

Reducing Preventable Adverse Drug Events in Hospital Settings

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Submitted to the Engineering Systems Division in Partial Fulfillment of the
Requirements for the Degree of

Master of Engineering in Logistics

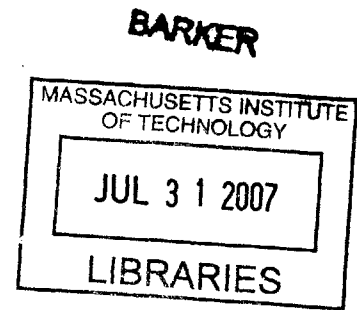
At the

Massachusetts Institute of Technology

June 2007

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Abstract

It has been estimated that on average, every patient admitted to a hospital is subject to at least one medication error per day (IOM, 2006). Errors may occur during various stages of the Medication Use System; a system composed of various tasks performed from the point of prescribing medication to the point in which a patient is monitored for adverse effects. Studies have shown that a majority of the errors that occur during the Medication Use System have little if any adverse effect on patients. However, there are classes of medication errors known as Adverse Drug Events (ADE's) which can cause significant harm to a patient. ADE's are not only dangerous but they have been estimated to cost the health care industry and the public in excess of \$3.5 billion dollars per year (IOM, 2007).

While extensive, current literature that exists on preventable ADE's varies greatly in regards how prevalent the issue is. The lack of a nationwide information system for identifying and defining ADE's only exacerbates the problem. In addition, when significant errors do occur, the repercussions for clinicians and hospitals are far from proportional.

Several studies suggest that over one quarter of all medication related injuries are preventable (IOM, 2007). Many industry observers have long touted computerized information systems as the Holy Grail for reducing medication errors. While there is little question that computerized systems can reduce ADE's, hospitals and clinicians frequently ignore other solutions that can offer greater impact in improving the level of care that is being provided. The health care industry has long been touted as fostering a culture that supports at risk behavior and shuns the use of standardized processes. The lack of transparency into the health care industry coupled with an unwillingness to embrace cultural change continues to be one of the largest barriers in reducing the number of preventable ADE's.

This paper recommends 4 different solutions that will change the culture of the health care industry, incent hospitals to focus on reducing preventable ADE's, improve the processes already in place for providing patient care and provide clinicians with the most up to date health care information available.

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Acknowledgements

I would like to thank Cardinal Healthcare for all of their support and resources. Without their help this thesis would not have been possible.

Biographical Note

Gregg Ramos is a candidate for the Master of Engineering in Logistics (MLOG). Prior to attending MLOG, Gregg spent 14 years at UPS working in various operational and sales roles within the organization.

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1 Introduction

Every year, approximately 32 million people are admitted into U.S. hospitals for medical treatment (IOM, 2006). For many, medication is often part of their daily care regimen performed while under the supervision of a clinician. Most people don't think twice about the possibility that the medication being administered has the potential to cause them serious harm.

A recent survey of 173 people found 72% believe that a patient admitted to a hospital is subject to zero medication administering errors per day (Appendix A). In contrast, a recent study by the Institute of Medicine estimates that on average, every hospital patient is subject to at least one medication error per day (IOM, 2007).

Medication errors made within hospitals often go unnoticed or have little if any adverse impact on a patient's health. Common medication errors of this type would include a clinician who is instructed to administer two aspirin to a patient but instead administers three. In this instance an error was clearly made, however the impact to the patient would typically be negligible. In contrast, there are other types of medication errors known as preventable Adverse Drug Events or preventable ADE's. Preventable ADE's differ from typical medication errors in that they cause varying degrees of harm to a patient. An example of such an error would be a nurse who administers penicillin to a patient known to be allergic to the drug. Typical allergic reaction to a drug could vary from something as simple as a rash up to and including patient death.

It has been estimated that between 380,000 and 450,000 preventable ADE's occur each year in the United States, while creating additional costs between \$3 billion and \$15 billion dollars (Classen et al., 1997; Bates et al., 1995b; IOM, 2006). Additional studies have shown that every year approximately 7,000 people are killed and approximately 1.5 million are injured by medication errors (USA Today, 2006).

Today, the public has limited means of assessing the level of care being provided by their hospital. There are agencies such as JCAHO (Joint Commission on Accreditation of Healthcare Organizations) that provide hospital safety accreditation programs and reports from organizations like U.S. News & World Report which have attempted to help the public in determining the best hospitals in the country. However, many within the industry question the means used in ranking and rating hospitals and attempting to utilize statistical data to quantify the quality of care has long been a subject of much debate. What is clear is that medication error or preventable ADE incident rates are not used in either the JCAHO or U.S. News & World Report's accreditation and ranking studies. Even worse, the most widely respected accreditation agency in the U.S., JCAHO, is jointly financed by the same hospitals that seek accreditation. Studies have also shown that approximately 99% of all facilities that seek accreditation pass which has caused many to question the validity of the program (Gual, 2005).

The objective of this thesis is to examine medication administering practices, health care culture and the hospital industry to identify solutions that will have the greatest impact in reducing the number of preventable ADE's.

The remainder of this thesis is organized as follows; Chapter 2 covers the current literature that exists regarding medication errors and preventable ADE's. In addition, the

difficulties in using previous research studies to determine preventable ADE incident rates are discussed. Chapter 3 briefly discusses how the terms “medication errors” and “preventable ADE’s” have been used in past studies and how their various definitions have impact incident rate reduction. The chapter also covers the methods used for detecting and reporting errors within a hospital including the estimated ADE costs to the health care industry. Finally, I examine the current reporting systems used by governmental and third party agencies to collect medication error data from hospitals.

Chapter 4 covers the Medication Use System in detail by breaking down each of the 5 stages into their individual tasks. Each task is then covered in greater detail with an emphasis put on those that have been shown to be highly associated with causing preventable ADE’s.

Chapter 5 discusses the difficulty in attempting to use multiple studies in performing a quantitative analysis of where the majority of errors occur during the Medication Use System. The chapter touches on the possible reasons for the large discrepancy in the number of observed ADE’s between different studies and the criteria used in selecting “High Rates of Adverse Drug Events in a Highly Computerized Hospital” as the main paper used in the analysis (Nebeker et al, 2005). Finally, the errors associated with preventable ADE’s are categorized into the Medication Use System in an attempt to determine what solutions would have the greatest impact in reducing preventable ADE’s.

