studdert, and Wendy Levinson. "Disclosing Harmful Medical Errors to Patients." *New England Journal of Medicine* 356, no. 26 (2007): 2713-19.
- Gallagher, Thomas H, Jane M Garbutt, Amy D Waterman, David R Flum, Eric B Larson, Brian M Waterman, W Claiborne Dunagan, Victoria J Fraser, and Wendy Levinson. "Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients." *Archives of Internal Medicine* 166, no. 15 (2006): 1585-93.

- Gao, Ge, Nancy Burke, Carol P Somkin, and Rena Pasick. "Considering Culture in Physician–Patient Communication During Colorectal Cancer Screening." *Qualitative Health Research* (2009). 778-89.
- Garber, Jeannie Scruggs, Monty Gross, and Anthony D Slonim. *Avoiding Common Nursing Errors*. Lippincott Williams & Wilkins, 2010.
- Garbutt, Jane, Amy D Waterman, Julie M Kapp, William Claiborne Dunagan, Wendy Levinson, Victoria Fraser, and Thomas H Gallagher. "Lost Opportunities: How Physicians Communicate About Medical Errors." *Health Affairs* 27, no. 1 (2008): 246-55.
- Garchar, Kimberly, and John Kaag. "Classical American Philosophy and Modern Medical Ethics: The Case of Richard Cabot." *Transactions of the Charles S. Peirce Society: A Quarterly Journal in American Philosophy* 49, no. 4 (2013): 553-74.
- Garland, Allan, Ziad Shaman, John Baron, and Alfred F Connors Jr. "Physician-Attributable Differences in Intensive Care Unit Costs: A Single-Center Study." *American journal of respiratory and critical care medicine* 174, no. 11 (2006): 1206-10.
- Garland, Allan. "Effect of Collaborative Care on Cost Variation in an Intensive Care Unit." *American Journal of Critical Care* 22, no. 3 (2013): 232-38.
- Gawande, Atul A, Eric J Thomas, Michael J Zinner, and Troyen A Brennan. "The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992." *Surgery* 126, no. 1 (1999): 66-75.
- Gawande, Atul, and John Bedford Lloyd. "Better: A Surgeon's Notes on Performance." (2007).
- Gawande, Atul. *The Checklist Manifesto: How to Get Things Right*. Vol. 200: Metropolitan Books New York, 2010.
- General Medical Council. "End of life treatment and care: Good practice in decisionmaking," Retrieved from: <u>http://www.gmcuk.org/CONSULTATION_DRAFT_GUIDANCE.pdf_25417410.</u> <u>pdf.</u> Principles and decision-making framework, Accessed Feb 2015.
- Gert, Bernard, Charles M Culver, and K Danner Clouser. *Bioethics: A Systematic Approach*. Oxford University Press, 2006.
- Gert, Heather J. "Avoiding Surprises: A Model for Informing Patients." *Hastings Center Report* 32, no. 5 (2002): 23-32.

- Giard, RWM. "The Epidemiology of Medical Errors: A Few Issues in Methodology." *The International Journal of Risk and Safety in Medicine* 18, no. 1 (2006): 65-72.
- Giersson, Heimir, and Margaret Holmgren. *Ethical Theory: A Concise Anthology*. Broadview Press, 2000.
- Gill, Robin. *Health Care and Christian Ethics*. Vol. 26: Cambridge University Press, 2006.
- Gilmour, Joan M. "Patient Safety, Medical Error and Tort Law: An International Comparison." Retrieved from: <u>https://apps.osgoode.yorku.ca/osgmedia.nsf/0/094676DE3FAD06A58525723300</u> <u>59253C/\$FILE/FinalReport_Full.pdf</u>.
- Gluck, Eric H, and Daniel O Dugan. "Informed Consent in the Intensive Care Unit." *Critical Care Medicine* 6, no. Part 2 (2001): 1.
- Gohsman, Robyn. *Law and Ethics*. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2009.
- Gone, Joseph P. "Reconciling Evidence-Based Practice and Cultural Competence in Mental Health Services: Introduction to a Special Issue." *Transcultural Psychiatry* 52, no. 2 (2015): 139-49.
- Good, Mary-Jo DelVecchio, and Seth Donal Hannah. ""Shattering Culture": Perspectives on Cultural Competence and Evidence-Based Practice in Mental Health Services." *Transcultural Psychiatry* 52, no. 2 (2015): 198-221.
- Goodale, Mark. *Surrendering to Utopia: An Anthropology of Human Rights*. Stanford University Press, 2009.
- Gopher D, Olin M, Badihi Y, et al. "The nature and causes of human errors in medical intensive care unit. In: Proceedings of Human Factor Society's 33rd Annual Meeting. (1989), 956-960.
- Gorbach, Christy, Linda Blanton, Beverly A Lukawski, Alex C Varkey, E Paige Pitman, and Kevin W Garey. "Frequency of and Risk Factors for Medication Errors by Pharmacists During Order Verification in a Tertiary Care Medical Center." *American Journal of Health-System Pharmacy* 72, no. 17 (2015): 1471-74.
- Graber, Mark, Ruthanna Gordon, and Nancy Franklin. "Reducing Diagnostic Errors in Medicine: What's the Goal?". *Academic Medicine* 77, no. 10 (2002): 981-92.

- Graf, J, A Von den Driesch, K- C Koch, and U Janssens. "Identification and Characterization of Errors and Incidents in a Medical Intensive Care Unit." *Acta anaesthesiologica scandinavica* 49, no. 7 (2005): 930-39.
- Grant, Scott B, Parth K Modi, and Eric A Singer. "Futility and the Care of Surgical Patients: Ethical Dilemmas." *World journal of surgery* 38, no. 7 (2014): 1631-1637.
- Green, Sol F., "The cost of poor blood specimen quality and errors in pre-analytical processes," *Chemical Biochemistry 46* no. 13-14 (2013): 1175-1179.

Greene, Jan, "Who Will Get Care" Trustee 61, no 9 (2008): 8-11.

- Griffin, Simon J, Ann-Louise Kinmonth, Marijcke WM Veltman, Susan Gillard, Julie Grant, and Moira Stewart. "Effect on Health-Related Outcomes of Interventions to Alter the Interaction between Patients and Practitioners: A Systematic Review of Trials." *The Annals of Family Medicine* 2, no. 6 (2004): 595-608.
- Griffith, Charles H, John F Wilson, Shelby Langer, and Steven A Haist. "House Staff Nonverbal Communication Skills and Standardized Patient Satisfaction." *Journal* of General Internal Medicine 18, no. 3 (2003): 170-74.
- Grober, Ethan D, and John MA Bohnen. "Defining Medical Error." *Canadian journal of surgery* 48, no. 1 (2005): 39-44.
- Groene, O, Kringos, D, & Sunol, R. "Seven Ways to Improve Quality and Safety in Hospitals: An Evidence-Based Guide." Retrieved from: <u>http://www.duque.eu/uploads/DUQuE_Seven_Ways_To_Improve_Quality_And_Safety_2014.pdf.</u>
- Groopman, Jerome E, and Michael Prichard. *How Doctors Think*. Vol. 82: Houghton Mifflin Boston, 2007.
- Grossman, Eric, and Peter Angelos. "Futility: What Cool Hand Luke Can Teach the Surgical Community." *World journal of surgery* 33, no. 7 (2009): 1338-1340.
- Groves Jr, Robert H, Barry W Holcomb Jr, and Marshall L Smith. "Intensive Care Telemedicine: Evaluating a Model for Proactive Remote Monitoring and Intervention in the Critical Care Setting." *Studies in health technology and informatics* 131 (2008): 131-46.
- Gruenewald, David A. "Can Health Care Rationing Ever Be Rational?". *The Journal of Law, Medicine & Ethics* 40, no. 1 (2012): 17-25.
- Gullo, Antonino, and Philip D Lumb. *Intensive and Critical Care Medicine*. Springer, 2009.

- Gutierrez, Karen M. "Prognostic Categories and Timing of Negative Prognostic Communication from Critical Care Physicians to Family Members at End- of-Life in an Intensive Care Unit."*Nursing inquiry* 20, no. 3 (2013): 232-44.
- Halasyamani, L, S Kripalani, E Coleman, J Schnipper, C Van Walraven, J Nagamine, P Torcson, *et al.* "Transition of Care for Hospitalized Elderly Patients— Development of a Discharge Checklist for Hospitalists." *Journal of Hospital Medicine* 1, no. 6 (2006): 354-60.
- Halbach, Joseph L, and Laurie L Sullivan. "Teaching Medical Students About Medical Errors and Patient Safety: Evaluation of a Required Curriculum." *Academic Medicine* 80, no. 6 (2005): 600-06.
- Hales, Brigette M, and Peter J Pronovost. "The Checklist—a Tool for Error Management and Performance Improvement." *Journal of critical care* 21, no. 3 (2006): 231-35.
- Halevy, Amir, and Baruch A Brody. "A Multi-Institution Collaborative Policy on Medical Futility." *Jama* 276, no. 7 (1996): 571-574.
- Hall, Richard I, Graeme M Rocker, and Dawnelda Murray. "Simple Changes Can Improve Conduct of End-of-Life Care in the Intensive Care Unit." *Canadian Journal of Anesthesia* 51, no. 6 (2004): 631-36.
- Halperin, Edward C., Carlos A. Perez, and Luther W. Brady. Perez and Brady's Principles and Practice of Radiation Oncology. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2008.
- Halpern, Neil A, Stephen M Pastores, John M Oropello, and Vladimir Kvetan. "Critical Care Medicine in the United States: Addressing the Intensivist Shortage and Image of the Specialty*."*Critical care medicine* 41, no. 12 (2013): 2754-61.
- Hamdi, Naser, Rami Oweis, Hamzeh Abu Zraiq, and Denis Abu Sammour. "An Intelligent Healthcare Management System: A New Approach in Work-Order Prioritization for Medical Equipment Maintenance Requests." *Journal of medical systems* 36, no. 2 (2012): 557-67.
- Hammami, Muhammad M, Sahar Attalah, and Mohammad Al Qadire. "Which Medical Error to Disclose to Patients and by Whom? Public Preference and Perceptions of Norm and Current Practice." *BMC Medical Ethics* 11, no. 1 (2010): 1-11.
- Hanan, AL-Ahmadi, and Martin Roland. "Quality of Primary Health Care in Saudi Arabia: A Comprehensive Review." *International Journal for Quality in Health Care* 17, no. 4 (2005): 331-46.
- Hannawa, Annegret F. "Principles of Medical Ethics: Implications for the Disclosure of Medical Errors." *Medicolegal Bioethics* 2 (2012): 1-11.

