

Seton Hall University eRepository @ Seton Hall

Seton Hall University Dissertations and Theses
(ETDs)

Seton Hall University Dissertations and Theses

2011

Factors Associated with Nurses' Recognition of a Need to Initiate Patients' Capacity Assessment

Gellert Toth
Seton Hall University

Follow this and additional works at: <https://scholarship.shu.edu/dissertations>

 Part of the [Nursing Commons](#)

Recommended Citation

Toth, Gellert, "Factors Associated with Nurses' Recognition of a Need to Initiate Patients' Capacity Assessment" (2011). *Seton Hall University Dissertations and Theses (ETDs)*. 1417.
<https://scholarship.shu.edu/dissertations/1417>

FACTORS ASSOCIATED WITH NURSES' RECOGNITION OF A NEED TO
INITIATE PATIENTS' CAPACITY ASSESSMENT

BY

Gellert Toth

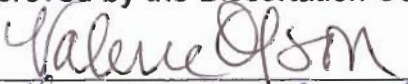


Dissertation Committee:

Dr. Valerie Olson, Chair

Dr. Terrence Cahill

Dr. Deborah A. DeLuca

Approved by the Dissertation Committee:

	Date: 4/5/11
	Date: 4/5/11
	Date: 4/5/11

Submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in Health Sciences

Seton Hall University

2011

ACKNOWLEDGEMENTS

I would like to gratefully and sincerely thank all who contributed to my dissertation journey. Without this support, the journey never would have progressed from just a thought to a scholarly work that we can all be proud of.

I would specifically like to thank Dr. Valerie Olson for her guidance, patience, kindness and encouragement during the dissertation as well as my time at Seton Hall University. Her leadership has had a profound effect on how my own thinking evolved over the years not only from the perspective of academic life but life overall. For your mentorship, guidance, and words of support, Dr. Olson, I will be forever grateful. Thank you.

I would also like to express my gratitude to members of my dissertation committee, Dr. Deborah DeLuca and Dr. Terence Cahill. It would not be possible to be here today without their perspectives that carried me from the infancy of my dissertation to the conclusion of the journey. Of course, both of you molded my thinking not only during the dissertation process but ever since I entered the program years ago. I can honestly say that what I learned from both of you made me a better scholar and person. Thank you for your guidance, help and unwavering support.

I would also like to thank the faculty and students of the Program, who helped me with their constructive criticism and ideas during research forums, in the classrooms and beyond.

Finally, and most importantly, I would like to thank my wife Dayna. Your support, unconditional love, and devotion serve as the foundation of my life.

With you, anything is possible!

TABLE OF CONTENTS

ACKNOWLEDGEMENTS.....	2
TABLE OF CONTENTS	4
LIST OF TABLES.....	6
LIST OF FIGURES.....	8
ABSTRACT	9
I. INTRODUCTION.....	11
Background of the Problem	11
Need for the Study.....	15
Purpose of the Study	21
Research Questions	22
Research Hypotheses.....	23
II. REVIEW OF RELATED LITERATURE.....	24
Introduction	24
The Ethical Provision of Healthcare.....	25
Informed Consent.....	33
Competence	44
Capacity.....	48
The Healthcare Professional's Responsibility	52
When to Assess Capacity	54
Conclusion.....	64
Tables.....	66
III. METHODS.....	70
Design.....	70
Variables and Instrumentation	72
Setting.....	77
Sample.....	77
Reliability	78
Procedure	79
Data Analysis.....	80

IV. RESULTS.....	85
Characteristics of the Sample	85
Tables	88
Univariate Results.....	96
Clinician Factor	96
Situational Factor	97
Patient Factor	98
Tables.....	100
Results of the Test of Hypotheses	104
Tables.....	111
Exploratory Factor Analysis	121
Table.....	124
V. DISCUSSION.....	125
General Discussion of Study Findings	125
Limitations.....	134
Table.....	137
Implications.....	138
Table.....	140
VI CONCLUSIONS.....	141
Conclusions	141
Future Directions	143
REFERENCES	145
APPENDIX	161
A. Capacity Assessment Survey	161
B. Demographic Questionnaire	164
C. Solicitation Letter	166
D. Reminder	168
E. IRB Approvals	169
F. Informal Request Form	171

LIST OF TABLES

Table I.	Properties Necessary for Informed Decision-making	66
Table II.	Foundations of Competence to Consent.....	67
Table III.	Physicians' Ethical Dilemmas	68
Table IV.	Distribution of Respondents: Type of Nursing License	88
Table V.	Distribution of Respondents: Certificate Earned.....	89
Table VI.	Distribution of Research Volunteers: Holding DEA and CDS Certification.....	90
Table VII.	Distribution of Respondents: Practice Setting	91
Table VIII.	Distribution of Respondents: Level of Education.....	92
Table IX.	Distribution of Respondents: Age.....	93
Table X.	Distribution of Respondents: Practice Length	94
Table XI.	Distribution of Respondents: Practice Length	95
Table XII.	Mean Scores Indicated by Variable on a +3 to -3 Scale ...	100
Table XIII.	Distribution of Respondents' Answers: Variables in Clinician Factor.....	101
Table XIV.	Distribution of Respondents' Answers: Variables in Situation Factor	102
Table XV.	Distribution of Respondents' Answers: Variables in Patient Factor	103
Table XVI.	Estimates of Regression Weights and Corresponding P-values.....	112
Table XVII.	Standardized Regression Weights: Factor Loadings	113
Table XVIII.	Covariances and Correlations of Factors	114

Table XIX.	Model Fit Summary	115
Table XX.	Estimates of Regression Weights and Corresponding P-values.....	117
Table XXI.	Standardized Regression Weights: Factor Loadings	118
Table XXII.	Squared Multiple Correlations: Variance Explained	119
Table XXIII.	Model Fit Summary	120
Table XXIV.	Rotated Factor Matrix with Corresponding Factor Loadings	124
Table XXV.	Distribution of Solicitations Mailed by County	137
Table XXVI.	Suggested Variables for Inclusion in Future Studies about Noticing that a Patient may not Have the Capacity for Decision Making.....	140

LIST OF FIGURES

Figure 1. Variability in Test Selection	69
Figure 2. Results of Confirmatory Factor Analysis: Model Structure	111
Figure 3. Final Factor Structure and Structural Equation Model.....	116

ABSTRACT

FACTORS ASSOCIATED WITH NURSES' RECOGNITION OF A NEED TO
INITIATE PATIENTS' CAPACITY ASSESSMENT

Gellert Toth

Seton Hall University
2011

Background & Purpose of the Study: It is unclear if and how nurses follow guiding principles pertaining to informed consent, particularly when recognizing the need to assess their patients' capacity. Further, it is unknown what factors influence nurses' behavior when it comes to capacity assessments.

Methods: The study design followed a sequential exploratory strategy employing a mixed design with a qualitative pilot and a quantitative cross-sectional survey to identify factors associated with nurses' recognition of a need to initiate patients' capacity assessment. Respondents were asked to indicate their level of agreement with whether they found it important to evaluate a patient's ability to make decisions when he or she exhibited certain characteristics, or if certain situations arose during an interaction between nurses and patients. Nurses' level of agreement was measured on a semantic differential bipolar scale.

A total of 1,000 valid names with corresponding addresses were randomly selected and mailed research materials, and 126 Registered Nurses consented to participate in the study.

Results: Confirmatory Factor Analysis revealed that the behavior of noticing patients not being able to thoughtfully make decisions about their care was correlated with a first order latent variable termed *Perception of Expectations from Others*. Factor loadings also showed that there was a stronger influence of those who have a collaborative relationship with the nurse, i.e. co-workers and patients compared to those with a hierarchical relationship, i.e. physicians.

Conclusion: The presence of the *Perception of Expectations from Others* factor suggests that clinicians are actively being influenced by and seek advice or approval of those they are involved with during the treatment of patients.

Chapter I

INTRODUCTION

Background of the Problem

Patients' capacity in medical decision-making has been the subject of intense moral, ethical, and legal debate since the 1960's. Nurses have a pivotal role as advocates and care providers in facilitating that patients' capacity is at the forefront of ethical care (Connelly, 2009; Nursing's Social Policy Statement, 2003; Nursing: Scope and Standards of Practice, 2004). However, a significant gap exists in peer-reviewed, published literature examining nurses' behavior in the context of capacity assessments. In fact, how nurses make decisions when they detect their patients' potential lack of sufficient capacity has not been investigated.

Aveyard (2005) proclaims that it is a universally accepted principle that nurses should obtain consent prior to nursing care procedures. Further, the practice of informed consent is an important founding block of the ethical provision of healthcare together with the protection of patients' autonomy and the beneficence/no malfeasance principle (White, 1994; Dunn, et al., 2006).

During a typical interaction between patients and nurses, the balance of power shifts to the nurse further emphasizing the importance of moral, ethical

and legal considerations (Santillan-Doherty, Cabral-Castañeda, & Soto-Ramírez, 2003). Informed consent is the moral, ethical and legal basis for the delivery of healthcare aimed at preserving personal autonomy of those requiring medical treatment (Mallardi, 2005). In a broader context, informed consent encompasses all actions that enable a person to make autonomous decisions about a practice, act, and product that impact that person's physical or mental domains.

When healthcare professionals practice informed consent, they provide all necessary information to their patients, allow their patients to make voluntary decisions about healthcare and ensure that their patients have enough capacity to make an informed decision (Grisso, 2002). Assessing the abilities of understanding, appreciation, reasoning, and expressing a choice is an important aspect of determining decision-making capacity. (Mayo & Wallhagen, 2009).

Having enough capacity requires that patients are able to express a choice regarding their healthcare, able to reason with information provided to them by healthcare professionals, understand the information, and appreciate the significance of their choice in the context of the situation (Parmar, 2008; Applebaum & Grisso, 1988; Drane, 1985; Roth et al., 1977).

Awareness and appreciation of the ethical demands of patient care are a pivotal component of commitment of nurses to ensure their patients safety while preserving their autonomy (Grady & Edgerly, 2009). In that context,

nurses must ensure that a patient has enough capacity to make medical decisions. (White ,1994; Grisso, 2002; Berg et al., 2001). As a result, the concept of informed consent is multifaceted yet essential to the ethical provision of healthcare (Whitcher, 2009).

Deciding whether someone is legally competent to make decisions regarding his or her own treatment requires an assessment of mental capacity. The assessed capacity required for legal competence increases with the seriousness of what is at stake. The usual explanation is that patient autonomy is being balanced against best interests. An alternative explanation is that we require smaller room for error when the consequences are serious (Buchanan, 2006).

Capacity assessments have moral consequences (Dunn, et al., 2006; White, 1994): Incorrect capacity determinations can be damaging as preventing someone from exercising autonomy is disrespectful, demeaning, and stigmatizing. It may result in the unwarranted deprivation of an individual's civil liberties, and could result in financial/legal damage to the assessor. As a result, it is not surprising that the number of court cases as well as regulations regarding informed consent have increased significantly making it difficult to understand, and interpret by nurses. Also, the high volume of judicial and legislative intervention regarding informed consent suggests that the topic is of great importance (Eriksson, Höglund, & Helgesson, 2008).

Most healthcare professional-patient encounters are “eventless” from a capacity perspective, but the question of having enough capacity for medical decision making may arise occasionally. (White, 1994). Nurses are an integral part of the informed consent process, and knowingly or unknowingly participate in it, whether for a routine patient contact or for a complex research study (Sims, 2008).

The literature provides guidance to healthcare professionals about definitions of capacity, and even protocols regarding what should trigger a capacity assessment have been published. (White, 1994; Grisso, 2002; Parmar, 2008). Established codes regarding informed consent specifically for nurses do exist and have appeared in publications by the American Academy of Nurse Practitioners (AANP) standards of practice for NPs, and codes of ethics from the American Nurses Association (ANA) and the American Medical Association (AMA). However, some of these rules, moral judgments and duties could be at odds with each other, and do not detail components of informed consent, such as capacity assessment. As a result, some scholars attempted to review the existing codes and standards of practice for nurses, and tried to develop a new ethical code by utilizing the established codes and standards with limited success (Peterson & Potter, 2004). Therefore, it is not surprising that healthcare workers, including nurses, lack adequate knowledge about how to assess capacity and deal with issues ensuring capacity assessments (Evans, Warner, & Jackson, 2007).

Need for the study

The ethical provision of healthcare is based on healthcare professionals' responsibility to protect their patients' autonomy, to act in the best interest of their patients while causing no harm (beneficence/non-maleficence), and to obtain informed consent from their patients prior to any procedure or intervention (White, 1994). Simply stated, when healthcare is provided ethically, autonomous patients must participate in the maintenance of their own well-being based on information provided to them by healthcare professionals.

White (1994) argues that healthcare providers demonstrate total respect to their patients' autonomy when they inform patients about the situation, help patients to understand the information, do not interfere with patients' choices, and finally implement the autonomously chosen options. Without full disclosure of information or understanding that information, patients may make therapeutic choices that may be contrary to their value systems, thereby violating their autonomy. Furthermore, autonomous decision-making provides patients with the foundation to select or forgo treatment options that closely align with their own value system, without interference from their healthcare provider or other entities.

Beneficence/non-maleficence is the active promotion and protection of a patient's well-being. The concept requires healthcare professionals to provide the most beneficial treatment option to their patients (White, 1994).

Informed consent is grounded on the ethical and moral premise that patients are entitled to acquire sufficient information about their illness and treatment options so that they can make meaningful and autonomous decisions about their care (Applebaum, Lidz, & Meisel, 1987). The goals of informed consent are two fold, according to White (1994). First, it must ascertain that decision makers can determine their own path to the future. Second, it must also ensure that healthcare services aim at and maintain the well-being of self-determining individuals.

During the past few decades, informed consent transformed from being solely a legal issue present in a few court cases to the ethical basis for the provision of healthcare, according to Mallardi (2005). As a result, informed consent has a profound influence and effect on the daily activities of healthcare providers, while it also retained strong presence in the judicial system. In sum, when healthcare providers practice informed consent, they ensure that their patients receive all necessary information for medical decision-making, and voluntarily make decision regarding their healthcare, while having enough capacity to make such decisions.

Having enough capacity means that a patient can express a choice regarding his or her healthcare, is able to reason with the information provided, understand the information, and appreciate the significance of the situation (Applebaum & Roth, 1982; White, 1994). The above definition of capacity has been generally accepted by ethicists, and the health care

industry (Karlawish, 2008). As a consequence, healthcare professionals' responsibility includes ensuring that patients have enough capacity to make medical decisions (Tunzi, 2001).

In fact, every healthcare professional-patient encounter is a test of capacity. Most of the time, assessing capacity is not an issue because it is obvious that the patient does have the capacity to decide on a task (Tunzi, 2001). While, the majority of healthcare professional-patient encounters are "eventless" from a capacity perspective, the question of enough capacity for medical decision-making may arise occasionally.

The literature provides guidance to healthcare professionals about definitions of capacity, and even protocols regarding what should trigger a capacity assessment have been published. For example, making a choice and expressing it simply requires a patient to indicate his or her willingness to undergo a proposed treatment. Most often, making and communicating a choice is carried out by having the patient sign a consent form. However, evidencing a choice seems to be an easy criterion to fulfill, but at times it may be difficult to establish (Applebaum & Roth, 1981). The ability to understand relevant information is defined as the functional ability to comprehend the illness, proposed treatment path, and the risks and benefits of the treatment (Grisso, 2003). In contrast to understanding, the ability to reason with the information provided means the rational utilization of available information to arrive at a decision (Applebaum & Grisso, 1995). In other words, it is a

patient's ability to manipulate the information rationally refers to weighing different treatment paths with different risk and benefit considerations (Grisso, 2003). Finally, the definition of appreciation of the nature of the situation includes a patients' level of awareness and insight into a problem, which manifests itself in the patient's ability to appreciate the risk/benefit ratio of medical intervention (Applebaum & Grisso, 1995).

However, it is unclear if these recommendations are followed, or if the definitions and triggers are practical for practicing healthcare professionals. More specifically, it is not known whether nurses follow recommendations of the literature or specific protocols when recognizing the need to assess their patients' capacity. It is also unclear what factors influence nurses' behavior when it comes to capacity assessments. Empirical evidence regarding factors associated with nurses to question whether a patient has sufficient capacity does not exist.

Capacity assessments have moral consequences as incorrect capacity determinations can be damaging as preventing someone from exercising autonomy is disrespectful, demeaning, and stigmatizing, and it may result in the unwarranted deprivation of an individual's civil liberties, and could result in financial/legal damage to the assessor. As a result, Appelbaum and Grisso (1998) suggest healthcare professionals become familiar with the issues pertaining to capacity, and measure their patients' capacity accordingly.

Capacity plays an extremely important role in the ethical provision of healthcare because, in practice, the role patients play in decisions about their health care is a function of whether their clinicians judge them to have enough decision-making capacity. Since capacity plays a pivotal role in healthcare provided that the concept is one of the cornerstones of the ethical provision of healthcare, clinicians have an ethical, moral and legal obligation to understand it (Ganzini, et al., 2004). Grisso and Applebaum (2003) argue that clinicians should be prepared to evaluate the capacity of their patients, which requires that healthcare practitioners are familiar with the ethical, legal and clinical issues associated with such a task. Since the clinical evaluation of capacity is a test of cognitive functioning, i.e. the ability to understand information, the ability to reason with that information while appreciating the situation, and selecting and signaling a choice, healthcare professionals should be comfortable with the task of judging capacity (Grisso & Applebaum, 2003).

Nurses face the same issues when they provide healthcare ethically (Aveyard, 2005). Therefore, the research focused on triggers of capacity assessment during a nurse-patient interaction. Indeed, assessing capacity, or in a broader sense, ensuring the ethical provision of healthcare is a behavior that could be influenced by a myriad of factors that ranged from: (a) beliefs about consequences; (b) social influences; (c) moral norm; (d) role and identity; (e) characteristics of healthcare provider; (f) habit or past

behavior; and (g) beliefs about capabilities (Godin, Belanger-Gravel, Eccles, & Grimshaw, 2008). Therefore, the study explored factors associated with nurses' perceptions of their need to assess patient capacity.

Purpose of the Study

The main purpose of the study was to identify factors associated with nurses' recognition of a need to initiate patients' capacity assessment.

Research Questions

Prior scholarly work has concluded that capacity is a fundamental aspect of personal autonomy (Berg et al., 2001; Grisso, 1986; Tepper & Elwork, 1984). Empirical evidence also suggests that capacity refers to a patient's cognitive and emotional capacity, when a patient selects among treatment alternatives or refuses treatment.

Further, capacity assessment has been described as a process for determining whether there is sufficient evidence to declare a person capable or incapable of managing their affairs. (Parmar, 2008). However, it is not known whether nurses follow recommendations of the literature or specific protocols when recognizing the need to assess their patients' capacity, and it is unclear what factors influence nurses' behavior when it comes to capacity assessments. Finally, empirical evidence regarding factors associated with nurses to question whether a patient has sufficient capacity does not exist. As a result, the following three primary research questions were developed.

- 1) Is there a significant correlation between patient factors and nurses' perceptions of their need to assess patient capacity?
- 2) Is there a significant correlation between situational factors and nurses' perceptions of their need to assess patient capacity?
- 3) Is there a significant correlation between clinician factors and nurses' perceptions of their need to assess patient capacity?

Research Hypotheses

Based on the research questions, three hypotheses emerged. The hypotheses propose an associative relationship between nurses' perceptions of the need to assess patients' capacity and three factors:

H1: Patient factors are significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.

H2: Situational factors are significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.

H3: Clinician factors are significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.

Chapter II

REVIEW OF RELATED LITERATURE

Introduction

The ethical provision of healthcare in the United States is based on the protection of patients' autonomy, healthcare providers' duty to "do good/cause no harm" and the practice of informed consent (Furrow, Greaney, Johnson, Jost, & Schwartz, 2009). In fact, when healthcare providers practice informed consent, they ensure that their patients receive all necessary information for medical decision making and voluntarily make decision regarding their healthcare, while having enough capacity to make such decisions (Grisso, 2002). Having enough capacity means that the patient can express a choice regarding his or her healthcare, is able to reason with the information provided, can understand the information, and can appreciate the significance of the situation.

It is a healthcare professional's responsibility to ensure that a patient has enough capacity to make medical decisions, therefore, healthcare professionals must assess their patients' capacity at every encounter (Kapp, 1992). While the majority of healthcare professional-patient encounters are

“eventless” from a capacity perspective, the question of enough capacity for medical decision making may arise occasionally.

Literature provides guidance to healthcare professionals about definitions of capacity, and even protocols regarding what should trigger a capacity assessment have been published. However, it is unclear if these recommendations are followed, or if the definitions and triggers are practical for practicing healthcare professionals. Capacity assessments have moral consequences: incorrect capacity determinations can be damaging as preventing someone from exercising autonomy is disrespectful, demeaning, and stigmatizing, and it may result in the unwarranted deprivation of an individual's civil liberties, and could result in financial/legal damage to the assessor.

The Ethical Provision of Healthcare

The ethical provision of healthcare in the United States is based on the protection of patients' autonomy, healthcare providers' duty to “do good/cause no harm” and the practice of informed consent.