Chapter 6 discusses the need for solutions to be implemented on a national level to have the greatest chance of significantly reducing the number of preventable ADE’s. In addition solutions must first change the health care industries culture from one of accepting at risk behavior to one of accountability. Various studies have shown that clinicians simply fail to use

computerized systems that offer risk reduction (ISMP, 2007). Hospitals must then be incented to include preventable ADE reduction into their daily operating plans. The processes that are utilized in each hospital during the MUS must be streamlined and examined for compliance. Finally, hospitals can then begin to use new computerized decision support systems which will help reduce the variance in care that is received between the worst and best clinician.

Finally, while many of the solutions can have a significant impact on preventable ADE reduction, there are financial and political repercussions in regards to their implementation. Chapter 8 outlines future research that may further help to understand what solutions offer the biggest benefit to the public while still providing a profitable environment for hospitals to operate in.

2 Research Methods

The research information and data gathered for this paper was accumulated from various medication error studies completed during the past fifteen years, newspaper articles, medical journals and textbooks. In addition, two hospitals were visited to observe general care practices and to interview hospital personnel regarding how medication errors are generally addressed in a hospital setting. Finally, an online survey was conducted in order to gauge public perceptions and opinions regarding medication errors and preventable ADE's (Appendix A). Direct observation of medication errors or preventable ADE's were not possible due the time allotted for this thesis, the inability to provide the necessary technical expertise in identifying ADE's and the lack of access to all stages within the Medication Use System.

All hospital visits were conducted at facilities within the United States. All hospitals and personnel interviewed have requested to remain anonymous. Interviews consisted of discussions regarding various stages of the Medication Use System and how medication errors and preventable ADE's were perceived within each facility. In addition the interviews covered how medication errors were tracked in each hospital and what processes or technologies had been implemented in an effort to minimize the number of preventable ADE's.

The current literature regarding medication errors, while extensive, fails to clearly indicate how pervasive preventable ADE's are within hospital settings. Broad and varying medication error definitions used in the industry make it difficult to merge quantitative data

between multiple studies. One study may define medication errors as “any inappropriate use of a drug, regardless of whether that use resulted in harm” (Nebeker, 2004). In contrast, another may use the definition “clinically significant” (Lesar, Briceland, & Stein, 1997). In addition, the detection methods used in identifying errors significantly impact the number of incidents observed (IOM, 2006). For example, several studies have noted that voluntarily reporting methods substantially under represent the true number of medication errors and preventable ADE’s (IOM, 2007). In contrast, direct observation methods were the most effective in detecting the highest number of errors (Flynn et al., 2002).

One of the major objectives of this thesis was to identify the various types of errors within the Medication Use System that lead to preventable ADE’s. However, a majority of the journal articles and studies reviewed did not provide enough information to categorize errors into the Medication Use System framework.

Finally, research and hospital reporting systems report error rates in varying ways; errors per order/dose/opportunity, errors per 1,000 patient-days, and errors per 1,000 patient admissions (IOM, 2006). For this reason there were various papers and studies that could not be combined into the final results.

Because of the variances between how data is gathered, categorized and calculated, a decision was made to utilize one study as the basis for observing preventable ADE incident rates and segmenting contributing errors within the Medication Use System. After reviewing multiple studies, Nebeker et al 2005 was used to provide the majority of the incident rate data used in this thesis. The study examined ADE incident rates and errors across all stages of the Medication Use System. In addition, the hospital examined was highly computerized, with a fully integrated

CPOE (Computerized Physician Order Entry) system, bar-code administering system and an electronic MAR (Medication Administration Record). It is important to note that the computerized system installed in the hospital did not have decision support functionality such as recommended drug selection, medication dosing or patient monitoring (Nebeker et al., 2005).

3 Medication Errors & Adverse Drug Events

Hospitals utilize various processes and guidelines when providing health care services to their patients. When administering medications health care professionals strive to adhere to what are called the “5 rights”; the right drug, in the right dose, by the right route, at the right time, to the right patient (IOM, 2006). In general, any failure to adhere to these “five rights” constitutes a medication error. However, medication errors can be classified in several different ways according to various factors such as whether the error in question was foreseeable or how significant the impact was on the patient.

It is important to clearly outline the various types of medication errors that exist within the health care industry including the definitions that will be used within this research paper. The lack of common definitions has always been a controversial subject and has led to vast differences in how medical errors are studied and the incident rates at which they are detected. Unfortunately, while the medical community has recently attempted to create common system wide definitions for various types of medical errors, confusion is still commonplace in the industry (IOM, 2007). For the purposes of this research paper the table below lists the common terms and definitions that will be used.

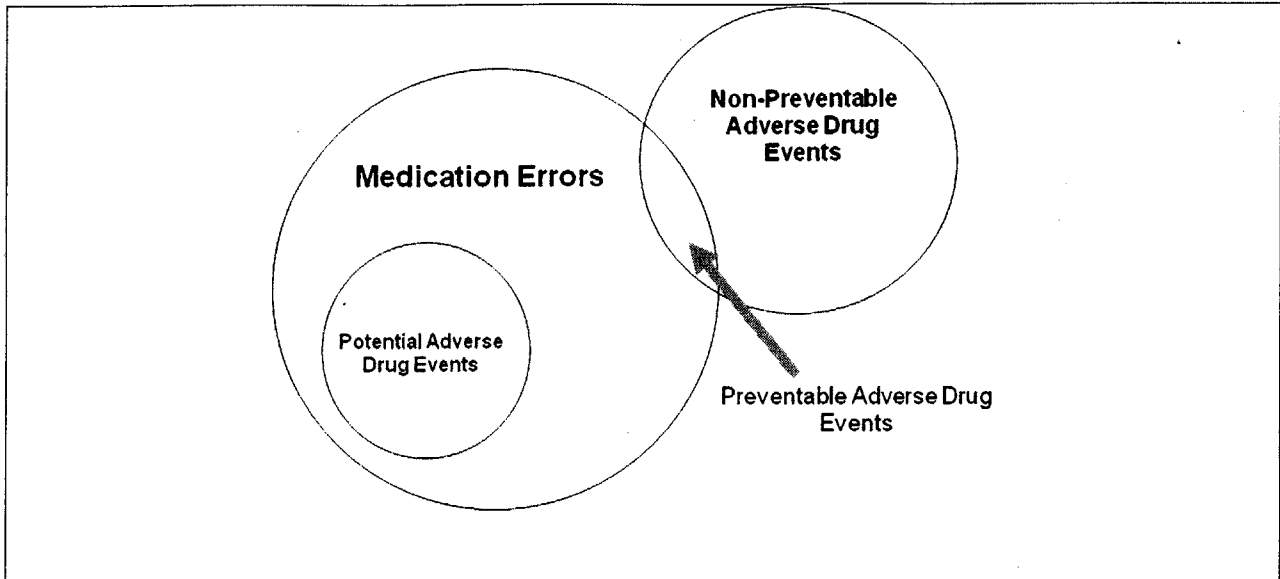
Table 1 - Medical Error Definitions

Incident	Definition	Example
Adverse drug event (ADE)	Injury due to any medication	Drug rash
<i>Preventable</i>	<i>Due to any error</i>	<i>Coma due to overdose of sedative</i>
<i>Non-preventable</i>	<i>Injury, but no error involved</i>	<i>A allergic reaction due to a medication given (Allergy not known by patient or clinician)</i>
Medication error	Any error in any stage of the Medication Use System	Medication given at the wrong time
Potential ADE	An incident with potential for injury; all potential ADEs are medication errors	An order was written for an overdose of medication but the mistake was intercepted by the pharmacy