- Harris, John. *The Value of Life: An Introduction to Medical Ethics*. London, UK: Routledge, 2006.
- Harris, Lee. "Tort Reform as Carrot-and-Stick." *Harvard Journal on Legislation* 46 (2009): 163-209.
- Harvey, Janet. "The Technological Regulation of Death: With Reference to the Technological Regulation of Birth." *Sociology* 31, no. 4 (1997): 719-735.
- Health, Minnesota Department of. "Adverse Healthcare Events Reporting System: What Have We Learned?" <u>http://www.health.state.mn.us/patientsafety/publications/09aheeval.pdf</u>
- Hebert, Philip C, Alex V Levin, and Gerald Robertson. "Bioethics for Clinicians: 23. Disclosure of Medical Error." *Canadian Medical Association Journal* 164, no. 4 (2001): 509-13.
- Heisler, Elayne J. "Physician Supply and the Affordable Care Act." *Congressional Research Service. op. bna. com/hl. nsf/id/crsdoctor. pdf January* 15 (2013): 24.
- Helmons, Pieter J, Lindsay N Wargel, and Charles E Daniels. "Effect of Bar-Code-Assisted Medication Administration on Medication Administration Errors and Accuracy in Multiple Patient Care Areas." *Am J Health Syst Pharm* 66, no. 13 (2009): 1202-10.
- Helmreich, Robert L. "On Error Management: Lessons from Aviation." *BMJ: British Medical Journal* 320, no. 7237 (2000): 781-85.
- Helseth, Lynn D., Jeffrey L. Susman, Benjamin F. Crabtree, and Patrick J. O'Connor. "Primary care physicians' perceptions of diabetes management. A balancing act." *The Journal of family practice* 48, no. 1 (1999): 37-42.
- Hendrick, Judith. Law and Ethics in Nursing and Health Care. Nelson Thornes, 2000.
- Henneman, Elizabeth A, and Anna Gawlinski. "A "near-Miss" Model for Describing the Nurse's Role in the Recovery of Medical Errors." *Journal of Professional Nursing* 20, no. 3 (2004): 196-201.
- Hernu, Romain, Martin Cour, Sylvie de la Salle, Dominique Robert, and Laurent Argaud."Cost Awareness of Physicians in Intensive Care Units: A Multicentric National Study." *Intensive Care Medicine* (2015): 1-9.
- Herwaldt, Loreen A, and William A Rutala. "Disinfection and Sterilization of Patient-Care Items." *Infection Control & Hospital Epidemiology* 17, no. 06 (1996): 377-84.

- Heyland, Daren K, Graeme M Rocker, Christopher J O'Callaghan, Peter M Dodek, and Deborah J Cook. "Dying in the Icu: Perspectives of Family Members." *CHEST Journal* 124, no. 1 (2003): 392-97.
- Heyland, Daren K, Graeme M Rocker, Peter M Dodek, Demetrios J Kutsogiannis, Elsie Konopad, Deborah J Cook, Sharon Peters, Joan E Tranmer, and Christopher J O'Callaghan. "Family Satisfaction with Care in the Intensive Care Unit: Results of a Multiple Center Study*." *Critical care medicine* 30, no. 7 (2002): 1413-18.
- Hickson, Gerald B, Ellen Wright Clayton, Penny B Githens, and Frank A Sloan. "Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries." Jama 267, no. 10 (1992): 1359-63.
- Hobgood, Cherri, and Armando Hevia. "Disclosing Medical Error: A Professional Standard." (2004).
- Hobgood, Cherri, Bryan Weiner, and Joshua H Tamayo- Sarver. "Medical Error Identification, Disclosure, and Reporting: Do Emergency Medicine Provider Groups Differ?". *Academic Emergency Medicine* 13, no. 4 (2006): 443-51.
- Hobgood, Cherri, Clifford R Peck, Benjamin Gilbert, Kathryn Chappell, and Bin Zou. "Medical Errors—What and When: What Do Patients Want to Know?". Academic Emergency Medicine 9, no. 11 (2002): 1156-61.
- Hoffmaster, Barry, and Cliff Hooker. "Tragic Choices and Moral Compromise: The Ethics of Allocating Kidneys for Transplantation." *Milbank Quarterly* 91, no. 3 (2013): 528-557.
- Hofstede, Geert, Culture's consequences. Thousand Oaks: Sage, 2001.
- Holland, Stephen. Public Health Ethics. Cambridge, UK; Malden, MA: Polity, 2007.
- Honigman, Benjamin, Patrice Light, Russel M Pulling, and David W Bates. "A Computerized Method for Identifying Incidents Associated with Adverse Drug Events in Outpatients." *International journal of medical informatics* 61, no. 1 (2001): 21-32.
- Hooper, AJ, and J Tibballs. "Comparison of a Trigger Tool and Voluntary Reporting to Identify Adverse Events in a Paediatric Intensive Care Unit." *Anaesthesia and intensive care* 42, no. 2 (2014): 199.
- Hope, Tony, John Mcmillan, and Elaine Hill. "Intensive Care Triage: Priority Should Be Independent of Whether Patients Are Already Receiving Intensive Care." *Bioethics* 26, no. 5 (2012): 259-266.

- Hopper, Kenneth D, Thomas R TenHave, Danielle A Tully, and Tanya EL Hall. "The Readability of Currently Used Surgical/Procedure Consent Forms in the United States." Surgery 123, no. 5 (1998): 496-503.
- Hospital, Royal Adelaide. "Intensive Care Unit Manual." Retrieved from: http://www.icuadelaide.com.au/manual/manual_icu.pdf.
- Houghton, Douglas, "End-of-life and Palliative Care" in *Critical Care: Concepts, Role,* and Practice for the Acute Care Nurse Practitioner, ed. Wychoff, Mary. New York, NY: Springer Pub., 2009.
- Huesch, Marco D. "One and Done? Equality of Opportunity and Repeated Access to Scarce, Indivisible Medical Resources." *BMC medical ethics* 13, no. 1 (2012): 11.
- Hughes, R G., "Nurses at the "Sharp End" of patient care, in *Patient safety and quality: An evidence based handbook for nurses.*" Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK2672/</u>.
- Hurley, Ann C, Jeffrey M Rothschild, Mary Lou Moore, Colleen Snydeman, Patricia C Dykes, and Sofronia Fotakis. "A Model of Recovering Medical Errors in the Coronary Care Unit." *Heart & Lung: The Journal of Acute and Critical Care* 37, no. 3 (2008): 219-26.
- Hurst, J Willis. "Cognitive Errors (Can They Be Prevented?)." *The American journal of cardiology* 101, no. 10 (2008): 1513-17.
- Hussein, AHM. "Relationship between Nurses' and Physicians' Perceptions of Organizational Health and Quality of Patient Care." *Eastern Mediterranean Health Journal* 20, no. 10 (2014): 634.
- Hyman, D., and Charles Silver. "Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid." *Vand. L. Rev.* 59 (2006): 1085-1136.
- Idemoto, Lori M., Barbara L. Williams, Joan M. Ching, and C. Craig Blackmore, "Implementation of a custom alert to prevent medication-timing errors associated with computerized prescriber order entry," *American Journal of Health-System Pharmacy* 72 no. 17 (2015): 1481-1484.
- Illinois, University of. "Online Icu Guidebook." Retrieved from: <u>http://chicago.medicine.uic.edu/UserFiles/Servers/Server_442934/Image/1.1/resid</u> entguides/final/icuguidebook.pdf.
- Imhof, Michael. *Malpractice in Surgery: Safety Culture and Quality Management in the Hospital.* Vol. 6: Walter de Gruyter, 2012.

- Irwin, Richard S, and James M Rippe. *Irwin and Rippe's Intensive Care Medicine*. Lippincott Williams & Wilkins, 2008.
- Iyer, Patricia W. Nursing Home Litigation: Investigation and Case Preparation. Lawyers & Judges Publishing Company, 2006.
- Jeffery, Maren E, Paul N Lanken, and Darren B Taichman. "Ethical Issues in the Intensive Care Unit." *Pulmonary Disease* 11, no. 3 (2004): 1-12.
- Jenicek, Milos. Medical Error and Harm: Understanding, Prevention, and Control. CRC Press, 2010.
- Jennane, Naoual, Naoufel Madani, Rachida OuldErrkhis, Khalid Abidi, Ibtissam Khoudri, Jihane Belayachi, Tarik Dendane, Amine A Zeggwagh, and Redouane Abouqal. "Incidence of Medication Errors in a Moroccan Medical Intensive Care Unit." *International archives of medicine* 4, no. 1 (2011): 32-39.
- Jeremias, Allen, and David L. Brown. *Cardiac Intensive Care*. (Philadelphia, PA: Saunders/Elsevier, 2010.
- Jesson, Luncinda E, and Peter B Knapp. "My Lawyer Told Me to Say I'm Sorry: Lawyers, Doctors, and Medical Apologies." *Wm. Mitchell L. Rev.* 35 (2008): 1410.
- Jesus, John, Peter Rosen, James Adams, Arthur R Derse, Shamai Grossman, and Richard Wolfe. *Ethical Problems in Emergency Medicine: A Discussion-Based Review*. John Wiley & Sons, 2012.
- Johnstone, Megan-Jane. *Bioethics: A Nursing Perspective*. Elsevier Health Sciences, 2011.
- Jonsen, Albert R. "3. Bentham in a Box: Technology Assessment and Health Care Allocation." *L. Med. & Health Care* 14 (1986): 172.
- Jonsen, Albert R. A Short History of Medical Ethics. Oxford University Press, 2000.
- Kachalia Allen, "Disclosure of Medical Error," Retrieved from: <u>https://psnet.ahrq.gov/perspectives/perspective/70</u> Perspective, <u>accessed</u>, <u>December</u>, 6, 2015.
- Kachalia, Allen, Samuel R Kaufman, Richard Boothman, Susan Anderson, Kathleen Welch, Sanjay Saint, and Mary AM Rogers. "Liability Claims and Costs before and after Implementation of a Medical Error Disclosure Program."*Annals of Internal Medicine* 153, no. 4 (2010): 213-21.