Autonomy typically means self-governance or self-determination. “The principle of respect for autonomy requires that health-care professionals not interfere with the effective exercise of patient autonomy” (Mappes & DeGrazia, 2001, p.27). Autonomous decision-making is based on principles and laws (White, 1994), which were first placed in a model by utilitarian philosophers Jeremy Bentham and John Stuart Mill (Mappes & DeGrazia,

2001). However, it was Immanuel Kant's deontology that first defined the supreme principle of morality from which all human actions should originate by developing a framework for principled human behavior. Kantian deontology, therefore, became known as "ethics of respect for persons" (Mapes & Degraza, 2001, p.18). In fact, ethics is the philosophical study of morality. Subsequently, morality is a code of conduct that defines what is right and what is wrong.

Based on the philosophy of Immanuel Kant, White (1994) argued that autonomy is the consequence of morality; therefore it is clearly understood by human beings. Consequently, all people have the ability to decide what is right and what is wrong, and are able to articulate the rationale of why right is the appropriate choice. White further stipulates the meaning of autonomy, and concludes that autonomous people are allowed to independently develop a set of principles that governs their behavior, and evaluate whether their actual behavior is within the boundaries of those previously established principles. White claims that people can combine their values, goals, beliefs and interests in several ways to form a system. Freely choosing one of the combinations is the definition of principled action in Kantian thought. Carrying out a principled action means exercising autonomy, according to White (1994). She termed this autonomous choice as "choosing a value structure".

White concluded that in the context of healthcare, as more information becomes available regarding the illness and treatment options, the

background value structure of a patient will change accordingly until the patient exercises an autonomous choice but most importantly, that value structure may not be interfered with by healthcare professionals. In fact, when healthcare professionals respect their patients' value structure, they are actually honoring their patients' autonomy. White argued that healthcare providers demonstrate total respect of their patients' autonomy when they inform patients about the situation, help patients to understand the information, do not interfere with patients' choices, and finally, implement the autonomously chosen option, even if the therapeutic choice of a patient is not be aligned with what a healthcare provider considers optimal. As a result, the respect for autonomy places limits on what healthcare professionals can do to patients (Mapes & Degraza, 2001).

Without demonstrated respect of patients' autonomy by healthcare providers, patients may make therapeutic choices that may be contrary to their value systems, thereby violating their autonomy. However, respecting autonomy at times may place a healthcare provider at odds with his other obligation from the perspective of the ethical provision of healthcare, beneficence. For example, autonomy and beneficence often conflict each other when a patient does not want what his physician thinks is in the patient's best interest (Furrow, Greaney, Johnson, Jost, & Schwartz, 2001). Examples of such conflicts often end in litigation. The most frequently occurring cases that involve a conflict between autonomy and beneficence

include determination of when life supporting systems should be discontinued, physician's assistance in suicide, right to die, etc.

In addition to autonomy, beneficence/non-maleficence is a second of three basic building blocks of the ethical provision of healthcare, and is termed as the active promotion and protection of a patient's well-being (White, 1994). In medicine, the Hippocratic Oath specifically addresses the issue of beneficence as a foundation of ethical provision of healthcare: "I will use those dietary regimens which will benefit my patients according to my greatest ability and judgment, and I will do no harm or injustice to them" (Hippocratic Oath, NIH, http://www.nlm.nih.gov/hmd/greek/greek_oath.html).

Cross referencing autonomy and beneficence may result in an interesting dilemma. Beneficence/non-maleficence requires healthcare professionals to provide the most beneficial treatment option for their patients; however, it may be challenging to establish patients' definition of the most beneficial, according to White (1994). For example, a patient may autonomously choose a treatment alternative that is contrary to what the majority of patients would choose based on their healthcare professional's recommendation. However, in some cases it is very difficult to establish if a patient's behavior is within the value system based on his or her values, goals, beliefs and interests (White, 1994). Patients suffering from dementia may not be able to say what their value system may have been in the absence of the illness.

Informed consent in patient care is a legal condition whereby a person gives consent to undergo a specific treatment based on his or her appreciation and understanding of the facts and implications of such choice, according to White (1994). The doctrine of informed consent evolved during the 20th century based on the U.S. Court System's protection of individual autonomy. As a result, every patient has the right to choose freely among alternatives (Furrow, Greaney, Johnson, Jost, & Schwartz, 2001).

White (1994) argues that the goals of informed consent are two fold. On the one hand, healthcare providers are ethically, morally and legally bound to ensure that their patients make their own decision about a proposed treatment. On the other hand, the goal of healthcare providers must be the maintenance of their self-determining patients' well-being. Both legal and medical goals result in a single conclusion: patients should have to the opportunity to choose between the recommended treatment or an alternative approach or no treatment at all, in other words, patients must be self-determining. Still, healthcare providers are faced with the fact that the goals of informed consent are more far reaching and are intertwined with the goals of medicine.

Informed consent is grounded on the ethical and moral premise that patients are entitled to acquire sufficient information about their illness and therapy options in order to make meaningful and autonomous decisions about their healthcare (Applebaum, Lidz, & Meisel, 1987). Furthermore, patients

should be able to choose among treatment options or forgo treatment autonomously. Such autonomous decision-making ensures that a patient's choice is closely aligned with the patient's value system.

The U.S. Department of Health and Human Services (2004) outlined that the purpose of informed consent is the preservation of self-determination, freedom of choice, and protection of individuals from harm, abuse and deception. Such ethical principles closely correspond with beneficence/non-maleficance and the respect of autonomy, all of which serve as the basis for the ethical provision of healthcare in the U.S.

Capron (1972) identified six areas that informed consent is intended to target:

- 1) Protect individual patients' autonomy;
- 2) Protect patient's status as a human being;
- 3) Avoid fraud or duress;
- 4) Encourage doctors to carefully consider their decisions;
- 5) Foster rational decision-making by the patient; and
- 6) Involve the public generally in medicine.

Informed consent is more than simply getting a patient to sign a written consent form, as it is a process of communication between a patient and a healthcare professional that results in the patient's authorization or agreement to undergo a specific medical intervention. Informed consent is more than the protection of patients' rights and autonomy; it is also a physician's obligation.

The informed consent doctrine governs medical decision-making and guides the interaction between healthcare professionals and their patients (Furrow, Greaney, Johnson, Jost, & Schwartz, 2001).

Autonomy and informed consent are interrelated. One must recall White who termed autonomous choice as choosing a value structure (White, 1994). Therefore, if informed consent is to be given based on a value structure, the following criteria must be fulfilled. First, the person must be informed, in other words, he or she must have all material information that is necessary for decision-making. Second, the person must make a choice based on his or her understanding of the information. This means that the person must understand and appreciate the information. Finally, the person must make a voluntary choice based on all necessary information understood by him or her. That is the reason why autonomous choices must be informed and must not be coerced (Refer to Table I).

Beauchamp and Childress (1994) categorized elements of informed consent, all of which need to be fulfilled for the condition to be present. Threshold elements or preconditions were competence and voluntary decision-making. Information elements were the disclosure of information, recommendation of a treatment plan, and patients' understanding of both the information presented as well as the treatment plan. Finally, consent elements included the decision in favor of a plan, and patients' authorization to execute the proposed treatment plan (Beauchamp & Childress, 1994).

In addition to categorizing the elements of informed consent, one can think of them as sequential steps with the end goal of achieving informed consent. First, a healthcare professional must disclose all relevant information about a proposed treatment including the risks and benefits of the treatment, and potential treatment alternatives. Second, the healthcare professional's patient must voluntarily indicate whether he or she is ready to undergo that treatment or will follow an alternative option. Finally, as the first two conditions are fulfilled, the patient must demonstrate his or her competence (Grisso, 2002).

During the past few decades, healthcare professionals' and the public's understanding of informed consent has changed considerably. While laws have protected patients' rights to decide whether to undergo medical treatment, the role of explicit consent by patients has neither been well defined nor enforced, according to Faden and Beauchamp (1986). The definition of explicit patient consent, or what is now known as informed consent, became a radically different legal approach to the physician-patient interaction, and evolved over three decades of litigation in the U.S. court system beginning in the mid-1950's (Berg, Appelbaum, Lidz, & Parker, 2001). In fact, several landmark cases were closely followed by the medical community and had a profound influence and effect on the daily activities of healthcare providers, while maintaining a strong presence in the judicial system. Since informed consent has become one of the cornerstones of the ethical provision of healthcare, all healthcare decisions must be made in the

context of informed consent, except in certain circumstances when a patient is found incompetent to make decisions (Grisso, 2003). As a result of landmark court cases, informed consent has now become the ethical basis for the provision of healthcare (Mallardi, 2005), and the three requirements for informed consent emerged, proper information disclosure, competence, and voluntary participation of patients.

Informed Consent

When healthcare providers practice informed consent, they ensure that their patients receive all necessary information for medical decision-making and voluntarily make decision regarding their healthcare, while having enough capacity to make such decisions. Informed consent is based on three requirements, proper information disclosure, competence, and voluntary participation of patients (Berg, Applebaum, Lidz, & Parker, 2001). First, healthcare providers must disclose all relevant information to their patients. Patients must also have the ability to make decisions about their healthcare voluntarily. Lastly, decision makers must be competent to make an informed decision based on the information provided, and on the patient's value system, which is a unique combination of values, goals, beliefs and interests pertaining to a specific patient. Recall that autonomous choice as choosing a value structure (White, 1994).

Based on the evolving judicial system, it has been explicitly stated that every human being has the right to decide what should be done to his or her body based on relevant information. The courts also communicated that it is up to the patient to decide what information he considers relevant when making a decision about medical treatment. Further, it has also been determined that healthcare providers must fulfill five conditions to achieve the adequate information disclosure.

1. The healthcare provider must inform the patient of the disease for which he or she will receive treatment. Treatment in this case refers to the course of action a healthcare provider is going to take to medically address the disease or illness, either by managing it or curing it. Discussion must take place about medical steps preceding diagnosis, including tests and their alternatives. Physicians also must disclose the risks of not undergoing diagnostic procedures, if applicable;
2. The healthcare provider must disclose information about the therapy he or she recommends to the patient. Information disclosure means either verbal or written communication between the healthcare provider and his or her patient about the recommended treatment;
3. The healthcare provider must discuss with the patient the likelihood of successful outcome of the recommended treatment. Successful outcome may mean effective management of disease, prolonging survival, easing pain;

4. A discussion must take place about the risks of proposed therapy.

Risks mean unintended outcomes of the recommended treatment including death, and should address both temporary and permanent risks; and

5. The healthcare provider must disclose alternative treatment options as well as the risks and benefits of alternative therapy options. Alternative treatment means a course of action that is different from the recommended approach, while still referring to the same disease (Furrow, Greaney, Johnson, Jost, & Schwartz, 2001).

Based on the informed consent concept healthcare professionals are prohibited from providing healthcare to patients who are either incompetent or have not given consent for treatment. As a result, assessing competence is the first step in the process of obtaining informed consent. Since informed consent must be obtained from everyone, healthcare providers must make sure that all their patients are competent before providing consent and undergoing treatment. In most cases, it is obvious if a patient is competent or incompetent. However, in some cases, patients may be neither obviously competent nor obviously incompetent, and an in-depth investigation of competence may be necessary (Grisso, 2003).

Grisso (2002) also noted that while informed consent requires full information disclosure and the absence of coercion, a third component, competence must also be present. Interestingly, patients are considered

competent unless they are proven otherwise incompetent through the legal process (Raymont, 2002).

Culver and Gert (1982) competence as the capability to know what action steps must be taken to complete a task, while having the ability to take those steps. The authors argued that a person should be deemed competent if he or she is able to complete a task with specific action items associated with it, while he or she understands and knows how to complete those action items. In addition, a person must also have physical and mental ability and knowledge to complete those actions.

Competence may be present in two ways, either as a matter of law or as a matter of demonstrated lack of functional abilities, in other words as a matter of fact (Applebaum & Grisso, 1998). A matter of law is a legal contention that is examined and decided upon by a judge, who is versed in law. A matter of fact is also a legal contention, but since facts are disputed, a jury must weigh and decide about the outcome of the dispute. For example, minor children are considered incompetent as matter of law, and the law denies children the right to independently decide for or against a treatment choice. In contrast, adult patients may be declared incompetent by a court if it is proven that gaps exist in the patients' functional abilities, as a matter of fact.

Determination of competence is made as a matter of fact on a task-by-task basis. In other words, the jury must decide, whether a patient is competent to carry out a specific task based on the factual information

provided. Therefore, competence is a task associated issue, patients may be competent to carry out one task, but may be incompetent to carry out another, or vice versa. For example, a person may be competent to drive a car, but the same person could be found incompetent to carry out tasks of personal finance, such as balancing a checkbook or banking. It is foreseeable that a person is considered competent to drive a car, but as a patient, he or she may be found incompetent to make medical decisions for him or herself.

Task specific competence is further complicated by its dynamic nature, which means that patients, who are deemed incompetent to complete a certain task, may be found competent at another time. In other words, competence and incompetence are not only task specific, but also time specific (Grisso, 2003).

Finally, task and time specific competence is judged on a sliding scale by the courts. In other words, the threshold of competence may be different from case to case (Drane, 1984). It is not surprising that the threshold of competence is higher when very risky treatment options are considered, and lower when the potential consequences of treatment are not likely to result in a dangerous outcome. In a later article, Applebaum and Grisso (1998) stated that courts have already been influenced by Drane's "sliding scale competence", and have been applying such criteria to their decision on competence.

Also, one must understand that the issue of competence may arise independent of mental illness, or neurological conditions (Grisso, 2003).

Trauma and sudden illness may also render a person either permanently or temporarily incompetent, as can stress, fear, pain, drugs, and pathophysiology of disease (White, 1994). At the same time, the presence of mental illness, neurological conditions, trauma, etc. does not necessarily mean that patients are considered incompetent.

Moberg and Kniele (2006) argued that there was no empirical evidence determining what cognitive abilities were necessary to establish competence. The authors cited significant disagreement among neuropsychologists with respect to what cognitive abilities determine capacity, which may fall in the context of the multidimensional capacity model based on four constructs: expression of choice, understanding, appreciation and ability to reason developed by Grisso and Applebaum (1998) or other models by Drane (1994) and Marson, Earnst, Jamil, Bartolucci, and Harrell, (2000). However, it is unclear what cognitive measurement tools are best suited for use when considering the above models. Moberg and Kniele (2006) examined the relationship between executive function, a management of cognitive functioning, and capacity. The National Center for Learning Disabilities defines executive function as a term used to describe mental processes that enables an individual to bridge past experience with current action. Several activities require executive function: paying attention, remembering details, and strategizing. Norman and Shallice (2000) listed five items that describe executive functioning:

- (a) planning and decision making;
- (b) error correction or trouble shooting;
- (c) responding to situations with new action sequences;
- (d) responding to danger or technically difficult situations; and
resisting temptation, or overcoming strong habitual responses.

Moberg and Kniele (2006) found that clinicians who regularly measure executive functioning consider it an excellent predictor of capacity. In fact, 57% of surveyed experts considered executive functioning the most reliable predictor of capacity (Refer to Figure 1).

Based on the work of early pioneers, such as Roth, Meisel and Lidz (1977), competence was based on five broad categories: a) evidencing a choice, b) reasonable outcome of choice, c) choice based on rational reasons, d) ability to understand, and e) actual understanding. However, Applebaum and Roth (1982) further expanded standards that measure competence, and developed a scheme that is used in courts today. These standards include evidencing a choice, factual understanding of the issues, rational manipulation of information, and appreciation of the nature of the situation. Others, such as Karlawish (2008), also support the requirement for the four constructs referenced by Applebaum and Roth, (1982) to establish competence: (a) expression of choice, (b) understanding relevant information, (c) appreciating the situation, and (d) being able to reason. Karlawish's work (2008) centered on the elderly as he developed a set of characteristics whose

presence must be positively identified in order to deem the examined person competent to consent, and thereby permitted to undergo treatment.

Others also tried to create a framework to establish competence that loosely aligns with the Applebaum and Roth model (1982). White (1994) listed nine criteria organized into four broad categories required for competence (Refer to Table II). The presence of informability, cognitive and effective capability, the ability to choose and the ability to recount one's own decision making were required for competence to be upheld, but courts today have continued to use the model first outlined by Applebaum and Roth (1977).

Informability means that a patient can see, hear or feel, in other words his or her central nervous system is capable of receiving a stimulus. White argues that patients can be adequately, marginally or inadequately informable. Even marginally informable patients can be deemed competent, despite the fact their cognitive abilities may be compromised (White, 1994). As a result, the concept of task-specific competence emerged, in other words marginally informable patients may be able to comprehend information given to them about treatment options, therefore, they may be able to provide informed consent provided that all other criteria of informed consent are present.

A higher level of cognitive impairment requires more assistance from a healthcare provider, up to the point when a patient is deemed uninformed.

Once uninformativity is established, the patient may no longer provide informed consent. The ability to recognize relevant information refers to the ability to focus on relevant data while extracting that information from noise, Noise is also information that does not have relevance to the focus of the topic, and can block or interfere with the meaning of the information about the topic discussed by healthcare providers.

Therefore the ability to recognize relevant information is about focusing on relevant information and rationally processing that information. Finally, White argues that uninformativity is also based on the functional ability to remember. Remembering information is not just about recently acquired knowledge regarding treatment, diagnosis or prognosis but it also consists of remembering one's value structure, which is a foundation of autonomy (White, 1994).

Cognitive and affective capability was defined as the capacity to relate the situation to one's life, and based on that relation, the ability to reason about and rank alternatives. In other words, patients must be able to evaluate which treatment option is best for them based on their value structure (White, 1994). Coincidentally, those being able to reason and choose among alternatives, tend to be those who can explain how they arrived at a decision. As a result, ability to choose and ability to recount one's decision making process become intertwined concepts, yet both are necessary for competence. Competent patients can indeed make choices among alternatives, and are able to live

with the consequences of that choice. Furthermore, they are able to explain how they arrived at a particular choice. In short, patients can be considered legally competent only if they satisfy all four requirements of competence: evidencing a choice, factual understanding, rational manipulation of information, and appreciation of the situation.

In sum, White (1994) points out that competence consists of two components: having the knowledge about the task and its consequences and having the ability to carry out the task. She argues that having knowledge and having ability are impossible to separate, since the acquisition of knowledge partly depends on the ability to absorb and process information. At the same time, increased knowledge can enhance the ability to absorb and process information. Please see Table II for a comprehensive view of foundations of competence to consent.

In addition to information disclosure, voluntary participation is a key component of informed consent. When patients voluntarily act, they are not coerced, in other words, they are not manipulated to act involuntarily, according to Grisso (2003). Coercion could include overt threats of retaliation, intimidation, mental or physical pressure or application of force. The goal of coercion is the cooperation of patients, who would act differently in the absence of coercion. The source of coercion could be healthcare providers or family members. Whatever its source, means, and goals, coercion automatically negates informed consent, because coerced patients

do not act voluntarily, and therefore could not provide informed consent (Grisso, 2002).

Cox (2001) argued that the positive or negative context of the consultation also influenced consent. When giving verbal information, physicians and nurses used predominantly positive language. Cox conducted 55 in-depth interviews with patients suffering from cancer whose treatment included experimental pharmaceutical products. She found that 73% of patients recalled that the information presented to them appeared in a positive light. During the consultation, investigators almost never used the word "trial" but substituted it by a significantly more positive word, "study". Also, physicians often described the investigational agent as "new", "American" all of which suggested that the investigational product was better than the drugs tested before, thereby generating false hope. The overwhelmingly enthusiastic clinical researcher and his/her staff was a major influence, but the autonomy of patients may have been jeopardized. One must remember that expressions used by physicians are part of the contract signified by the physician patient relationship (Furrow et al., 2001). Since physicians and patients enter into a contract for a specific result, enthusiasm from a physician may signal false information to a patient. As a result, the physician may be found liable for breach of conduct if the implied agreement is violated.

Competence

A clear definition of competence is difficult to find in scientific publications, but incompetence is easier to define. "Incompetence constitutes a status of the individual that is defined by functional deficits (due to mental illness, mental retardation, or other mental conditions) judged to be sufficiently great that the person currently can not meet the demands of a specific decision-making situation, weighed in light of its potential consequences" (Grisso and Applebaum, 1998, p.27).

Still, abundant literature exists regarding the components of competence. Legal competence is based on four constructs: evidencing a choice, factual understanding, rational manipulation of information, and appreciation of the situation. Evidencing a choice, the simplest of the four constructs, and the least difficult to demonstrate, simply requires a patient to indicate his or her willingness to undergo a proposed treatment. Most often, evidencing a choice is carried out by having the patient sign a consent form (White, 1994).

However, Applebaum and Roth (1981) indicated that evidencing a choice seems to be an easy criterion to fulfill, but at times it may be difficult to establish. Examples of such difficulty may be exhibited when a patient is under considerable stress, is under the influence of drugs or if he or she has psychological issues. Patients under the influence of sedatives, narcotics or alcohol may have difficulty providing evidence of their choice. Patients suffering from dementia or head trauma victims may not be able to signal a

choice, as patients decision making may also be compromised by fear that resulted from trauma or illness. However, the presence of dementia, trauma, fear, sedatives, etc. does not automatically mean that the patient can not evidence a choice. Factual understanding of treatment is considered the norm when establishing competence, because the concept combines the ability to understand with actual understanding, both of which are measurable. (Sarat and Lavi, 2001).

