Spring 5-5-2014

A Novel Method for Assessing Medication-Related Adverse Outcomes in a Community Hospital

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Doctor of Nursing Practice Program

May 5, 2014

A project submitted in partial

fulfillment of the requirements for the degree of

Doctor of Nursing Practice (DNP)

in the California State University Northern California Consortium DNP Program

California State University, Fresno and San José State University

May 5, 2014

APPROVED

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Acknowledgements

To my parents Anne and Bill for leading me to the profession of nursing and teaching me to always persevere in reaching my goals

To my wife Mary for her unwavering faith and support on this journey called life, and for making all the sacrifices that make my success possible

To my children Christina and Laura for always setting a good example for their father in their own pursuit of knowledge

To Dr. R.C. "Charlie" Ziehl who taught me about the doughnut and the hole

To my project mentor Cleo Mutebi who always believed in the project, and who remains to this day the finest working partner I have known

To my project chair Sylvia Miller for her abundant encouragement and improvements to this project and for coming to know the project as well as I

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Abstract

The use of medications for hospitalized patients is universal, and unfortunately medication-related adverse outcomes are common. The accurate assessment of medication-related harm in hospitalized patients is foundational to the development of an effective hospital medication safety program. Every hospital has its own unique "fingerprint" of harm, accurate determination of the nature of medication-related harm specific to each hospital is necessary to facilitate prevention of that harm with specific and effective interventions. This project has provided a community hospital with its first systematic methodology for assessing medication-related harm. The methodology is adapted from that used in a recent national-level study.

Several commonly accepted methods of assessment of medication-related adverse events are in use, but no single method is capable of giving a complete picture of harm at the hospital level. Using a method nearly identical to one employed in large national studies the author examined rates and types of medication-related adverse outcomes in a California community hospital. The hospital had about one-third the national rate of adverse events. An incidental finding was a 4-year pattern of increasing incidence of adverse outcomes followed by 2 years of declining incidence of adverse outcomes. The information gained from the novel assessment method provided a clearer picture of patient harm, a basis for a more effective medication safety plan, and promoted interprofessional collaboration.

A Novel Method for Assessing Medication-Related Adverse Outcomes in a Community Hospital

Patient safety is an important national health concern, and the use of medications in hospitals is essential, but medications do cause significant harm. In 2000 the Institute of Medicine (IOM) published a landmark work entitled *To Err is Human: Building a Safer Healthcare System*. This report demonstrated that medical error contributes to the deaths of between 44,000 and 98,000 hospitalized patients annually in the U.S. According to the report, if medical error were considered as a cause of death of Americans, it would fall somewhere between the fifth and eighth leading causes.

Adverse events attributable to both medication use and misuse comprise a significant, if not the single most prevalent mechanism of patient injury associated with hospitalization. In one U.S. governmental study examining nosocomial harm of any cause, events related to medication use accounted for 31% of the harm (more than any other type of harm) experienced by hospitalized Medicare beneficiaries (Levinson, 2010).

A distinction should be made between medication errors and medication-related adverse outcomes (harm). Medication errors are endemic in hospitals; a recent systematic review of the prevalence and nature of medication errors placed the rate of their occurrence at between 10 and 20% of doses administered (Keers, Williams, Cooke, & Ashcroft, 2013). The vast majority of these errors cause no patient harm; about half, in fact, are timing errors. In 2006 the IOM published *Preventing Medication Errors*, in which the authors assert that significant confusion exists on the definition of a medication error. The IOM report asserts that medication errors can be so broadly defined as to include any variance in the intended use of medications ranging from their procurement by a hospital to the monitoring of the medication's effects.

The IOM (2006) defines "medication-related harm" as any physical, mental or functional injury due to the use of medication (page 37). Two familiar examples of medication-related harm are unexpected gastrointestinal bleeding in a patient taking aspirin for management of osteoarthritis symptoms and muscle pain in a patient taking a statin drug. In hospitals, common examples of medication-related harm would include skin rashes and mental confusion (IOM, 2006). From the patient's perspective, errors are not the problem; harm is the problem.

Problem Statement and Project Purpose

Patient safety has been defined as the absence of preventable injury (harm) due to healthcare activities (IOM, 2000). Thus it logically follows that medication safety is concerned with the prevention of medication-related harm. The purpose of this project was to produce a more accurate assessment of medication-related harm at the level of the community hospital, to do it efficiently, and to do it in a way that can be replicated by others. The accurate and complete assessment of rates and types of medication-related harm in hospitalized patients is foundational to quality improvement efforts. Additionally, a plan to improve hospital medication safety is required by law (CA Senate Bill 1875, 2000). In hospitals, the methods in use (incident reports, direct observation, chart review and trigger tools) for assessment of medication-related harm paint an inconsistent and incomplete picture (Meyer-Massetti et al., 2011). Meyer-Massetti (2011) observed that expedient methods (incident reports, in particular) are often used as assessment tools and much harm is missed.

In this hospital, incident reports are for practical purposes the only data source used for assessment of medication-related harm, and yet they rarely describe harm. In the author's experience analyzing these reports over many years, the most commonly reported issues pertain to problematic nursing workflow (related to medication use). For example, a nurse might need a

first dose of medication from pharmacy, and have to call several times to determine when the dose will be ready. In another example, discrepancies in use of controlled substances are required to be (and frequently are) reported. In this hospital, only 14% of incident reports submitted during the calendar year 2012 described any level of patient harm (such as rashes, oversedation or mental confusion). This hospital's incident reporting process does incorporate a nationally recognized nine-point scale to describe levels of patient harm associated with medication use (NCC-MERP, 2008).

Second, the incident reporting system in the author's hospital was apparently not ideally designed (it was built by the hospital in 1998, before the California legislation) to support the development of a medication safety plan. For example, the electronic incident reporting form only specifies seven different therapeutic classes of medications (narcotics, cardiovascular drugs, antibiotics, anticoagulants, electrolytes, insulin, chemotherapy drugs and "other"). The result of this design is that in 2012, the incident reporting system identified "other" as the therapeutic class of medication most commonly associated with harm (29% of harmful events). "Other" is a class that is not helpful in developing a medication safety plan. To cite one example, statin drugs can cause significant harm (muscle tissue breakdown and mental confusion) in hospitals (Sharma et al., 2009). This hospital would not easily be able to detect statin harm using incident reports since a statin drug would be classified as "other." By comparison, the method adapted (Lucado, Paez & Elixhauser, 2011) for the DNP project identifies 17 different therapeutic classes of medications and would classify a statin drug as an "antilipemic," which is much more precise.

In an effort to conduct a more accurate and complete assessment of medication-related harm and contribute to the development of an effective medication safety plan, this project adapted the methodology of a study of medication-related harm at the national level (Lucado,

Paez & Elixhauser, 2011). The study (Lucado, Paez & Elixhauser, 2011) is described in this paper as having been adapted by the author (as opposed to replicated), because the study also examined medication-related harm in hospital outpatients. This project's scope is limited to the population of hospital inpatients. The methodology in the national study produced an accurate assessment of medication-related harm; the author adapted the methods of the national research study to the study of medication-related harm at the community hospital level.