- Kagawa-Singer, Marjorie, and Leslie J Blackhall. "Negotiating Cross-Cultural Issues at the End of Life: You Got to Go Where He Lives." *Jama* 286, no. 23 (2001): 2993-3001.
- Kaldjian, Lauris C, Elizabeth W Jones, Barry J Wu, Valerie L Forman-Hoffman, Benjamin H Levi, and Gary E Rosenthal. "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians in Teaching Hospitals." *Archives of internal medicine* 168, no. 1 (2008): 40-46.
- Kale, Abhivyakti, Carol A Keohane, Saverio Maviglia, Tejal K Gandhi, and Eric G Poon.
 "Adverse Drug Events Caused by Serious Medication Administration Errors." *BMJ quality & safety*(2012): bmjqs-2012-000946.
- Kalra, Jawahar, K Lorne Massey, and Amith Mulla. "Disclosure of Medical Error: Policies and Practice." *Journal of the Royal Society of Medicine* 98, no. 7 (2005): 307-09.
- Kalra, Jay. Medical Errors and Patient Safety: Strategies to Reduce and Disclose Medical Errors and Improve Patient Safety. Vol. 1: Walter de Gruyter, 2011.
- Kapielian, V., Truls Ostbye, Samuel Warburtn, Devdutta Sangvai and Lloye Michener, *A* system to describe and reduce medical Errors in primary care. Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK43616/.</u>
- Kaplan, Robert S, and Mary L Witkowski. "Better Accounting Transforms Health Care Delivery." *Accounting Horizons* 28, no. 2 (2014): 365-83.
- Kaprielian, Victoria, Truls Østbye, Samuel Warburton, Devdutta Sangvai, and Lloyd Michener. "A System to Describe and Reduce Medical Errors in Primary Care." (2008). Retrieved from: <u>http://www.ncbi.nlm.nih.gov/books/NBK43616/.</u>
- Kaufman, Jon, Mark Twite, Cindy Barrett, Christine Peyton, Julianne Koehler, Michael Rannie, Michael G Kahn, *et al.* "A Handoff Protocol from the Cardiovascular Operating Room to Cardiac Icu Is Associated with Improvements in Care Beyond the Immediate Postoperative Period." *The Joint Commission Journal on Quality and Patient Safety* 39, no. 7 (2013): 306-06.
- Kaushik, N., and S. Green. "Pre-analytical errors: their impact and how to minimize them." *MLO: medical laboratory observer* 46, no. 5 (2014): 22-24.
- Keers, Richard N, Steven D Williams, Jonathan Cooke, and Darren M Ashcroft. "Causes of Medication Administration Errors in Hospitals: A Systematic Review of Quantitative and Qualitative Evidence." *Drug safety* 36, no. 11 (2013): 1045-67.

- Kegley, Jacquelyn Ann K., "A new Bioethics Framework for Facilitating better Decision-Making about Genetic Information" in *Public Health Policy and Ethics*, ed. Boylan, Michael (Springer Science & Business Media, 2006), 93-97.
- Kerstein, Samuel J, and Greg Bognar. "Complete Lives in the Balance." *The American Journal of Bioethics* 10, no. 4 (2010): 37-45.
- Kleinpell, Ruth, David Thompson, Lynn Kelso, and Peter J Pronovost. "Targeting Errors in the Icu: Use of a National Database." *Critical care nursing clinics of North America* 18, no. 4 (2006): 509-14.
- Kohn, Linda T, Janet M Corrigan, and Molla S Donaldson. *To Err Is Human: Building a Safer Health System*. National Academies Press, 2000.
- Kopec, D, MH Kabir, D Reinharth, O Rothschild, and JA Castiglione. "Human Errors in Medical Practice: Systematic Classification and Reduction with Automated Information Systems." *Journal of medical systems* 27, no. 4 (2003): 297-313.
- Kopp, Brian J, Brian L Erstad, Michelle E Allen, Andreas A Theodorou, and Gail Priestley. "Medication Errors and Adverse Drug Events in an Intensive Care Unit: Direct Observation Approach for Detection." *Critical care medicine* 34, no. 2 (2006): 415-25.
- Koppel, Ross, Joshua P. Metlay, Abigail Cohen, Brian Abaluck, A. Russell Localio, Stephen E. Kimmel, and Brian L. Strom "Role of computerized physician order entry systems in facilitating medication errors," *JAMA* 293 no. 10 (2005):1197-1203.
- Kronman, Andrea C, Michael Paasche-Orlow, and Jay D Orlander. "Factors Associated with Disclosure of Medical Errors by Housestaff." *BMJ Quality & Safety* (2011): 271-78.
- Kucukarslan, Suzan N, Michael Peters, Mark Mlynarek, and Daniel A Nafziger.
 "Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units."*Archives of Internal Medicine* 163, no. 17 (2003): 2014-18.
- Kuhn, Gloria J. "Diagnostic Errors." *Academic Emergency Medicine* 9, no. 7 (2002): 740-50.
- Lamb, Rae M, David M Studdert, Richard MJ Bohmer, Donald M Berwick, and Troyen A Brennan. "Hospital Disclosure Practices: Results of a National Survey." *Health Affairs* 22, no. 2 (2003): 73-83.
- Landrigan, Christopher P, Jeffrey M Rothschild, John W Cronin, Rainu Kaushal, Elisabeth Burdick, Joel T Katz, Craig M Lilly, *et al.* "Effect of Reducing Interns'

Work Hours on Serious Medical Errors in Intensive Care Units." *New England Journal of Medicine* 351, no. 18 (2004): 1838-48.

- Lane-Fall, Meghan B., Rinad S. Beidas, Jose L. Pascual, Meredith L. Collard, Hannah G. Peifer, Tyler J. Chavez, Mark E. Barry, Jacob T. Gutsche, Scott D. Halpern, Lee A. Fleisher, and Frances K. Barg. "Handoffs and Transitions in Critical Care (Hatricc): Protocol for a Mixed Methods Study of Operating Room to Intensive Care Unit Handoffs." <u>http://www.biomedcentral.com/1471-2482/14/96.</u>
- Lautrette, Alexandre, Maïté Garrouste-Orgeas, Pierre-Marie Bertrand, Dany Goldgran-Toledano, Samir Jamali, Virginie Laurent, Laurent Argaud, *et al.* "Respective Impact of No Escalation of Treatment, Withholding and Withdrawal of Life-Sustaining Treatment on Icu Patients' Prognosis: A Multicenter Study of the Outcomerea Research Group." *Intensive care medicine* 41, no. 10 (2015): 1763-1772.
- Lazare, Aaron. "Apology in Medical Practice: An Emerging Clinical Skill." *jama* 296, no. 11 (2006): 1401-04.
- Leape, Lucian L, David D Woods, Martin J Hatlie, Kenneth W Kizer, Steven A Schroeder, and George D Lundberg. "Promoting Patient Safety by Preventing Medical Error." JAMA 280, no. 16 (1998): 1444-47.
- Leape, Lucian L, David J Cullen, Margaret Dempsey Clapp, Elisabeth Burdick, Harold J Demonaco, Jeanette Ives Erickson, and David W Bates. "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit." Jama 282, no. 3 (1999): 267-70.
- Leape, Lucian L. "Error in Medicine." Jama 272, no. 23 (1994): 1851-57.
- LeClaire, Michele M, J Michael Oakes, and Craig R Weinert. "Communication of Prognostic Information for Critically Ill Patients." *Chest Journal* 128, no. 3 (2005): 1728-35.
- Leonard, Michael, Suzanne Graham, and Doug Bonacum. "The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care." *Quality and Safety in Health Care* 13, no. suppl 1 (2004): i85-i90.
- Levine, Cynthia S, and Nalini Ambady. "The Role of Non- Verbal Behaviour in Racial Disparities in Health Care: Implications and Solutions." *Medical Education* 47, no. 9 (2013): 867-76.
- Levy, Mitchell M. "Shared Decision-Making in the ICU: Entering a New Era*." *Critical care medicine* 32, no. 9 (2004): 1966-68.

- Li, Pin, Jamie M Boyd, William A Ghali, and Henry T Stelfox. "Stakeholder Views Regarding Patient Discharge from Intensive Care: Suboptimal Quality and Opportunities for Improvement."*Canadian Respiratory Journal* 22, no. 2 (2015): 109-18.
- Liebman, Carol B., and Chris Stern Hyman. "Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania."<u>http://www.pewtrusts.0rg/~/media/legacy/uploadedfiles/wwwpewt</u> <u>mstsorg/reports/</u> medical_liability/LiebmanReportpdf.pdf. .
- Lilly, Craig M, Dawn L De Meo, Larry A Sonna, Kathleen J Haley, Anthony F Massaro, Robert F Wallace, and Sean Cody. "An Intensive Communication Intervention for the Critically III." *The American journal of medicine* 109, no. 6 (2000): 469-75.
- Lippert-Rasmussen, Kasper. *Deontology, Responsibility, and Equality*. Cognition and Communication, U of Copenhagen, 2005.
- Lo, Bernard. *Resolving Ethical Dilemmas: A Guide for Clinicians*. Lippincott Williams & Wilkins, 2012.
- Localio, A Russell, Ann G Lawthers, Troyen A Brennan, Nan M Laird, Liesi E Hebert, Lynn M Peterson, Joseph P Newhouse, Paul C Weiler, and Howard H Hiatt.
 "Relation between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study Iii." *New England Journal of Medicine* 325, no. 4 (1991): 245-51.
- Luce, John M, and Douglas B White. "A History of Ethics and Law in the Intensive Care Unit." *Critical care clinics* 25, no. 1 (2009): 221-37.
- Ludmerer, Kenneth M, and Michael ME Johns. "Reforming Graduate Medical Education." *Jama* 294, no. 9 (2005): 1083-87.
- MacCourt, Duncan, and Joseph Bernstein. "Medical Error Reduction and Tort Reform through Private, Contractually-Based Quality Medicine Societies." Am. JL & Med. 35 (2009): 505-561.
- MacDonald, Russell D. "Articles That May Change Your Practice: Crew Resource Management." *Air medical journal* 35, no. 2 (2016): 65.
- Mack, Jennifer W, Joanne Wolfe, E Francis Cook, Holcombe E Grier, Paul D Cleary, and Jane C Weeks. "Hope and Prognostic Disclosure." *Journal of Clinical Oncology* 25, no. 35 (2007): 5636-42.
- Maglin, Nan Bauer, and Donna Marie Perry. *Final Acts: Death, Dying, and the Choices We Make*. Rutgers University Press, 2010.