The second criterion for competence is the ability to understand relevant information: which refers to the functional ability to comprehend the illness, proposed treatment path, and the risks and benefits of the treatment (Grisso, 2003). However, how information should be disclosed is not clear cut (Verheggen & Vijmen, 1996). For example, too much information may be overwhelming and interfere with the patient's ability to understand or worse, it could become interference from healthcare professionals. Patient demographics, such as level of education may be a factor in the amount of information a patient could understand. The difficulty of the language used during a consultation may also impact one's ability to understand. The implication of such problems is that interference with patients' understanding automatically means interference with competence, which in turn has an impact on informed consent. More explicitly, if too little or too much information or complicated language during an informed consent consultation results in lack of understanding from a patient, that patient may not be

considered competent to make a decision about medical care addressing that specific medical issue. Therefore, incompetent patients may not be able to provide informed consent (Kusec, Oreskovic, Skegro, Korolija, Basic, and Horzic, 2006).

Moseley, Wiggins, and O'sullivan (2006) investigated how patients' ability to recall information is influenced by presentation modality, such as verbal communication only, written communication only, using visual aids, etc. The authors found that presentation modality had an impact on study participants' ability to recall information, and concluded that visual aids enhanced understanding and recall beyond verbal presentation alone.

The quantity of information may also influence informed consent (Edwards, Lilford, Thornton, & Hewison, 1998). The authors found that patients significantly better understood proposed treatments, which were offered in the context of a clinical trial, when they participated in a supplementary interview with a nurse rather than just going through the standard consent procedure. Therefore, the authors concluded that volunteers' understanding was greatly enhanced by providing not only a large quantity of information but also information of very high quality. Better understanding builds a stronger case for competence. Since the threshold for competence for high risk procedures or treatment such as a clinical trial is high, a stronger case for competence will better support informed consent

The third criterion required for competence is the appreciation of the nature of the situation. Applebaum and Grisso (1995) argued that the concept was influenced by the level of awareness/insight into a problem and the ability to appreciate the risk/benefit ratio of the research. For example, delusional beliefs could result in patients understanding an illness while denying the actual presence of the illness. Such patients may not be able to apply the information to their situation, therefore will not be found competent, and could not give informed consent to undergo treatment (Grisso, 2003).

The fourth criterion for competence is the ability to rationally manipulate information. The ability to manipulate the information rationally refers to weighing different treatment paths with different risk and benefit considerations (Grisso, 2003). Rational manipulation of information is more difficult to measure because it investigates how subjects use available information to arrive at the decision to consent to treatment. Ulrich (2001) defined rational manipulation of information as an individual's ability to see the connections between pieces of information, and the ability to establish further connections between the information provided and the resulting actions they will take. Ulrich warned, however, that one can not apply uniform rules of logic when evaluating whether a patient is able to manipulate information rationally. For example, for Jehovah's witnesses, the refusal to use blood products is logically connected to the information they have about God's Law.

Capacity

Competence and capacity have been used synonymously by many, creating confusion. Some authors do acknowledge the fact that capacity and competence are two distinct constructs but claim that they are used interchangeably, and move onto their chosen focus of research. Others exhibit lack of understanding of how competence differs from capacity, and miss the idea of them being two distinct concepts that have a unique link with one another (Sturman, 2005).

Assessment of decision making capacity is a distinct concept from determination of competence. Competence is determined by the legal system, while capacity is assessed by healthcare professionals. Kapp (1992) argued that capacity and competence are related but they are distinct constructs. Capacity is strictly a clinical concept, and will be used only in a healthcare setting. Competence is strictly a term used by the judicial system. The most important distinction is that a judge will most likely consider clinical capacity findings from testimony of a healthcare professional, but he will also look to legal sources, such as precedent, case law, and principles of equity, when making a determination of competence (Marson, 2001). Since competence is a determination that has serious legal consequences, it is always based on a binary scale. In other words, a patient is either competent or incompetent. Capacity, on the other hand is assessed by a healthcare professional, and is based on medical opinion using a continuum. (Ortiz,

2007). In fact, capacity is also evaluated based on the same four constructs, although the healthcare system uses a scale, while the legal system uses binary variables depicting the presence or absence of competence.

Capacity plays an extremely important role in the ethical provision of healthcare because, in practice, the role patients play in decisions about their health care is a function of whether their clinicians judge them to have decision-making capacity. Because of the pivotal role capacity plays in healthcare related decision making, health care providers who work with patients have an ethical, moral and legal obligation to understand this concept (Ganzini, Volicer, Nelson, Fox, & Derse, 2004).

Beauchamp and Faden (1994) developed a framework, a sequential set of tests and establishment of criteria, for assuring informed consent is established. While they referred to only two core conditions required for informed consent, competence and voluntariness, information disclosure was still a major part of their framework albeit molded into the voluntariness concept. In their model, healthcare professionals first had to clarify whether their patients are competent or incompetent to decide on their treatment plan. Once it is clear that the patient is competent to proceed with consent, health care professionals must disclose all relevant information and a recommended plan. Health care professionals then must ensure that the patient understands all information and recommendations. As a consequence of the process, a patient giving informed consent actually provides authorization to

execute a treatment plan. In other words, the patient clearly exhibits signs of his or her competence, demonstrates that he or she fully understood the disclosed information, and clearly articulates that he or she decides to favor a recommended option or an alternative option as a treatment. (Beauchamp and Faden, 1994).

Still, capacity and competence have a unique relationship. When a healthcare professional is assessing decision-making capacity, he or she is measuring a patient's abilities related to individual decision tasks. In contrast, competence is a state in which patients' decision-making abilities are sufficiently intact for decisions to be honored (Appelbaum & Grisso, 1998). Competence, however, is a legal issue and can only be determined by the judicial system. Coincidentally, the judicial system can only base a determination of competence on facts, most often in the form of testimony from experts. Experts are medical professionals, who can only assess the capacity of a patient, and provide that expert opinion to the courts. However, their expert opinion is given to the courts through testimony, which then is translated into a determination of competence by the court. In other words, it is the judicial system that determines whether a patient is competent to make a decision.

As a result, Appelbaum and Grisso (1998) suggest that healthcare professionals (in this case physicians specifically) become familiar with the issues pertaining to both competence and capacity, and measure their

patients' capacity accordingly. It is not surprising that Appelbaum and Grisso arrived at the conclusion that the practical consequences of deeming a patient lacking capacity to carry out a certain task is the same as declaring the patient incompetent, although the first appears in the medical system and the latter in the judicial system. Again, incompetence is specific to the task and time of medical decision making that the physician is involved in.

According to Grisso (2003), general consensus exists regarding the abilities essential for decision making in healthcare from a legal perspective, which consists of the ability to communicate a choice, to understand relevant information, to appreciate the relevant information, and to manipulate the information rationally. The four abilities are required to establish competence in the legal system, and have migrated into the healthcare system because of the unique relationship between capacity and competence. One must recall that physicians evaluate capacity and offer expert opinion to the courts. The courts then determine competence based on that testimony.

Healthcare providers assume that patients have sufficient level of capacity to make medical decisions when dealing with routine medical issues such as treating the patient for a cold. However, in high risk procedures or procedures with uncertain outcomes, such as a clinical trial, a physician may choose to pause and assess their patient's capacity. Further, during the first interaction with a patient, it may become clear to the physician that the patient

may not have enough capacity to make a medical decision, and a deeper understanding of the patient's abilities may be necessary.

When the issue of capacity arises, healthcare professionals may select several paths in dealing with their potentially incompetent patients. Berg et al. (2001) discovered that many healthcare providers, specifically physicians, proceeded with a treatment that had been considered a patient's choice, although it was unclear whether the patient had been incompetent, and been able to provide informed consent to undergo the treatment.

Some physicians seek an alternate decision maker, while others use persuasion or a longer decision making process. Grisso and Applebaum (1998) also found that many physicians request a non-judicial review, a review of a patient's capacity by a professional trained to assess the four constructs of capacity. In fact, some institutions require such review when high-risk or irreversible procedures are being evaluated by patients (Grisso and Applebaum, 1998). High-risk procedures could include therapies that could result in death or irreversible procedures such as amputation of a limb, or clinical trials where the outcome of treatment is unknown.

The Healthcare Professional's Responsibility

Sims (2008) argued that nurses are an integral part of the informed consent process no matter the circumstance, whether it is preceding a routine procedure or participation in a clinical trial. In fact, nurses have a unique

relationship with their patients as patient advocates and direct care providers (Connelly, 2009). Patient advocacy means healthcare professionals provide medical care that is in the best interest of their patients (Whitcher, 2008). In fact, during capacity assessments, the best interest of the patient is weighed against his or her autonomy. Such a trade off is evaluated in the context of risk associated with medical care. In other words, treatment associated with higher risk requires a significantly more thorough evaluation of competence, than routine interventions (Buchanan, 2004)

It is a healthcare professional's responsibility to ensure that a patient has enough capacity to make decisions about his or her healthcare; therefore, healthcare professionals must assess their patients' capacity at every encounter. Most of the time, healthcare providers quickly and spontaneously confirm their patients' ability to understand their medical condition and the recommended care. While the majority of these interactions are straightforward, in some cases, the assessment of competence may be more challenging (Tunzi, 2001). Most often, it is evident if a patient has enough capacity for decision-making (Simon, 2007). For example, the presence of severe dementia is relatively obvious to recognize for trained healthcare professionals. Also, there can be little doubt about the presence of adequate level of capacity associated with "a well-groomed coherent young man who agrees to an appendectomy," according to Simon.

While the majority of healthcare professional-patient encounters are “eventless” from a capacity perspective, the question of enough capacity for medical decision-making may arise occasionally. General impressions of a clinician about the capacity of patients are mostly acceptable and routine because the clinician has no reason to doubt the patient’s competence. Also, in certain cases, lack of competence may be obvious due to neurologic or psychiatric conditions. However, in certain situations the healthcare professional may be uncertain about the patient’s capacity. In such cases, clinicians must investigate whether the patient has the capacity for decision making. (Ethchells, et al. 1996)

When to Assess Capacity

Literature provides guidance to healthcare professionals about definitions of capacity, and even protocols regarding what should trigger a capacity assessment have been published. Tunzi (2001) identified four broad categories when healthcare professionals should become concerned about their patients’ capacity. Patients exhibiting abrupt changes in their mental status should alarm healthcare providers, and could be caused by a wide variety of conditions. Refusal of treatment should also cause a healthcare provider to question the status of the patient from a capacity perspective, especially if the refusal is surrounded by unusual circumstances. Such circumstances could include unwillingness to discuss the refusal, lack of

clarity about the reasons for the refusal, or refusal due to irrational or faulty information. Quickly deciding to undergo risky interventions should also be considered a cause for investigation. Finally, the presence of certain conditions such as chronic neurologic or psychiatric conditions should automatically raise a healthcare professional's concern about a patient's level of capacity. (Tunzi, 2001)

However, it is unclear if these recommendations are followed, or if the definitions and triggers are practical for practicing healthcare professionals. The clinical evaluation of capacity is a test of cognitive functioning to determine whether a patient is capable receiving and understanding information, and is able to appreciate and use the information for decision making. As a result, Grisso and Applebaum claim that physicians should be comfortable with the task of evaluating capacity. Psychiatric consultation is a possibility if an attending physician is not comfortable assessing the patient's capacity.

Further, Grisso and Applebaum (2003) argue that clinicians should be prepared to evaluate the capacity of their patients, which requires that healthcare practitioners are familiar with the ethical, legal and clinical issues associated with such a task. The objectives of assessing capacity are to come to the same conclusion as the court system would when determining a patient's competence; therefore, clinicians should be knowledgeable about

the concept of competence and how it is judged by the courts (Grisso & Applebaum, 2003).

Despite the serious consequences associated with not fully understanding informed consent in clinical practice, Joffe and his colleagues (2001) found significant shortcomings in the process of obtaining informed consent both from patients and healthcare providers. The cross-sectional survey demonstrated that in clinical practice, the legal definitions of competence can be poorly understood, and healthcare professionals often exhibit gaps in their knowledge about topics that include one of the most frequently misunderstood frameworks, the difference between competence and capacity. Further, misunderstandings and knowledge gaps may present a problem in the context of the ethical provision of healthcare.

Sturman (2005) examined the issue of competence by reviewing several instruments designed to measure some or all aspects of competence. The author stated that capacity and competence are often used interchangeably despite the two concepts being separate entities.

Marson (2001) established capacity as a measure of decision-making capability based on clinical criteria and evaluation by a health care professional. In contrast, he concluded that competence was a legal term measured by the court system. However, Marson recognized that capacity and competence were difficult to separate, and noted that healthcare professionals often act as the judicial system and judge competence, when in

fact they do not have the legal authority to do so and are evaluating capacity. Legal determinations of incompetence are binding and can only be reversed by the courts, while a determination of incapacity is non-legally binding in the medical arena (Marson, 2001).

Corta-Bilajac, Bazdaric, Brozovic, and Agich (2008) surveyed healthcare professionals regarding the type of ethical issues healthcare professionals face most frequently during their practice. The authors also asked respondents to rank ethical issues based on their level of difficulty, frequency of use of in-hospital services to deal with ethical issues, healthcare professionals' training and confidence in ethical decision-making. The survey was distributed to internists, oncologists, emergency physicians and nurses working at responding physicians' departments. The most frequently cited ethical issue was uncertainty regarding impaired decision-making capacity. About two-thirds of physicians and 47% of nurses indicated such uncertainty as a major ethical issue. The second most frequently identified ethical issue was surpassing limitation of treatment at the end of life with 60% of physicians, and 31% of nurses agreeing, followed by disagreements among family members. About 47% of physicians and 31% of nurses identified disagreements as a major ethical issue today, according to Corta-Bilajac. About 12% of physicians and 3% of nurses indicated ever using in-hospital ethics support services, while 5% of physicians and 6% of nurses claimed to be confident about their knowledge in ethics.

Ganzini, Volicer, Nelson, and Derse (2003) asked psychiatric consultants about the most common pitfalls they observe from their referring colleagues when assessing decision-making capacity. On an unaided basis, respondents identified 23 issues and rated all as frequently occurring "common pitfalls". The most frequently occurring misconception among healthcare professionals was the notion that a patient who lacks capacity for one type of medical decision also lacks capacity for all medical decisions.

In another article, Ganzini, Volicer, Nelson, Fox, & Derse (2004) described the 10 most common myths about capacity among healthcare professionals as identified by the National Ethics Committee (NEC) of the Veterans Health Administration (VHA), which demonstrates that a significant knowledge gap exists among healthcare professionals regarding capacity and competence, and the need for education.

- 1) decision-making capacity and competency are the same;
- 2) lack of decision-making capacity can be presumed when patients go against medical advice;
- 3) there is no need to assess decision-making capacity unless patients go against medical advice;
- 4) decision-making capacity is an "all or nothing" phenomenon;
- 5) cognitive impairment equals lack of decision-making capacity;
- 6) lack of decision-making capacity is a permanent condition;

- 7) patients who have not been given relevant and consistent information about their treatment lack decision-making capacity;
- 8) all patients with certain psychiatric disorders lack decision-making capacity;
- 9) involuntarily committed patients lack decision-making capacity; and
- 10) only mental health experts can assess decision-making capacity (Ganzini, Volicer, Nelson, Fox, & Derse, 2004, p.239).

A knowledge gap seems to exist not only about the definition and medical application of capacity but about legal definitions of competence as well, despite the fact that Appelbaum and Grisso (1998) communicated the importance of being knowledgeable about the medical and legal definitions of the concepts, and how they apply to informed consent (Markson, Kern, Annas, & Glantz, 1994) investigated if physicians know and can apply the legal standard for determining competence. The survey presented an actual court case involving an elderly patient who refused life saving surgical intervention. The case provided respondents with the patient's medical history and rationale to refuse treatment, as well as a consultant psychiatrist's opinion of the patient being incompetent. Information about an appellate court's decision to deem the patient competent was withheld. Respondents indicated whether they believed the patient to be incompetent, whether they would consult a physician well versed in capacity assessments, as well as their proposed path forward. About 58% of the respondents correctly judged

the patient to be competent, and nine of 10 would have consulted a psychiatrist. After reading the psychiatrist's opinion, only 30% still thought the patient was competent, a marked improvement indicating that physicians who are unclear about capacity and competence should consult experts such as psychiatrists. Markson, Kern, Annas, and Glantz (1994) also found that nine of 10 physicians correctly knew the standards required for competence, but most were unable to apply this knowledge. Physicians' inability to apply their knowledge about competence resulted in a high level of discomfort with the topic which manifested itself by physicians reaching out to and relying on consultants to a much larger degree than they would have with other topics. Consulting in cases when the physician is uncomfortable making a decision is important, especially if it involves a field that physicians are not that familiar with, yet their decisions have far reaching consequences ethically, medically and legally.

Schofield (2008) also revealed significant knowledge gaps after investigating how knowledgeable healthcare professionals were, and found that physicians needed additional education about capacity. However, research about what healthcare professionals do or do not know about capacity may be focused, and combined with research about physicians attitudes regarding the subject, one may uncover an insight into whether the autonomy of patients are truly respected in everyday clinical practice. A

combination of knowledge and attitudes may have a profound impact on the triggers to investigate capacity when it becomes suspect.

In another study by Evans, Warner, and Jackson (2007) emergency doctors, nurses and ambulance staff showed lack of knowledge about capacity. About 67% of physicians, 10% of nurses and none of the ambulance staff answered questions about the topic of assessing capacity to consent to or refuse treatment correctly. The authors concluded that emergency healthcare workers lack the necessary knowledge about how to assess capacity, and what to do when the issue arises.

Marson, Earnst, Jamil, Bartolucci, and Harrell (2000) investigated the consistency of physician judgments of treatment consent capacity for patients with Alzheimer's disease when the five specific legal standards constituting competence were used. Again, physicians used the CCTI to establish their capacity judgment. In the evaluation of patients' ability to demonstrate a choice, physicians' judgment was correct in 84% of the cases. However, the agreement rate dropped to 67% when physicians examined patients' ability to appreciate the consequences of their decision. The mean agreement for all five legal standards was 76%. Marson et al. concluded that the use of legal standards in capacity judgments would enhance the quality of the judgment, and should be common practice for physicians experienced in assessing capacity.

Jackson and Warner (2002) surveyed 190 physicians and last year medical students about their knowledge regarding capacity issues, and discovered significant room for improvement. For example, about 58% of the psychiatrists, 34% of the geriatricians, 20% of the general practitioners and 15% of students demonstrated a significant knowledge gap about capacity.

A significant portion of physicians exhibited unfavorable attitudes to ethical issues. For example, 29% of respondents were hesitant to seek ethical consultation because it was considered too time consuming, 15% indicated that the consult may make things worse, and 11% believed that consultants were unqualified. Interestingly, 72% of respondents believed ethical consultation to be useful because it would help future decision-making, a seeming contradiction to other findings of the study (DuVal, Clarridge, Gensler, Danis, 2004). Please see Table III for a comprehensive view of issues registered by specialty.

Earnst, Marson, and Harrell (2000) investigated how physicians usually decide whether their patients have sufficient capacity to consent to treatment. The research measured whether cognitive abilities of patients suffering from Alzheimer's disease predict physicians' judgments of their patients' capacity to consent to undergo treatment. The study included five physicians who were asked to make capacity judgments on patients suffering from either mild or moderate dementia vs. a control group of older patients without having the disease. The study utilized measurements from the Capacity to Consent to

Treatment Instrument (CCTI), which tests competency based on the legal standards developed by Grisso and Applebaum (1998). The study blinded the participating physicians with respect to the patients' diagnosis and neuropsychological test performance. Classification logistic regression analysis showed a range of capacity judgments across individual physicians when evaluating the same patient; in other words, the inter-rater reliability was poor. The legal standards are different in terms of difficulty to place patients in the "having capacity" range, and the difficulty of legal standards proved to be highly related to capacity judgments. When evidencing a choice, the least difficult of the all standards, measures of semantic knowledge and receptive language predicted judgments. When making a reasonable treatment choice, measures of semantic knowledge, short-term verbal recall, and simple reasoning ability predicted judgments.

When appreciating the consequences of a treatment choice, and providing rational reasons for a treatment choice, as well as understanding the treatment situation and choices, capacity competency judgments were identical. Following the examination of patients with Alzheimer's disease, short-term memory proved to be a good predictor of incompetence or lack of capacity, as simple reasoning was a moderately high predictor, while semantic knowledge measure was associated with lower incompetence outcome rates (Earnst, Marson, & Harrell, 2000).

The study also found that the CCTI correctly classified about eight of every 10 patients. In conclusion, Ernst et al. showed that the evaluation of semantic knowledge, verbal recall, and simple reasoning abilities should be part of any capacity assessment protocol, and should be considered in competence decisions

Capacity assessments have moral consequences: incorrect capacity determinations can be damaging as preventing someone from exercising autonomy is disrespectful, demeaning, and stigmatizing, and it may result in the unwarranted deprivation of an individual's civil liberties, and could result in financial/legal damage to the assessor.

Conclusion

Informed consent and its core components serve as the foundation to the provision of healthcare in the United States. Informed consent is a legal concept aimed at protecting autonomy of patients making decisions about their healthcare. As a result of it being a legal concept, its definition and applications have been widely documented. It is well understood that informed consent, together with patient autonomy, voluntary participation, and beneficence/non-maleficence provide a platform for the ethical provision of healthcare. It is also well documented that informed consent can only be given if four constructs are present: disclosure of information, legal competence, expression of a choice, and understanding relevant information.

Yet, upon close examination of competence, there is evidence of confusion about this complex concept, especially because competence is a legal concept interpreted by the judicial system, while the healthcare system uses capacity, a non-legal standard, to explain whether it is appropriate to allow a patient to make decisions about his or her medical care.

Resolution of this confusion is paramount because healthcare professionals face the issue of informed consent every time they interact with a patient.