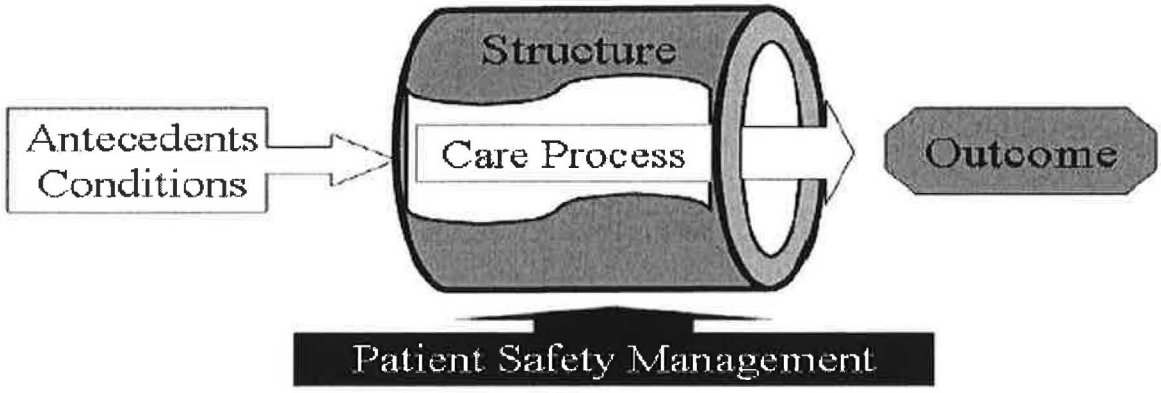
Project

The DNP project explores a novel approach to the assessment of medication-related harm in hospitalized patients at the community level. The essential feature of the DNP project is the use of International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) codes abstracted from patients' electronic medical records (EMR) to identify medication-related harm in hospitalized patients, providing a more complete assessment of harm. The ICD-9-CM system assigns alphanumeric codes to medical diagnoses; this methodology of abstraction and analysis of medical records coding using the world's most widely accepted taxonomy of disease and injury has been used internationally for many years (McKenzie, 2009). In fact, use of this taxonomy is the only feasible way to assess the medication-related harm of nearly 40 million U.S. inpatients in a single study, as was done by the Healthcare Cost and Utilization Project (HCUP), a branch of the U.S. Department of Health and Human Services Agency for Health Care Research & Quality (AHRQ) in 2004 and 2008 (Lucado, Paez & Elixhauser, 2011). This (Lucado, Paez & Elixhauser, 2011) study is the one that was adapted for use in the project; it will be referred to often in this paper as the HCUP study. The DNP project utilizes the methods of the (national) HCUP study to assess medication-related harm in the (local) community hospital.

Theoretical Framework

This project is guided by Donabedian's Theory of Quality Health Care, a complex theoretical framework proposed in 1965 by Avedis Donabedian (2005). The Theory of Health Care Quality is grounded in systems theory (Papakostidi & Tsoukalas, 2012) as well as in Parson's Theory of Social Action (Dubois, D'Amour, Pomey, Girard, & Brault, 2013). Donabedian's eventual (1980) patient safety model (adapted from the Theory of Quality Health Care) is graphically depicted (Figure 1) as a system comprising antecedents and conditions (becoming care processes) within a structure, linked by a unidirectional arrow moving toward an outcome (Donabedian, 1980).

Figure 1. Donabedian model of patient safety, Adapted from Donabedian, 1980.



Quality is the central construct in Donabedian's theory, although he does not specifically define this term (Mark, 1995). Donabedian's perspective relative to social action can be found in his assertion that health care practitioners have a responsibility to improve quality (1987), including the identification of sources of poor quality.

Donabedian (1987) proposed the evaluation of three domains in health care quality: structure, process and outcome (Donabedian, 2005). Donabedian's theory asserts that patient

outcomes are the result of both health care resources (structures) and of the processes (the ways in which the resources are utilized). Thus if one desires to change an outcome, one must change something about the process of care and/or the resources used to provide the care. For example, the structures related to medication use in hospitals include the medications approved for use and the level of physician, pharmacist and nurse staffing available to prescribe, dispense and administer medications. The process of medication use includes the use of various prescribing pathways such as the electronic, handwritten or verbal transmission of medication orders and the hospital-specific policies and procedures in place governing medication use. Outcomes of medication use include both (intentional) control and cure of illness as well as unintentional injury (IOM, 2006).

The Donabedian framework was highly influential in the development of the Joint Commission's method for evaluating the quality of hospital care (Larson & Muller, 2002). Donabedian's Theory of Quality Health Care has come to be used extensively in the evaluation of medical quality (Wübker, 2007) and nursing services (Kobayashi, Takemura, & Kanda, 2011).

The Donabedian (2005) framework was useful in the development of the DNP project in at least three important ways. First, it is a simple model that helps organize complex phenomena related to the different phases of the medication use process. For example, a hospital's drug formulary can be considered part of the *structure* of medication use. The drug formulary in this hospital lists more than 3000 items. Patterns of prescribing and administration methods can be considered parts of the *process* of medication use, and patient harm is an example of an (undesirable) *outcome* (of the medication use process).

Second, the model is useful in maintaining the focus of improvement efforts on the process (of medication use) rather than on the *people* using the care process. This focus is

consistent with the viewpoint of Dr. Lucien Leape of Massachusetts General Hospital, an eminent patient safety researcher, that patient safety is about interprofessional relationships and that the single greatest obstacle to patient safety is punishing caregivers for making mistakes (Buerhaus, 2007). The Donabedian (2005) model facilitates promotion of the concept that process improvement is the best method for producing more favorable patient outcomes. The focus on process rather than people is important to the development of a safer, fairer, and more just healthcare culture (Frankel, Leonard, & Denham, 2006). The primary goal of this project is a more accurate assessment of medication-related harm. A secondary goal is that care providers of diverse disciplines will collaborate with a focus on fixing medication use systems and not blaming others (or themselves) for errors and harm; use of the Donabedian model facilitates achievement of both goals.

Third, the framework reminds the clinician that they have a (social action) responsibility to improve quality, and to act on their knowledge (Donabedian, 1987), (Dubois, D'Amour, Pomey, Girard, & Brault, 2013).

Review of Relevant Literature

To establish a foundation for this project, the author explored recent literature on three topics relevant to the issue of medication-related harm. First, on the scope and significance of medication-related harm. Second, on the various methods of assessment of medication-related harm currently used in hospitals. Lastly, on the use of ICD-9-CM coding for the identification of medication-related harm.

Scope and Significance of Medication-Related Harm

In its landmark work *To Err is Human: Building a Safer Healthcare System*; the IOM (2000) called attention to the unacceptable levels of harm and death associated with medical

errors in hospitalized patients. This study demonstrated that medical error contributed to the deaths of 44,000 to 98,000 hospitalized patients annually in the U.S. In the (2000) IOM report, patient safety was framed as an important public health issue; the authors estimated that if medical error were considered as a single cause of death of Americans, it would fall somewhere between the fifth and eighth leading causes. The IOM followed the *To Err is Human* report with another work in 2001 entitled *Crossing the Quality Chasm: A New Health Care System for the 21st Century*. In this work, the IOM estimated that at least 7000 patients annually die in hospitals due to medication errors. The most current work of the IOM (2007) estimates that at least 400,000 harmful medication-related events occur annually, costing hospitals an estimated $3.5 billion.