- Magnus, Victoria S, and Leisa Turkington. "Communication Interaction in Icu—Patient and Staff Experiences and Perceptions." *Intensive and Critical Care Nursing* 22, no. 3 (2006): 167-80.
- Maguire, Peter, Susan Fairbairn, and Charles Fletcher. "Consultation Skills of Young Doctors: I--Benefits of Feedback Training in Interviewing as Students Persist." Br Med J (Clin Res Ed) 292, no. 6535 (1986): 1573-76.
- Makoul, G., "Essential elements of communication in medical encounters: The Kalamazoo consensus statement." *Academic Medicine* 76 no. 4 (2001): 390:393.
- Manasse, Henri Richard, and Kasey K Thompson. *Medication Safety: A Guide for Health Care Facilities*. Ashp, 2005.
- Manser, T. "Teamwork and Patient Safety in Dynamic Domains of Healthcare: A Review of the Literature." *Acta Anaesthesiologica Scandinavica* 53, no. 2 (2009): 143-51.
- Marchev, Mimi, Jill Rosenthal, and Maureen Booth. "How States Report Medical Errors to the Public: Issues and Barriers." <u>http://www.nashp.org/sites/default/files/reporting_medical_errors.pdf.</u>
- Marcin, James P, Anthony D Slonim, Murray M Pollack, and Urs E Ruttimann. "Long-Stay Patients in the Pediatric Intensive Care Unit." *Critical care medicine* 29, no. 3 (2001): 652-57.
- Mardon, Russell E, Kabir Khanna, Joann Sorra, Naomi Dyer, and Theresa Famolaro. "Exploring Relationships between Hospital Patient Safety Culture and Adverse Events." *Journal of patient safety* 6, no. 4 (2010): 226-32.
- Marik, Paul Ellis. *Handbook of Evidence-Based Critical Care*. Springer Science & Business Media, 2010.
- Marini, John J, and Arthur P Wheeler. *Critical Care Medicine: The Essentials*. Lippincott Williams & Wilkins, 2010.
- Martin, Heather, Sharon E. Metcalfe, and Ramona C. Whichello, "Specimen Labeling Errors: A Retrospective Study," *Online Journal of Nursing Informatics 19* no. 2 (2015), 9-9. Retrieved from: <u>http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=4</u> <u>2740</u>.
- Mastroianni, Anna C, Michelle M Mello, Shannon Sommer, Mary Hardy, and Thomas H Gallagher. "The Flaws in State 'Apology'and 'Disclosure'laws Dilute Their Intended Impact on Malpractice Suits." *Health Affairs* 29, no. 9 (2010): 1611-19.

- Matlow, Anne, Polly Stevens, Christine Harrison, and Ronald M Laxer. "Disclosure of Medical Errors." *Pediatric Clinics of North America* 53, no. 6 (2006): 1091-104.
- Mattox, Elizabeth Andersson. "Identifying Vulnerable Patients at Heightened Risk for Medical Error." *Critical care nurse* 30, no. 2 (2010): 61-70.
- Matusitz, Jonathan, and Jennifer Spear. "Effective Doctor-Patient Communication: An Updated Examination." *Social Work in Public Health* 29, no. 3 (2014): 252-66.
- Maynard, Edwin P., Karen Coblens, Errol D. Crook, Lee Dunn, Arthur W. Feinberg, Lloyd W. Kitchens, Bernard Lo et al. "American college of physicians ethics manual." *Annals of Internal Medicine* 117, no. 11 (1992): 947-60.
- Mazor, Kathleen M, George W Reed, Robert A Yood, Melissa A Fischer, Joann Baril, and Jerry H Gurwitz. "Disclosure of Medical Errors: What Factors Influence How Patients Respond?" *Journal of General Internal Medicine* 21, no. 7 (2006): 704-10.
- Mazor, Kathleen M, S. R. Simon, and J. H. Gurwitz. "Communicating with Patients About Medical Errors: A Review of the Literature." *Arch Intern Med* 164, no. 15 (2004): 1690-7.
- Mazor, Kathleen M, Steven R Simon, Robert A Yood, Brian C Martinson, Margaret J Gunter, George W Reed, and Jerry H Gurwitz. "Health Plan Members' Views About Disclosure of Medical Errors." *Annals of Internal Medicine*140, no. 6 (2004): 409-18.
- Mazor, K., Sarah M. Greene, Douglas Roblin, Celeste A. Lemay, Cassandra L. Firneno, Josephine Calvi, Carolyn D. Prouty, Kathryn Horner, and Thomas H. Gallagher.
 "More than words: patients' views on apology and disclosure when things go wrong in cancer care." *Patient education and counseling* 90:3 (2013): 341-346.
- Mazzocco, Karen, Diana B Petitti, Kenneth T Fong, Doug Bonacum, John Brookey, Suzanne Graham, Robert E Lasky, J Bryan Sexton, and Eric J Thomas. "Surgical Team Behaviors and Patient Outcomes." *The American Journal of Surgery* 197, no. 5 (2009): 678-85.
- McAdam, Jennifer L, and Kathleen Puntillo. "Symptoms Experienced by Family Members of Patients in Intensive Care Units." *American Journal of Critical Care* 18, no. 3 (2009): 200-09.
- McDowell, Sarah E, Harriet S Ferner, and Robin E Ferner. "The Pathophysiology of Medication Errors: How and Where They Arise." *British journal of clinical pharmacology* 67, no. 6 (2009): 605-13.

- McGough, Laura J, Steven J Reynolds, Thomas C Quinn, and Jonathan M Zenilman. "Which Patients First? Setting Priorities for Antiretroviral Therapy Where Resources Are Limited." *American Journal of Public Health* 95, no. 7 (2005): 1173.
- McGowan, Michele, and Bernard J Healey. "The Enormous Cost of Medical Errors." Academy of Health Care Management Journal 6, no. 2 (2009): 27-29.
- McGowan, Michele, and Bernard J Healey. "The Enormous Cost of Medical Errors." Academy Of Health Care Management Journal 6, no. 1 (2010): 17-24.
- McLaren, Margaret Cameron. Interpreting Cultural Differences: The Challenge of Intercultural Communication. Peter Francis Publishers, 1998.

Meier, Eileen. "Efforts launched to address medical errors." *Nursing Economics* 18, no. 5 (2000): 265.

- Mello, Michelle M, and Thomas H Gallagher. "Malpractice Reform—Opportunities for Leadership by Health Care Institutions and Liability Insurers." *New England Journal of Medicine* 362, no. 15 (2010): 1353-56.
- Menzel, Linda K. "Factors Related to the Emotional Responses of Intubated Patients to Being Unable to Speak." *Heart & Lung: The Journal of Acute and Critical Care* 27, no. 4 (1998): 245-52.
- Metcalfe, M Alison, Andrew Sloggett, and Klim McPherson. "Mortality among Appropriately Referred Patients Refused Admission to Intensive-Care Units." *The Lancet* 350, no. 9070 (1997): 7-11.
- Metzloff, Thomas B, Ralph A Peeples, and Catherine T Harris. "Empirical Perspectives on Mediation and Malpractice." *Law and Contemporary Problems* 60, no. 1 (1997): 107-52.
- Meyers, Allan R. "'Lumping It': The Hidden Denominator of the Medical Malpractice Crisis." *American Journal of Public Health* 77, no. 12 (1987): 1544-48.
- Milic, Michelle M, Kathleen Puntillo, Kathleen Turner, Denah Joseph, Natalie Peters, Rio Ryan, Cathy Schuster, *et al.* "Communicating with Patients' Families and Physicians About Prognosis and Goals of Care." *American Journal of Critical Care* 24, no. 4 (2015): e56-e64.
- Mills, Don Harper. "Medical Insurance Feasibility Study: A Technical Summary." *Western Journal of Medicine* 128, no. 4 (1978): 360-65.

- Minnesota, Children's Hospitals and Clinics of. "What We've Learned: Stories and Milestones from the Patient Safety Journey." <u>http://www.childrensmn.org/web/aboutus/072550.pdf.</u>
- Mistry, Kshitij P, Christopher P Landrigan, Donald A Goldmann, and David W Bates. "Communication Error During Post-Operative Patient Hand Off in the Pediatric Intensive Care Unit 47."*Critical Care Medicine* 33, no. 12 (2005): A12.
- Mohammed, Shan, and Elizabeth Peter. "Rituals, Death and the Moral Practice of Medical Futility." *Nursing Ethics* 16, no. 3 (2009): 292-302.
- Mokhtar, SA, AA El Mahalli, S Al-Mulla, and R Al-Hussaini. "Study of the Relation between Quality of Inpatient Care and Early Readmission for Diabetic Patients at a Hospital in the Eastern Province of Saudi Arabia." *Eastern Mediterranean health journal* 18, no. 5 (2012): 474.
- Moore, Carlton, Juan Wisnivesky, Stephen Williams, and Thomas McGinn. "Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting." *Journal of general internal medicine* 18, no. 8 (2003): 646-51.
- Morreim, EH. "Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank." *Ohio State Journal on Dispute Resolution* 27, no. 1 (2012).
- Morrison, Eileen E. *Health Care Ethics: Critical Issues for the 21st Century*. Jones & Bartlett Publishers, 2009.
- Moskop, John C, Joel M Geiderman, Cherri D Hobgood, and Gregory L Larkin.
 "Emergency Physicians and Disclosure of Medical Errors." *Annals of emergency medicine* 48, no. 5 (2006): 523-31.
- Moyen, Eric, Eric Camiré, and Henry Thomas Stelfox. "Clinical Review: Medication Errors in Critical Care." *Crit Care* 12, no. 2 (2008): 208-15.
- Multz, Alan S, Donald B Chalfin, Israel M Samson, David R Dantzker, Alan M Fein, Harry N Steinberg, Michael S Niederman, and Steven M Scharf. "A "Closed" Medical Intensive Care Unit (Micu) Improves Resource Utilization When Compared with an "Open" Micu." *American journal of respiratory and critical care medicine* 157, no. 5 (1998): 1468-73.
- Murff, Harvey J, Vimla L Patel, George Hripcsak, and David W Bates. "Detecting Adverse Events for Patient Safety Research: A Review of Current Methodologies." *Journal of biomedical informatics* 36, no. 1 (2003): 131-43.
- Nagel, Thomas. Mortal Questions. Cambridge University Press, 2012.