Table I

Properties Necessary for Informed Decision-making

Construct	Meaning of construct
Informed	Decision maker has all material information necessary for decision making
Made with understanding	Decision maker understands and appreciates information
Uncoerced	Decision maker's choice is voluntary, free from interference

Note. Adapted from "Competence to Consent," by B.C. White, 1994, p. 17,

Copyright by Georgetown University Press.

Table II

Foundations of Competence to Consent

Construct	Component of Construct
Informability	Capacity to receive information
	Capacity to recognize the relevant information as information
	Capacity to remember the information
Cognitive and effective capability	Relate situations to oneself
	Reason about alternatives
	Rank alternatives
Ability to choose	Select an option
	Resign oneself to a choice
Ability to recount one's decision-making process	Ability to explain how one came to a decision

Note. Adapted from "Competence to Consent," by B.C. White, 1994, p. 154,

Copyright by Georgetown University Press.

Table III

Physicians' Ethical Dilemmas

	Most Recent Ethical Dilemmas			Ethical Dilemmas Leading to Ethics Consultation		
	General IM	Hematology/Oncology	Critical Care/Pulmonology	General IM	Hematology/Oncology	Critical Care/Pulmonology
N	82	119	113	48	65	9
End of life, %*	51†	55	78	69	71	79
Patient autonomy, %	35†	36	61	54	51	63
Justice, %	23†	13	6	0	0	2
Conflicts between parties, %	35	34	38	38	43	38
Professional conduct, %	11	8	4	6	5	2
Truth telling, %	6‡	12	4	0	5	3
Religious or cultural issues, %	6	4	4	10	5	3
Other, %	10	12	6	8	7	7

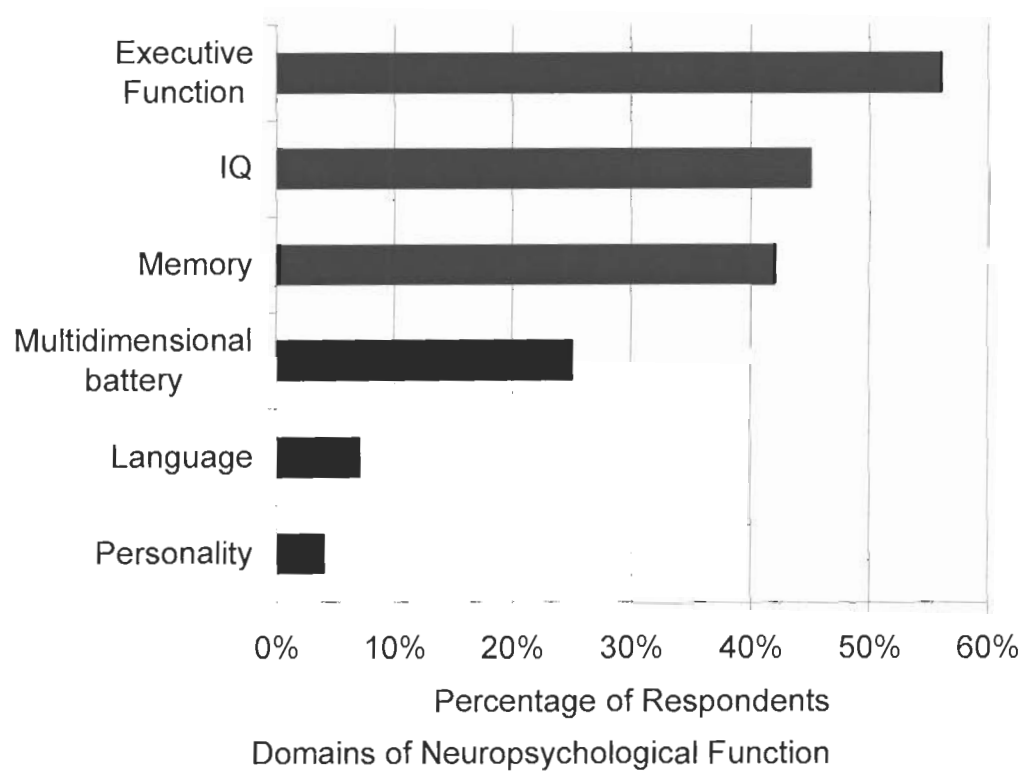
Note* The percentage of responses that were assigned to each code from the scheme outlined in the Appendix. Results add up to more than 100% because up to 3 codes were assigned to each response. Responses of "don't know," "no," and uninterpretable responses were omitted.

† Percentages differ among subspecialties; $P < .01$. ‡ Percentages differ among specialties; $P < .05$.

§ Other dilemmas involved abortion, genetic testing, substance abuse, research participation, and beneficence.

Adapted from "A National Survey of U.S. Internists' Experiences with Ethical Dilemmas and Ethics Consultation," by DuVal, G. et al., 2004, *Journal of General Internal Medicine*, 19(3), pp. 251-258.

Figure 1.

Variability in Test Selection

Note. Domains or factors considered to be most important in determining competency (respondents to survey, N = 62).
Adapted from "Evaluation of Competency: Ethical Considerations for Neuropsychologists," by Moberg and Kniele, 2006, *Applied Neuropsychology*, 13(2), 101-104.

Chapter III

METHODS

Design

The study design followed a sequential exploratory strategy employing a mixed design with a qualitative pilot and a quantitative cross-sectional survey to identify factors associated with nurses' recognition of a need to initiate patients' capacity assessment. A mixed study design is appropriate when empirical evidence regarding a topic is not available. A qualitative phase is recommended when the topic of research is not top-of-mind (Creswell, 1998). In a qualitative setting, subjects can express their thought process that can be used to answer scientific inquiry. The method allows an in-depth exploration of the views and opinions of study subjects, obtain information regarding participants' experiences and views about capacity assessment, and prompt the discussion of individual experiences with capacity assessment and its triggers. Further, qualitative research may allow the researcher to seek in-depth responses to the moderators guided discussion as well as responses to interviewees' discussions, while providing a specific context where people live and work to find better understanding.

The qualitative phase employed several methods designed to elicit group discussion (Yuhas, & Wilcox, 1986): a) identification, b) paralleling experiences, and c) controlled projection. Identification was referred to as subjects identifying themselves in a focus group setting based on their situation. Paralleling experiences were discussions about historical experiences among subjects regarding capacity assessment. Finally, controlled projection was used to aid to bring the discussion to a more personal level as subjects discussed their own experiences.

During the analytical phase of the qualitative pilot, the trustworthiness of the study was ensured. Credibility was ensured via prolonged engagement among the moderator and subjects. For example, multiple focus groups resulted in data saturation to reduce biases. In fact, consistent observations across multiple focus groups and triangulation of findings within the focus groups as well as to the literature increased the credibility of the qualitative pilot. Transferability was achieved by offering a detailed description of findings so that an audience familiar with the topic could judge whether study findings would be transferable. Transferability was also enhanced by choosing a convenience sample with the ability to discuss every aspect of the informed consent process at great length. Consistency or dependability was realized by conducting an inquiry audit, a systematic review of the documentation, process of inquiry and review of data and methods of analysis

used. Finally, confirmability was established by reviewing all documentation relevant to the qualitative pilot study.

The qualitative pilot served as the beginning of a sequential exploratory strategy, and sought information about what potential factors may exist in the realm of nursing that drive behavior when it comes to capacity assessments. As a result, the qualitative phase provided themes and served as an aid to decide on what to examine quantitatively.

During the quantitative cross-sectional phase, the theory developed during the pilot was tested statistically. The quantitative phase used confirmatory factor analysis, exploratory factor analysis and structural equation modeling to examine relationships between nurses' behavior and various factors developed during the qualitative pilot phase.

Variables and Instrumentation

Clinicians listed a wide range of issues that could influence them to recognize the need to assess their patients' capacity. It became evident that variables that potentially are related to decision making about whether a nurse realizes the need to assess his or her patients' capacity could be distributed into three broad factors: patient factor, situational factor, and clinician factor. These hypothetical factors were used to create a model for testing via confirmatory factor analysis and structural equation modeling during the dissertation study.

Group 1 Variables: Patient Factor

A patient factor was a group of variables describing patients during an interaction with nurses when nurses recognized the need to initiate their patients' capacity assessment. Variables loading into the patient factor served as independent variables.

The patient factor included variables that measured characteristics of the patient that may have made the patient at risk for impaired decision-making. All variables were measured on a semantic differential bipolar scale. Respondents were asked to indicate their level of agreement with whether they found it important to evaluate a patient's ability to make decisions when he or she exhibited certain characteristics. Respondents were asked to check mark one of seven ratings that best described their level of agreement with a statement. The anchors used to rate items were presented as follows: +3, +2, +1, 0, -1, -2, -3. In order to provide some level of clarity +3 was defined as agree, 0 as neither agree nor disagree, and -3 as disagree.

The following list of variables measured in the survey instrument mapped to the patient factor:

- 1) Patient is accompanied by someone such as nurse's aid or caregiver;
- 2) Patient is in considerable pain;
- 3) Patient is physically restrained;
- 4) Patient is over 75 years of age;
- 5) Patient is diagnosed with dementia, mental illness, etc.;

- 6) Patient is unable to speak English;
- 7) Patient has impaired or slurred speech;
- 8) Patient is unable to repeat what he/she is being told;
- 9) Patient is unable to write;
- 10) Patient frequently asks for repetition or clarification (i.e. "what did you say?"); and
- 11) Patient appears intoxicated.

Group 2 Variables: Situational Factor

A situational factor was a group of variables describing the situation during an interaction between nurses and their patients, when nurses recognized the need to initiate their patients' capacity assessment. In fact, the situational factor dealt with patients' place along the treatment continuum, as well as the clinical setting of nurses during the interaction. The situational factor was also an independent variable and was measured on the same semantic differential bipolar scale as the patient factor. Respondents were asked to indicate their level of agreement with whether they found it important to evaluate a patient's ability to make decisions when certain situations developed during the course of medical practice. Respondents were asked to check mark one of seven ratings that best described their level of agreement with statement. The anchors used to rate items were presented as follows: +3, +2, +1, 0, -1, -2,

-3. In order to provide some level of clarity +3 was defined as agree, 0 as neither agree nor disagree, and -3 as disagree.

The following list of variables measured in the survey instrument mapped to the situational factor:

- 1) Patient consents to treatment that is especially risky or invasive.
- 2) Patient arrives in a wheelchair or stretcher;
- 3) Patient behaves in an unsafe manner;
- 4) Patient disagrees with recommended treatment;
- 5) Patient has values or beliefs that are in conflict with nurse's values or beliefs;
- 6) Patient exhibits abrupt changes in his/her mental state; and
- 7) Patient asks a healthcare worker to make a decision for him/her.

Group 3 Variables: Clinician Factor

The clinician factor was a group of variables describing nurses during an interaction between nurses and their patients, when nurses recognized the need to initiate their patients' capacity assessment. Variables loading into the clinician factor focused on nurses' opinions of conditions that may warrant capacity assessments, nurses' attitudes towards capacity assessment, stakeholders with influence over nurses' beliefs and behaviors, as well as the strength of influence of other stakeholders on nurses' behavior.

The clinician factor was also measured on a semantic differential bipolar scale. Respondents were asked to indicate their level of agreement with

whether they would do what they think other important stakeholders would do when noticing that a patient may not have the ability to make decisions. As with the other two factors, respondents were asked to check mark one of seven ratings that best described their level of agreement with a statement. The anchors used to rate items were presented as follows: +3, +2, +1, 0, -1, -2, -3. In order to provide some level of clarity +3 was defined as agree, 0 as neither agree nor disagree, and -3 as disagree. The following list of variables measured in the survey instrument mapped to the situational factor:

- 1) Motivation to do what a patient thinks the nurse should do;
- 2) Motivation to do what co-workers think the nurse should do;
- 3) Motivation to do what a supervisor thinks the nurse should do;
- 4) Motivation to do what a physician thinks the nurse should do; and
- 5) Motivation to do what the organization/system guidelines dictate the nurse should do.

Setting

The study was implemented via a mail survey that was sent to Registered Nurse volunteers who were licensed to practice in New Jersey and retained a valid mailing address in the State.

Sample

Subjects were identified from a list obtained from the New Jersey Board of Nursing at the Division of Consumer Affairs of the New Jersey Office of the Attorney General. The list was assembled by the Management Information Systems Department, which manages all licensed nurse records and contained approximately 110,869 valid names and mailing addresses in a database. The database represented the entire universe of Registered Nurses licensed to practice in the State of New Jersey in September 2010. The database was scanned for valid New Jersey addresses of nurses licensed to practice in the state. Those residing outside of New Jersey were removed from the database, and did not have the opportunity to participate.

A convenience sample of 126 nurses participated in the study. Several scientific journals have been published on the topic of required sample size for CFA. The sample size required usually depends on model complexity, the fit statistics used, and distributional characteristics of collected data (Kline, 1998).

A wide body of literature indicates that a general rule in sample size when conducting CFA does not exist and is not practical (MacCallum, Wideman,

Zhang, & Hong, 1999). In fact, the minimum sample size acceptable for CFA depends on many aspects of the study design, such as the communality of variables which measures the variance in a given variable explained by all the factors jointly (Garson, 2005). Since CFA uses a pre-determined factor structure, communality of variables tends to be high (MacCallum, Wideman, Zhang, & Hong, 1999). The authors also suggested that communalities should be greater than 0.6. Another construct that impacts acceptable sample size is the degree of over determination, also known as the factor-to-variable ratio. A high degree of determination is achieved by six indicators per factor if a small number of factors exist and many communalities are under 0.50 (MacCallum, Wideman, Zhang, & Hong, 1999).

Reliability

Three nurses survey reviewed the instrument for general clarity and understanding of questions. The inclusion criteria for participation in this phase of survey design were the same as for the dissertation study. Additionally, a panel of three survey experts reviewed the survey to assess content validity and survey construction. Experts have had at least ten years of experience in the field of social psychology and have been involved in survey design and execution for at least ten years.

Procedure

The Institutional Review Board of Seton Hall University reviewed and approved the research protocols.

First, the entire database of 110,869 Registered Nurses was scanned for a valid New Jersey address. As a result, 93,984 records (84.8%) of New Jersey residents were retained, and 16,884 records (15.2%) were excluded due to having an out-of-state residence.

A total of 1,000 valid names with corresponding addresses were randomly selected and mailed research materials. Randomization was conducted with Microsoft Excel's random number generator function. Each Registered Nurse was assigned a random number between 0 and 1. Each random number was represented by 15 decimals. Following the random assignment of numbers, the database was sorted from lowest to highest based on the random numbers, and the first 1,000 records were selected for inclusion in the mailing. The following materials were mailed to every potential respondent: a) solicitation letter, b) Capacity Assessment Survey, c) Demographic Questionnaire, and d) a postage paid return envelope.

Potential respondents were asked to fill out the survey, and mail it back in the enclosed postage paid envelope. The data collection period was four weeks in duration. A reminder postcard was sent to all 1,000 research volunteers during the third week of the data collection period informing potential subjects of the deadline for returning filled out surveys.

Data was entered into the Statistical Package for the Social Sciences (SPSS) Version 17.0 (SPSS, 2009), and saved on the primary investigator's hard drive. Personal information such as name, address, phone, social security numbers, hospital names or any other identifiers were not collected during the study to ensure the confidentiality of respondents.

Data Analysis

SPSS Version 17.0 (SPSS, 2009), and AMOS Version 17.0 (SPSS, 2009) were utilized for data analysis. Two main groups of statistical procedures were employed for analysis of the data: descriptive and inferential statistics.

Descriptive Statistics

Descriptive statistics were used to report on the general make-up and demographic profile of the sample. Further, the average score for each variable measured and their corresponding standard deviations were calculated. Finally, frequency counts and percentages of research volunteers answering a question on a -3 to +3 scale were calculated via descriptive statistics.

Inferential Statistics

The types of inferential statistics were used, Confirmatory Factor Analysis (CFA), which is a special case of Structural Equation Modeling (SEM), SEM

and Exploratory Factor Analysis (EFA). Technically, SEM and subsequently CFA is an extension of general linear modeling, which includes ANOVA and multiple regression analysis (Lei and Wu, 2007).

Factor analysis is a statistical technique to find unobserved or latent variables (factors), which can account for the covariance in a large set of observed variables (Albright, 2008). Factor analysis can be conducted as an investigation or exploration of data patterns known as exploratory factor analysis (EFA), or as a test of explicit hypotheses known as confirmatory factor analysis (CFA) (Munro, 2001). While EFA requires four statistical assumptions, CFA is free of such requirement. For example, EFA requires that either all or none of the variables are correlated with one another, and that all items are directly affected by all other factors. Also, in EFA none of the measurement error is associated with the items correlated with each other, and all items are presumed to be equally affected by the measurement error.

Another major difference between the two approaches is that EFA can only test three hypotheses about the structure of the model. EFA can answer which items to include in analysis, which rotational structure fits a model best, and allows decision making on the number of factors. In contrast, CFA can measure whether assumed relationships between observed and latent variables exist or if there is a relationship between two or more latent variables. Therefore, the purpose of CFA is to examine if there is evidence

that the specified model fits the collected data well or if the model needs to be modified (Albright, 2008). . In contrast, CFA allows the investigator to test any particular factor structure.

CFA follows the following process, according to Bollen (1989): 1) Model specification, 2) Identification, 3) Estimating the parameters of the measurement model, 4) Evaluation of the data-model fit, and 5) Model modification, if necessary.

Model specification requires the investigator to specify the structural components of the model (Mueller, 1996). Confirmatory models use path diagrams in which squares represent observed variables and circles represent latent variables, connected by an arrow indicating the direction of assumed causal influence. Identification is the evaluation if the known information about statistical relationships between structural components exceed the unknown information about relationships (Bollen, 1989) Estimating the parameters of the measurement model means that the investigator tests the model by using observed data to make estimates of factor loadings, residuals, etc. (Munro, 2005). Several fitting functions exist in AMOS to measure how close the implied covariance matrix and the sample covariance matrix overlaps but for categorical variables the Weighted Least Squares approach is most often used and is recommended (Albright, 2008). The next step, evaluation of the data-model fit requires the examination of the estimated parameter estimates for which a wide variety of fit statistics are

available (Bollen & Long, 1993). Goodness of Fit statistics also can employ multiple approaches. According to Barrett (2007), a good model fit usually provides an insignificant result at a 0.05 confidence level, therefore Chi-square statistic is often a test of “lack of” a significant result. Most scientific papers reporting on CFA results still use Chi-squared but its interpretation could be problematic because of its sensitivity to sample size (Joreskog, 1969). The test requires multivariate normality, and non-normally distributed data often results in model rejections (McIntosh, 2006). Also, Chi-square statistics is extremely sensitive to sample size, and large sample sizes almost always result in rejection of a specified model (Bentler and Bonnet, 1980). At the same time, when using small sample sizes, the test lacks power and is often incapable of discriminating between good and bad model fits (Kenny and McCoach, 2003)

The most often used alternative is the Root Mean Square Error of Approximation (RMSEA) (Steiger and Lind, 1980; Arbuckle, 2005). The RMSEA provides information about how well the model would fit the population covariance mix (Diamantopoulos & Siguaaw, 2000).

Rules have been developed regarding, which statistics to use in various situations, and cut-off values have been developed for declaring significance (Hu & Bentler, 1999). Recently, the RMSEA value of 0.06 is considered the cut-off value when the investigator may consider the model to fit the population co-variance structure (Steiger, 2000).

A plethora of other fit statistics have been developed as well: Goodness-of-fit statistic (GFI) and the adjusted goodness-of-fit statistic (AGFI), Root mean square residual (RMR) and standardized root mean square residual (SRMR) are being the most widely reported. Since different fit statistics test different parts of the model, there is a temptation to report only those that fit the best, but authorities on the subject warn against it (Hayduk, et al., 2007). Instead, it is customary to report, Chi-square statistics, and at least one additional fit statistic measure. Kline (2005) and Boomsma (2000) strongly recommend reporting the Chi-Square test, the RMSEA, the (Comparative Fit index (CFI) and the SRMR.

If fit statistics show that the model needs to be modified, investigators may change the model structure by assessing how the model fits each of the constructs to see if some items are particularly weak. Items with low r^2 should be removed from the model and the new model should once again be tested.

All statistics used in this study assumed a 0.05 power to reduce erroneous acceptance of significant results that achieved significance due to chance. The statistical methodology is appropriate for analysis of the data collected to answer the research questions and test subsequent hypotheses.

Chapter IV

RESULTS

Characteristics of the Sample

A total of 126 Registered Nurses consented to participate in the study by returning the survey. Approximately 86% (n=109) of returned surveys were valid for analysis, while 14% (n=17) were disqualified due to incomplete answers or predetermined screening criteria. For example, 47% (n=8) were disqualified as a result of working in a school or pediatric nursing setting, where capacity is not an issue due to the age of the patient population. Approximately 29% (n=5) did not complete the survey, 18% (n=3) reported being retired, and one respondent worked as an administrator not in direct patient care.

While the recruitment database only included registered nurses, 12% of the sample (n=15) indicated being an Advanced Practice Nurse, 79% (n=100) being a Registered Nurse, and 9% (n=11) provided no answer (Table IV). Approximately 20% (n=21) reported having a sub-specialty with the following distribution: 6% had a sub-specialty in Adult Health (n=7), 2% in Family Health (n=3); 2% in Pediatric or School Nursing (n=2), 1% in OB/GYN (n=1), 1% in Adult Psychiatric and Mental Health (n=1), 3% in Critical Care (n=4)

and 2% in Rehab Medicine (n=3). The remaining 74% (n=93) did not have a sub-specialty, and 10% (n=12) did not provide an answer (Table V).