Medication errors are quite common in the hospital setting. A systematic review of the prevalence and nature of medication errors in hospitals using direct observation revealed that when timing errors are included in the assessment, almost 20% of medications were given in error; when timing errors were excluded from the assessment about 10% of medications were given in error (Keers et al., 2013). In this community hospital, approximately 5.1 million doses of medications were administered in 2012 (Sandoval, 2014). Using the methods of Keers, et al., (2013), up to one million doses may have been subject to erroneous administration of some type. Keers' systematic review, considered by its authors to be the first of its kind, examined 91 unique medication error studies. Keers et al. found that half of medication errors observed in hospitals would cause no harm; these errors were "created" by policy definitions. For example, a medication given more than 30 minutes after the prescribed time would have been described as an administration (timing) error.

Medication errors are not solely responsible for medication-related harm; harm occurs even when the medications are properly used (Classen, Jaser, & Budnitz, 2010). Since so many hospitalized patients are treated with medications, it is not surprising that medication-related harm has been found to be among the most prevalent forms of nosocomial injury (Brennan et al., 2004). In the Brennan et al. study, most medication-related harm was traced to adverse reactions (such as allergies) that were not preventable.

A study by the Office of the Inspector General found that medication-related harm made up 31% of all harm experienced by hospitalized Medicare beneficiaries (Levinson, 2010). The types of harm most commonly identified in the study were bleeding, altered mental status, and hypoglycemia. The therapeutic classes of medications found associated with the most commonly identified types of harm were anticoagulants (with bleeding), opioids (with altered mental status), and insulin (with hypoglycemia).

Methods of Assessment of Medication-Related Harm

The science of assessment of medication-related harm in hospitals is relatively young. Two recent systematic reviews examined for this project were described as the first studies of their kinds: Keers et al. (2013) and Meyer-Massetti et al. (2011). Systematic reviews can produce some of the strongest evidence supporting a practice position (Melnyk & Fineout-Overholt, 2011). Both systematic reviews were helpful to this project's development in different ways.

The Keers study initially identified over 20,000 articles related to medication errors, narrowing the research studies to a final 91 studies that utilized direct observation to identify prevalence and typology of medication-related errors including administration timing errors. Keers et al. found that up to 20% or medications are given in error when timing errors are

included. The Keers study findings indicated that when timing errors are excluded, the prevalence of medication errors ranges between 6-10%, the most common non-timing error was an omitted dose. The Keers study was important to this project in understanding medication error prevalence and typology, in the knowledge that most errors do not cause harm, and in learning that although direct observation was the most accurate method of assessing error, it was difficult and impractically expensive to assess medication-related harm by this method.

The Meyer-Massetti study was important to the authors' DNP project for several reasons. First, the methodology of the study was a systematic review of more than 2100 studies of assessment of medication-related harm. One inclusion criterion for the final 28 articles in the Meyer-Massetti et al. (2011) study was the use of one of four accepted main methods of (hospital) medication harm assessment: incident report review, direct observation, trigger tool review, and medical record review. Another inclusion criterion was a comparison of at least two of the methods with respect to efficiency and accuracy. The reader may not be familiar with the term "trigger tool"; it is the use of a marker, or trigger, to identify an antecedent event (Carter, 2010). A common example of a trigger is the identification of an administered dose of opioid reversal agent (Narcan®) to signal the antecedent opioid overdose.

The second reason the Meyer-Massetti et al. (2011) study was important to the authors' DNP project was that the study was conducted in California. California is the only state in the U.S. to require as a condition of hospital licensure, according to legislation (CA Senate Bill 1875, 2000) enacted over a decade ago, a plan to "eliminate or substantially reduce medication-related errors." The law requires that methods of assessment of medication-related harm in hospitals be "objective, relevant and able to inform policy and decision makers' efforts to reduce medication-related errors."

A third reason this study was important was its interdisciplinary nature. The study involved collaboration among nurse, physician, and pharmacist researchers in San Francisco and Switzerland. As previously stated, the study identified four principal methods of assessment of medication-related harm in hospitals. Each of the principal methods has several subtypes. For example, video recording is a subtype of direct observation, and use of ICD-9-CM coding is a subtype of medical record review. The subtypes were not discussed in the study. This is an important point: the use of ICD-9-CM coding to identify medication-related harm (in the hospital setting) is novel. Each of the four methods of assessment reveals different types of harm with varying degrees of efficiency and accuracy, and there is little overlap in utility between methods. Each method is briefly discussed here.

Incident report review. Incident report review was consistently found to be the most common method used and the least likely to identify medication-related harm, although when it did detect events, the accuracy was superior to the other methods. Incident report review was relatively efficient, requiring less time than either medical record review or trigger tool review. One important limitation of incident report analysis is the tendency of physicians not to utilize this modality (Eckman & Bäckström, 2009); the vast majority of hospital incident reports involving medication-related adverse events (including harm) are submitted by nursing staff.

According to Eckman and Backstrom (2009), physicians feel that incident reporting is duplicative because they already document harm in the medical record. It is precisely this physician-documented harm that is coded using the ICD-9-CM taxonomy.

Direct observation. Direct observation yielded the greatest number of events of any of the methods. Its accuracy was good, but the method is relatively expensive. Direct observation

methods utilize trained observers, typically nurses, pharmacists, and physicians, to witness and document instances of patient harm in the clinical setting (Meyer-Massetti et al., 2011)

Trigger tool review. Trigger tool review (the use of a separate indicator to identify a potential episode of medication-related error or harm) was found to be the most accurate method overall, but not very time-efficient. Thus only a small sample of charts can be audited using this methodology. Typically, trigger tool-assisted audits sample 20-25 charts per month (Classen, et al., 2008), because the recommended method requires an interprofessional team for review.

Medical record review. Medical record review consistently yielded high rates of identification of medication-related harm. The accuracy of medical record review was good, second only to incident report review. The method was judged to be labor intensive, second only to direct observation in this respect. As with direct observation and trigger tool review, effective medical record reviews are conducted by interprofessional teams (nurse, pharmacist, physician), but assembling and coordinating the activities of these teams is difficult and expensive.

Use of ICD-9-CM Coding to Identify Medication-Related Harm

The use of ICD-9-CM coding was not discussed in the Meyer-Massetti et al. (2011) systematic review because it has not typically been used at the community level, but it has been used in studies of larger populations, as in the HCUP (2011) study. This method is a subtype of medical record review and involves the examination of medical records using ICD-9-CM coding. It is recognized as a form of data mining, an emerging applied science utilizing computers and software to search for meaningful patterns in large data sets (Page, 2010). Identification of patient harm utilizing coding is a specialized form of medical record review that can be automated to improve efficiency. The hospital in which the author practices discharged 21,897 inpatients during the calendar year 2012, and using ICD-9-CM coding review methods these data

can be abstracted in a few minutes once the programming is complete. Analysis of the data and development of improvement plans will generally take a bit longer! Once completed, the programming requires only periodic maintenance as new ICD codes are added. It should be noted that the ICD-9-CM taxonomy is being replaced in 2014 by the newer ICD-10-CM taxonomy. The usefulness of ICD-9-CM coding in identifying patient harm during hospitalization has been recognized for at least 20 years (Langlois, Buechner, O'Connor, Nacar, & Smith, 1995). In a systematic review of the accuracy of ICD-9-CM coding (McKenzie, 2009), the method was found to have between 64% and 85% accuracy in identifying medication-related harm.