- Nagpal, Kamal, May Abboudi, Lukas Fischler, Tanja Schmidt, Amit Vats, Chhavi Manchanda, Nick Sevdalis, *et al.* "Evaluation of Postoperative Handover Using a Tool to Assess Information Transfer and Teamwork." *Annals of surgery* 253, no. 4 (2011): 831-37.
- Naidu, Aditi. "Factors Affecting Patient Satisfaction and Healthcare Quality." *International journal of health care quality assurance* 22, no. 4 (2009): 366-81.
- Nau, Konrad, "Disclosing Medical Error to Patients," Retrieved from: <u>http://slideplayer.com/slide/7041421/</u>
- Naylor, Robert. Medication Errors. Lessons for Education and Healthcare. Abingdon: Radcliffe Medical Press, 2002.
- Negash, Gediwon, Yonathan Kebede, and Segewkal Hawaze. "Medication Errors in the Adult Emergency Unit of a Tertiary Care Teaching Hospital in Addis Ababa." *Archives of Pharmacy Practice* 4, no. 4 (2013): 147-53.
- Nelson, Judith E, Alice F Mercado, Sharon L Camhi, Nidhi Tandon, Sylvan Wallenstein, Gary I August, and R Sean Morrison. "Communication About Chronic Critical Illness." *Archives of internal medicine* 167, no. 22 (2007): 2509-15.
- Nguyen, Anh Vu T, and Dung A Nguyen. *Learning from Medical Errors: Clinical Problems*. Radcliffe Publishing, 2005.
- Nicholas, Lauren Hersch, Kenneth M Langa, Theodore J Iwashyna, and David R Weir. "Regional Variation in the Association between Advance Directives and End-of-Life Medicare Expenditures." *Jama* 306, no. 13 (2011): 1447-53.
- Nilsson, Lena, A Pihl, M Tågsjö, and Elisabeth Ericsson. "Adverse Events Are Common on the Intensive Care Unit: Results from a Structured Record Review." *Acta anaesthesiologica Scandinavica* 56, no. 8 (2012): 959-65.
- Norton, Sally A, Laura A Hogan, Robert G Holloway, Helena Temkin-Greener, Marcia J Buckley, and Timothy E Quill. "Proactive Palliative Care in the Medical Intensive Care Unit: Effects on Length of Stay for Selected High-Risk Patients." *Critical care medicine* 35, no. 6 (2007): 1530-35.
- O'Connor, Patrick J., JoAnn M. Sperl-Hillen, Paul E. Johnson, William A. Rush, and George Biltz. "Clinical Intertia and Outpatient Medical Errors," in Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology), eds. K. Henriksen, J. B. Battles, and E. S. Marks (Rockville, MD: Agency for Healthcare Research and Quality, 2005), 293-308.

- Olden, Peter C, and William C McCaughrin. "Designing Healthcare Organizations to Reduce Medical Errors and Enhance Patient Safety." *Hospital topics* 85, no. 4 (2007): 4-9.
- Oliffe, John, and Sally Thorne. "Men, Masculinities, and Prostate Cancer: Australian and Canadian Patient Perspectives of Communication with Male Physicians." *Qualitative Health Research* 17, no. 2 (2007): 149-61.
- Ong, Mei-Sing, and Enrico Coiera. "A Systematic Review of Failures in Handoff Communication During Intrahospital Transfers." *The Joint Commission Journal on Quality and Patient Safety* 37, no. 6 (2011): 274-74.
- Organization, World Health. "Hospital Emergency Response Checklist." Retrieved from: http://www.euro.who.int/__data/assets/pdf_file/0008/268766/Hospitalemergency-response-checklist-Eng.pdf.
- Organization, World Health. "Implementation Manual: Who Surgical Safety Checklist." Retrieved from: <u>http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_fina</u> <u>lJun08.pdf.</u>
- Organization, World Health. "Patient Safety Checklists." Retrieved from: http://www.who.int/patientsafety/implementation/checklists/en/.
- Organization, World Health. "Who Draft Guidelines for Adverse Event Reporting and Learning System." Retrieved from: <u>http://osp.od.nih.gov/sites/default/files/resources/Reporting_Guidelines.pdf.</u>
- Pape, Tess M. "Applying Airline Safety Practices to Medication Administration." *Medsurg nursing: official journal of the Academy of Medical-Surgical Nurses* 12, no. 2 (2003): 77-93.
- Parker, Sharon M, Josephine M Clayton, Karen Hancock, Sharon Walder, Phyllis N Butow, Sue Carrick, David Currow, et al. "A Systematic Review of Prognostic/End-of-Life Communication with Adults in the Advanced Stages of a Life-Limiting Illness: Patient/Caregiver Preferences for the Content, Style, and Timing of Information." Journal of pain and symptom management34, no. 1 (2007): 81-93.
- Pasick, Rena J, Carol N D'Onofrio, and Regina Otero-Sabogal. "Similarities and Differences across Cultures: Questions to Inform a Third Generation for Health Promotion Research." *Health Education Quarterly* (1996). S142-61.
- Peberdy, Mary Ann, William Kaye, Joseph P Ornato, Gregory L Larkin, Vinay Nadkarni, Mary Elizabeth Mancini, Robert A Berg, *et al.* "Cardiopulmonary Resuscitation of Adults in the Hospital: A Report of 14 720 Cardiac Arrests from the National

Registry of Cardiopulmonary Resuscitation." *Resuscitation* 58, no. 3 (2003): 297-308.

- Pellegrino Edmund D., and David C. Thomasma. "Limitations of Autonomy and Paternalism: Towards a Model of Beneficence." In *for Patient's Good*. Oxford University: Oxford University Press, 1988.
- Pellegrino, Edmund D. "Decision at the End-of-Life: Use and Abuse of the Concept of Futility." In In the Dignity of the Dying Person: Proceedings of the Fifth Assembly of the Pontifical Academy for Life, edited by Juan De Dios Vial Correa and Elio Sgreccia. Vaticano: Italy: Libreria Editrice Vaticanoz, 2000.
- Penson, Richard T, Sasha S Svendsen, Bruce A Chabner, Thomas J Lynch, and Wendy Levinson. "Medical Mistakes: A Workshop on Personal Perspectives." *The Oncologist* 6, no. 1 (2001): 92-99.
- Perrin, Kathleen Ouimet, and James McGhee. *Quick Look Nursing: Ethics and Conflict.* Jones & Bartlett Publishers, 2008.
- Persad, Govind, Alan Wertheimer, and Ezekiel J Emanuel. "Principles for Allocation of Scarce Medical Interventions." *The Lancet* 373, no. 9661 (2009): 423-431.
- Pham, Julius Cuong, George R Kim, Jeffrey P Natterman, Renee M Cover, Christine A Goeschel, Albert W Wu, and Peter J Pronovost. "Recasting the Rca: An Improved Model for Performing Root Cause Analyses." *American Journal of Medical Quality* 25, no. 3 (2010): 186-91.
- Phillips, Lawrence S., William T. Branch, Curtiss B. Cook, Joyce P. Doyle, Imad M. El-Kebbi, Daniel L. Gallina, Christopher D. Miller, David C. Ziemer, and Catherine S. Barnes. "Clinical inertia." *Annals of internal medicine* 135, no. 9 (2001): 825-834.
- Phillips, Sally. "Current Status of Surge Research." *Academic emergency medicine* 13, no. 11 (2006): 1103-1108.
- Physicians, American College of Emergency. "Code of Ethics for Emergency Physicians." <u>http://www.emcongress.org/barcelona03/handouts/larkin_2.pdf.</u>
- Physicians, American College of. "Medical Liability Reform: Innovative Solutions for A new Health Care System". Retrieved from: <u>https://www.acponline.org/acp_policy/policies/medical_liability_reform_2014.pd</u> <u>f</u>.
- Piper, August. "Truce on the Battlefield: A Proposal for a Different Approach to Medical Informed Consent." *The Journal of Law, Medicine & Ethics* 22, no. 4 (1994): 301-13.

Plows, CW, RM Tenery, A Hartford, D Miller, L Morse, H Rakatansky, FA Riddick, et al. "Medical Futility in End-of-Life Care-Report of the Council on Ethical and Judicial Affairs." JAMA-JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 281, no. 10 (1999): 937-941.

Polifko-Harris, Karin. *The Practice Environment of Nursing*. New York: Cengage Learning, 2009.

- Pope, Catherine, Paul van Royen, and Richard Baker. "Qualitative Methods in Research on Healthcare Quality." *Quality and Safety in Health Care* 11, no. 2 (2002): 148-52.
- Post, Linda Farber, Jeffrey Blustein, and Nancy Neveloff Dubler. *Handbook for Health Care Ethics Committees*. JHU Press, 2007.
- Prendergast, Thomas J, Michael T Claessens, and John M Luce. "A National Survey of End-of-Life Care for Critically III Patients." *American Journal of Respiratory and Critical Care Medicine* 158, no. 4 (1998): 1163-1167.
- Pronovost, Peter J, David A Thompson, Christine G Holzmueller, Lisa H Lubomski, Todd Dorman, Fern Dickman, Maureen Fahey, *et al.* "Toward Learning from Patient Safety Reporting Systems." *Journal of critical care* 21, no. 4 (2006): 305-15.
- Quality, Agency for Healthcare Research and, "Full Disclosure of Medical Errors Reduces Malpractice Claims and Claim Costs for Health System," Retrieved from: <u>https://innovations.ahrq.gov/profiles/full-disclosure-medical-errors-reduces-</u> <u>malpractice-claims-and-claim-costs-health-system</u>.
- Quality, Agency for Healthcare Research and. "Ahrq's Patient Safety Initiative: Building Foundations, Reducing Risk." Retrieved from: <u>http://archive.ahrq.gov/research/findings/final-reports/pscongrpt/psini2.html.</u>
- Quality, Agency for Healthcare Research and. "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." Retrieved from: <u>http://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html</u>.
- Rafferty, Anne-Marie, Jane Ball, and Linda H Aiken. "Are Teamwork and Professional Autonomy Compatible, and Do They Result in Improved Hospital Care?". *Quality in Health care* 10, no. suppl 2 (2001): ii32-ii37.
- Rathert, Cheryl, and Win Phillips. "Medical Error Disclosure Training: Evidence for Values-Based Ethical Environments." *Journal of business ethics* 97, no. 3 (2010): 491-503.