Approximately 10% (n=9) of respondents held a Drug Enforcement Administration (DEA) or Controlled Dangerous Substances (CDS) certification to prescribe controlled dangerous substances, 83% (n=105) did not hold such certification, while 10% (n=12) refrained from answering (Table VI). About 29% (n=36) of respondents were licensed to practice in a state in addition to New Jersey, while 62% (n=78) only held New Jersey licenses, and 10% (n=12) did not indicate a choice.

The majority of respondents, 62% (n=78) practiced in a hospital setting, while 2% (n=2) practiced solely in an office of a physician, 6% (n=8) provided home healthcare services, 9% (n=11) were employed by nursing care facilities, and 8% (n=10) in other settings. School/pediatric setting accounted for 6% of the total (n=8), while the rest were either retired, not in direct patient care or simply did not offer an answer (n=9; 7%) (Table VII).

The distribution of education level was skewed toward Bachelor's degrees with 56% (n=71) of respondents reporting as having a degree from a four year college. In contrast, 21% of respondents (n=26) had Master's degrees, 2% (n=3) PhDs, and 6% (n=7) obtained Associate's degrees. A large portion (n=19; 15%) chose not to indicate their level of education (Table VIII).

About 7% of respondents (n=9) reported to be 25-36 years of age, and 20% (n=25) were between the ages of 36-45. Approximately 35% (n=44)

reported being 46-55 years of age, 24% (n=30) being 56-65, and 4% (n=5) reported being older than 65. The remaining 10% (n=13) did not indicate their age (Table IX). The average length in clinical practice since completing studies in nursing was reported to be 22.4 years (SD=12.0 years) (Table X). The distribution of practice length was relatively evenly distributed in ten-year intervals between 1 and 40 years (Table XI).

Respondents reported their average weekly patient volume of 48.8 under their care (SD=97.3). The reported range was wide between 1 and 750.

Table IV

Distribution of Respondents: Type of Nursing License (N=126)

	Frequency	Percent
Registered Nurse	100	79.4
Advanced Practice Nurse	15	11.9
Did not answer	11	8.7
Total	126	100.0

Table V

Distribution of Respondents: Certificate Earned (N=126)

	Frequency	Percent
Adult Health	7	5.6
Family	3	2.4
Pediatric	1	.8
School	1	.8
OB/GYN	1	.8
Adult Psychiatric & Mental Health	1	.8
Critical care	4	3.2
Rehabilitation	3	2.4
None	93	73.8
Did not answer	12	9.5
Total	126	100.0

Table VI

Distribution of Respondents: Holding DEA/CDS Certification (N=126)

	Frequency	Percent
Holds DEA or CDS Certificate	11	8.7
Does not hold DEA or CDS Certificate	92	73.0
Did not answer	11	8.7
Total	126	100.0

Table VII

Distribution of Respondents: Practice Setting (N=126)

	Frequency	Percent
Hospital	78	61.9
Office of physician	2	1.6
Home-healthcare-services	8	6.3
Nursing care facility	11	8.7
Other	10	7.9
Did not answer	5	4.0
Retired	3	2.4
Not in patient care/Administration	1	0.8
Total	126	100.0

Table VIII

Distribution of Respondents: Level of Education (N=126)

	Frequency	Percent
Associate's	7	5.6
Bachelor's	71	56.3
Master's	26	20.6
PhD	3	2.4
Did not answer	19	15.1
Total	126	100.0

Table IX

Distribution of Respondents: Age (N=126)

	Frequency	Percent
25-35	9	7.1
36-45	25	19.8
46-55	44	34.9
56-65	30	23.8
65+	5	4.0
Did not answer	13	10.3
Total	126	100.0

Table X

Practice Length of Respondents (N=126)

	Years
Average practice length	22.4
Std. Deviation	12.0
Minimum	1
Maximum	50

Table XI

Distribution of Respondents: Practice Length (N=126)

	Frequency	Percent
1-10	21	16.7
11-20	33	26.2
21-30	32	25.4
31-40	23	18.3
41-50	4	3.2
Did not answer	13	10.3
Total	126	100.0

Univariate Results

Items in the Capacity Assessment Survey were measured on a semantic differential bipolar scale ranging from +3 to -3. A positive score signified agreement with the importance of evaluating a patient's ability to make decisions when the respondent noticed the presence of certain characteristics of a situation. A negative score meant disagreement with the same, while 0 signified neither disagreement nor agreement.

Clinician factor

In the case of variables pertaining to the clinician, a positive score meant agreement with the respondent doing what he/she thought an important stakeholder would do when noticing that a patient may not have the ability to make decisions. The average scores for variables pertaining to the clinician factor ranged from -.45 for the *Patient* variable, *I usually do what my patients think I should do* to 1.97 for the *Guidelines* variable, *I usually do what my Organization/system guidelines dictate* (Table XII). Approximately 41% of research volunteers (n=46) indicated at least some level of disagreement with the statement that they usually do what their patients think they should do when noticing patients' lack of decision making ability. In contrast, 33% (n=37) showed at least some influence of patients on their actions, and 25% (n=28) neither agreed nor disagreed with their patients being an influence.

The distribution of answers was similar for the *Co-worker* variable (32% negative (n=36); 39% positive (n=44); 25% neutral (n=31)). However, respondents indicated significant positive influence from their supervisor (22% negative (n=25); 51% positive (n=57); 26% neutral (n=29), from physicians (18% negative (n=20); 62% positive (n=69); 20% neutral (n=22)) and from organizational/system guidelines (7% negative (n=8); 86% positive(n=95), 7% neutral (n=8)) (Table XIII).

Situational Factor

The lowest average score for the *Situation* factor was -1.1 for different values exhibited by a patient as respondents disagreed that it was important to evaluate a patient's ability to make decisions when he or she exhibited such condition. In contrast, a patient exhibiting abrupt changes in his/her behavior appeared to be an important stated trigger for evaluating a patient's ability to make decisions with the highest mean score of 2.46. (Table XII)

Most respondents stated that they were influenced by the situation to some degree when it came to the evaluation of their patients' ability to make decisions. For example, 85% (n=93) of all research volunteers marked one or higher on the importance scale when their patients appeared unable to express their choice, 93% (n=102) when their patients appeared unable to understand and reason with information given, and 81% (n=89) when their

patients could not appreciate the significance of their diagnosis or prognosis (Table XIV).

Patient Factor

Scores for the *Patient* factor ranged from a low of .19 for a variable indicating a patients' inability to write to a high of 2.4 for a variable signifying the presence of dementia or mental illness. All variables pertaining to the patient factor had a positive mean, and ranged between .10 (patient unable to write) to 2.40 (patient is diagnosed with dementia or mental illness) (Table XII).

Approximately 78% of research volunteers (n=86) agreed to at least some degree that it was important to evaluate their patients' ability to make decision when the patient was in pain, 80% (n=88) when the patient was restrained, 91% (n=100) when the patient was diagnosed with dementia or mental illness, 67% (n=74) when the patient has slurred speech, 86% (n=94) when the patient was unable to repeat what he/she was being told, 76% (n=83) when the patient needed frequent clarification, and 87% (n=96) when a patient was intoxicated.

More polarized answers were given about the importance of evaluating patients' ability to make decision when the patient was accompanied by someone (23% negative (n=25); 56% positive (n=62); neutral 21% (n=23)); older than 75 of age (34% negative (n=37); 41% positive (n=45); 26% neutral

(n=28)), unable to speak English (26% negative (n=28); 59% positive (n=65); neutral 16% (n=17)), and unable to write (36% negative (n=39); 42% positive (n=46); 23% neutral (n=25)) (Table XV).

Table XII

Mean Scores Indicated by Variable (+3 to -3 Scale)

	Clinician Factor Mean Score	Situation Factor Mean Score	Patient Factor Mean Score
Patient	-.45	Express choice	Accompanied
Co-worker	-.22	Understand	Pain
Supervisor	.31	Appreciate	Restrained
Physician	.77	Risky	75+
Guidelines	1.97	Wheelchair	Dementia
		Unsafe	No English
		Disagreement	Slurred
		Different values	Can't repeat
		Abrupt chg.	Can't write
		Asks for decision	Needs clarification
			Intoxicated

Table XIII

Distribution of Respondents' Answers: Variables in Clinician Factor

Level of agreement with each variable					
	Patient	Co-worker	Supervisor	Physician	Guidelines
Percent of research volunteers					
-3	31.5	22.5	17.1	15.3	6.3
-2	8.1	5.4	4.5	1.8	.0
-1	1.8	4.5	.9	.9	.9
0	25.2	27.9	26.1	19.8	7.2
1	9.9	22.5	19.8	14.4	9.9
2	12.6	12.6	22.5	29.7	19.8
3	10.8	4.5	9.0	18.0	55.9

Table XIV

Distribution of Respondents' Answers: Variables in Situation Factor

	Express choice	Understand	Appreciate	Risky	Wheelchair
Level of agreement	Percent of research volunteers				
-3	3.6	.9	4.5	1.8	28.2
-2	1.8	.9	1.8	3.6	6.4
-1	4.5	.9	1.8	3.6	6.4
0	5.5	4.5	10.9	10.0	30.9
1	11.8	6.4	10.0	11.8	6.4
2	15.5	15.5	18.2	9.1	8.2
3	57.3	70.9	52.7	60.0	13.6
	Unsafe	Disagree	Different values	Abrupt chg.	Asks for decision
Level of agreement	Percent of research volunteers				
-3	1.8	15.5	40.9	.9	8.2
-2	1.8	8.2	10.9	1.8	2.7
-1	2.7	10.9	4.5	.0	2.7
0	5.5	25.5	28.2	5.5	20.0
1	13.6	11.8	2.7	5.5	10.0
2	12.7	10.9	2.7	11.8	16.4
3	61.8	17.3	10.0	74.5	40.0

Table XV

Distribution of Respondents' Answers: Variables in Patient Factor

	Accompany	Dementia	Restrain.	Needs clarification	Pain	75+
Level of agreement	Percent of research volunteers					
-3	10.0	4.5	5.5	6.4	7.3	17.3
-2	5.5	.0	1.8	2.7	0	6.4
-1	7.3	.0	1.8	2.7	3.6	10.0
0	20.9	4.5	10.9	12.7	10.9	25.5
1	15.5	4.5	10.0	20.9	23.6	10.0
2	9.1	10.0	22.7	11.8	19.1	8.2
3	31.8	76.4	47.3	42.7	35.5	22.7

	Slurred	Can't repeat	Can't write	Intoxicated	No English
Level of agreement	Percent of research volunteers				
-3	6.4	2.7	20.0	6.4	17.3
-2	4.5	.9	7.3	.0	5.5
-1	5.5	1.8	8.2	.9	2.7
0	16.4	9.1	22.7	5.5	15.5
1	15.5	16.4	6.4	4.5	9.1
2	12.7	20.9	10.9	10.9	10.0
3	39.1	48.2	24.5	71.8	40.0

Results of the Test of Hypotheses

Two distinct analytical steps were taken to test the three hypotheses. First, CFA was completed to establish the existence of hypothesized factor structure. Following the completion of CFA, structural equation modeling examined the relationship between factors and target variable of the hypotheses.

First, the hypothesized factor structure was submitted to CFA with the hope that the specified model would confirm the existence of three factors: a) nurse, b) situation, and c) patient. The path diagram displayed the standardized regression weights, which could be considered factor loadings for the three common factors and each of the indicators pertaining to their corresponding factors. The squared multiple correlation coefficient (R^2) was also displayed indicating the amount of variance the common factor explained in the observed variable.

Hypothesis 1: *Patient factor is significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.*

When focusing on the patient factor, standardized regression weights or factor loadings were between .35-.80 and the R^2 coefficients (Squared multiple correlations) were between .21-.64 (Figure 2). All regression weights were statistically significant with a p-value of less than 0.05 (Table XVI). However, the model revealed a strong covariance (0.73; $p=0.01$) between the

Situation and Patient factors suggesting that the *Patient f* factor may not exist independently as hypothesized (Table XVIII).

Following the model estimation, several tests were completed to establish how well the model fit the observed data. In CFA, it is customary to report several fit statistics (Hu & Bentler, 1999) Chi-square is a widely used statistic although it is considered very sensitive to sample size, and at smaller sample sizes it commonly allows for an erroneous acceptance of good model fit. The null hypothesis suggests that the hypothetical covariance matrix is the same as the observed covariance matrix, therefore a statistically significant Chi-square statistic would indicate a poor model fit (Jöreskog, 1969). The model resulted in a Chi-square of 597.3 (degrees of freedom = 296) with a highly significant p-value ($p < 0.01$), suggesting a poor model fit (Table XIX).

Alternative fit statistics also pointed to a poor model fit. The Root Mean Square Error of Approximation (RMSEA) is one of the most frequently used alternative fit statistic that is related to residual in the model and can range from 0 to 1. Smaller values are considered better fit, and 0.05 is considered the threshold of good model fit (Hu & Bentler, 1999; Arbuckle, 2005). The RMSEA yielded .097 far exceeding the suggested value of 0.05 or less. Several other fit statistics also suggested a poor model fit including the Comparative Fit Index (CFI), and Normed Fit Index (NFI). (CFI=.755; NFI=.611). The fit of CFA is considered acceptable if the indices are 0.90 or

greater (Hu & Bentler, 1999) (Table XIX). As a result, a *Patient factor* as hypothesized and described may not exist.

Hypothesis 2: *Situational factor is significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.*

When focusing on the *Situation* factor, factor loadings ranged from .34 to .66, and R^2 coefficients ranged from .12 to .43 (Figure 2). Similar to the patient factor loadings, all standardized regression weights pertaining to the situational factor were statistically significant with p-values of less than 0.05. As discussed earlier, the model also revealed a strong covariance (0.73; $p < 0.01$) between the situation and patient factors hinting at a questionable independent existence of a situational factor. Fit statistics established that the model was a poor fit indicating that a *Situational* factor did not exist (Table XIX). In fact, all fit statistics showed poor model fit as RMSA exceeded the required .05 threshold, CFI, NFI failed to reach the required 0.9 limit, and the Chi-square coefficient was statistically significant.

Hypothesis 3: *Clinician factor is significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment.*

Considering the *Clinician* factor, standardized regression weights or factor loadings were between .45 and .86, and R^2 i.e. the variance the common factor accounts for in each observed variable ranged between .21 to .74 (Figure 2). As with all factors, regression weights for all variables loading into the *Clinician* factor were statistically significant with a p-value below 0.05

(Table XVI). The *Clinician* factor did not appear to co-vary with the situation factor (.09; $p = .298$) or with the *Patient* factor (.11; $p = .234$) (Table XVIII).

While initial fit statistics indicated a poor model fit, examination of the data suggested a need for further testing and model modification. First, the strong correlation between the *Patient and Situation* factors suggested merging them into a single factor. The new factor structure once again resulted in poor model fit based on all conventionally used fit indices. The merged factor was then eliminated leaving only the *Clinician* factor intact, which resulted in a moderately good fit based on a non-significant p -value pertaining to Chi-squared ($p = 0.014$), Above 0.90 values for several fit indices (CFI=.952; NFI=.930). However, the RMSEA was still above the acceptable threshold at .134. Adding a factor that represented clinical relationships to the already existing *Clinician* factor resulted in a completely stable factor model with excellent fit statistics and highly significant p -values. The new factor was termed perception of expectations from others.

Factor loadings of variables onto the perception of expectations from others factor ranged between .23 and .67, while factor loadings of the original *Clinician* factor were .33-.95 (Figure 3). Interestingly, three variables (patient, physician, and co-workers) loaded into both factors.

In order to establish the relationship between the new factor structure and the target variable, SEM was used resulting in a multifactor solution. In this new model, the *Perception of Expectations from Others* factor had

standardized regression weights (factor loadings) of 0.64 for the *Patient* variable, .25 for the *Physician* variable, and .43 for the *Co-worker* variable. The *Clinician* factor had factor loadings of .34 for the *Patient* variable, .78 for the *Physician* variable, .67 for the *Co-worker* variable, .46 for the *Guidelines* variable, and .96 for the *Supervisor* variable. The *Clinician* factor also had a -.20 factor loading for practice length, indicating a negative correlation between the factor and practice experience. The two factors together explained a significant portion of the variance for the patient ($R^2=.53$), physician ($R^2=.68$), and co-worker ($R^2=.64$) variables. The *Clinician* factor alone also explained .22 of the variance for the *Guidelines* variable and .91 of the variance for the *Supervisor* variable, all very strong correlation coefficients. However, the *Clinician* factor only minimally explained the variance in the *Practice Length* variable. Finally, there was a moderate albeit statistically significant relationship between the *Perception of Expectations from Others* factor and the outcome variable (the patient volume recognized as not having enough capacity to make decisions).

In the model, the *Perception of Expectations from Others* factor was a significant predictor of the outcome variable ($p=.023$), although it explained only 12% of its variance. The original *Clinician* factor did not have any relationship with the outcome variable. A brief literature review revealed that R^2 at .12 signifies a relatively weak relationship. Godin and his colleagues (2008) reviewed 78 studies examining healthcare professionals' intentions

and behavior based on cognitive theories, and found 72 addressing factors determining intention, and 16 studies provided information about factors influencing behavior. The average frequency-weighted mean R^2 was 0.31 for behavior, while 0.59 of the variance was explained for intention. The current study measured actual behavior not intention, but R^2 was significantly lower at 12%.

Godin and his colleagues (2008) found that studies utilizing larger sample sizes achieved better prediction of behavior. They also found that self-reported surveys resulted in $R^2=0.44$, while observational studies achieved only an R^2 of 0.13, indicating that self-reported data will provide significantly better predictive values when evaluating predictors of behavior. The correlation between intention and behavior was high for all studies using a self-reported data collection methodology. Interestingly, the efficacy of prediction of intention was not influenced by sample size to the same degree as prediction of behavior. However, the R^2 associated with the prediction of intention ranged between 0.50 and 0.61, depending on sample size, while the R^2 of prediction of behavior ranged between 0.22 and 0.38.

Fit statistics revealed that the model was a good fit. Chi-square statistic of 2.709 (df=11) was not statistically significant ($P=.994$) to reject the null hypothesis, and RMSEA was well below the recommended cutoff of .05 at .000. Other fit statistics also suggested a good fit with the NFI index at .988

and the CFI index at 1.000, exceeding the recommended cutoff of .9 (Table XXII).

In conclusion, the *Clinician* factor was not significantly correlated with nurses' recognition of a need to initiate patients' capacity assessment but another factor, *Perception of Expectations from Others* emerged as a significant predictor of behavior.

Figure 2.