The Agency for Healthcare Research and Quality (AHRQ), an arm of the U.S. Department of Health and Human Services, has a stated mission of improving the quality, safety, efficiency, and effectiveness of healthcare for all Americans (AHRQ, n.d.). One of the identified areas of AHRQ's expertise concerns production of information on the cost and utilization of healthcare resources. Research in these areas is conducted by the Health Care Utilization Project division of AHRQ, known by its acronym HCUP. HCUP maintains the largest all-payer collection of hospital inpatient care statistical information in the United States (AHRQ, 2013). One of the data sets utilized by HCUP is the nationwide inpatient sample (NIS), which contains information about 95% of the inpatient stays in the U.S. The AHRQ makes this sample available to researchers at a nominal cost through the HCUP website (AHRQ, 2013).

In both 2004 and 2008, researchers at HCUP used ICD-9-CM coding to identify medication-related harm in the nationwide inpatient sample (Lucado et al., 2011). The research produced interesting findings. First, the researchers found medication-related harm in 4.7% of all inpatient stays (1.9 million of 39.8 million total stays in 2008). Second, they noted that in the

five years between 2004 and 2008, the incidence of medication-related harm (measured using the same methodology in 2004 and 2008) increased by 52%. Third, in the inpatient setting, corticosteroids such as prednisone were found to have caused the greatest percentage (16.1%) of all harmful events. Other classes of medications found to commonly cause harm were analgesics (especially opioids) at 12.5% and agents that affect blood constituents (especially anticoagulants) at 11.6%. As a medication safety professional, the author wondered if the HCUP study methodology could be replicated at the local community hospital level, and this replication became the basis for the DNP project.

Methods

The author developed a plan that, in the setting of a community hospital, adapted the methodology of the national HCUP study of medication-related adverse events (Lucado et al., 2011). Because the original study was conducted under the auspices of AHRQ, it was taxpayer-funded and the procedures and tools were offered without fee to other researchers for use with other populations. Whereas the HCUP study utilized the entire nationwide inpatient sample, this project was conducted in a single community hospital.

Project Design

This study is retrospective and descriptive. The number of ICD-9-CM codes that currently exist is about 13,500, and approximately 500 of these codes describe medication-related harm (Lucado et al., 2011). The DNP project utilized a retrospective examination of the coded medical records of patients discharged during the calendar year 2012. The retrospective design was necessary because coding of medical records cannot begin until the patients have

been discharged (either alive or dead) from the hospital, and this process usually takes 10 to 14 days.

Performing a descriptive, retrospective analysis at the hospital level was attractive to the author for two reasons. In the first place, the data, although abstracted retrospectively, were relatively current. Analysis of this type with current "real-time" data is something that national-level research is unable to achieve for any specific hospital. The HCUP study, for example, was published in April 2011 using analysis of calendar year 2008 data. Second, the results produced in this project were specific to the local community hospital. In the nationwide inpatient sample, the most prevalent type of medication-related harm related to the use of corticosteroids. The prominence of corticosteroid-related harm may or may not have been the experience of each hospital in the HCUP study and therefore may not be the best focus of every hospital's medication safety improvement efforts. Each hospital has its own medication use structures and processes and, consequently, its own outcomes. The DNP project is designed to reveal the pattern of medication-related harm specific to a particular hospital.

Setting

This study was conducted in a large general acute-care community hospital in California. The hospital has a licensed capacity of over 500 beds; the average daily census is approximately 400 patients. The hospital provides most acute-care services including cardiac surgery, acute rehabilitation, and inpatient mental health services. This is a teaching hospital, with residents in family medicine, emergency medicine, pharmacology and nursing.

Population and Sample

All closed medical records of patients staying at least one night in the hospital during the calendar year 2012 were included in the study. Only medical records of patients discharged from

the hospital were included in the study; again, this is because completion of the coding process requires a period of 10-14 days following discharge. In some hospitals, but not in the study hospital, a concurrent medical records coding process is employed (medical records are coded while the patient is still hospitalized). This would at least in theory facilitate the discovery of medication-related harm during the patients' hospital stay, when prompt corrective action could be taken. The number of inpatient discharges in calendar year 2012 from the community hospital totaled 21,897; this number represents the entire population of interest. Another advantage of this study methodology is its capacity to examine the entire population (as opposed to a sample of that population) thus eliminating the possibility of sampling error.

Data Collection

The DNP project utilized one calendar year (2012) of community hospital data. The data, which consisted of electronic medical records containing ICD-9-CM codes, were archived in a data warehouse accessible by authorized hospital staff. Approvals of the Institutional Review Boards of both the hospital and the (DNP) university were obtained, permitting the author to proceed with the project. The author did not access the medical records data directly, but partnered with an internal information technology specialist employed in the hospital's Decision Support department. The author supplied the free query tools (a list of ICD-9-CM codes made available to the public on the HCUP website), and the technology specialist developed the data warehouse query from these tools. The author was given access to a secure web-based interface enabling him to perform queries of the data warehouse as desired. The electronic medical records were queried and 263 codes, each representing one instance of medication-related harm, were abstracted. These data were exported to Microsoft Excel© for analysis.

Data Analysis

To remain consistent with the data analysis methodology in the HCUP study, a simple overall percentage of harmful events and percentages of events stratified by therapeutic class of medication were calculated. The results were displayed in a tabular fashion and a comparison was made with the results from the HCUP study.

Ethical Considerations

The Institutional Review Boards of both the study hospital and the university overseeing the DNP program approved this study prior to initiation of the data collection. The primary concerns of the hospital regarding protection of human subjects in this study were the privacy and security of the electronic medical records information. Privacy and security were assured by storing all study-related data in a password-protected electronic folder; only the author and the hospital Director of Nursing Practice have access to the folder. The data will be destroyed after the results of the study are presented to the hospital Institutional Review Board 12 months following approval (June 2014).

Another ethical consideration was that if high levels of medication-related harm were to be found, the reputation of the hospital might be negatively affected. It was conceivable that if high levels of harm were to be identified and published, the information might attract the attention of regulators. For this reasons, the hospital is not identified with greater specificity than the fact that it is located in California and its approximate number of licensed beds.

Bias

Owing to the design of the study the effects of investigator bias on the results of this study were negligible, if any. The data of interest were electronically abstracted from closed medical records using a method very similar to that of the HCUP study. The data coded in these records were not subject to manipulation; they could only be abstracted and analyzed. Of course,

the documentation of medication-related harm by physicians probably reflects some bias, but any such bias would be speculation on the part of the author. It is possible, for instance, that a physician who made a prescribing error would neglect to document resultant harm that might bring negative attention to the prescriber. It is also possible that a physician might perceive harm as either unavoidable or trivial and decide not to document that harm.