Rawls, John. A Theory of Justice. Harvard university press, 2009.

- Reader, Tom W, Rhona Flin, and Brian H Cuthbertson. "Communication Skills and Error in the Intensive Care Unit." *Current opinion in critical care* 13, no. 6 (2007): 732-36.
- Reddy, Bhavani S. "Apology and Medical Error Full Disclosure Programs: Is Saying 'I'm Sorry' the Answer to Reducing Hospital Legal Costs?"<u>http://www.law.uh.edu/healthlaw/perspectives/2006\(BR)</u> ApologiesFinal. pdf.
- Relis, Tamara. Perceptions in Litigation and Mediation: Lawyers, Defendants, Plaintiffs, and Gendered Parties. Cambridge University Press, 2009.
- Remington, Joseph Price, David B Troy, and Paul Beringer. *Remington: The Science and Practice of Pharmacy.* Vol. 1: Lippincott Williams & Wilkins, 2006.
- Riccardi, Vincent M., and Suzanne M. Kurtz, *Communication and counseling in healthcare*. Springfield, IL: Charles C. Thomas, 1983.
- Ridgway, Malcolm. "Optimizing Our Pm Programs." *Biomedical Instrumentation & Technology* 43, no. 3 (2009): 244-54.
- Riley, Gerald F, and James D Lubitz. "Long- Term Trends in Medicare Payments in the Last Year of Life." *Health services research* 45, no. 2 (2010): 565-576.

Rin, Giorgio. "Pre-analytical workstations as a tool for reducing laboratory errors." *Journal of Medical Biochemistry* 29, no. 4 (2010): 315-324.

- Robbennolt, J. K. "Apologies and Medical Error." *Clinical Orthopaedics and Related Research* 467, no. 2 (2009): 376-82.
- Robbennolt, Jennifer K. "Apologies and Legal Settlement: An Empirical Examination." *Michigan Law Review* 102, no. 3 (2003): 460-516.
- Rocker, Graeme, Kathleen Puntillo, and Élie Azoulay. *End of Life Care in the Icu: From Advanced Disease to Bereavement*. Oxford University Press, 2008.
- Rosner, Fred, Jeffrey T Berger, Pieter Kark, Joel Potash, and Allen J Bennett. "Disclosure and Prevention of Medical Errors." *Archives of Internal medicine* 160, no. 14 (2000): 2089-92.
- Rosner, Fred. "Allocation or Misallocation of Limited Medical Resources." *Cancer investigation* 22, no. 5 (2004): 810-812.

Ross, W. D., The Right and the Good. Oxford: Clarendon, 1930.

- Rossi, Michael J, Dan Guttmann, Megan J MacLennan, and James H Lubowitz. "Video Informed Consent Improves Knee Arthroscopy Patient Comprehension." *Arthroscopy: The Journal of Arthroscopic & Related Surgery* 21, no. 6 (2005): 739-743.
- Rothschild, Jeffrey M, Ann C Hurley, Christopher P Landrigan, John W Cronin, Kristina Martell-Waldrop, Cathy Foskett, Elisabeth Burdick, Charles A Czeisler, and David W Bates. "Recovery from Medical Errors: The Critical Care Nursing Safety Net." *Joint Commission Journal on Quality and Patient Safety* 32, no. 2 (2006): 63-72.
- Rothschild, Jeffrey M, Christopher P Landrigan, John W Cronin, Rainu Kaushal, Steven W Lockley, Elisabeth Burdick, Peter H Stone, *et al.* "The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care." *Critical care medicine* 33, no. 8 (2005): 1694-700.
- Rowell, David, Hong Son Nghiem, C Jorm, and TJ Jackson. "How Different Are Complications That Affect the Older Adult Inpatient?" *Quality and Safety in Health Care* 19, no. 6 (2010): e34.
- Runciman, Bill, and Merrilyn Walton. Safety and Ethics in Healthcare: A Guide to Getting It Right. Ashgate Publishing, Ltd., 2007.
- Russ, Ann J, and Sharon R Kaufman. "Family Perceptions of Prognosis, Silence, and the "Suddenness" of Death." *Culture, medicine and psychiatry* 29, no. 1 (2005): 103-23.
- Rutala, WA, and DJ Weber. "Infection Control: The Role of Disinfection and Sterilization." *Journal of Hospital Infection* 43 (1999): S43-S55.
- Rutala, William A, and David J Weber. "Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know." *Clinical infectious diseases* 39, no. 5 (2004): 702-09.
- Rutala, William A., and David J. Weber. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Retrieved from: <u>http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf.</u>
- Sage, William M. "Role of Medicare in Medical Malpractice Reform, The." J. Health Care L. & Pol'y 9 (2006): 217.
- Sales, Christopher S, and Anthony L Schlaff. "Reforming Medical Education: A Review and Synthesis of Five Critiques of Medical Practice." *Social Science & Medicine* 70, no. 11 (2010): 1665-68.

- Sandars, John, and Aneez Esmail. "The Frequency and Nature of Medical Error in Primary Care: Understanding the Diversity across Studies." *Family practice* 20, no. 3 (2003): 231-36.
- Sayeed, Sadath A. and Robert D. Troug. "Malpractice and Disclosure of Errors," *America Academy of Pediatrics*. Retrieved from: <u>https://www2.aap.org/sections/bioethics/PDFs/ Curriculum_Session8.pdf</u>, 51-56, <u>Accessed Mar</u>, 2015.
- Schaefer, Kristen G, and Susan D Block. "Physician Communication with Families in the Icu: Evidence-Based Strategies for Improvement." *Current opinion in critical care* 15, no. 6 (2009): 569-77.
- Schaufel, Margrethe Aase, Jan Erik Nordrehaug, and Kirsti Malterud. ""So You Think I'll Survive?": A Qualitative Study About Doctor-Patient Dialogues Preceding High-Risk Cardiac Surgery or Intervention." *Heart* 95, no. 15 (2009): 1245-49.
- Schenker, Yael, Anita Stewart, Beeya Na, and Mary A Whooley. "Depressive Symptoms and Perceived Doctor-Patient Communication in the Heart and Soul Study." *Journal of General Internal Medicine* 24, no. 5 (2009): 550-56.
- Schneider, Carl. The Practice of Autonomy: Patients, Doctors, and Medical Decisions. Oxford University Press, 1998.
- Schoenbaum, Stephen C, and Randall R Bovbjerg. "Malpractice Reform Must Include Steps to Prevent Medical Injury." *Annals of Internal Medicine* 140, no. 1 (2004): 51-53.
- Schoenborn, Nancy L., Alicia I. Arbaje, Kathryn J. Eubank, Kenric Maynor, and Joseph A. Carrese. "Clinician roles and responsibilities during care transitions of older adults." *Journal of the American Geriatrics Society* 61, no. 2 (2013): 231-236.
- Schroter, Sara, Ros Plowman, Andrew Hutchings, and Adrian Gonzalez. "Reporting Ethics Committee Approval and Patient Consent by Study Design in Five General Medical Journals." *Journal of medical ethics* 32, no. 12 (2006): 718-723.
- Schulman-Green, Dena, Ruth McCorkle, Emily Cherlin, R Johnson-Hurzeler, and Elizabeth H Bradley. "Nurses' Communication of Prognosis and Implications for Hospice Referral: A Study of Nurses Caring for Terminally III Hospitalized Patients." *American Journal of Critical Care* 14, no. 1 (2005): 64-70.
- Schwappach, David LB, and Christian M Koeck. "What Makes an Error Unacceptable? A Factorial Survey on the Disclosure of Medical Errors." *International Journal for Quality in Health Care* 16, no. 4 (2004): 317-26.

- Schwartz, Denise Baird, "Ethical Considerations in the Critically Ill Patient" in *Nutrition* Support for the Critically Ill Patient: A Guide to Practice, ed. Cresci, Gail. Boca Raton: Taylor & Francis, 2015.
- Scriven, Michael. "The Logic and Methodology of Checklists." Retrieved from: https://www.wmich.edu/sites/default/files/attachments/u350/2014/logic%26metho dology_dec07.pdf.
- Segall, Noa, Alberto S Bonifacio, Rebecca A Schroeder, Atilio Barbeito, Dawn Rogers, Deirdre K Thornlow, James Emery, et al. "Can We Make Postoperative Patient Handovers Safer? A Systematic Review of the Literature." Anesthesia & Analgesia 115, no. 1 (2012): 102-15.
- Selph, R Brac, Julia Shiang, Ruth Engelberg, J Randall Curtis, and Douglas B White. "Empathy and Life Support Decisions in Intensive Care Units." *Journal of general internal medicine* 23, no. 9 (2008): 1311-17.
- Services, Centers for Medicare and Medicaid. "National Health Expenditures 2014 Highlights." Retrieved from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf.
- Services, U.S. Department of Health and Human. "A Physician's Practical Guide to Culturally Competent Care." <u>https://cccm.thinkculturalhealth.hhs.gov.</u>
- Services., U.S. Department of Health & Human. "*Effective Communication in Hospitals.*" Retrieved from: <u>http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication</u> <u>/.</u>
- Shanafelt, Tait D., Charles M. Balch, Gerald Bechamps, Tom Russell, Lotte Dyrbye, Daniel Satele, Paul Collicott, Paul J. Novotny, Jeff Sloan, and Julie Freischlag.
 "Burnout and medical errors among American surgeons." *Annals of surgery* 251, no. 6 (2010): 995-1000.
- Shanawani, Hasan, Marjorie D Wenrich, Mark R Tonelli, and J Randall Curtis. "Meeting Physicians' Responsibilities in Providing End-of-Life Care." *Chest Journal* 133, no. 3 (2008): 775-86.
- Shannon, Claude Elwood. "A Mathematical Theory of Communication." *ACM* SIGMOBILE Mobile Computing and Communications Review 5, no. 1 (2001): 3-55.
- Shannon, Diane. "Cultural Competency in Health Care Organizations: Why and How?". *Physician Executive* 36, no. 5 (2010): 18-22.