Source: Gandhi et al., 2000

Various studies have shown that the frequency of medication errors and preventable ADE's vary greatly from study to study. While medication errors in general occur much more frequently and the percentage of medication errors that lead to ADE's are minimal, this research paper will only focus on preventable ADE's within the Medication Use System. It is important to note that any type of medication error can be one of commission or omission. While it would be beneficial to include both types of errors within this paper, there are significant gaps with data in relation to medication errors created by acts of omission. Therefore, only preventable ADE's created by errors of commission will be included in the study.

The table below visually depicts the relationship between medication errors and the various types of Adverse Drug Events.



Source: IOM, 2007

Figure 1 - Medication Error Relationship

There are several different reasons on why this paper only focuses on preventable ADE's. In general, it is believed that preventable ADE's occur due to factors such as various breakdowns in the decision making process, failure to comply with general administering processes, lack of knowledge about medications or drug reactions and poor communication between hospital staff. These are all areas in which a health care IT (Information Technology) system with decisions support functionality could potentially impact the rate of preventable ADE's. In addition, beyond the significant costs that are associated with ADE's, serious cases of preventable errors tend to be highly publicized. Events such as these can greatly impact the reputation of a hospital and the overall public's trust in the health care system.

3.1 Adverse Drug Event Costs

There have been several studies which have attempted to estimate the financial impact of a preventable ADE. One study estimated the costs of preventable ADE's to be \$8,750 per incident in 2006 dollars (Bates et al., 1997). These estimates only accounted for additional costs inside the hospital such as additional days spent receiving care or additional treatment and medication. Using an estimate of 400,000 preventable ADE's per year the costs would be in excess of \$3.5 billion in 2006 dollars (Bates et al., 1997). Many industry observers argue that the additional costs created by ADE's are much higher when including a patients lost wages, additional hospitalization and increased insurance premiums.

While large variances in estimates make it difficult to gain consensus regarding the true financial impact of ADEs, most researchers and industry observers agree that ADE costs are significant and severely impact the public and the health care industry.

3.2 Adverse Drug Event Detection

Studies have used various types of detection methods in an attempt to determine the number of preventable ADE's within a hospital. The incident rates of ADE's detected in various studies are directly correlated to the types of detection methods used (IOM, 2006).

The chart below lists the most common methods, the general yield rates and the typical limitations experienced when utilizing each method.

Table 2 - Error Rate Detection Method

Incident	Method of identification	Rates Detected	Limitations
ADEs	Voluntary reporting	Low	Low yield
	Chart review	Highest	High cost / time
	Computerized monitoring	High	Mostly number driven
	Direct Observation	High	High cost

Source: (Bates & Gawande, 2000)

Historically, voluntary detection methods only capture approximately 5% of actual ADE occurrences. There are multiple reasons that account for the large variances between this method and other detection methods. First, hospitals have long feared that voluntary reporting will increase the chances of facing litigation from patients that have experienced an ADE and therefore only the most severe cases are reported (IOM, 2006). In addition, hospitals also believe that an increase in the reporting of preventable ADE's will lead to possible reprisal from governmental health organizations such as JCAHO (IOM, 2004).

Studies that use a chart review detection method tend to show the highest incident rates of preventable ADE's when compared to other methods. The high rates observed can be attributed to the fact that a patients MAR should contain all of the necessary information to determine if a preventable ADE occurred. However, there are drawbacks to using chart review as the main detection method. The process of reviewing charts requires a large amount of training, a high level of medical expertise and is extremely time consuming. In addition, the process is expensive to conduct and the very fact that humans are asked to use their judgment on whether an ADE has occurred based on information in a chart means that there can be a great deal of variation when using this method.

Computerized monitoring allows users to quickly analyze records for preventable ADE's. Users can create queries that contain constraints used to identify preventable ADE's (Bates & Gawande, 2000). An example would be a system that flags any orders for Serum Vancomycin > 50mg/l; knowing that any level of this drug over this identified threshold is toxic and therefore the system identifies that an error has occurred. The use of this type of automated detection method is inexpensive when the costs of the IT systems themselves are not included. While this type of detection method tends to be very accurate one should note that computerized detection methods have difficulty in identifying ADE's that are expressed qualitatively.

3.3 Adverse Drug Event Reporting

There are various types of voluntary and mandatory reporting systems that exist to capture medical error events. Some reporting systems are used solely by the health care industry while others also have the ability to accept consumer inputted information. In many cases these programs allow for the input of a wide range of medical errors beyond the category of ADE's. Unfortunately many of these reporting programs share the same challenges; difficult to use interfaces, low usage rates and poor data integrity.

3.3.1 Institutional Reporting Programs

Institutional reporting programs can include reporting systems that exist within the four walls of a hospital and external reporting programs such as U.S. Pharmacopeia's MedMarx Program and the Veterans Administration Patient Safety Reporting System.

While a reporting system inside of a hospital might be deemed as mandatory in relation to reporting ADE's, external institutional programs are strictly voluntary. The health care

industry has continually stated that any medical error reporting system must be free of punitive consequences if the goal of such systems is to improve patient care (IOM, 2006). However, studies have shown that such reporting programs are very rarely used, especially when compared to observed rates of ADE's within a hospital (IOM, 2004). In addition there is little, if any evidence beyond anecdotal references to these types of voluntary institutional reporting systems improving the level of patient care (IOM, 2006). Many industry observers and politicians are beginning to question the effectiveness of reporting systems created and governed by the health care industry themselves (IOM, 2006).

3.3.2 State Reporting Programs

According to the National Academy for State Health Policy (NASHP), an organization that tracks state instituted reporting programs, 25 of the 50 states in the U.S. have instituted a mandatory ADE reporting program in one form or another (NASHP, 2006). Each of the 25 states has different definitions of what types of ADE's must be reported and to what agencies information must be forwarded to. However, many of the state implemented reporting programs are difficult at best to understand. The table below shows the reporting definition for errors within the state of South Dakota.