Summary of Results

In this study, 293 instances of physician-documented medication-related harm represented by ICD-9-CM codes were abstracted from 21,897 closed medical records of inpatients discharged during the calendar year 2012. This number represents an overall incidence of harm of 1.33%. This is approximately one third the 4.7% incidence of medication-related harm demonstrated in the HCUP study (Lucado et al., 2011).

Statistics and Data Analysis

Replicating the methodology of the HCUP study, several types of cases were excluded from data analysis once the ICD-9-CM code data were abstracted from the electronic medical record. These cases include events where there is evidence of accidental or purposely self-inflicted drug overdose and where drug poisoning by illegal substances was evident (such as heroin, cocaine, and hallucinogens).

The data were analyzed utilizing simple descriptive statistics and a side-by-side comparison with the HCUP study. The objective of the analysis was to calculate the ranked percentages of medication-related harm per therapeutic class of drug.

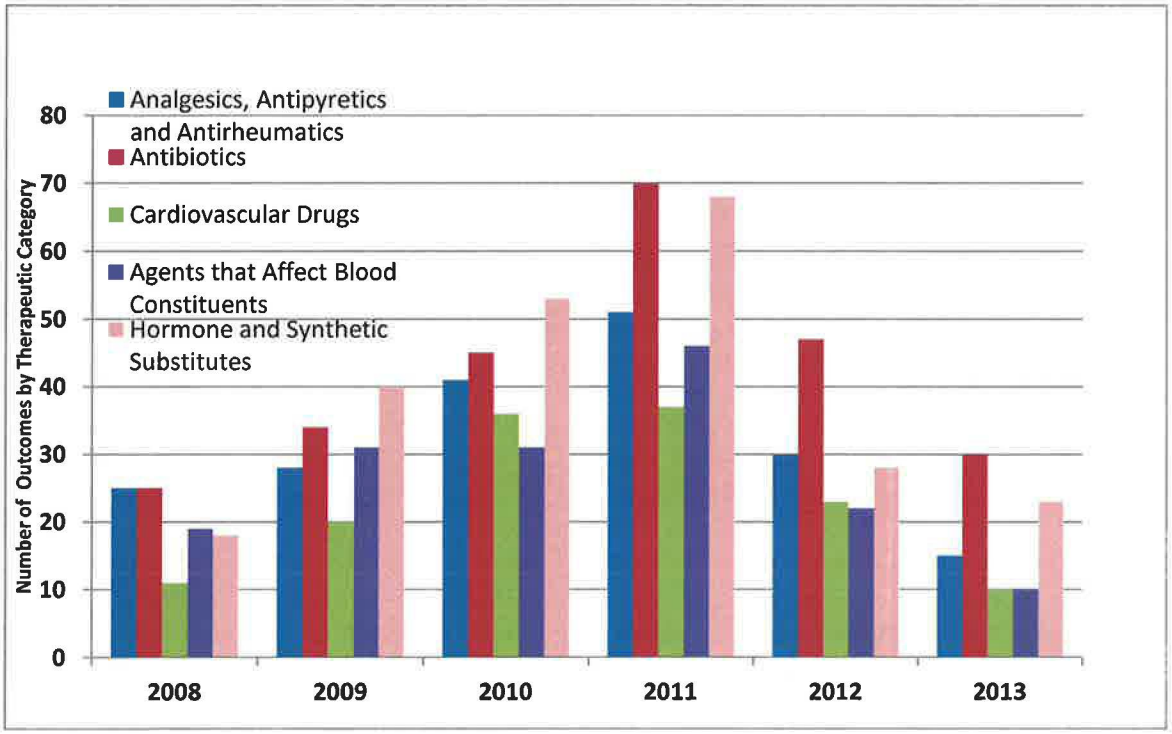
Table 1 compares the ranked causes of medication-related harm by drug class for inpatient stays at the study hospital with the percentages of harm by drug class found in the (2008) nationwide inpatient sample.

Table 1. Percentage of Medication-related Adverse Outcomes, 2012 Hospital Cases vs. 2008 HCUP National Cases

Therapeutic Class	Hospital Cases	2012 Hospital Case Percentages	2008 HCUP National Percentages
Antibiotics	44	16.7	6.1
Other and unspecified drugs	42	16.0	6.9
Analgesics, antipyretics and antirheumatics	30	11.4	12.5
Hormone and synthetic substitutes	26	9.9	16.1
Cardiovascular drugs	23	8.7	8.9
Sedatives and hypnotics	21	8.0	3.1
Agents that affect blood constituents	21	8.0	11.6
Psychotropic agents	16	6.1	5.4
Water, mineral, and uric acid metabolism drugs	13	4.9	5.2
CNS depressants	10	3.8	1.2
Systemic agents	5	1.9	10.9
Drugs affecting the autonomic nervous system	4	1.5	1.5
Agents acting on smooth and skeletal muscles	3	1.1	0.8
Other anti-infectives	2	0.8	1.7
Anticonvulsants and anti-Parkinson drugs	1	0.4	0.4
Agents affecting the gastrointestinal system	1	0.4	0.4
Agents affecting skin, mucous membranes, eye, ENT, and dental	1	0.4	0.4
Total overall harm incidence	263	1.33%	4.7%

At the time this project was conceived, the author did not realize that it was possible to abstract ICD-9-CM codes from the closed medical records of not only patients discharged in 2012, but also patients discharged from 2008 to 2013 inclusive. Upon this discovery, the author constructed a chart displaying annual events of medication-related harm by the five most common drug classes for this 6-year period (Figure 2).

Figure 2. Hospital-level medication-related adverse outcomes, 2008-2013.



Study Results

The overall incidence of medication-related harm in 2012 found in the study was 1.33%, about one third the rate of harm in the HCUP study of the nationwide inpatient sample (4.7%). In the HCUP study, the top three therapeutic classes of medications associated with medication-related harm were hormones and synthetic substitutes (16.1% of all medication-related harm), analgesics (12.5% of harm), and agents that affect blood constituents (11.6% of harm). These national results roughly compare to the local hospital results with one exception. In the hospital results, the top three therapeutic classes of medications causing harm were antibiotics (16.7% of harm), analgesics (11.4% of harm), and hormones and synthetic substitutes (9.9% of harm).

Discussion of Results

The difference between national and local results illustrates the uniqueness of rates and types of medication-related harm to specific hospitals. The existence of these differences further strengthens the need (for improved methods of measurement) to accurately assess these outcomes at the hospital level as opposed to relying on national averages. The implications for local medication safety professionals are important. For example, if this hospital were to consider only national-level data, the organization would direct medication safety improvement efforts at the prevention of harm due to hormones and synthetic substitutes such as corticosteroids. The hospital would in effect "chase" harm that would be incorrectly prioritized. In fact, this hospital should direct more efforts at the prevention of antibiotic-related harm, such as infections related to the emergence of antibiotic-resistant organisms.