- Shapiro, Susan P. "Advance Directives: The Elusive Goal of Having the Last Word." *NAELA Journal* 8, no. 2 (2012): 205-32.
- Sharbaugh, Robert J. "Cleaning Reusable Equipment in the Icu." *Critical care nursing quarterly* 24, no. 2 (2001): 48-54.
- Shirley, Peter J, and Julian F Bion. "Intra-Hospital Transport of Critically Ill Patients: Minimising Risk." *Intensive care medicine* 30, no. 8 (2004): 1508-10.
- Sidebotham, David. *Cardiothoracic Critical Care*. Philadelphia, Pa: Butterworth-Heinemann Elsevier Health Sciences, 2007.
- Siegel, Mark D. "End-of-Life Decision Making in the Icu." *Clinics in chest medicine* 30, no. 1 (2009): 181-94.
- Silva, Mary Cipriano, and Ruth Ludwick. "Interstate Nursing Practice and Regulation: Ethical Issues for the 21st Century." Online Journal of Issues in Nursing 4, no. 2 (1999): www.nursingworld.org//MainMenuCategories/ANAMarketplace/ANAPeriodicals /OJIN/TableofContents/Volume41999/No2Sep1999/InterstateNursingPracticeand Regulation.aspx. Accessed December, 6, 2015.
- Silveira, Maria J, Wyndy Wiitala, and John Piette. "Advance Directive Completion by Elderly Americans: A Decade of Change." *Journal of the American Geriatrics Society* 62, no. 4 (2014): 706-10.
- Simpson, Michael, Robert Buckman, Moira Stewart, Peter Maguire, Mack Lipkin, Dennis Novack, and James Till. "Doctor-Patient Communication: The Toronto Consensus Statement." *BMJ: British Medical Journal* 303, no. 6814 (1991): 1385-7.
- Sittig, Dean F, and William W Stead. "Computer-Based Physician Order Entry: The State of the Art." *Journal of the American Medical Informatics Association* 1, no. 2 (1994): 108.
- Slevin, M, J Mossman, A Bowling, R Leonard, W Steward, P Harper, M McIllmurray, and Nick Thatcher. "Volunteers or Victims: Patients' Views of Randomised Cancer Clinical Trials." *British Journal of Cancer* 71, no. 6 (1995): 1270.
- Snowdon, Claire, Jo Garcia, and Diana Elbourne. "Making Sense of Randomization; Responses of Parents of Critically Ill Babies to Random Allocation of Treatment in a Clinical Trial." Social science & medicine 45, no. 9 (1997): 1337-1355.
- Snyder, Lois, and Cathy Leffler. "Ethics Manual." *Annals of Internal Medicine* 142, no. 7 (2005): 560-582.

- Sorokin, Rachel, Jeff M Riggio, and Constance Hwang. "Attitudes About Patient Safety: A Survey of Physicians-in-Training." *American Journal of Medical Quality* 20, no. 2 (2005): 70-77.
- Stambouly, JJ, LL McLaughlin, FS Mandel, and RA Boxer. "Complications of Care in a Pediatric Intensive Care Unit: A Prospective Study." *Intensive care medicine* 22, no. 10 (1996): 1098-104.
- Stamm, Jason A, Karen A Korzick, Kristen Beech, and Kenneth E Wood. "Medical Malpractice: Reform for Today's Patients and Clinicians." *The American journal* of medicine 129, no. 1 (2016): 20-25.
- Steinbrook, Robert. "Protecting Research Subjects—the Crisis at Johns Hopkins." N Engl J Med 346, no. 9 (2002): 716-20.
- Stewart, Anita L, Anna M Nápoles- Springer, Steven E Gregorich, and Jasmine Santoyo-Olsson. "Interpersonal Processes of Care Survey: Patient- Reported Measures for Diverse Groups." *Health Services Research* 42, no. 4 (2007): 1235-56.
- Stewart, Anita L, Anna Nápoles- Springer, and Eliseo J Pérez- Stable. "Interpersonal Processes of Care in Diverse Populations." *Milbank Quarterly* 77, no. 3 (1999): 305-39.
- Steyrer, Johannes, Michael Schiffinger, Clemens Huber, Andreas Valentin, and Guido Strunk. "Attitude Is Everything?: The Impact of Workload, Safety Climate, and Safety Tools on Medical Errors: A Study of Intensive Care Units." *Health care management review* 38, no. 4 (2013): 306-16.
- Stockwell, David C., and Anthony D Slonim. "Quality and Safety in the Intensive Care Unit." *Journal of intensive care medicine* 21, no. 4 (2006): 199-210.
- Strobel, M. D. "The technology is there: options for preventing lab labeling and tracking errors." *MLO: medical laboratory observer* 45, no. 2 (2013): 22-22.
- Studdert, David M, Michelle M Mello, Atul A Gawande, Tejal K Gandhi, Allen Kachalia, Catherine Yoon, Ann Louise Puopolo, and Troyen A Brennan. "Claims, Errors, and Compensation Payments in Medical Malpractice Litigation." *New England Journal of Medicine* 354, no. 19 (2006): 2024-33.
- Sulmasy, Daniel P, and Jeremy Sugarman. "Are Withholding and Withdrawing Therapy Always Morally Equivalent?". *Journal of medical ethics* 20, no. 4 (1994): 218-224.
- Sultz, Harry A, and Kristina M Young. Health Care, USA: Understanding Its Organization and Delivery. Sudbury, Massachusetts: Jones & Bartlett Learning, 2006.

- Taft, Lee. "Apology and Medical Mistake: Opportunity or Foil." *Annals Health L.* 14 (2005): 1-40.
- Taghipour, Sharareh, Dragan Banjevic, and Andrew KS Jardine. "Prioritization of Medical Equipment for Maintenance Decisions." *Journal of the Operational Research Society* 62, no. 9 (2011): 1666-87.
- Taghipour, Sharareh. "Reliability and Maintenance of Medical Devices." Citeseer, 2011. Retrieved from: <u>https://tspace.library.utoronto.ca/bitstream/1807/29886/6/Taghipour_Sharareh_20</u> <u>1106 PhD_thesis.pdf</u>.
- Taib, Ibrahim Adham, Andrew Stuart McIntosh, Carlo Caponecchia, and Melissa T Baysari. "A Review of Medical Error Taxonomies: A Human Factors Perspective." Safety Science 49, no. 5 (2011): 607-15.
- Tay, Catherine, and Sim Leng, Tien. *Biomedical Ethics and Medical Law in Blood Transfusion Practice: Case Scenarios.* Singapore: Armour Pub., 2010.
- Taylor, Helen. Assessing the Nursing and Care Needs of Older Adults: A Patient-Centered Approach. Radcliffe Medical Press, 2005.
- Taylor, Kathryn M. "'Telling Bad News': Physicians and the Disclosure of Undesirable Information." *Sociology of Health & Illness* 10, no. 2 (1988): 109-32.
- Teno, Joan M, Andrea Gruneir, Zachary Schwartz, Aman Nanda, and Terrie Wetle. "Association between Advance Directives and Quality of End- of- Life Care: A National Study." *Journal of the American Geriatrics Society* 55, no. 2 (2007): 189-94.
- Tevlin R, Doherty E, Traynor O. "Improving disclosure and management of medical error - an opportunity to transform the surgeons of tomorrow," *Surgeon*. 11, no. 6 (2013): 338-343.
- The Joint Commission Resources. *Improving care in the ICU*. Oakbrook Terrace, Ill: Joint Commission Resources, 2004.
- The Joint Commission Resources. Understanding and Preventing Sentinel and Adverse Events in Your Health Care Organization. Oakbrook Terrace, IL: Joint Commission Resources, 2008.
- The Joint Commission. "Sentinel Events and Alerts. "<u>http://www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf.</u>
- Thomasson, Joseph, Tommy Petros, Shauna Lorenzo-Rivero, Richard A Moore, and J Daniel Stanley. "Quality of Documented Consent for the De-Escalation of Care

on a General and Trauma Surgery Service." *The American Surgeon* 77, no. 7 (2011): 883-87.