Table 3 - South Dakota Mandatory Error Reporting Definition

Mandatory Error Reporting Definition (South Dakota)

44:04:01:07. Reports. Each licensed facility, when requested by the department, shall submit to the department the pertinent data necessary to comply with the requirements of SDCL chapter 34-12 and this article.

Each nursing facility shall report to the department within 24 hours and any other licensed facility shall report to the department within 48 hours of the event any death resulting from other than natural causes originating on facility property such as accidents, abuse, negligence, or suicide; any missing patient or resident; and any allegation of abuse or neglect of any patient or resident by any person.

Each facility shall report the results of the investigation within five working days after the event.

Each facility shall also report to the department as soon as possible any fire with structural damage or where injury or death occurs; any partial or complete evacuation of the facility resulting from natural disaster; or any loss of utilities, such as electricity, natural gas, telephone, emergency generator, fire alarm, sprinklers, and other critical equipment necessary for operation of the facility for more than 24 hours.

Each facility shall notify the department of any anticipated closure or discontinuation of service at least 30 days in advance of the effective date.

Source: South Dakota Legislature (<http://legis.state.sd.us/rules/DisplayRule.aspx?Rule=44:04:01:07>)

In the case of South Dakota it appears that only ADE's that lead to the death of the patient must be reported. Other serious types of drug errors such as those that lead to physical impairment or a surgery on the wrong patient do not appear to rise to the level of being forwarded to the state or other governmental agency.

While South Dakota is only one example, other states utilize just as confusing definitions regarding what constitutes a reportable medical error or Adverse Drug Event.

Similar to institutional reporting systems, evidence which supports that mandatory state programs have improved patient care is largely anecdotal (Leape, 2002). Errors meeting the requirements of mandatory reporting are not communicated to the proper agencies because of fear of litigation (Leape, 2002). During an interview one hospital employee commented “In today’s litigious society we do not inform patients of medical errors if we don’t have too”.

3.3.3 Federal Reporting Programs

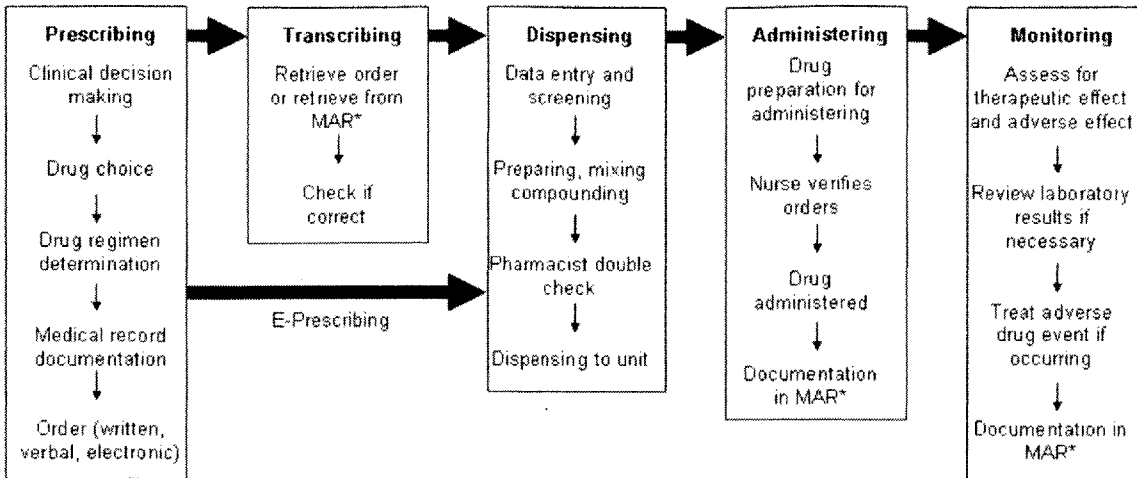
There are various reporting programs that have been instituted by federal agencies like the FDA and the CDC. These federal reporting programs generally are composed of voluntary reporting data from the health care industry and consumers in addition to mandatory reports from drug manufactures (IOM, 2006). While many federal reporting systems gather data regarding potential ADE events, their main goal is to address unknown effects of drug on drug interactions or new information regarding recently released drugs. At this time there are no specific mandatory ADE reporting programs in place at the federal level to monitor patient safety in the health care industry.

4 Medication Use System

The Medication Use System is a generally accepted framework within the health care industry that is used to communicate the numerous steps involved in administering medication to patients. Individual steps are segmented into 5 major groupings; prescribing, transcribing, dispensing, administering and monitoring. It is important to note that this framework applies to a hospital setting only. Different processes are used in other settings such as private doctor's offices, outside pharmacies, ambulatory care and outpatient health care facilities. In addition, while the framework shows the typical steps involved in administering medication it should only be used as a guideline. No two hospitals operate in the same manner and actual processes will vary from facility to facility.

The framework, used in conjunction with error rate observation data, helps to identify where in the process the majority of errors occur which lead to preventable ADE's.

The figure below depicts the Medication Use System and various tasks which are related to each category.



Source: IOM 2007

Figure 2 - Medication Use System

4.1 Prescribing Process

The prescribing stage of the Medication Use System involves several steps which ultimately lead to a medication being prescribed for a patient. Generally a clinician will meet with a patient to evaluate their current health state and to address the patient's particular ailment. In addition, the clinician uses this time to discuss possible treatment plans, medications that address the underlying ailment and finally should answer questions that the patient might have regarding the treatment plan or the medication. A typical doctor's visit requires that the clinician weigh multiple factors in determining the type of care to be provided. Clinicians must take into account a patient's health history, potential drug side effects, interactions with over the counter supplements, medication dosage in relation to desired effect and whether the formulary being prescribed is covered by the patients insurance (Goodman & Gilman, 2001).

Studies have shown that most errors that occur within the prescribing process are due to a lack of knowledge by the physician (Bates et al., 1995a). This lack of knowledge may include

current information regarding treatments for diseases or the most up to date information regarding drug on drug interactions. One of the major issues identified during the prescribing process is the physician’s poor handwriting and the use of abbreviations when manually filling out prescriptions. The table below identifies some of the “Do Not Use” lists that have been created by JCAHO.

Table 4 - Do Not Use Medication List

Do not use:	Potential problem	Use Instead
U (unit)	Mistaken for “0” (zero), the number “4” (four) or “cc”	Write “unit”
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write “International Unit”
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write “daily”
Q.O.D., QOD, q.o.d, qod (every other day)	Period after the Q mistaken for “l” and the “O” mistaken for “l”	Write “every other day”
MS	Can mean morphine sulfate or magnesium sulfate	Write “morphine sulfate”
M _{SO} ₄ and MgSO ₄	Confused for one another	Write “magnesium sulfate”

Source : Adapted from www.ismp.org

Once a medication regimen has been established the clinician must then translate these orders into a prescription. Prescription orders can be generated in several different ways depending on the systems that are in place within a hospital. The process of creating the prescription and sending the order to the pharmacy or the nurse is part of the transcribing process.