Differences between national and local results. There are two important differences in results between the national study and the local study. First, the local incidence of medication-related harm is only about one third the national average, and second, antibiotic-related harm is much more prevalent at the local hospital than at the national level. Donabedian (2005) considers the resources (structure) that an organization has at its disposal, the ways those resources are used (process) and the results achieved (outcome).

The HCUP study produced a measurement of national averages of rates and types of medication-related harm, but just what is an "average" hospital? Hospitals across the country number more than 5,700 (AHA, 2014). Using the Donabedian model, hospital location, type and size would be considered structural characteristics. According to the American Hospital Association (2014), U.S. hospitals may be located in urban or rural areas, may be operated for profit or not-for-profit, and may range in bed size from less than a dozen to more than 1700.

These hospitals undoubtedly differ significantly in the characteristics of the patient populations they serve. Assessments of national averages of harm may not be useful in developing strategies to prevent harm at the level of a particular hospital, because no particular hospital's performance is likely to match the national average. Any particular hospital is likely to demonstrate patterns of harm that are better, worse or different than the national average.

Once a physician has documented an instance of medication-related harm, the next step in producing data is coding of the medical record. In Donabedian's model, coding would be considered a process variable. It is possible that lower staffing levels of coding staff or inferior skills of the coding staff of the study hospital could explain the reduced number of codes representing medication-related harm, but the author has effectively ruled these conditions out as likely causes. It was explained (Sipunu, 2014) to the author that the hospital assures accurate medical records coding using three principal methods. First, the hospital benchmarks its units of service with respect to the staffing levels of coding personnel against national utilization benchmarks; the levels of coding staff in the hospital are not different from national benchmarks. Second, the hospital employs nationally certified medical records coders whose level of expertise is comparable to others across the nation. Third, samples of coded medical records are randomly selected each month and a second-level review is performed for the specific purpose of assuring accurate coding. The results of these practices are a consistent coding accuracy on 95%-95%, which is consistent with industry standards.

Far more likely explanations of the difference in results are differences in hospital patient demographics and differences in the supply of physicians at national and local levels. For example, in the local hospital over 20% of inpatient stays are related to childbirth. Across the nation only 10% of hospitalizations are related to childbirth (Centers for Disease Control and

Prevention, 2011). Young mothers, in comparison to other hospitalized patients, tend to be relatively healthy, take fewer medications, have shorter lengths of stay, and experience fewer episodes of medication-related harm. In fact, these patients have so few adverse events related to medication use that they are often excluded when patterns of medication-related harm are studied (Samore, et al., 2004). Therefore, hospitals with a greater percentage of admissions due to childbirth might be expected to have comparatively fewer documented episodes of medication-related harm.

Additionally, physicians (and not other health care workers) must document medication-related harm in the medical record before it can be coded and quantified, and the study hospital region is significantly underserved with respect to physician services. According to the California Health Care Foundation (2009), the number of specialty physicians per 100,000 persons in the U.S. is 140 whereas the number of specialty physicians per 100,000 persons in the local hospital region of California is 74, only slightly more than half the national average. Similar patterns are found when levels of primary care practitioners in the nation and the local region are compared. In the local hospital, specialty physicians (cardiology, oncology, nephrology, gastroenterology, orthopedics, and infectious disease specialties) typically care for most hospitalized patients and document any medication-related harm. A smaller number of hospitalized patients are admitted and cared for by primary care physicians (family medicine, internal medicine, and women's health specialties), but the bottom line is that if the physicians are not available, the documentation and eventual coding are not likely to be present either.

Regarding the differences in the levels of demonstrated harm per therapeutic class of medications, again there are plausible explanations, although the link between these explanations and the outcomes may be weaker. At the local hospital level, antibiotics were implicated in the

largest number of events. The local hospital has two infectious disease specialty physicians on staff, one of whom is the medical director of the pharmacy and therapeutics committee and also acts as the chair of the medication safety committee. This physician is perceived to be meticulous and thorough in his documentation behavior; it is possible that his exemplary behavior in this regard drives an observed difference in results. Patient demographics also are likely to be a factor. The region serves a population with a very high prevalence of diabetes; predisposition to infections and overuse of antibiotics might help explain the results.

Incidence patterns. A finding that was unplanned but interesting was an observed longitudinal pattern in the incidence of medication-related harm. The ability to query the data warehouse for ICD-9-CM codes enabled the author to include a broader date range than initially planned (from 2008-2013) in a separate query. The results (Figure 1) demonstrated a pattern of annual increases in the incidence of medication-related harm from 2008 through 2011 with a decline in incidence after 2011 through 2013. The information gained from the novel assessment method has provided the hospital a clearer picture of the harm its patients experience and promoted interprofessional collaboration and some interesting discussions. For example, the "credit" for reducing the observed incidence of medication-related harm has been variously "claimed," in a good-natured manner, by the departments of medicine, pharmacy, and nursing.

Indeed there have been significant changes in the medication use process at this hospital between 2008 and 2013. Most importantly, a technology shown to have significant medication safety benefits (Simon, Keohane, Amato, Coffey Cadet, Zimlichman & Bates, 2013) was introduced to the hospital in 2010. This technology, termed Computer Prescriber Order Entry or CPOE works by changing the way medications are ordered by prescriber. The prescriber enters his or her order directly into a computer system integrated with the electronic medical record,

thus eliminating errors due to illegibility, transcription by nurses and pharmacists, and taking advantage of decision support tools in the electronic medical record. Also in 2010, a technology known as Bar Code Medication Administration or BCMA was introduced. This technology has also been shown (Seibert, Maddox, Flynn & Williams, 2014) to significantly reduce medication errors in the hospital setting. BCMA works by warning the bedside clinician (via scans of patient identification and medication barcodes) that he/or she might be about to administer a medication in error. The implementation of these new medication safety systems might at least partially explain the observed decline in the incidence of medication-related harm since 2011, but prior to the results of the DNP project the hospital had no perspective on the outcomes produced by these technologies.

Limitations of the Study

The chief limitation of this study is that the creation of the data of interest relies on the knowledge, vigilance, and, as previously discussed, the simple presence of human beings. In order for the author to have detected an episode of medication-related harm, four things need to have happened. First, the actual harm had to occur. Second, the harm had to have been documented in the medical record by a physician. Third, a member of the medical records coding staff must have read the physician documentation, interpreted the documentation as medication-related harm, and assigned the incident the correct alphanumeric (ICD-9-CM) code. Fourth, the electronic query must have identified the code and abstracted it from the medical record where the author could analyze it.

Another important limitation of this study is the difficulty in generalizing the results from this organization to any other organization. The results of this study should be used only to improve medication safety in this hospital. Because of differences among healthcare

organizations in culture, definitions of error and harm, patient populations, and reporting/detection methods, the use of medication error data to compare organizations (benchmarking) is of no value (National Coordinating Council, 2008). There is no acceptable rate of medication-related harm in an organization; the goal of any healthcare provider should be zero harm. Knowing that the comparison of medication error data across organizations is of little benefit is important; without this understanding, an organization's medication safety practitioner may feel pressure from both within and outside the organization to "benchmark" against other organizations. If in the future, healthcare organizations are able to achieve standardization in terms of at least definitions of error and harm and reporting detection methods, the results of this project will facilitate comparison and benchmarking.