Results of Confirmatory Factor Analysis: Model Structure

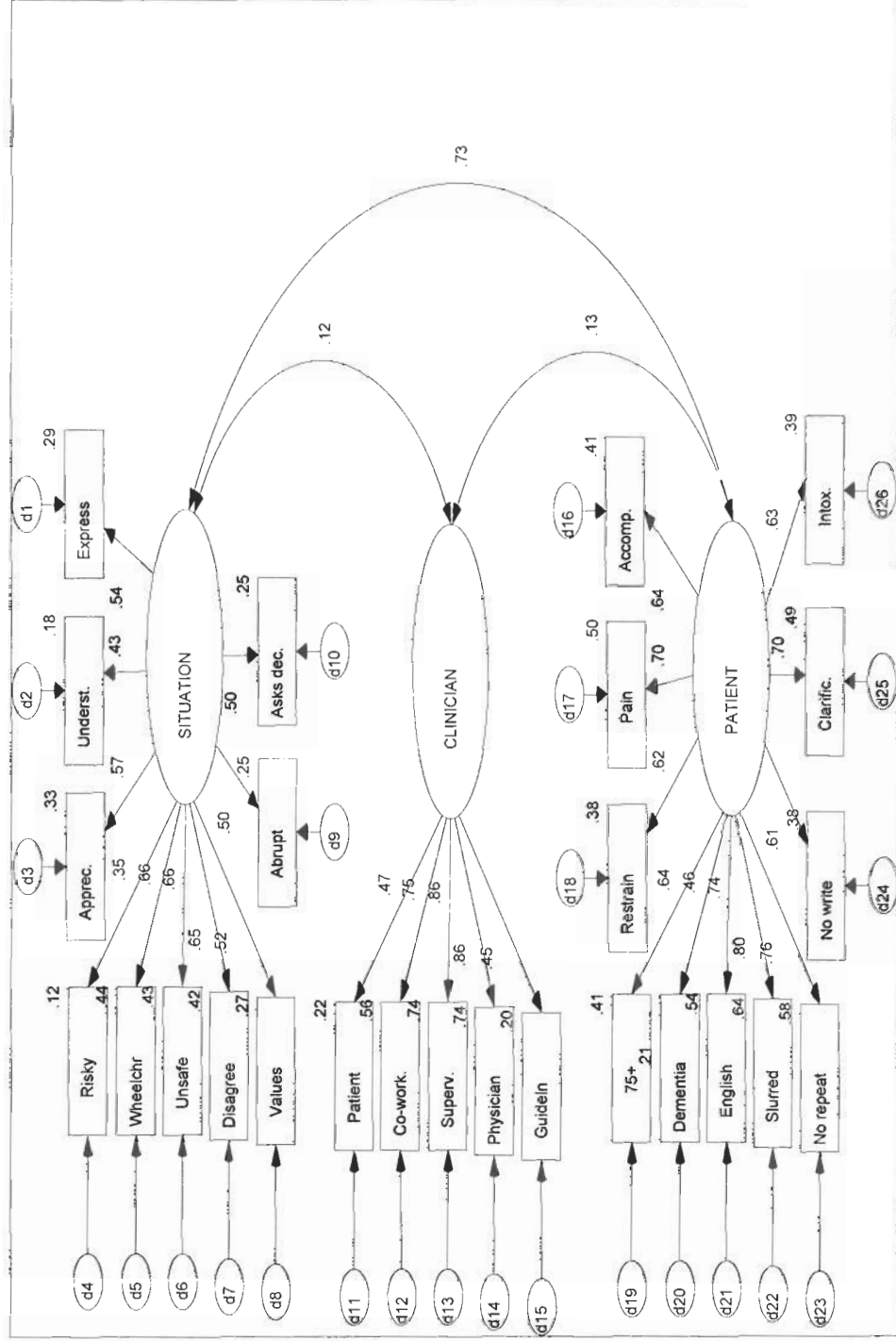


Table XVI

Estimates of Regression Weights and Corresponding P-values

Variable	Factor Name	Estimate of Regression Weight	Standard Error of Regression Weight	Critical ratio for regression weight	p
Organization	<--- CLINICIAN	1			
Physician	<--- CLINICIAN	2.27	0.486	4.674	<.01
Supervisor	<--- CLINICIAN	2.194	0.469	4.673	<.01
Co-workers	<--- CLINICIAN	1.866	0.416	4.487	<.01
Patients	<--- CLINICIAN	1.358	0.382	3.557	<.01
No repeat	<--- PATIENT	1			
Slurred	<--- PATIENT	1.38	0.161	8.554	<.01
No English	<--- PATIENT	1.566	0.201	7.811	<.01
Dementia	<--- PATIENT	0.592	0.127	4.666	<.01
75+	<--- PATIENT	1.25	0.187	6.702	<.01
Values	<--- SITUATION	1			
Disagrees	<--- SITUATION	1.238	0.265	4.681	<.01
Unsafe	<--- SITUATION	0.876	0.186	4.718	<.01
Wheelchair	<--- SITUATION	1.324	0.28	4.732	<.01
Risky	<--- SITUATION	0.519	0.173	2.998	3
Express	<--- SITUATION	0.818	0.196	4.169	<.01
Understand	<--- SITUATION	0.449	0.126	3.546	<.01
Appreciate	<--- SITUATION	0.893	0.206	4.342	<.01
Abrupt chg.	<--- SITUATION	0.538	0.136	3.957	<.01
Asks decis.	<--- SITUATION	0.901	0.227	3.967	<.01
Restrained	<--- PATIENT	0.951	0.149	6.396	<.01
Pain	<--- PATIENT	1.11	0.149	7.428	<.01
Accompanied	<--- PATIENT	1.19	0.177	6.721	<.01
No write	<--- PATIENT	1.263	0.198	6.389	<.01
Clarification	<--- PATIENT	1.153	0.157	7.362	<.01
Intoxicated	<--- PATIENT	0.936	0.144	6.512	<.01

Table XVII

Standardized Regression Weights: Factor Loadings

Variable		Factor Name	Standardized Regression Weights/Factor Loadings	Squared Multiple Correlations/Variance
Organization	<---	CLINICIAN	0.452	.205
Physician	<---	CLINICIAN	0.861	.741
Supervisor	<---	CLINICIAN	0.86	.739
Co-workers	<---	CLINICIAN	0.751	.565
Patients	<---	CLINICIAN	0.467	.218
No repeat	<---	PATIENT	0.76	.577
Slurred	<---	PATIENT	0.798	.637
No English	<---	PATIENT	0.737	.543
Dementia	<---	PATIENT	0.458	.210
75+	<---	PATIENT	0.642	.412
Values	<---	SITUATION	0.522	.273
Disagrees	<---	SITUATION	0.65	.422
Unsafe	<---	SITUATION	0.659	.434
Wheelchair	<---	SITUATION	0.662	.439
Risky	<---	SITUATION	0.345	.119
Express	<---	SITUATION	0.537	.288
Understand	<---	SITUATION	0.427	.182
Appreciate	<---	SITUATION	0.572	.327
Abrupt chg.	<---	SITUATION	0.497	.247
Asks decis.	<---	SITUATION	0.499	.249
Restrained	<---	PATIENT	0.615	.379
Pain	<---	PATIENT	0.705	.496
Accompanied	<---	PATIENT	0.644	.415
No write	<---	PATIENT	0.615	.378
Clarification	<---	PATIENT	0.699	.488
Intoxicated	<---	PATIENT	0.626	.391

Table XVIII

Covariances and Correlations of Factors

Factors	Covariances			Correlations
	Estimate of Covariance	Standard Error of Covariance	p	Estimate of Correlation
SITUATION <--> CLINICIAN	.094	.090	.298	.123
NURSE <--> PATIENT	.105	.088	.234	.133
SITUATION <--> PATIENT	.824	.212	<.01	.734

Table XIX

Model Fit Summary

Statistics	Estimate
Chi-square	597.343
Degrees of freedom	296
P-value for Chi-square	0.000
RMSEA	.097
NFI	.611
CFI	.751

Figure 3.

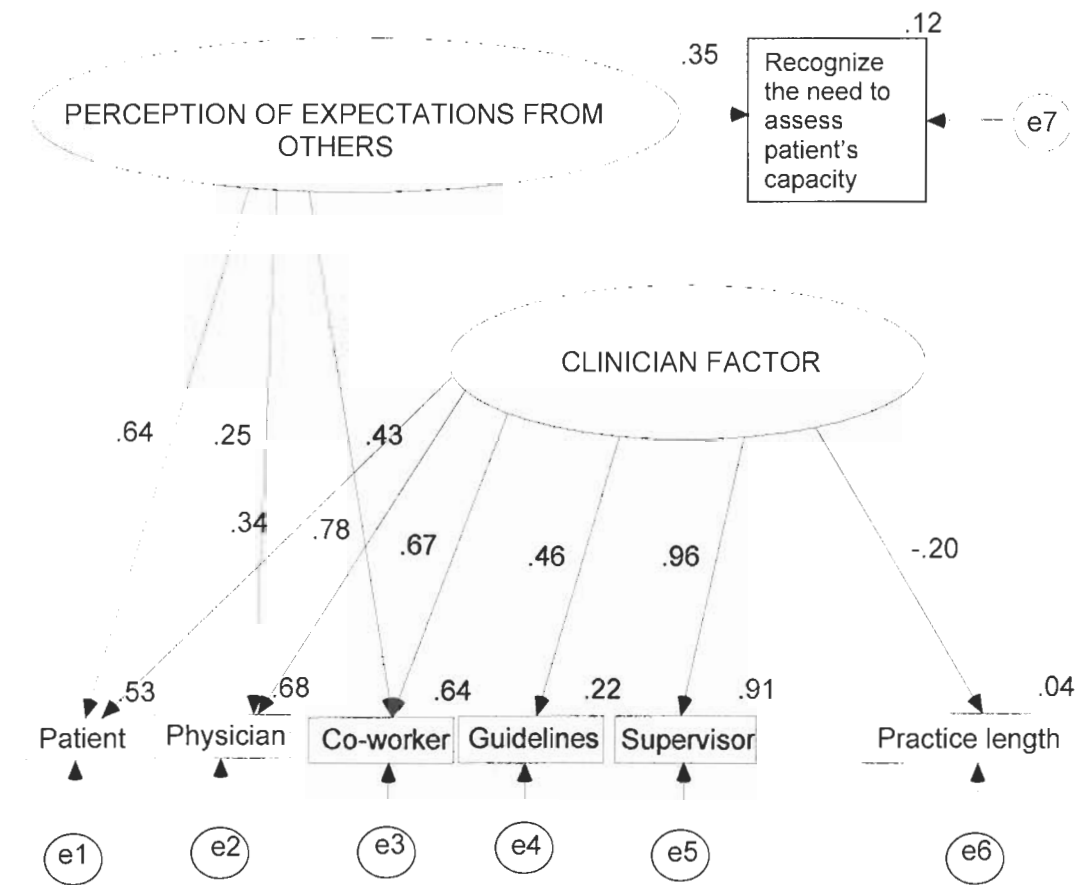
Final Factor Structure and Structural Equation Model

Table XX

Estimates of Regression Weights and Corresponding P-values

Variable		Factor Name	Estimate of Regress.Weight	Standard Error of Regress.Weight.	Critical ratio for Regress. Weight	p
% noticed	<---	PERCEPTION OF EXPECTATIONS - OTHERS	6.965	3.063	2.274	0.023
Physician	<---	PERCEPTION OF EXPECTATIONS - OTHERS	0.356	0.173	2.061	0.039
Practice length	<---	CLINICIAN FACTOR	-3.094	1.63	-1.898	0.058
Physician	<---	CLINICIAN FACTOR	2.016	0.417	4.832	<.01
Patients	<---	PERCEPTION OF EXPECTATIONS - OTHERS	1			
Patients	<---	CLINICIAN FACTOR	0.961	0.321	2.999	0.003
Co-workers	<---	PERCEPTION OF EXPECTATIONS - OTHERS	0.574	0.218	2.629	0.009
Co-workers	<---	CLINICIAN FACTOR	1.637	0.36	4.543	<.01
Organization	<---	CLINICIAN FACTOR	1			
Supervisor	<---	CLINICIAN FACTOR	2.379	0.507	4.694	<.01

Table XXI

Standardized Regression Weights: Factor Loadings

Variable		Factor Name	Standardized Regression Weights/Factor Loadings
% noticed	<---	PERCEPTION OF EXPECTATIONS FROM OTHERS	0.345
Physician	<---	PERCEPTION OF EXPECTATIONS FROM OTHERS	0.252
Practice length	<---	CLINICIAN FACTOR	-0.2
Physician	<---	CLINICIAN FACTOR	0.782
Patients	<---	PERCEPTION OF EXPECTATIONS FROM OTHERS	0.641
Patients	<---	CLINICIAN FACTOR	0.338
Co-workers	<---	PERCEPTION OF EXPECTATIONS FROM OTHERS	0.431
Co-workers	<---	CLINICIAN FACTOR	0.674
Organization	<---	CLINICIAN FACTOR	0.464
Supervisor	<---	CLINICIAN FACTOR	0.956

Table XXII

Squared Multiple Correlations: Variance Explained

Variable	Squared Multiple Correlations
Practice length	0.04
Physician	0.676
Organization	0.215
Supervisor	0.913
Co-workers	0.64
% noticed	0.119
Patients	0.525

Table XXIII

Model Fit Summary

Statistics	Estimate
Chi-square	7.298
Degrees of freedom	7
P-value for Chi-square	.399
RMSEA	.021
NFI	.965
CFI	.998

Exploratory Factor Analysis

When CFA fails, an exploratory strategy may be appropriate (DeCoster, 1998). Exploratory factor analysis (EFA) may be a good approach to assess the strength of relationships between variables, to identify the number of factors present in the collected data, and to explore why certain items may not have loaded on a factor or loaded on multiple factors (DeCoster, 1998).

While Confirmatory Factor Analysis resulted in a rejection of all three hypotheses and the conclusion that the hypothesized factor structure did not exist, exploratory factor analysis was conducted to examine whether a new factor matrix may emerge. In fact, exploratory factor analysis may be an appropriate step following unsuccessful confirmatory factor analysis.

First, item analysis was performed with the intent of removing items from the factor analysis. The criterion for inclusion was at least minimal correlation of .3 (Fleury, 1998). In factor analysis, a correlation matrix is the basis for analysis, therefore items that are not correlated with any other items could be removed before submitting the data to factor analysis (Munro, 2005). However, all items were correlated to at least one other item with a correlation coefficient of .3 or higher, therefore factor analysis included all variables of the survey.

Next, several extraction modalities were tried. Based on the findings of CFA, the existence of latent factors not directly measured in the survey was assumed with measurement error that had a systematic component

accounting for measurement error of the latent factor. Therefore, principal components extraction was deemed inappropriate because that method assumes measurement error to be random and distributes it equally to all variables (Ferketich & Muller, 1990). The extraction method chosen was Maximum likelihood (Albright & Park, 2009). Following the extraction, several rotation methodologies were tried finally arriving at Equimax rotation. The different rotation methods (Varimax, Quantimax, Oblimin) were used to find items that always loaded together and distinguished them from items that were sensitive to rotation modalities.

Based on Eigen values greater than 1, a six factor solution emerged accounting for 55% of the variance between items (Albright & Park, 2009). According to DeCoster (1998), a factor matrix should contain a number of factors that equal the number of Eigenvalues greater than one. A visual Scree plot showed that the number of Eigenvalues prior to the major drop in explaining variance was six.

All factors contained several items with factor loadings of greater than .5 following the rotation of factors (Table XXIV). The six factors were named: a) *Communication Issues*; b) *Disagreement with the Indigent*; c) *Stakeholders*; d) *Dependent on Others*; e) *Pillars of Capacity*; f) *Altered Ability*. *Communication Issues* included variables signifying the inability to communicate clearly in English such as the patient not being able to speak the English language, the patient in need of frequent clarification, or slurred

speech patterns. The factor titled *Disagreement with the Indigent* had strong factor loadings of items discussing advanced age (75+), being wheelchair-bound, and the patient having different values than the clinician. The *Stakeholders* factor included items similar to the results of the CFA, i.e. physicians, co-workers and the patient, but it also included the supervisor, all important stakeholders in recognizing capacity issues.

The *Dependent on Others* factor included patients being restrained or accompanied by others, while the *Pillars of Capacity* factor included variables measuring the importance of understanding information, and ability to signal a choice among treatment alternatives. Finally, the *Altered Ability* factor showed the loading of dementia and inability to repeat as well as organizational guidelines.

Table XXIV
Rotated Factor Matrix with Corresponding Factor Loadings

	Disagreement					
	Communication Issues	with the Indigent	Stakeholders	Dependent on Others	Pillars of Capacity	Altered Ability
No English	0.759					
Needs clarification	0.661					
Slurred	0.608					
Pain	0.493		0.481			
Wheelchair		0.742				
75+		0.669				
Different values		0.617				
Can't write	0.568	0.588				
Disagreement		0.581				
Physician			0.814			
Supervisor			0.812			
Co-worker			0.795			
Patient			0.539			
Restrained				0.943		
Accompanied				0.450		
Understand					0.722	
Express choice					0.574	
Abrupt chg.					0.523	
Unsafe					0.504	
Appreciate					0.475	
Guidelines						0.529
Can't repeat	0.516					0.521
Dementia						0.505
Intoxicated						0.467

Chapter V

DISCUSSION

General Discussion of Study Findings

A sequential exploratory study with a mixed design involved a convenience sample for its qualitative phase, and random cross-sectional sampling for its quantitative phase. During the quantitative phase, a 12% return rate was achieved, resulting in 126 total responses, of which 109 were complete and useable for analysis. The sample consisted of registered nurses licensed to practice in the State of New Jersey. Since solicitation to participate in the study was based on a random sample of the entire RN population in New Jersey, the sample could be considered representative of registered nurses practicing in New Jersey.

Clarity regarding the triggers of recognizing the necessity to more formally evaluate patients' capacity to make decisions regarding one's care was investigated, since empirical data about the subject is scarce. Further, clinicians may not have a complete understanding of capacity and how it relates to medical practice, yet the construct is a fundamental component of the ethical provision of healthcare.

The survey questions were developed to ascertain respondents' perception of behaviors related to patients' ability to make decisions. Nurses identified the level of importance of the specific behaviors pertaining to the patients or the presence of certain situations. Respondents also had to indicate their level of agreement with statements about the perceived role of nurses when it is unclear if a patient has enough capacity to make decisions about their healthcare. One would theorize that the presence of certain conditions that are deemed important triggers of evaluation of capacity by clinicians, who work with a larger number of patients without appropriate decision making ability are correlated with such behavior.

Several variables were indicated as important determinants of capacity evaluations. In fact, more than 80% of research volunteers indicated that it would be important to evaluate a patient's ability to make decisions when any of the following conditions were present:

- a.) The patient was unable to express a choice regarding his/her treatment, was unable to understand and reason with the information given to him or her, and/or could not appreciate the significance of the diagnosis or prognosis.
- b.) The patient consented to especially risky or invasive treatment, behaved in an unsafe manner, and/or exhibited abrupt changes in his or her mental state.

- c.) The patient was physically restrained, was diagnosed with dementia or mental illness, was unable to repeat what was being told to him or her, and/or was intoxicated.
- d.) Organizational or system guidelines also seemed to be an important influence of research volunteers' behavior regarding the assessment of patients' capacity.

Since all variables described some aspect of the patient or the situation in a compromised state from the perspective of capacity, the hypothesis of a correlation between variables that are considered important triggers of capacity assessment and actual capacity evaluating behavior was supported.

However, statistical analysis revealed that variables measured in the research instrument did not load into factors as hypothesized. Further, CFA revealed that the behavior of noticing patients not being able to thoughtfully making decisions about their care was correlated with a first order latent variable, identified as the *Perception of Expectations from Others*. Since factors are considered the cause of variables in CFA, one could argue for a significant predictive relationship between the *Perception of Expectations from Others* factor and the target behavior of recognizing lack of enough capacity for decision making.

The presence of the factor suggests that clinicians are actively being influenced and seek advice or approval of those they are involved with during the treatment of patients. In other words, *Perception of Expectations from*

Others is a factor that is a cluster of stakeholder influences during the treatment of patients. Factor loadings also show that there is a stronger influence (stronger factor loadings) of those who have a collaborative relationship with the nurse, i.e. co-workers and patients than by physicians who present a hierarchical relationship with the nurse. In contrast, the *Clinician* factor does not have a direct relationship with the target behavior, but it contributes to the explanation of the patient, physician and co-worker variables.

Finally, the negative relationship between practice length and the *Clinician* factor suggests that with experience, nurses are less reliant on the advice and guidance of others, and are less inquisitive about what others think.

It is striking that variables with relatively low stated importance scores seem to be more correlated with the target behavior, in comparison to the variables with significantly stronger stated importance scores. For example, the patient variable had an average score of -.45, and 41% of research volunteers reacted unfavorably to the variable, *I usually do what my patients think I should do*. Only 33% agreed that they usually do what their patients think a nurse should do when noticing a potential lack of decision making ability. Similar findings can be reported about the *Co-worker* variable with a mean score of -.22 on the bipolar scale ranging from +3 to -3. Approximately 32% of respondents disagreed that they usually do what their co-workers think a nurse should be doing when noticing that a patient may not have the

ability to make decisions, while 40% agreed. The *Physician* variable with a mean importance score .77 on a bipolar scale ranging from +3 to -3, and 18% negative vs. 62% positive reactions revealed a stronger position on a stated importance basis. Still, none of these variables were marked as important triggers for noticing the need for capacity assessment compared to other variables that were deemed important by well over 80% of all respondents.

The final model shows that a single factor called *Perception of Expectations from Others* factor is closely correlated with the measured behavior of *Noticing When Patients May Not Be Able to Thoughtfully Make Decisions about Their Treatment*. The newly emerged relationship of factors was limited with the *Clinician* factor, although the two factors together explained a significantly larger portion of the variance in the patient, *Physician* and *Co-worker* variables.

Both factors measure perceived normative pressure from people of importance. In behavioral research, such factor is often referred to as subjective norm and measures a person's perception of whether significant others want them to engage in a particular behavior, according to the Theory of Reasoned Action (Ajzen & Fishbein, 1975). Conner and his colleagues (2002) referred to normative pressure or subjective norm as social pressure.

Still, it is surprising that clinicians' notice of their patients' inability to thoughtfully make decisions about treatment options is partially explainable by patients', physicians' and co-workers' influence on the clinician. Interestingly

other, non-clinical relationships such as requirements by organization/systems guidelines, and supervisors were not correlated with the target behavior despite the authoritative nature of their relationship with clinicians.

The model suggests that nurses actively look to their patients, physicians working with them, and co-workers in search of what those important individuals may do in a similar situation.

The loading of the three mentioned variables to the *Clinician* factor suggests that nurses do evaluate how the perceived feedback from patients, physicians and co-workers compare to what guidelines, and a supervisor dictates in the same situation. However, such assessment has no impact on the ultimate behavior of recognizing the need to assess patients' capacity.

It is also possible that the relationship of patient, physician and co-worker variables with the *Perception of Expectations from Others* factor is clinical in nature. Nurses look to the three stakeholders for guidance in order to achieve an acceptable clinical outcome. Yet, the relationship of the three stakeholder variables with the *Clinician* factor seems to be organizational in nature and is focused on protocols of the workplace that govern the interaction between different stakeholders.

In behavioral research, the existence of subjective norm is not without controversy. For example, Armitage and Conner (2001) found the subjective norm construct a poor predictor of behavior, and argued that it needed to be

expanded or revised. Several authors did not include subjective norm in their models when studying a wide array of behaviors. (Sparks, Shepherd, Wieringa, & Zimmermann, 1995). Nevertheless, in the current study, the factor explained 12% of the variance of target behavior that was statistically significant.

The study failed to show a positive correlation between attitudes to patients and the target behavior. Similarly, the *Situation* factor and the target behavior were not correlated. Similar to a study conducted by Conner et al. (2002), attitudes in the model were presented as personal evaluations of the action where likely outcomes of a behavior determined attitudes (Conner et al., 2002).

Several operational definitions of attitudes exist, with the more recent definitions focusing on behavior. In fact, in all definitions, a method based on reasoning, intuition or perception that describes an attitude is overtly tied to the concept of behavior (Jaccard & Blanton, 2005).