4.2 Transcribing Process

Hospitals may use varied methods and processes for communicating prescription orders to the pharmacy or the nurse. Prescriptions may be communicated by carbon copies of original orders, faxes, scanned copies, phone and electronic orders or complicated CPOE systems (IOM, 2006; Manasse, Thompson, 2005). The size of a hospital's budget may also adversely impact the transcribing process by limiting the ability to use solutions known to reduce errors.

Once a prescription has been created by a physician and communicated to the pharmacist the prescriptions must then be filled. The orders that are sent to the pharmacy from the physician typically contain the patient's name, drug name, dosage, formulation, route, frequency, units, flow rates, duration and reconstitution information (IOM, 2006; Manasse, Thompson, 2005). If the pharmacist or the nurse has any questions regarding the order it is standard procedure that they must directly contact the physician who wrote the prescription (Cohen, 2000; IOM 2006).

The majority of errors that occur during the transcribing process are related to the ability of the pharmacist to interpret written prescriptions. Even prescriptions that are written clearly can become illegible depending on the method of communication such as faxing. While poor hand writing by a physician is identified as a major issue during the prescription stage, the use of certain abbreviations and symbols can also create potential problems. The table below lists some common forms of abbreviations and symbols that have been identified to cause errors.

Table 5 - Error Prone Abbreviations and Symbols

Abbreviations	Intended Meaning	Misinterpretation	Correction
@	At	Mistaken as "2"	Use "at"
&	And	Mistaken as "2"	Use "and"
cc	Cubic centimeter	Mistaken as "u" (units)	Use "ml"
➤ And <	Greater than and less than	Mistaken as opposite of intended; mistakenly use incorrect symbol; "< 10" mistaken as "40"	Use "greater than" or "less than"

Source: Adapted from www.ismp.org

Misinterpreting a symbol or an abbreviation typically does not impact the actual drug that is prescribed but can affect the dosage or the form (liquid, pill, IV). In addition, the wrong drug can be filled due to the fact that many medications have similar names.

The table below lists several examples of medications that can easily be confused for other drugs.

Table 6 - Confusing Drug Names

Drug Name	Possibly Confused With
Accupril	Aciphex
Altacor	Advicor
Cedax	Cidex
Cozaar	Zocor
Femara	Femhrt
Metadate CD	Metadate ER

Source : Adapted from www.ismp.org

Finally, pharmacists that do not have access to a computerized pharmacy drug database and patient information lack the ability to perform an in depth medication reaction review. This lack of information and knowledge about the patient's history and the medications they are taking can also lead to preventable ADE's.

Once the physician's prescription has been reviewed and verified the medication must then be obtained and put into dose form for the patient. The tasks involved are known as the dispensing process.

4.3 Dispensing Process

Studies have estimated that dispensing errors account for approximately 6% to 12% of all medication errors (IOM, 2006). Following the review of a prescription by a pharmacist the order must then be entered into a pharmacy database system. Pharmacy database systems are used to screen for possible drug interactions, patient's history to allergies, dosage tolerance levels and possible duplicate prescriptions. More complicated pharmacy database systems have the ability to screen prescription orders against patients test results which have been shown to help reduce potential ADE's (Manasse & Thompson, 2005; IOM, 2006).

Studies have shown that approximately 91% of hospitals and pharmacies have a computerized pharmacy data base system. Of the hospitals and pharmacies that have these types of database systems approximately 87% include data such as patient admission and discharge records (Ringold et al., 1999). It is important to note that any changes made to a prescription necessitates that the original physician be contacted. The physician must then determine if the

changes are valid. The prescription should then be resubmitted and the entire verification process proceeds as normal.

Once the order has been verified and entered into the database system it must then be fulfilled by the pharmacist. This process can involve the counting or measuring of the medication and in some instances the mixing of multiple compounds to create the final drug. In addition, the pharmacist may be required to repackage the drug and label the contents. Within the dispensing process these steps have been found to attribute to the greatest number of medication errors within the pharmacy (Manasse & Thompson, 2005; IOM, 2006). It has been shown that between 79% and 99% of hospital pharmacists repackage oral medications and 29% repackage medications that can be injected (IOM, 2007). Because of the potential risk involved in labeling and repackaging medications in hospital settings a new federal regulation will go into effect in 2007 that will require manufactures to provide medications to hospitals already in unit dose form (FDA, 2004). Because these requirements are relatively new, there are no studies which address the impact this new regulation has had on reducing medication errors or preventable ADE's.

Studies have shown that a majority of the errors that occur during the dispensing process are due to workload issues, distractions during the processing of the medication and a lack of a computerized pharmacy database system or one with outdated or incorrect information (IOM, 2007).

Computerized drug database systems are a vital piece of the preparation and dispensing process due to their ability to automatically detect potential ADE's that the pharmacist could possibly miss. In addition, the rate at which new medications are released into the market has

made it difficult for even the best pharmacists to remain educated regarding potential drug reactions and side effects. A study also determined that dispensing errors are directly correlated to the amount of interruptions and distractions a pharmacist faces during the dispensing process (Flynn et al., 1999).

Once the prescription has been verified and repackaged into a single patient dosage the medication must be made available to the nurse. It is important to note that both the pharmacist and the nurse are involved in properly making the medication available and retrieving the medication from storage.

In most hospitals medications are retrieved from ward based medication storage units. These units could be as simple as shelving units within the ward and as complicated as computerized automated dispensing cabinets (Appendix B) which can run reports, limit access to certain personnel and complete other dispensing tasks. Decentralized automated dispensing systems have been shown to help reduce errors during the dispensing process (Cohen, 2000). In an automated dispensing unit scenario the pharmacist is responsible for inputting the correct patient data into the system and making sure that the corresponding medication is available in each bin. The nurse is then responsible for retrieving the medication from the automated dispensing unit, verifying the medication and administering it to the correct patient.

4.4 Administering Process

The administering stage of the Medication Use System is the last step in which many preventable ADE's can be detected prior to causing harm to a patient. In cases where medications are administered by intravenous methods, ADE's can occur quite rapidly, with little if any time to address errors (IOM, 2007).