Lastly, this study was limited to the inpatient population, although the HCUP (2011) study addressed both inpatient and outpatient (primarily emergency department) populations. The author is interested in the outpatient population as the community hospital treats over 80,000 emergency department patients annually (Kaweah Delta, 2014). The assessment of the emergency department population was not feasible during the DNP project period.

Implications for Nursing Practice

The American Nurses Association (2014) defines nursing as "the protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response, and advocacy in the care of individuals, families, communities, and populations" (What is Nursing? para.1). By helping produce a more accurate assessment of medication-related harm, this project enables nursing leaders in the community hospital to better protect patients, better prevent injury and more effectively advocate for the needs of the patients cared for.

Before the author completed this project, the hospital relied largely on anecdotal (incident) reports of problematic medication management and medication errors to form the basis of its medication safety plan. Few harmful events were detected by the methods in place prior to completion of the project. As a result, the hospital medication safety plan (ideally intended to reduce harm) included goals such as increasing the number of incident reports submitted and replacing outdated drug references. These goals were not derived from analysis of harmful events; they have little potential to decrease harm. This is not to say that the methods in place prior to the project should be rejected; they remain a source of information useful in the context of improving a comprehensive hospital medication management plan. The project methods should be adopted because they help complete the overall assessment of medication use by demonstrating specific instances of patient harm. We simple cannot take steps to prevent the harm that we are unaware of.

This project has made new knowledge available: a much more complete picture of medication-related harm in the hospital. The project's approach to the assessment of medication-related harm should be considered for adoption in community hospitals. As Donabedian has asserted (1987), a health care practitioner has a legitimate responsibility to apply available knowledge to improve the quality of health care. Now that there is an efficient and sustainable method for detecting medication-related harm, future medication safety goals can be more specifically directed at harm reduction strategies. The author will use this new process to improve the medication safety plan and help avoid future instances of harm. For instance, the knowledge that antibiotic-related harm is occurring in the community hospital at nearly three times the national rate is concerning, and will require urgent attention from the interprofessional medication safety team. "Armed" with more accurate, complete and current data representing

antibiotic-related harm, the author is in a stronger position to advocate for process change, such as improvement in antibiotic selection and stewardship.

Additionally, the more accurate and complete assessment of medication-related harm will facilitate the ongoing monitoring and evaluation of medication safety activities. It has been observed (Figure 2), that there is a recognizable pattern of medication-related harm in this hospital. For several years, a trend toward fewer harmful events is evident. Should this trend reverse itself, this project has enabled a method for early detection of that change. New data points (representing harmful events) are added monthly, and these data are now displayed as a component of the hospitals' medication safety "dashboard" monitoring plan.

This project provides the underpinnings of a platform that the medication safety professional can use to lead change in his or her local health care organization. As has been previously stated in this paper, an accurate assessment of the incidence and typology of medication-related harm is foundational to the development and success of specific medication safety strategies per individual hospital. Like any good patient care plan, no "one size fits all" organizational medication safety plan exists. This project helps an organization demonstrate (with evidence-based outcome measures) the degree to which its medication use process is safe. The medication safety professional can use this new knowledge to lead positive changes in the structure and process of medication use; this will lead to improvements in medication safety outcomes, most importantly a reduction of the incidence of medication-related harm.

Summary and Conclusion

This project was conceptually simple: Adapt the methodology of a national-level study of medication-related harm to use at the level of a single hospital. The project's results helped

produce a more accurate and complete picture of medication-related harm, and the project methods have been adopted in the author's hospital.

The application of the methodology used by the HCUP researchers at the local hospital level is novel; the method produces results that should be part of a comprehensive medication safety plan in every hospital. The method is accurate and efficient, and promotes interprofessional collaboration by "giving voice" to physicians' documentation of harm, often missed by traditional methods of assessing medication-related harm. Developing the ability to utilize the methodology in a hospital setting should be within the grasp of all but the most resource-challenged organizations. Once developed, the query tools perform satisfactorily with only small, infrequent updates necessary (excepting the looming conversion to the ICD-10-CM taxonomy).

The benefits of a study such as this to any hospital are significant. For many hospitals, examination of the ICD-9-CM codes attached to episodes of medication-related harm would produce the first systematic and repeatable method of collecting *outcomes* data related to medication safety. Hospitals have a wealth of information about their errors but scarce information about their harm; this state is sometimes characterized as being "data-rich and information-poor" (DRIP). This project produces data to be sure, but further processes these data and adds a critical new piece of information…"Your patient has been harmed." The efficiency and repeatability of the methodology make it useful for quality and patient safety management and monitoring. In hospitals practicing concurrent coding, the data can be available while the patient is still hospitalized, with near "real-time" speed.

A somewhat less tangible but potentially very important benefit of a study such as this is improvement in interprofessional relationships, particularly the relationship between physicians

and hospital leaders of diverse disciplines. Physicians do not typically submit incident reports, nor do they typically (as independent contractors) engage in other activities designed to assess medication safety in hospitals. What physicians do typically engage in is documenting their patients' conditions in the medical record (history and physical, progress note, consultation, and discharge summary, to cite a few examples), and this documentation frequently includes "stories" of medication-related harm. Physicians expect and trust that hospital leaders read these stories and act on the information. This project enables hospital leaders to do just that.

This project introduces a novel method that helps keep patient safety professionals focused on harm and not on error. Error is inevitable; harm is preventable. In the end, error is not the problem in patient safety; harm is the problem. This method utilizes an assessment approach that helps makes patients safer by helping practitioners develop quality improvement plans specifically targeted at reducing harm.

References

Agency for Healthcare Research and Quality. (n.d.). About us. Retrieved from http://www.ahrq.gov/about/index.html

Agency for Healthcare Research and Quality. (2013). *Healthcare Cost and Utilization Project.* (2013). Retrieved March 10, 2013, from http://www.hcup-us.ahrq.gov/

American Hospital Association (2014). Fast facts on American hospitals. Retrieved March 26, 2014, from http://www.aha.org/research/rc/stat-studies/fast-facts.shtml

American Nurses Association (2014). What is Nursing? Retrieved April 16, 2014 from http://www.nursingworld.org/EspeciallyForYou/What-is-Nursing

Brennan, T., Leape, L., Laird, N., Hebert, L., Localio, A., Lawthers, A., & ... Hiatt, H. (2004). Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *Quality & Safety in Health Care*, *13*(2), 145-152. doi:10.1136/qshc.2002.003822

Buerhaus, P. I. (2007). Is hospital patient care becoming safer? A conversation with Lucian Leape. *Health Affairs*, *26*(6), w687-w696. doi:10.1377/hlthaff.26.6.w687

California HealthCare Foundation. (2009). *Fewer and more specialized: A new assessment of physician supply in California.* Oakland, CA: Author. Retrieved from http://www.chcf.org/publications/2009/06/fewer-and-more-specialized--a-new-assessment-of-physician-supply-in-california

CA Senate Bill 1875. Chapter 816 (2000). Act to Add Chapter 2.05 to Division 2 of the Health and Safety Code, Relating to Health.