“An attitude is a disposition to react with characteristics judgments and with characteristics goals across a variety of situations” (Anderson, 1981, p.93).

“An attitude is an idea charged with emotion which predisposes a class of actions to a particular class of social situations” (Tirandis, 1971, p.2).

“An attitude is a learned predisposition to respond to an object consistently favorable or unfavorable way” (Fishbein & Ajzen, 1975, p.6).

“An attitude is a mediating process grouping a set of objects of thought in a conceptual category that evokes a significant pattern of responses” (McGuire, 1985, p. 239).

The operational definition of attitudes suggests it to be a psychological inclination that is demonstrated by assessing an entity with some degree of like or dislike (Eagly & Chaiken, 1993). In turn, the degree of favor or disfavor manifests itself as cognitive, affective and behavioral responses. Therefore, people’s attitudes and their overt behaviors should show some degree of positive correlation. However, attitudes determine only a portion of one’s behavior, and work together with other factors to guide one’s actions.

In the current study, no relationship existed between the attitudes captured by the hypothetical Patient and Situational factors. An explanation to this finding may be based on research by Fishbein and Ajzen (1975) who showed that intention predicted behavior, while attitudes related to behaviors through their relationship with intentions. Intention therefore became a construct distinctly different from attitudes. The model, now termed as the Theory of Reasoned Action, suggested that attitudes develop toward behaviors, not toward targets. In fact, attitude toward a behavior became one of the factors that determine intentions.

Another explanation for the lack of relationship between variables measuring attitudes to patients, as well as the situation and the target behavior, could be that attitudinal factors do exist, but the factor matrix may

be different from the one submitted to confirmatory factor analysis. The exploratory factor analysis did in fact demonstrate a six-factor matrix with five entirely different factors emerging, while leaving a sixth factor intact as hypothesized originally.

Exploratory factor analysis demonstrated the convergence of variables describing the patient, the situation and the clinician in terms of communication issues. Also, respondents tended to think of items describing a situation when elderly or wheelchair-bound patients disagreeing with the value system of the clinician in the same realm. *Noticing Dependency on Others* appeared to be a factor as did *Altered mental Ability Due to Disease* (such as dementia or mental illness) or alcohol. Interestingly, items correlated with textbook definitions of capacity loaded into a single factor. Finally, the subjective norm appeared as a single factor.

Limitations

The current study has several limitations that stems from the study design, methodology and statistical analysis.

While the sample was a probability sample, it drew respondents from New Jersey, therefore generalizability to states outside of New Jersey is not appropriate. Further, geographical distribution of the sample may be different from the geographic distribution of the population. In order to protect the confidentiality of respondents, no records were collected about the location of respondents, therefore only the geographic distribution of solicitations mailed is available for analysis (Table XXV).

The study was exploratory and correlational in nature, which makes it impossible to assume causal relationships between variables. Such limitation is extremely important to recognize, since factors are assumed to be the cause of variables in CFA, but that does not substitute the need for experimental study designs, which are the only studies designed to establish causal relationships between variables.

The study used self reported data for analysis, which may have introduced some bias. While research volunteers were asked to indicate the number of patients they notice as not having enough capacity to thoughtfully make decisions about their medical care, a recalled number may have been altered by perception.

One must also consider the sample size achieved (n=126) and its appropriateness for CFA. The sample size that is appropriate for CFA remains a subject of intense scrutiny and scholarly argument.

In the current model, communalities were high, the number of expected factors was relatively small, and the model error was relatively low. Preacher and MacCallum (2002) argued that the above conditions may appropriately prompt scholars not to be very concerned with small sample sizes. However, several authors advocated for the “Rule of 200” stating that any type of factor analysis, whether it be confirmatory or exploratory, should have at least 200 subjects (Guilford, 1954; MacCallum, Wideman, Zhang, & Hong, 1999; Arrindel & van der Ende, 1985).

While the Capacity Assessment Survey was completed by 126 respondents, and all modeling was based on that sample, the demographic questionnaire had significant issues with research volunteers not indicating a choice in several questions. As a result, many of the demographic variables were deemed inappropriate for utilization in model development and specification. Consequently, only responses to importance scales were considered, as well as the variable that captured length of practice, which was answered by most.

The Capacity Assessment Survey used a “paper-pencil” collection methodology, therefore some potential respondents may have found it intrusive, and may not have wanted to participate as a result.

While the model revealed that the *Perception of Expectations from Others* factor was a significant predictor of the target behavior, it explained only 12% of its variance. In other words, the target behavior is largely driven by other reasons, which are currently unknown.

Table XXV

Distribution of Randomly Selected Solicitations Mailed by County

County	Frequency	Valid Percent
Monmouth	101	10.1
Ocean	92	9.2
Bergen	92	9.2
Middlesex	89	8.9
Camden	71	7.1
Burlington	71	7.1
Morris	58	5.8
Union	56	5.6
Passaic	53	5.3
Essex	51	5.1
Gloucester	49	4.9
Somerset	46	4.6
Atlantic	38	3.8
Mercer	27	2.7
Hudson	26	2.6
Sussex	22	2.2
Cumberland	16	1.6
Hunterdon	13	1.3
Cape May	13	1.3
Warren	11	1.1
Salem	4	.4
Unknown	1	.1
Total	1,000	100.0

Implications

The study started out by recognizing that the literature provides ample information about what constitutes impaired capacity. However, it was unclear what influenced nurses to recognize the need to initiate patients' capacity assessment. In fact, the purpose of the study was to identify factors associated with nurses' recognition of a need to initiate patients' capacity assessment. Only one factor was identified as being correlated with the outcome variable. The factor was termed *Perception of Expectations from Others*, and suggested that clinicians actively seek approval, advice and opinion of clinical stakeholders during the treatment of patients. The stakeholders whose opinions were considered included physicians, co-workers and patients themselves.

However, the newly developed model explained only a small portion of the reasons for recognizing the need for capacity evaluation. In fact, significant opportunity remains to further study and explain the reasons for the target behavior. One opportunity may be to utilize concepts from other areas of behavioral research with the hope of gaining further insight into the target behavior. One such measure may be Controllability, a construct that was first observed by Ajzen (2002), which refers to whether a person has access to resources that will allow him or her to control a behavior. Self-efficacy is yet another potential construct that may explain additional portion of the variance pertaining to the target variable and was first described an individual's belief

in being able to engage in a behavior in the context of a specific situation (Terry & O'Leary, 1995; Mansted & van Eekelen; 1998). Terry and O'Leary found a direct relationship between controllability and behavior, yet self-efficacy was related to behavior through the intention intermediary. Ajzen (2002) recognized the two distinct constructs argued that both accounted for a large portion of shared variance in the behavioral model.

One might experiment with higher order latent variables to achieve a better, more comprehensive model structure (Hagger, Chatzisarantis & Biddle; 2002).

The use of moderating variables was introduced by Barron and Kenny (1986). These variables may be qualitative such as gender, race, income, etc., or quantitative such as level of reward. The current study had significant issues with some respondents not filling out the demographics portion of the survey thereby limiting the study's ability to include moderating variables. Other behavioral models experimented with factors such as self-identity (Sparks & Shepherd, 1992), moral norms (Beck & Ajzen, 1991), and ambivalence (Conner et al., 2002). Ambivalence refers to the level of willingness to evaluate the object of an attitude positively or negatively (Thompson, Zanna, & Griffin, 1995). Other potential constructs for future studies are included in Table XXVI.

Table XXVI

Suggested Variables for Inclusion in Future Studies About Noticing That Patient May Not Have Enough Capacity for Decision Making

Suggested constructs	
Beliefs about consequences	Role and identity
Beliefs about capabilities	Emotion
Social influences	Knowledge
Past behavior	Environment
Knowledge	Beliefs about capabilities
Role & identity	Past behavior
Moral norm	Characteristics of HP
Emotion	Moral norm
Personal characteristics	Prediction of intention
Environmental factors	Beliefs about consequences
	Social influences

From, "Healthcare professionals' intentions and behaviors: A systematic review of studies based on social cognitive theories", by G. Godin, A. Belanger-Gravel, M. Eccles, and J. Grimshaw, 2008, *Implementation Science*.

Chapter VI

CONCLUSIONS

During the qualitative pilot phase of the study, it has been established that the issue of capacity appears in every clinician's practice regardless of practice setting or profession. Also, it became clear that nurses deemed capacity an important concept, yet the working knowledge of that concept varied greatly. Some were more proficient and were able to articulate some of the founding components of capacity recognizing the multi dimensional nature of the concept, while others were less savvy or knowledgeable.

Nurses reported a general lack of tools regarding capacity assessments. While nurses considered a physician the ultimate authority when assessing patients' capacity, they indicated discrepancies in terms of when to contact physicians provided that a patient's ability to make decisions was in question. Further, nurses communicated that recognizing capacity issues could be compromised by their busy workload or shift schedules.

Work experience seemed to allow respondents to assess their patients' capacity more effectively. In sum, it became evident that clinicians are generally aware of capacity as an issue, have excellent intuition regarding the

assessment of its components, but are not trained to recognize the need to assess their patients' capacity.

A thorough literature review also revealed that it was unclear if recommendations were followed regarding when and how nurses should recognize the need to initiate patients' capacity assessment. Empirical evidence regarding nurses' recognition of the need to initiate patients' capacity assessment did not exist, therefore it was necessary to determine nurses' perceptions of factors associated with such recognition. A quantitative study was conducted as a follow up to the qualitative pilot to explore factors associated with nurses' recognition of a need to initiate patients' capacity assessment.

The study examined several characteristics of patients, situations and nurses in terms of relative stated importance to recognize the need to assess patients' capacity. However, statistical analysis revealed that most characteristics stated as important actually did not increase the likelihood of recognizing patients' capacity. Interestingly, nurses were looking for guidance from other stakeholders during the treatment process. In fact, their behavior was shown to be correlated with their level of interest in what their co-workers, patients and physicians would want them to do. Organizational relationships were also important and helped explaining nurses' propensity to recognize the need for capacity assessment. However, such organizational relationships did not have a direct relationship with nurses' behavior. In fact,

nurses may report that organizational guidelines and their supervisor are an important part of their decision making when it comes to the recognition of the need for capacity assessment, in reality, such variables do not seem to correlate with such behavior.

Future Directions

The original confirmatory factor analysis did not result in a statistically significant, stable model, and several modifications were needed to establish a relationship between nurses' recognition of the need to assess their patients' capacity and variables describing patients, situations and clinicians. Also, the final model explained a relatively small portion of the variance in the target behavior, therefore new research may be needed to identify other factors that may influence such behavior.

The current study also captured significant amounts of data that was utilized in exploratory factor analysis. A new study could utilize the factor structure emerging from EFA and a new SEM model could test the relationship between the six new factors and nurses' propensity to recognize the need to assess their patients' capacity.

The study was based on answers given to two different questionnaires, the Capacity Assessment Survey and the Demographic Questionnaire. The protocol established that answers of respondents would be used only if they answered all questions within the Capacity Assessment Survey. At the same

time, respondents were not required to answer all questions in the Demographic Questionnaire.

As anticipated, many respondents did not provide answers to several demographic questions. In fact, practice length was the only variable indicated by all, other demographic variables were not answered by at least one respondent within the group of respondent who answered all questions in the Capacity Assessment Survey. Therefore, future work could employ a data collection strategy that would allow the utilization of a wide array of demographic variables in CFA, and measure the relationship between these variables *and* the target behavior.

REFERENCES

- Abernethy, V. (1984). Compassion, control, and decision about competency. *American Journal of Psychiatry*, 141, 53-60.
- Fishbein, M., & Ajzen, I. (1975). *Belief, attitude, intention, and behavior: An introduction to theory and research*. Reading, MA: Addison-Wesley.
- Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J.Kuhl & J.Beckman (eds.), *Action-control: from cognition to behavior*. Heidelberg, Germany: Springer.
- Ajzen, I., & Fishbein, M. (2000). Attitudes and the attitude-behavior relation: Reasoned and automatic processes. *European Review of Social Psychology*, 11, 1–33.
- Albright, J. J., & Park, H.M. (2008). Confirmatory factor analysis using Amos, LISREL, Mplus, and SAS/STAT CALIS. Retrieved on December 15th, 2010, from <http://www.indiana.edu/~statmath/stat/all/cfa/index.html>
- American Nurses Association, Nursing's Social Policy Statement, 2003. Retrieved on November 15th, 2010, from <http://www.csun.edu/~meh20426/303/13ANASocialPolicy2003.pdf>
- Applebaum, P., & Grisso, T. (1995). The MacArthur treatment competence study: I, mental illness and competence to consent to treatment. *Law and Human Behavior*, 19, 105-126.

- Applebaum, P., & Grisso, T. (1998). *Assessing Competence to Consent to Treatment: A guide for physicians and other health professionals*. New York and Oxford, Oxford University Press.
- Appelbaum, P. S., Lidz, C. W., & Meisel, A. (1987). *Informed consent: Legal theory and clinical practice*. New York: Oxford University Press.
- Applebaum, P.S., & Roth, L.H. (1981). Clinical issues in the assessment of competency. *American Journal of Psychiatry*, 138, 1462-1467.
- Applebaum, P.S., & Roth, L.H. (1982). Competency to consent to research: A psychiatric overview. *Archives of General Psychiatry*, 39, 951-958.
- Arbuckle, J.L. (2005). *Amos 6.0 user's guide*, Chicago, IL: SPSS Inc.
- Armitage, C. J. & Connor, M. (2001). Efficacy of the theory of planned behavior: A meta-analytic review. *The British Journal of Social Psychology*, 40(4), 471–499.
- Arrindell, W. A., & van der Ende, J. (1985). Cross-sample invariance of the structure of self-reported distress and difficulty in assertiveness: experiences with the Scale for Interpersonal Behaviour. *Advances in Behaviour Research and Therapy*, 7, 205–243.
- Aspen Publishers (2009) *Health Law, Keyed to courses using Furrow, Greaney, Johnson, Jost, & Schwartz's Health Law*, New York, NY: Walters Kluwer Law and Business.

- Ballard, A.B., Arbogast, D.A., Boeckman, J., Conlon, P., Fournier, J., Hozdic, L., Murcko, A., & American Nurses Association., (2004). *Nursing: Scope and Standards of Practice*, Silver Spring, MD: American Nurses Association.
- Baron, R.M. & Kenny, D.A. (1986). The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*, 51, 1173-1182.
- Barton, C.D., Mallik, H.S., Orr, W.B., & Janofsky, J.S. (1996). Clinicians' judgment of capacity of nursing home patients to give informed consent. *Psychiatric Services*, 47, 956-960.
- Barrett, P. (2007). Structural equation modeling: Adjudging model fit. *Personality and Individual Differences*, 42, 815–824.
- Barrett, P. T., & Kline. P. (1981). The observation to variable ratio in factor analysis. *Personality Study in Group Behavior*, 1, 23-33.
- Bentler, P.M., & Bonnett, D.G. (1980). Significance tests and goodness of fit in the analysis of covariance structures. *Psychological Bulletin*, 88, 588 - 606.
- Berg, J., Applebaum, P., Lidz, C., & Parker, B. (2001). *Informed consent: Legal theory and clinical practice*. (2nd ed.). New York: Oxford University Press.
- Beauchamp, T.L., & Childress, J.F. (1994). *Principles of Biomedical Ethics* (4th ed.). New York, NY: Oxford University Press.

- Beck, L. & Ajzen, I. (1991). Predicting dishonest actions using the theory of planned behavior. *Journal of Research and Personality*, 25, 285-301.
- Bollen, K.A. (1989). *Structural equation models with latent variables*. New York, NY: Wiley & Sons.
- Bollen, K.A., & Long, J.S., eds. (1993). *Testing structural equation models*. Newbury Park, CA: Sage.
- Boomsma, A. (2000). Reporting analyses of covariance structures. *Structural Equation Modeling*, 7, 461–483.
- Buchanan, A. (2006). Competency to stand trial and the seriousness of the charge. *Journal of the American Academy of Psychiatry and Law*, 34(4), 458-465.
- Canterbury v. Spence, 462 F2d 772 (1972).
- Capron, A. (1972). *Experimentation with human beings: The authority of the investigator, subject, professions and state in human experimentation* (J. Katz with assistance of A.M. Capron and E.S. Glass). New York, NY: Russell Sage Foundation.
- Casida, J.M. (2007). The Relationship of nurse managers' leadership styles and nursing unit organizational culture in acute care hospitals in New Jersey. (Doctoral dissertation, Seton Hall University, 2007), RT86.7 .C37 2007.
- Culver, C.M., & Gert, B. (1982). *Philosophy of medicine*. New York, NY: Oxford University Press.

- Connely, L.M. (2009). Staff nurses' responsibilities when caring for patients in a research study. *MEDSURG Nursing*, 18(6), 385-386.
- Conner, M., Sparks, P., Povey, R. James, R., Shepherd, R., & Armitage, C.J. (2002). Moderator effects of attitudinal ambivalence on attitude-behavior relationships. *European Journal of Social Psychology*, 32, 705-718.
- Corta-Bilajac, I., Bazdaric, K., Brozovic, B. & Agich, J. (2008). Croatian physicians' and nurses' experience with ethical issues in clinical practice. *Journal of Medical Ethics*, 34(6), 450-455.
- Cox, K. (2002). Informed consent and decision making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Education and Counseling*, 46, 31-38.
- Creswell, J. W. (1998). *Qualitative inquiry and research design: Choosing among five traditions*. Thousand Oaks, CA: Sage.
- DeCoster, J. (1998). *Overview of Factor Analysis*. Retrieved on November 15th, 2010, from <http://www.stat-help.com/notes.html>
- DeLuca, D. A. (2003, February). Legal issues in healthcare: The professional patient relationship. Handout presented in class. Seton Hall University, South Orange, NJ.
- Diamantopoulos, A. & Siguaw, J. (2000). *Introducing Lisrel: A guide for the uninitiated*. London: Sage.

- Drane, J. (1984). Competency to give informed consent: A model for making clinical assessment. *Journal of the American Medical Association*, 252, 925-927.
- Dunn, L.B., Nowrangi, M.A., Palmer, B.W., Jeste, D.V., & Saks, E.R. (2006). Assessing decisional capacity for clinical research or treatment: A review of instruments. *American Journal of Psychiatry*, 163(8), 1323-1334.
- DuVal, G., Clarridge, B., Gensler, G., & Danis, M. (2004). A national survey of U.S. internists' experiences with ethical dilemmas and ethics consultation. *Journal of General Internal Medicine*, 19(3), 251-258.
- Eagly, A.H. & Chaiken, A. (1993). *The psychology of attitudes*. Belmont, CA: Thompson-Wadsworth.
- Earnst, K.S., Marson, D.C., & Harrell, L.E. (2000). Cognitive models of physicians' legal standard and personal judgments of competency in patients with Alzheimer's disease. *Journal of American Geriatric Society*, 48(8), 919-927.
- Edwards, S.J.L., Lilford, R.J., Thornton, J., & Hewison, J. (1998). Informed consent for clinical trials: In search of the "best" method. *Social Science and Medicine*, 47(11), 1825-1840
- Eriksson, S., Höglund, A.T., & Helgesson, G. (2008). Do ethical guidelines give guidance? A critical examination of eight ethics regulations. *Cambridge Quarterly of Healthcare Ethics*, 17(1), 15-29.

- Etchells, E., Darzins, P., Silberfeld, M., Singer, P.A., McKenny, J., & Naglie, G., et al. (1999). Assessment of patient capacity to consent to treatment. *Journal of General Internal Medicine*, 14, 27-34.
- Evans, K., Warner, J., & Jackson, E. (2007). How much do emergency healthcare workers know about capacity and consent? *Emergency Medicine Journal*, 24(6), 391-393.
- Ferketich, S., & Muller, M. (1990). Factor analysis revisited. *Nursing Research*, 39, 59-62.
- Furrow, B.R., Greaney, T.L., Johnson, S.H., Jost, T.S., & Schwartz, R.L. (2001). *Health Law (4th ed.)*. St. Paul, MN: West Group.
- Ganzini, L., Volicer, L., Nelson, W., & Derse, A. (2003). Pitfalls in assessment of decision-making capacity. *Psychosomatics*, 44(3), 237-243.
- Ganzini, L., Volicer, L., Nelson, W.A., Fox, E., & Derse, A.R. (2004). Ten myths about decision-making capacity. *Journal of American Medical Directors Association*, 5(4), 263-267.
- Garson, G. (2005). *Structural equation modeling example using WinAMOS*. Retrieved on December 16th, 2010, from North Carolina State University Web Site: <http://www2.chass.ncsu.edu/garson/pa765/semAMOS1.htm>
- Godin, G., Bélanger-Gravel, A., Eccles, M., & Grimshaw, J. (2008). Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implementation Science*, 16(3), 36.

- Grady, C., & Edgerly, M. (2009). Science, technology, and innovation: nursing responsibilities in clinical research. *Nursing Clinics of North America*, 44(4), 471-81.
- Grisso, T. (2002). *Evaluating competencies: Forensic assessments and instruments*. (2nd ed.) New York, NY: Kluwer Academic/Plenum Publishers.
- Grisso, T., Appelbaum, P.S., Mulvey, E., & Fletcher, K. (1995). The MacArthur Treatment competence study, II: Measures of abilities related to competence to consent to treatment. *Law and Human Behavior*, 19, 127-148.
- Guilford, J. P. (1954). *Psychometric methods*. New York: McGraw-Hill.
- Hippocratic Oath, NIH, Retrieved on November 15th, 2010, from http://www.nlm.nih.gov/hmd/greek/greek_oath.html
- Hagger, M.S., Chatzisarantis, N.L.D., & Biddle, S.J.H. (2002). The influence of autonomous and controlling motives on physical activity intentions within the Theory of Planned Behaviour. *British Journal of Health Psychology*, 7, 283–297.
- Hu, L. & Bentler, P.M. (1999). Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. *Structural Equation Modeling*, 6, 1-55.