Once a drug is retrieved from a medical storage unit, medications should be kept separate to avoid contamination with other prescriptions. Once retrieved, the medications should be verified to make sure they are correct. Studies suggest that medications should be verified at three distinct stages; when retrieved from the storage unit, at bedside with the patient and after discarding (Cohen, 2000; Manias et al., 2005). Once the medication has been verified it is then administered to the patient and the MAR is updated with all relevant information.

There are various reasons within the administering process why errors can occur. The environment for nurses can be very demanding, with long work hours and inadequate staffing conditions (Castle & Engberg, 2005). Nurses are very often subject to tasks that interfere with providing high levels of patient care such as performing housekeeping tasks, delivering meals and performing other non-job related functions (IOM, 2004; IOM, 2006). On average hospitals incur a nurse turnover ratio of 21.3% per year (IOM, 2007). These high turnover ratios reduce the pool of educated and experience nurses in hospital settings.

Nurses must also ensure that drug infusion or administering devices are working correctly. Some devices are computerized and they must be programmed to ensure that the right dosage is being administered in the right time frame based on the prescription (IOM, 2007).

The verification of the medication by the nurse is seen as one of the most important step in the Medication Use System because studies have shown that nurses catch approximately 86% of all medication errors prior to administering (Leape et al., 1995). For this reason, nurses are also subject to many of the same issues that pharmacists experience. Medication administering instructions are often difficult to read, completely illegible or incomplete. If nurses are not diligent regarding drug verification procedures preventable ADE's can occur.

Finally, the rate at which new technology systems and medicines are being introduced make it difficult for clinicians to remain up to date best practice procedures.

4.5 Monitoring Process

Once a medication has been administered to a patient they must then be monitored. Monitoring enables the clinician to determine the effectiveness of the medication and to determine if there are any adverse reactions. The signs that accompany ADE's are often times difficult to diagnose depending on the drug administered and where in the Medication Use System occurred. For instance, the reaction in a patient to a drug that was administered in a toxic dose can be completely different when compared to an allergic reaction from the same drug.

Monitoring of a patient can involve different steps of evaluation, observation and surveillance (IOM, 2006). The monitoring process can differ greatly based upon multiple factors such as a patient's age, weight or additional medical procedures performed. Hospitals may also differ greatly in the frequency and length of time used in monitoring patients.

The process of monitoring a patient is seen as one of the most crucial steps in detecting or preventing ADE's (IOM, 2006). In a hospital setting the act of monitoring a patient and assessing drug impact is the primary responsibility of a nurse (IOM, 2007). Monitoring a patient is done by visual observation, using monitoring devices and assessing lab results or tests (Manasse & Thompson, 2005). During this time important vital signs are monitored such as heart rate, blood pressure, patient pain and fluid levels (IOM, 2006). The use of a cardiac monitor after the administering of a drug is an example of automated monitoring. If the monitor detected an abnormal change in heart rate the nurse would be immediately notified of a possible reaction to the drug and hence a possible ADE. It is important to note that many adverse reactions

to medications cannot be monitored solely by automated means and that a large part of the responsibility falls on the patient themselves to continually communicate any changes in their level of health (dizziness, dry mouth, rash) (IOM,2006).

In hospitals with electronic MAR's, pharmacists can play a role in the monitoring process. As MAR's are updated and additional prescriptions are ordered a pharmacist is better able to provide input as to the care a patient is receiving (IOM, 2006). Finally, during the various stages of the monitoring process patient information is recorded into the MAR in order to determine the progress of the healthcare being provided and to help other health care givers remain up to date regarding the patient's condition between shift transitions.

The majority of preventable ADE's that occur during the monitoring stage are due to failure in following monitoring procedures or missing the signs of a preventable ADE due to a lack of knowledge or education (IOM, 2004). In many cases patient's symptoms are either identified too late or are perceived as not being serious enough to immediately act upon.

5 Medication Error and Adverse Drug Events Incident Rates

One of the major objectives of this thesis was to use data from multiple studies in calculating an “average” preventable ADE incident rate per 1,000 hospital admissions. In addition, multiple studies would be used to determine what stages of the Medication Use System produced the majority of medication errors that lead to preventable ADE’s.

After reviewing the research data from multiple papers it became obvious that the qualitative and quantitative data variances between studies would make it impossible to merge information. There were several reasons for the large variances; the definition of an ADE varied dramatically from study to study, the methods used for error detection were varied, different ratios were used when calculating error rates and many of the studies did not identify errors using the Medication Use System.

An example of the dramatic differences in observed rates is shown below in Table 7.

Table 7 - Preventable Incident Rates (Per 1,000 Admissions)

Study	ADE's Per 1,000 Admissions	Proportion of ADE's Preventable
Classen et al., 1997	2.4	Approximately 50%
Senst et al., 2001	4.2	15%
Bates et al., 1995b	6.5	28%
Nebeker et al., 2005	52	27%

Source: IOM, 2007

Because of the significant variability observed in the studies in Table 7 and the difficulty in attempting to merge the data, an attempt was made to identify a single study that met the following criteria;

1. Electronic detection method utilized & chart review
2. Study completed within the past five years
3. Hospitals that utilized computer integrated systems (CPOE, MAR, etc)
4. Incident rates that could be segmented into the Medication Use System framework

The criteria listed above were selected for several reasons. First, detection methods using electronic methods and manual chart review have been shown to more accurately identify incidents when compared to other methods (IOM, 2006). Second, hospitals have made significant strides over the past 5 years in reducing medical error rates with the use of automation, improved processes and technology. A study that was recently conducted would give a more accurate representation of what is occurring in the health care industry today. Additionally, studying hospitals that have already implemented computer based systems such as CPOE and electronic MAR's could provide further insight into their impact on reducing preventable ADE's. Finally, studies where errors can be segmented into the Medication Use

System stages will provide the necessary insight into what types of solutions may offer the greatest impact in reducing preventable ADE's.

After reviewing in excess of 15 studies completed on medication errors within hospital settings the Nebeker et al 2005 study met the majority of the criteria. The study reviewed a 110-bed VA hospital that had integrated computerized medical systems which recorded all orders, results, medications and notes. The CPOE system was activated to check for allergies, several different types of drug-drug interactions and a small number of drug-disease interactions. At the time of the study the systems did not offer decision support algorithms such as drug selection, dosing or monitoring advice.

The hospital had a fully integrated bar coding system and had already implemented systems well known for reducing ADE's, including patient safety coordinators, unit dosing and clinical pharmacists that directly observe patients. The threshold for meeting an ADE was defined as "injury resulting from the use of a drug". Finally, all electronic record reviews were completed by at least two clinical pharmacists.