- Tissot E, Cornette C, Limat S, Mourand JL, Becker M, Etievent JP, Dupond JL, Jacquet M, Woronoff-Lemsi MC. "Observational study of potential risk factors of medication administration errors," *Pharm World Sci.* 25, no 6 (2003): 264-268.
- Torke, Alexia M, G Caleb Alexander, and John Lantos. "Substituted Judgment: The Limitations of Autonomy in Surrogate Decision Making." *Journal of general internal medicine* 23, no. 9 (2008): 1514-17.
- Tourgeman- Bashkin, O, D Shinar, and E Zmora. "Causes of near Misses in Critical Care of Neonates and Children." *Acta Paediatrica* 97, no. 3 (2008): 299-303.
- Truog, Robert D, Margaret L Campbell, J Randall Curtis, Curtis E Haas, John M Luce, Gordon D Rubenfeld, Cynda Hylton Rushton, and David C Kaufman.
 "Recommendations for End-of-Life Care in the Intensive Care Unit: A Consensus Statement by the American College of Critical Care Medicine." *Critical care medicine* 36, no. 3 (2008): 953-63.
- Tucker, Anita L, and Amy C Edmondson. "Why Hospitals Don't Learn from Failures: Organizational and Psychological Dynamics That Inhibit System Change." *California management review* 45, no. 2 (2003): 55-72.
- Tully, Mary P, Darren M Ashcroft, Tim Dornan, Penny J Lewis, David Taylor, and Val Wass. "The Causes of and Factors Associated with Prescribing Errors in Hospital Inpatients." *Drug safety*32, no. 10 (2009): 819-36.
- Tutorial, Tool. "Using aggregate root cause analysis to improve patient safety." *Joint Commission Journal on Quality and Safety* 29, no 8 (2003): 434.
- Tweedy, James T. Healthcare Hazard Control and Safety Management. CRC Press, 2005.
- Valentin, Andreas, and Julian Bion. "How Safe Is My Intensive Care Unit? An Overview of Error Causation and Prevention." *Current opinion in critical care* 13, no. 6 (2007): 697-702.
- Valiee, Sina, Hamid Peyrovi, and Alireza Nikbakht Nasrabadi. "Critical Care Nurses' Perception of Nursing Error and Its Causes: A Qualitative Study." *Contemporary nurse* 46, no. 2 (2014): 206-13.
- Van Beuzekom, M, F Boer, S Akerboom, and P Hudson. "Patient Safety: Latent Risk Factors." *British journal of anaesthesia* 105, no. 1 (2010): 52-59.
- Van den Bemt, Patricia MLA, Roel Fijn, Peter HJ van der Voort, Annet A Gossen, Toine CG Egberts, and Jacobus RBJ Brouwers. "Frequency and Determinants of Drug

Administration Errors in the Intensive Care Unit*." *Critical care medicine* 30, no. 4 (2002): 846-50.

- Van Geest, Jonathan B, and Deborah S Cummins. "An Educational Needs Assessment for Improving Patient Safety." *White paper report* 3 (2003): 1-28.
- Vawter, Dorothy E, J Eline Garrett, Karen G Gervais, Angela Witt Prehn, and Debra A DeBruin. "Dueling Ethical Frameworks for Allocating Health Resources." *The American Journal of Bioethics* 10, no. 4 (2010): 54-56.
- Veerabadran, Sethu, and Ian M Parkinson. "Cleaning, Disinfection and Sterilization of Equipment." *Anaesthesia & intensive care medicine* 11, no. 11 (2010): 451-54.
- Vincent, Jean Louis, Jacques Berré, and Jacques Creteur. "Withholding and Withdrawing Life Prolonging Treatment in the Intensive Care Unit: A Current European Perspective." *Chronic respiratory disease* 1, no. 2 (2004): 115-120.
- Vincent, Jean-Louis. "Forgoing Life Support in Western European Intensive Care Units: The Results of an Ethical Questionnaire." *Critical care medicine* 27, no. 8 (1999): 1626-33.
- Vincent, Jean-Louis. "Give Your Patient a Fast Hug (at Least) Once a Day*." *Critical care medicine* 33, no. 6 (2005): 1225-29.
- Vincent, Jean-Louis. "Withdrawing May Be Preferable to Withholding." *Crit Care* 9, no. 3 (2005): 226-229.
- Vlayen, Annemie, Sandra Verelst, Geertruida E Bekkering, Ward Schrooten, Johan Hellings, and Neree Claes. "Incidence and Preventability of Adverse Events Requiring Intensive Care Admission: A Systematic Review." *Journal of evaluation in clinical practice* 18, no. 2 (2012): 485-97.
- Vodinh, J, F Bonnet, C Touboul, JP Lefloch, JP Becquemin, and A Harf. "Risk Factors of Postoperative Pulmonary Complications after Vascular Surgery." Surgery 105, no. 3 (1989): 360-65.
- Wachter, Robert M. "Patient Safety at Ten: Unmistakable Progress, Troubling Gaps." *Health Affairs* 29, no. 1 (2010): 165-73.
- Wachter, Robert M. Understanding Patient Safety. McGraw Hill Medical, 2012.
- Waite, Michael. "To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error." *Health LJ* 13 (2005): 1-34.

Walton, Douglas. Ethical Argumentation. Lexington Books, 2009.

- Watts, Rosemary, Jane Pierson, and Heather Gardner. "Co- Ordination of the Discharge Planning Process in Critical Care." *Journal of clinical nursing* 16, no. 1 (2007): 194-202.
- Weick, Karl E. "Technology as equivoque: sensemaking in new technologies." (1990).
- Weingart, Saul N, Ross McL Wilson, Robert W Gibberd, and Bernadette Harrison. "Epidemiology of Medical Error." *BMJ: British Medical Journal* 320, no. 7237 (2000): 774-77.
- Weingarten, RM. "Preventable Medical Errors: What's the Cost?". *The Pennsylvania nurse* 68, no. 2 (2013): 4-9.
- Wenrich, Marjorie D, J Randall Curtis, Sarah E Shannon, Jan D Carline, Donna M Ambrozy, and Paul G Ramsey. "Communicating with Dying Patients within the Spectrum of Medical Care from Terminal Diagnosis to Death." Archives of Internal Medicine 161, no. 6 (2001): 868-74.
- Wheelan, Susan A, Christian N Burchill, and Felice Tilin. "The Link between Teamwork and Patients' Outcomes in Intensive Care Units." *American Journal of Critical Care* 12, no. 6 (2003): 527-34.
- Wheeler, Derek S, Hector R Wong, and Thomas P Shanley. *Pediatric Critical Care Medicine: Basic Science and Clinical Evidence*. London: Springer Science & Business, 2007.
- White, Douglas B, and Robert M Arnold. "The Evolution of Advance Directives." *JAMA* 306, no. 13 (2011): 1485-86.
- White, Douglas B, Ruth A Engelberg, Marjorie D Wenrich, Bernard Lo, and J Randall Curtis. "Prognostication During Physician-Family Discussions About Limiting Life Support in Intensive Care Units*." *Critical care medicine* 35, no. 2 (2007): 442-48.
- White, Douglas B. "The Language of Prognostication in Intensive Care Units." *Medical Decision Making* 30, no. 1 (2010): 76-83.
- Wikler, Daniel. "Patient Interests: Clinical Implications of Philosophical Distinctions." *Journal of the American Geriatrics Society* 36, no. 10 (1988): 951-58.
- Wilber, Charles K. Economics, Ethics, and Public Policy. Rowman & Littlefield, 1998.
- Wilkinson, Dominic, and Julian Savulescu. "A Costly Separation between Withdrawing and Withholding Treatment in Intensive Care." *Bioethics* 28, no. 3 (2014): 127-137.
- William M. Sage, "The role of medicare in medical malpractice," *Journal of Health Care Law and Policy* 9, no. 2 (2009): 217-234.
- William P. Sullivan. "New employment contract pitfalls to avoid," Retrieved from: http://www.acepnow.com/article/new-employment-contract-pitfalls-avoid/.
- Wise, Kristin R, Valery A Akopov, Byron R Williams, Moges S Ido, Kenneth V Leeper, and Daniel D Dressler. "Hospitalists and Intensivists in the Medical Icu: A Prospective Observational Study Comparing Mortality and Length of Stay between Two Staffing Models." *Journal of Hospital Medicine* 7, no. 3 (2012): 183-89.
- Wolf, Zane, and Ronda Hughes. "Error Reporting and Disclosure." Agency for Healthcare Research and Quality, http://archive.ahrq.gov/professionals/cliniciansproviders/resources/nursing/resources/nurseshdbk/WolfZ_ERED.pdf. accessed, February 7, 2016.
- Wong, JD, and J Rabin. "Encyclopedia of Public Administration and Public Policy." Taylor & Francis, 2003.
- Wu, Albert W, Angela KM Lipshutz, and Peter J Pronovost. "Effectiveness and Efficiency of Root Cause Analysis in Medicine." *Jama* 299, no. 6 (2008): 685-87.
- Wu, Albert W, Susan Folkman, Stephen J McPhee, and B Lo. "Do House Officers Learn from Their Mistakes." *Jama* 265, no. 16 (1991): 2089-94.
- Wu, Albert W, Susan Folkman, Stephen J McPhee, and Bernard Lo. "How House Officers Cope with Their Mistakes." Western Journal of Medicine 159, no. 5 (1993): 565-9.
- Wu, Albert W, Thomas A Cavanaugh, Stephen J McPhee, Bernard Lo, and Guy P Micco.
 "To Tell the Truth." *Journal of General Internal Medicine* 12, no. 12 (1997): 770-75.
- Wu, Albert W. "Medical Error: The Second Victim." Western Journal of Medicine 172, no. 6 (2000): 358-9.
- Wyszynski, Antoinette Ambrosino, and Bernard Wyszynski. *Manual of Psychiatric Care* for the Medically Ill. American Psychiatric Pub, 2008.
- Young, Gary, Martin Charns, Kamal Desai, Jennifer Daley, William Henderson, and Shukri Khuri. "Patterns of Coordination and Clinical Outcomes: A Study of Surgical Services." *Health Service Res* 33, no.5 (1998): 1212.

Youngberg, Barbara J. Patient Safety Handbook. Jones & Bartlett Learning, 2004.

- Zeggwagh, Amine Ali, Houda Mouad, Tarek Dendane, Khalid Abidi, Jihane Belayachi, Naoufel Madani, and Redouane Abouqal. "Preventability of Death in a Medical Intensive Care Unit at a University Hospital in a Developing Country." *Indian journal of critical care medicine: peer-reviewed, official publication of Indian Society of Critical Care Medicine* 18, no. 2 (2014): 88-94.
- Zhang, Baohui, Alexi A Wright, Haiden A Huskamp, Matthew E Nilsson, Matthew L Maciejewski, Craig C Earle, Susan D Block, Paul K Maciejewski, and Holly G Prigerson. "Health Care Costs in the Last Week of Life: Associations with Endof-Life Conversations." *Archives of internal medicine* 169, no. 5 (2009): 480-488.
- Zier, Lucas S, Jeffrey H Burack, Guy Micco, Anne K Chipman, James A Frank, and Douglas B White. "Surrogate Decision Makers' Responses to Physicians' Predictions of Medical Futility." *Chest Journal* 136, no. 1 (2009): 110-17.
- Zineldin, Mosad, Jonas Zineldin, and Valentina Vasicheva. "Approaches for Reducing Medical Errors and Increasing Patient Safety: Trm, Quality and 5 Qs Method." *The TQM Journal* 26, no. 1 (2014): 63-74.