- Hurst, S.A., Perrier, A., Pegoraro, R., Reiter-Theil, S., Forde, R., Slowther, A.M., Garrett-Mayer, E., & Danis, M. (2007). Ethical difficulties in clinical practice: experiences of European doctors. *Journal of Medical Ethics*, 33(1), 51-57.
- Jaccard, J., & Blanton, H. (2005). The origins and structure of behavior: Conceptualizing behavior ion attitude research. In D. Albarracin, B.T. Johnson, M.P. Zanna (Eds.). *The Handbook of Attitudes* (pp. 125-174). New York, NY: Psychology Press.
- Jöreskog, K.G. (1969). A general approach to confirmatory factor analysis, *Psychometrika*, 34, 183-202.
- Jackson, E., & Warner, J. (2002). How much do doctors know about consent and capacity? *Journal of the Royal Society of Medicine*, 95(12), 601-603.
- Kapp, M.B. (1992). Nursing home restraints and legal liability: Merging the standard of care and industry practice. *Journal of Legal Medicine*, 13(1), 1-32.
- Karlawish, J. (2008). Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals*, 16(1), 91-98.
- Keeter, S., Miller, C., Kohut, A., Groves, R., & Presser, S. (2000). Consequences of reducing nonresponse in a national telephone survey. *Public Opinion Quarterly*, 2000;64, 125-48.

- Kenny, D. A. & McCoach, D. B. (2003). Effect of the number of variables on measures of fit in Structural Equation Modeling. *Structural Equation Modeling, 10*, 333-351.
- Kline, R. B. (1998). *Principles and practice of structural equation modeling*. New York, NY: Guilford Press.
- Kusec, S., Oreskovic, S., Skegro, M., Korolija, D., Basic, Z., & Horzic, M. (2006). Improving comprehension of informed consent. *Patient Education and Counseling, 60*, 294-300.
- Lei, P. W. & Wu, Q. (2007). An NCME instructional module on introduction to structural equation modeling: Issues and practical considerations. *Educational Measurement, Issues and Practice, 26*(3), 33-44.
- Mallardi V. (2005). The origin of informed consent. *Acta Otorhinolaryngol Italiana, 25*(5), 12-27.
- Mappes, T.A., & DeGrazia, D. (2001). *Biomedical Ethics*. New York, NY: McGraw-Hill.
- Markson, L.J., Kern, D.C., Annas, G.J., & Glantz, L.H. (1994). Physician assessment of patient competence. *Journal of American Geriatric Association, 42*(10), 1074-1080.
- Marson, D. C., Ingram, K. K., Cody, H. A., & Harrell, L. E. (1995). Assessing the competency of patients with Alzheimer's disease under different legal standards. A prototype instrument. *Archives of Neurology, 52*(10), 949-954.

- Marson, D.C., Earnst, K.S., Jamil, F., Bartolucci, A., & Harrell, L.E. (2000). Consistency of physicians' legal standard and personal judgments of competency in patients with Alzheimer's disease. *Journal of American Geriatric Society*, 48(8), 911-918.
- Matter of Conroy, 486 A.2d 1209 (N.J. 1985).
- Matter of O'Brian, 517 N.Y.S.2d 364 (Sup. Ct. 1986).
- Mayo, A.M., & Wallhagen, M.I. (2009). Considerations of informed consent and decision-making competence in older adults with cognitive impairment. *Research in Gerontological Nursing*, 2(2), 103-111.
- MacCallum, R.C., Wideman, K.F., Zhang, S. & Hong, S. (1999). Sample size in factor analysis. *Psychological Methods*, 4(1), 84-99.
- Manstead, A.S.R., & van Eekelen, S.A.M. (1998). Distinguishing between perceived behavioral control and self efficacy in the domain of academic intentions and behaviors. *Journal of Applied Social Psychology*, 28, 1375-1392.
- McGuire, W.J. (1985). Attitudes and attitude change. In G Lindzey & E. Aronsons (Eds.), *Handbook of Social Psychology* (3rd ed., Vol. 2, 00 233-346). New York, NY: Random House.
- Mitchell v. Robinson, 334 S. W. 2d 11, (1960).
- Moberg, P.J. & Kniele, K. (2006). Evaluation of competency: Ethical considerations for neuropsychologists. *Applied Neuropsychology*, 13(2), 101-104.

- Moseley, T.H., Wiggins, M.N., & O'sullivan, P.S. (2006). Effects of presentation modality on the understanding of informed consent. *British Journal of Ophthalmology*, Abstract.
- Munro, B.H. (2004). *Statistical methods for healthcare research* (5th ed.). Philadelphia, PA: Lippinkott, Williams & Wilkins.
- Natanson v. Kline, 350 P.2d 1093 (1960).
- National Center for Learning Disabilities – Executive Function Fact Sheet. Retrieved on July 22, 2008, from <http://www.ncld.org/content/view/865/>
- National Library of Medicine, National Institute of Health. Greek Medicine – The Hippocratic Oath. Retrieved on June 3rd, 2008, from http://www.nlm.nih.gov/hmd/greek/greek_oath.html
- Norman, D.A., & Shallice, T. (2000). *Attention to action: willed and automatic control of behaviour*. In Gazzaniga M.S., *Cognitive neuroscience: a reader*. Oxford: Blackwell.
- Ortiz, J.J. (2007). Informed consent, capacity and competency. Florida Depart of Health Statewide Meeting Presentations, Retrieved on June 15th, 2008, from http://www.doh.state.fl.us/Disease_ctrl/tb/StatewideMeeting/2007/Statewide_Meeting_Presentations/Ortiz_Informed_Consent.doc
- Parmar, J. (2008). Assessment of decision making capacity, Retrieved on November 15th, 2010, from

https://www.onehealth.ca/r_alberta_nwt/video_conferences/R090522A-HO.pdf

Peterson, M., & Potter, R.L. (2004). A proposal for a code of ethics for nurse practitioners. *Journal of American Academy of Nurse Practitioners*, 16(3), 116-24.

Preacher, K.J. & MacCallum, R.C. (2002). Exploratory factor analysis in behavior genetics research: Factor recovery with small sample sizes. *Behavior Genetics*, 32(2), 153-161.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982). *Making healthcare decisions*. Washington, DC: U.S. Government Printing Office.

Raymont, V. (2002). Not in perfect mind - the complexity of clinical capacity assessment. *Psychiatric Bulletin*, 26, 201-204.

Rennie v. Klein, 462 F. Supp. 1131 (1978); modified, 476 F. Supp. 1294 (1979); stay denied, 481 F. Supp. 552 (1979); modified and remanded, 653 F2d 836 (1981); vacated and remanded, 50 USLW 3998.27 (1982).

Rogers v. Okin, 478 F. Supp. 1342 (1979); affirmed in part, reversed in part, vacated in part and remanded 643 F2d 650 (1980); vacated and remanded sub. nom.

Roth, L.H., Meisel, A., Lidz, C.W. (1977). Test of competency to consent to treatment. *American Journal of Psychiatry*, 134, 279-284.

- Santillan-Doherty, P., Cabral-Castañeda, A., & Soto-Ramírez, L. (2003). Informed consent in clinical practice and medical research. *Revista de Investigacion Clinica*, 55(3), 322-38.
- Schofield, C. (2008). Mental Capacity Act 2005 - What do doctors know? *Medical Science and Law*, 48(2), 113-116.
- Sims, J.M. (2008). Your role in informed consent. *Dimensions of Critical Care Nursing*, 27(2), 70-3.
- Sparks, P., Shepherd, R., Wieringa, N., & Zimmermans, N. (1995). Perceived behavioural control, unrealistic optimism and dietary change: An exploratory study. *Appetite*, 24(3), 243–255.
- Steiger, J.H. (2000). *Point estimation, hypothesis testing, and interval estimation using the RMSEA: Some comments and a reply to Hayduk and Glaser*. *Structural Equation Modeling*, 7, 149–162.
- Steiger, J. H. & Lind, J. (1980). *Statistically-based tests for the number of common factors*. Paper presented at the Annual Spring Meeting of the Psychometric Society, Iowa City.
- Sturman E.D. (2005). The capacity to consent to treatment and research: A review of standardized assessment tools. *Clinical Psychology Review*, 25, 954-974.
- Swetz, K.M., Crowley, M.E., Hook, C., & Mueller, P. (2007). Report of 255 clinical ethics consultations and review of literature. *Mayo Clinic Proceedings*, 82(6), 686-691.

- Tepper, A.M., & Elwork, A. (1984). Competence to consent to treatment as a psycholegal construct. *Law and Human Behavior*, 8(3/4), 205-223.
- Terry, D.J. & O'Leary, J.E. (1995). The theory of planned behaviour: The effects of perceived behavioural control and self-efficacy. *British Journal of Social Psychology*, 34, 199-220.
- Thompson, M., Zanna, M., & Griffin, D. (1995). Let's not be indifferent about (attitudinal) ambivalence. In R. E. Petty & J. A. Krosnick (Eds.), *Attitude strength: Antecedents and consequences* (pp. 361-386). Hillsdale, NJ: Lawrence Erlbaum.
- Tirandis, H.C. (1971). *Attitude and attitude change*. New York, NY: Wiley.
- Tomoda, A., Yasumiya, R., Sumiyama, T., Tsukada, K., Hayakawa, T., & Matsubara, K., et al. (1997). Validity and reliability of structured interview for competency incompetency assessment testing and ranking inventory. *Journal of Clinical Psychology*, 53, 443-450.
- Tunzi, M. (2001). Can the patient decide? Evaluating patient capacity in practice. *American Family Physician*, 64(2), 299-306.
- Yuhas, B.P. & Wilcox, J.R. (1991). Focus groups: A qualitative opportunity for researchers. *The Journal of Business Communication*, 28(1), 63-78.
- Verhegen, F.W.S.M., & Wijmen, F.C.B. (1996). Informed consent in clinical trials. *Health Policy*, 36, 131-153.
- White, B.C., (1994). *Competence to consent*. Washington, D.C.: Georgetown University Press.

Whitcher, J. (2008). Legal responsibilities: consent in emergency treatment.

Nursing Standard, 23(9), 35-42.

APPENDIX A

CAPACITY ASSESSMENT SURVEY

Capacity Assessment Survey

CAPACITY ASSESSMENT SURVEY

General Instructions to Main Survey:

In the questionnaire you are about to fill out, you will be asked questions which make use of rating scales with seven qualifying places. Please place a check mark in the place that best describes your opinion.

This questionnaire is concerned with nurse's views toward the need to evaluate a patient's ability to thoughtfully make a decision about his or her treatment. In addition to a few general questions, you will be asked about a specific situation that involves you noticing for the first time that a patient may or may not be able to thoughtfully make a decision about his or her treatment.

1. On a typical week, approximately how many patients are under your care in your primary work setting?

_____ patients

2. Of all patients under your care on a typical week, approximately what percent do you notice as NOT being able to thoughtfully make a decision about their treatment?

_____ %

NURSE

3. Please rate your level of agreement with the following statements.

	Agree		Neither			Disagree	
	+3	+2	+1	0	-1	-2	-3
When I notice that a patient may not have the ability to make decisions, I usually do what my... my...							
A. Patients think I should do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Co-workers think I should do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Supervisor thinks I should do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Physician thinks I should do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Organization/system guidelines dictate(s) _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX A

CAPACITY ASSESSMENT SURVEY (Page 2)

Capacity Assessment Survey

4. Please rate your level of agreement with the following statements.

	Agree			Neither			Disagree
	+3	+2	+1	0	-1	-2	-3
A patient's ability to make decisions should be evaluated when I notice that...							
A. He/she is unable to express a choice regarding his/her treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. He/she is unable to understand and reason with the information I have given him/her.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. He/she can NOT appreciate the significance of diagnosis/prognosis.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SITUATION

5. Please rate your level of agreement with the following statements.

	Agree			Neither			Disagree
	+3	+2	+1	0	-1	-2	-3
It is important to evaluate a patient's ability to make decisions when he/she...							
A. Consents to treatment that is potentially risky or invasive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Arrives in a wheelchair or stretcher.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Behaves in an unsafe manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Disagrees with recommended treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Has values or beliefs that are in conflict with my values or beliefs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. Exhibits abrupt changes in his/her mental state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G. Asks a healthcare worker to make a decision for him/her.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1

2

2

APPENDIX A

CAPACITY ASSESSMENT SURVEY (Page 3)

Capacity Assessment Survey

PATIENT

6. Please rate your level of agreement with the following statements.

It is important to evaluate a patient's ability to make decisions when he/she...	Agree		Neither			Disagree	
	+3	+2	+1	0	-1	-2	-3
A. is accompanied by someone such as nurse's aide or caregiver.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. is in considerable pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. is physically restrained.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. is over 75 years of age.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. is diagnosed with current mental illness etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. is unable to speak English.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G. Has impaired or slurred speech.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H. is unable to repeat what he/she is being told.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I. is unable to write.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
J. Frequently asks for repetition or clarification (i.e. "what did you say?")	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
K. Appears intoxicated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1

2

APPENDIX B

DEMOGRAPHIC QUESTIONNAIRE

Capacity Assessment Survey

DEMOGRAPHIC QUESTIONNAIRE:

The last section of the questionnaire will focus on key demographic information about you.

1. What is your position or area of responsibility at your primary employment? Please circle your current position only.

- a. Acute care nurse
- b. Adult Nurse Practitioner
- c. Adult Psychiatric & Mental Health Nurse Practitioner
- d. Child/Adolescent Psychiatric & Mental Health Clinical Nurse
- e. Family Nurse Practitioner
- f. Family Psychiatric & Mental Health Nurse Practitioner
- g. Forensic Nurse
- h. Gerontological Nurse
- i. Medical Surgical Nurse
- j. Pediatric Clinical Nurse
- k. Pediatric Nursing
- l. Public Health Nurse – Advanced
- m. Case Management Nursing
- n. Other (Please specify _____):

2. What is your highest level of education as a nurse?

- a. Bachelors Degree
- b. Masters Degree
- c. PhD

APPENDIX B

DEMOGRAPHIC QUESTIONNAIRE (Page 2)

Capacity Assessment Survey

3. Do you hold a certificate in any of the following? (Please circle all that apply)

- a. Ambulatory Care Nursing
- b. Cardiac/Vascular Nursing
- c. Case Management Nursing
- d. Psychiatric and Mental Health Nursing
- e. Informatics Nursing
- f. Gerontological/Clinical Nurse Specialist
- g. Pain Management
- h. Nurse Executive, Advanced
- i. Adult Health/Clinical Nurse Specialist
- j. Other (Please specify _____)

4. Since completing studies in nursing, approximately how many years have you been in clinical practice? (Please round to whole years)

_____ # of years in clinical practice

5. What is your age? (Please circle)

- a. 25-35
- b. 36-45
- c. 46-55
- d. 56-65
- e. 65+

APPENDIX C
SOLICITATION LETTER

SETON HALL UNIVERSITY
1 8 5 6

September 20, 2010

Dear Research Volunteer:

As a doctoral student in the Graduate Program in Health Sciences at Seton Hall University, I am conducting a dissertation research study about nurses' recognition of a need to initiate patients' capacity assessment. The title of the study is 'Factors associated with nurses' recognition of a need to initiate patients' capacity assessment'.

My study will examine Research Volunteers' views toward the need to evaluate a patient's ability to thoughtfully make a decision about his or her treatment. In addition to a few general questions, Research Volunteers will be asked about a specific situation that involves noticing for the first time that a patient may or may not be able to thoughtfully make a decision about his or her treatment.

Along with this letter, you will find a survey entitled 'Capacity Assessment Survey,' a demographic questionnaire, and a self-addressed stamped return envelope. After completion of the 'Capacity Assessment Survey,' and the demographic questionnaire, you can mail both in the self-addressed stamped return envelope.

Survey participation will take about 15 minutes.

Research Volunteers will be asked to indicate their level of agreement with statements regarding how attributes of a nurse, a specific situation and patients being treated in a hospital may influence them in recognizing the need to evaluate a patient's ability to thoughtfully make a decision about his or her treatment.

Study participation is completely voluntary, and you have the right to ask any question you don't want to answer. You also have the right to drop out of the study at any time for any reason. Discontinued participation will have no consequences.

Your privacy and confidentiality is of highest importance. Names and other identifiers of Research Volunteers will not be collected. Your answers will be kept strictly confidential and anonymous as study results will only be published as a sum of all answers. Only the principal investigator will have access to aggregated answers which will be stored on a USB disk, at the home of the principal investigator. The paper survey you are returning will be destroyed with a shredder. All data will be destroyed three years after the completion of the study.

Seton Hall University
Institutional Review Board

School of Health and Medical Sciences
Department of Graduate Programs in Health Sciences
Tel: 973.224.2010 • Fax: 973.224.1131

100 South Orange Avenue • North Orange, New Jersey 07170 • www.setonhall.edu

SEP 18 2010

SEP 20 2010

SEP 20 2010
1002 SEP 13 2010
SEP 20 2010

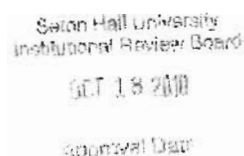
APPENDIX C
SOLICITATION LETTER (Page 2.)

If you are interested in participating, please fill out the survey in the enclosed packet and mail it back by December 18, 2010.

Thank you for your participation in this research project.

Sincerely,

Galen Toth
Doctoral Student, Graduate Program in Health Sciences, Seton Hall University



Expiration Date
OCT 18 2011

APPENDIX D

REMINDER

September 30, 2010

Dear Research Volunteer:

As a doctoral student in the Graduate Program in Health Sciences at Seton Hall University, I am conducting a dissertation research study about nurses' recognition of a need to initiate patients' capacity assessment.

Approximately three weeks ago you have received a packet inviting you to participate in a survey. The survey will take approximately 15 minutes of your time to complete.

Your participation in this research is completely voluntary, confidential and anonymous.

Please fill out "Capacity Assessment Survey" and demographic questionnaire, and return both in the postage paid, addressed envelope by December 15, 2010.

Your participation is greatly appreciated and will contribute to our understanding of how nurses recognize whether their patients' are in need of a more formal capacity assessment.

Best regards,

Gellert Toth
Doctoral Student, Graduate Program in Health Sciences, Seton Hall
University

APPENDIX E
IRB APPROVALS

OFFICE OF INSTITUTIONAL
REVIEW BOARD
SETON HALL UNIVERSITY

October 18, 2010

Gelert Toth
1124 Summit Lane
Mountainside, New Jersey 07092

Dear Mr. Toth,

The Seton Hall University Institutional Review Board has reviewed your research proposal entitled "Factors associated with nurses' recognition of a need to initiate patient's capacity assessment" and has approved it as submitted under exempt status.

Enclosed for your records is the signed Request for Approval form.

Please note that, where applicable, subjects must sign and must be given a copy of the Seton Hall University current stamped Letter of Solicitation or Consent Form before the subjects' participation. All data, as well as the investigator's copies of the signed Consent Forms, must be retained by the principal investigator for a period of at least three years following the termination of the project.

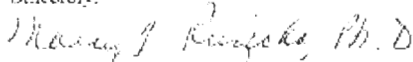
Should you wish to make changes to the IRB approved procedures, the following materials must be submitted for IRB review and be approved by the IRB prior to being instituted.

- Description of proposed revisions;
- *If applicable*, any new or revised materials, such as recruitment fliers, letters to subjects, or consent documents; and
- *If applicable*, updated letters of approval from cooperating institutions and IRBs.

At the present time, there is no need for further action on your part with the IRB.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

Sincerely,



Mary E. Ruticka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Valerie Olson

APPENDIX E

IRB APPROVALS (Page 2)

Please review Seton Hall University IRB's [Policies and Procedures](#) on website (<http://www.setonhall.edu/IRB/>) for more information. Please note the following requirements:

Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Amendments: If you wish to change any aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.

Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.

Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

General: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your final approved anniversary date. Note: No research may be conducted (except to prevent immediate harms to subjects), no data collected, nor any subjects enrolled after the expiration date.

APPENDIX F

INFORMAL REQUEST ORDER FORM



CHRIS CHRISTIE
Governor

KIM GUADAGNOLI
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Administration
Management Information Systems
124 Halsey Street, 7th Floor, Newark, NJ



PAUL J. DINE
Attorney General

SIJESHA M. JINWA
Acting Director

Mailing Address:
P.O. Box 48724
Newark, NJ 07101

INFORMAL REQUEST ORDER FORM

WILSON HALL SECURITY ELLERRE TECH
Company Name Contact Name

1124 SUMMIT AVE 9800 US 93 RD NJ 07020
Street Address City State Zip Code

732-597-9412 yellow@concast.net
Telephone Number (include area code) E-mail Address (if available)

Please specify List Type: Standard Custom

For Custom Request Only:

Professional License Category Codes: 2.602

File Format Preference: Excel
(Excel, ASCII, tab-delimited)

Please note: CDS license numbers are not provided.

Delivery: Lists are no longer available by email.

Computer CD (delivered via U.P.S. Ground)

*PAID
9/17/10
\$100*

Reference Number (INTERNAL USE ONLY): _____ Fee: _____