Of the 937 hospital admissions that were reviewed, 483 patients experienced an adverse drug event. Of the 483 patients that suffered an ADE, 27% were due to medication errors and therefore deemed to be preventable. In comparison to a landmark study completed by Bates et al. 1995b, the number of observed detected preventable ADE's in the Nebeker study were significantly higher.

The figure below shows that large variance between three of the major studies that are commonly referred to in the health care industry when addressing preventable ADE's.

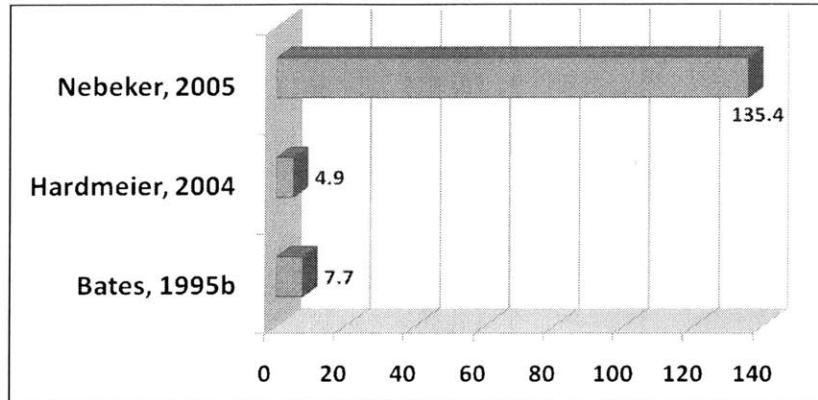


Figure 3 - Preventable ADE's Per 1,000 Admissions

The high number of detected ADE's in relation to other studies can be attributed to two major factors. First, only recently have ADE incident rates been studied in highly computerized hospitals. The study by Nebeker utilized electronic detection methods versus the manual chart review and prompted reporting methods used in the Bates study. Second, the Nebeker study used the broader WHO (World Health Organization) definition for what constituted an ADE in contrast to the more restrictive definitions used in other studies.

The high rate of observed ADE's bring into question both the effectiveness of previous studies in identifying ADE's and the impact that health care information technology systems have in ADE reduction.

Many studies have estimated that approximately one quarter of ADE's can be prevented with the use of IT solutions which can identify errors within the Medication Use System (Bates et al., 1995a; Nebeker et al., 2005). According to one study, CPOE and other automated

computer systems have been so successful in identifying ADE's that many have touted automation as being essential to reducing the number of events (Bates, 2001). However, the high rates of observed ADE's in the Nebeker study bring into question the effectiveness of such systems.

Extrapolating for 1,000 admissions, approximately 181 errors contributed to the 135.4 preventable ADE's observed in the study (Nebeker et al., 2005). The chart below shows the errors segmented into the 5 stages of the Medication Use System.

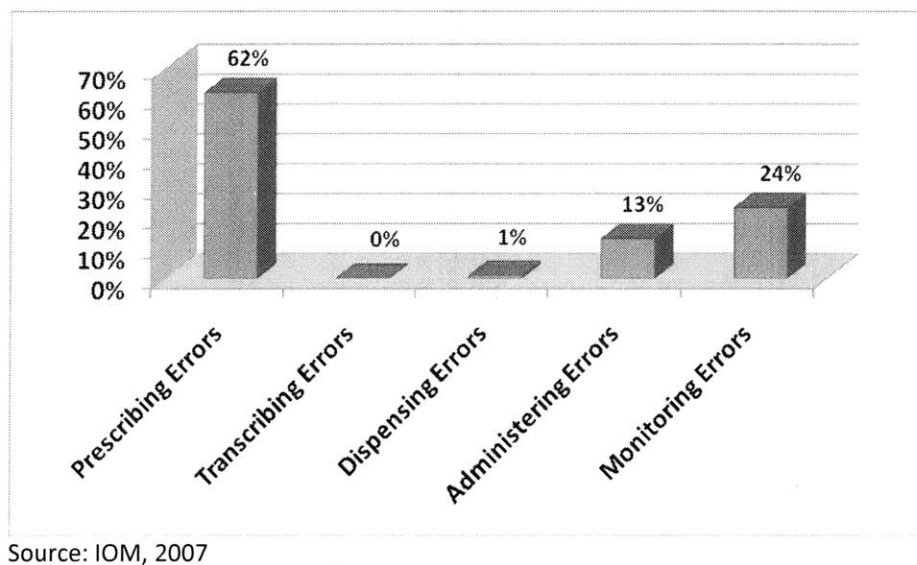


Figure 4 - Percentage of Errors by Stage

The observed rates of errors during the transcribing and dispensing stages, while low in comparison to other studies, reflect how a well integrated CPOE system and medication dispensing unit solution (Appendix B) can help reduce errors within the Medication Use System. These types of solutions are especially effective because typically, clinicians cannot bypass these systems and revert to older, more risky methods. For example, once a CPOE system is implemented, written prescriptions are no longer accepted and therefore any risk associated with

translating a doctor's poor handwriting is removed from the process. Depending on the type of medication error, an occurrence during the transcribing or dispensing phase is more likely to lead to a preventable ADE when compared to the prescribing phase. This is due to the fact that there is less of an opportunity for clinicians to identify an error the closer the occurrence is to the administering stage.

In contrast to the transcribing and dispensing stages, rates of errors observed during the prescribing, administering and monitoring stages are extremely high. These three stages rely heavily on a clinician's training and expertise when providing patient care. For example, during the prescribing stage, a physician must diagnose a patient's symptoms and correctly prescribe the correct medication and dose required. An incorrect diagnosis or an error in regards to the dose could lead to the administering of a drug which could cause an ADE. Another example would be during the monitoring stage, a nurse who fails to start or complete adequate monitoring for known common medication errors may miss signs of an impending ADE. The hospital involved in this study, while having an extensive computerized system installed, did not support advanced decision support functionality. Smart pumps (Appendix C) and computerized databases of up to date drug interaction information could help clinicians during these stages. However, unlike solutions which completely replace older processes, decision support systems are used as a supplement to the care being provided by clinicians. Therefore, they are often perceived as optional, severely reducing their effectiveness.

Reducing errors during these stages is difficult because only making decision support systems available to clinicians are not an effective strategy. Solutions must be coupled with a plan to induce a cultural change within the hospital that helps clinicians embrace the use of these systems. In a safety brief given by the ISMP it was determined that the majority of nurses in a

hospital bypassed the dose checking technology in all smart pumps (ISMP, 2007). There were several reasons given for not using the technology; perceived view of low risk, difficulty in using the technology and clinical emergencies.