Carter, M. (2010). Measuring harm levels with the Global Trigger tool. *Clinical Risk*, *16*(4), 122-126. doi:10.1258/cr.2010.010031

Centers for Disease Control and Prevention. (2011). *Fast facts: Birth and natality.* Retrieved from http://www.cdc.gov/nchs/fastats/births.htm

Classen, D., Jaser, L., & Budnitz, D. (2010). Adverse drug events among hospitalized Medicare patients: Epidemiology and national estimates from a new approach to surveillance. *Joint Commission Journal on Quality & Patient Safety*, *36*(1), 12-21.

Classen D., Lloyd, C, Provost, L., Griffin, F., Resar, R. (2008). Development and evaluation of the Institute for Healthcare Improvement Global Trigger tool. *Journal of Patient Safety. 2008 Sep;4(3):169-177.*

Dubois, C., D'Amour, D., Pomey, M., Girard, F., & Brault, I. (2013). Conceptualizing performance of nursing care as a prerequisite for better measurement: a systematic and interpretive review. *BMC Nursing*, *12*(1), 7-26. doi:10.1186/1472-6955-12-7

Donabedian A. (1980). Explorations in quality assessment and monitoring: the definition of quality and approaches to its assessment. Ann Arbor , MI: Health Administration Press; 1980.

Donabedian, A. (1987). Some basic issues in evaluating the quality of health care. In L. T. Rinke (Ed.), Outcome measures in home care (Vol. I, pp. 3–28). New York: National League for Nursing. [Original work published 1976.]

Donabedian, A. (2005). Evaluating the quality of medical care. *Milbank Quarterly*, *83*(4), 691-729. doi:10.1111/j.1468-0009.2005.00397.x

Ekman, E., & Bäckström, M. (2009). Attitudes among hospital physicians to the reporting of adverse drug reactions in Sweden. *European Journal of Clinical Pharmacology*, *65*(1), 43-46. doi:10.1007/s00228-008-0564-9

Frankel, A. S., Leonard, M. W., & Denham, C. R. (2006). Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability. *Health Services Research*, *41*(4p2), 1690-1709. doi:10.1111/j.1475-6773.2006.00572.x

Institute of Medicine. (2000). *To err is human: Building a safer health system.* Washington (DC): National Academies Press.

Institute of Medicine. National Research Council. (2001). *Crossing the quality chasm: A new health system for the 21st century.* Washington (DC): National Academies Press.

Institute of Medicine. National Research Council. (2007). *Preventing medication errors.* Washington (DC): National Academies Press.

Kaweah Delta Medical Center (2014). Guide to services. Online, accessed April 8, 14 at http://www.kaweahdelta.org/Services/Inpatient-Services/Emergency-Department/Default.aspx

Keers, R., Williams, S., Cooke, J., & Ashcroft, D. (2013). Prevalence and nature of medication administration errors in health care settings: A systematic review of direct observational evidence. *Annals of Pharmacotherapy 2013*, *47*(2), 237-256.

Kobayashi, H., Takemura, Y., & Kanda, K. (2011). Patient perception of nursing service quality: An applied model of Donabedian's structure-process-outcome approach theory. *Scandinavian Journal of Caring Sciences*, *25*(3), 419-425. doi:10.1111/j.1471-6712.2010.00836.x

Langlois, J. A., Buechner, J. S., O'Connor, E. A., Nacar, E. Q., & Smith, G. S. (1995). Improving the E coding of hospitalizations for injury: Do hospital records contain adequate documentation? *American Journal of Public Health*, *85*(9), 1261-1265.

Larson, J. S., & Muller, A. (2002). Managing the quality of health care. *Journal of Health & Human Services Administration*, *25*(3), 261-280.

Levinson D. (2010). *Adverse events in hospitals: National incidence among Medicare beneficiaries* (Report No. OEI-06-09-00090). Washington, DC: U.S. Department of Health and Human Services, Office of the Inspector General.

Lucado, J., Paez, K., & Elixhauser, A. (2011). *Medication-related adverse outcomes in U.S. hospitals and emergency departments, 2008* (HCUP Statistical Brief #109). Rockville, MD: Agency for Healthcare Research and Quality.

Mark, B. A. (1995). The black box of patient outcomes research. The Journal of Nursing Scholarship, 27(1), 42.

McKenzie, K. (2009). Accuracy of external cause-of-injury coding in hospital records. *Injury Prevention*, *15*(1), 60-64.

Melnyk, B., & Fineout-Overholt, E. (2011). Evidence-based practice in nursing and healthcare: A guide to best practice (2nd ed.). Philadelphia, PA: Wolters Kluwer Health.

Meyer-Massetti, C., Cheng, C. M., Schwappach, D. B., Paulsen, L., Ide, B., Meier, C. R., & Guglielmo, B. (2011). Systematic review of medication safety assessment methods. *American Journal of Health-System Pharmacy*, *68*(3), 227-240. doi:10.2146/ajhp100019

National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP). (2008). The use of medication error rates to compare health organizations is of no value. Retrieved from http://www.nccmerp.org/council/council2002-06-11.html

Page, D. (2010). Data mining is vital as meaningful use looms. *Hospitals & Health Networks*, *84*(2), 10.

Papakostidi, A., & Tsoukalas, N. (2012). Quality in health care and its evaluation. (English). *Archives Of Hellenic Medicine / Arheia Ellenikes Iatrikes*, *29*(4), 480-488

Samore, M. H., Evans, R., Lassen, A., Gould, P., Lloyd, J., Gardner, R. M., & ... Bright, R. A. (2004). Surveillance of Medical Device–Related Hazards and Adverse Events in Hospitalized Patients. *JAMA: Journal Of The American Medical Association*, *291*(3), 325-334.

Sandoval, R. (personal communication, March 23, 2014).

Seibert, H. H., Maddox, R. R., Flynn, E. A., & Williams, C. K. (2014). Effect of barcode technology with electronic medication administration record on medication accuracy rates. *American Journal Of Health-System Pharmacy*, *71*(3), 209-218. doi:10.2146/ajhp130332

Sharma, M., Ansari, M. T., Abou-Setta, A. M., Soares-Weiser, K., Teik Chye, O., Sears, M., & ... Moher, D. (2009). Systematic Review: Comparative Effectiveness and Harms of Combination Therapy and Monotherapy for Dyslipidemia. *Annals Of Internal Medicine*, *151*(9), 622-W200.

Simon, S. R., Keohane, C. A., Amato, M., Coffey, M., Cadet, B., Zimlichman, E., & Bates, D. W. (2013). Lessons learned from implementation of computerized provider order entry in 5 community hospitals: a qualitative study. *BMC Medical Informatics & Decision Making*, *13*(1), 1-10. doi:10.1186/1472-6947-13-67

Sipunu, S. (personal communication, March 14, 2014)

Wübker, A. (2007). Measuring the quality of healthcare: The connection between structure, process, and outcomes of care, using the example of myocardial infarction treatment in Germany. *Disease Management & Health Outcomes*, *15*(4), 225-238.