6 Recommendations

Unlike many industries, errors within hospital settings have significant consequences. Utilizing technology solutions has often been a major way in which hospitals have tried to improve the quality of their care. Solutions such as electronic MAR's and CPOE systems are extremely beneficial because they are typically not viewed as barriers by clinicians in their daily work routines and they are often difficult to bypass. On the other hand, the use of decision support systems is often presented to clinicians as optional. As an example, the use of smart IV pumps has been shown to significantly reduce the number of errors during the administering stage, yet in one study over half of all nurses in a hospital failed to use the safe dose-checking technology (ISMP, 2007). Hospitals must be strongly influenced to use solutions that improve patient care.

The health care industry has a culture that often supports at-risk behavior and technology workarounds while shunning standardized processes (ISMP, 2007). When addressing the failure of some hospitals to adopt standardized procedures when providing patient care, Dr Richard Croteau, executive director of patient safety initiatives for the JCAHO, stated, "Health care puts a high priority on individual autonomy, some of this goes against the traditional culture." (Kowalczyk, 2007).

Reducing the number of preventable ADE's involves creating a culture of accountability in the hospital industry, incenting facilities to reduce errors, improving processes already in place and adopting technology that reduces the variance in the level of care received between the best

and worst hospitals. The recommendations presented later in the chapter address all of these areas.

6.1 Cultural Change

The first step in driving cultural change within the industry is to implement policies which embrace accountability and provide the necessary information for educational and punitive purposes. One way to achieve this is to implement a transparent, mandatory nationwide reporting system which can account for all preventable ADE's in hospital settings. A mandatory reporting system would provide the necessary data to identify what types and where the majority of errors are occurring within the Medication Use System. This data could also be used to improve clinician education by incorporating the information into future decision support systems.

The recommended mandatory reporting program would require that all preventable ADE's be input into an online error database run by a segment of the U.S. government. Failure to input complete, accurate and timely data would result in punitive measures including fines and possible closure of facilities. Preventable ADE's would be defined as "any medication error that causes mental or physical injury, long or short term, and – or requires the use of additional medical intervention".

6.1.1 Reporting Structure

The reporting system would be web based with the ability to integrate into computerized hospital systems via XML and ODBC. Facilities that do not have integrated computerized systems would have the ability to enter error data via a browser interface. The system would also allow

for the entry of data by a patient where questions or concerns could be input requiring additional follow up by the hospital.

The reporting system would collect the following data;

- Patient specific data
- Preventable ADE
- Hospital employees involved in the ADE
- Stage of Medication Use System where ADE occurred
- Preventable ADE impact on the patient
- Intervention necessary due to the preventable ADE

The data gathered via the mandatory reporting system would not only be used to determine compliance but an additional educational component would be included. Information from the system would be used to create a best practices online decision support system accessible by all hospitals.

6.1.2 Network Design

The diagram below illustrates the flow of information between a hospital and the mandatory reporting system.

Network Diagram for Mandatory Reporting

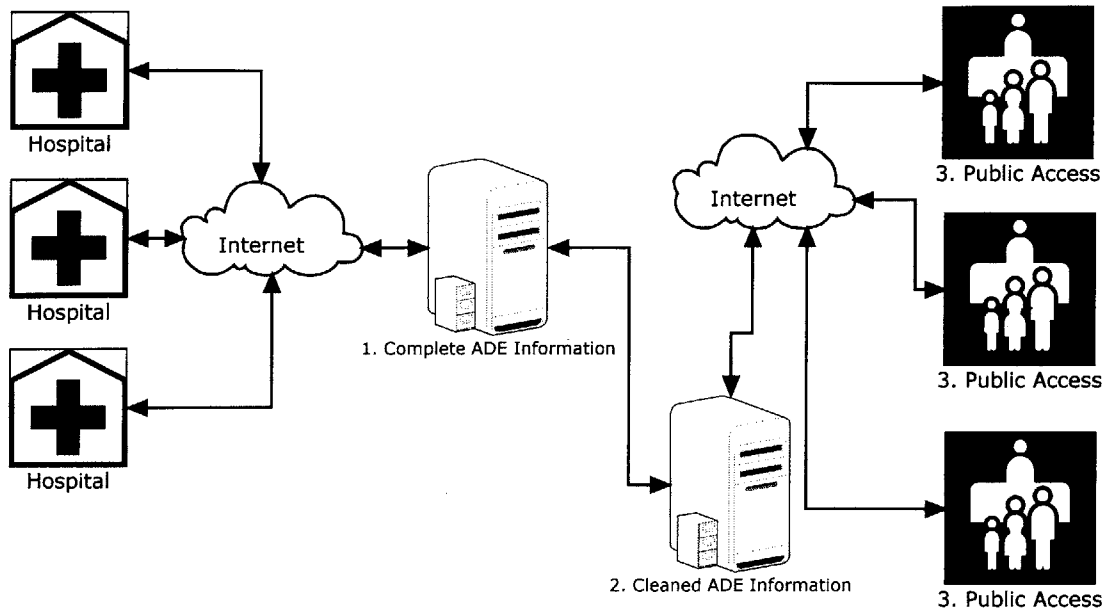


Figure 5 - Network Diagram Mandatory Reporting

The hospital would transmit the necessary data over in the internet where it would be compiled by an agency of the Federal Government (1). Once the data has been received and stored, a copy of the data will be created with all patient level detail removed so that each patient remain anonymous (2). The cleaned data would then be made available to the public via the internet (3). Each hospital in the country could be queried as to the number of preventable ADE's, how often they occurred and how severe the consequences were due to the error.

6.2 Incentive Structure

It is foolish to expect the health care industry to address preventable ADE's when their incentive structures are not impacted by the quality of care being provided. Simply put, hospitals are paid

based on the volume of services they render versus the level of care received by their patients. One way to incent hospitals to address preventable ADE reduction is to incorporate tiered based reimbursement systems where hospitals receive a larger portion of Medicare and Medicaid costs based upon the incident rates of preventable ADE's within their hospital.

The recommendation is to create a reimbursement system which takes into account incident rates for preventable ADE's. Hospitals receive a significant portion of their yearly revenue from the government for all Medicare and Medicaid patients. The recommended system would reimburse hospitals a greater portion of their claim depending upon their preventable ADE incident rate. An example would be a hospital that had an incident rate of 1% would receive 98 cents on every dollar. In comparison a hospital with a 3% incident rate would receive 85 cents on every dollar. A tiered based reimbursement system will help incent hospitals to improve the level of care that they are providing.

6.3 Process Improvement

As previously stated, the use of technology to reduce errors without addressing the underlying process will only achieve limited results. One common methodology used in process improvement is known as DMAIC or define, measure, analyze, improve and control. The methodology can be defined as follows;

- Define the process improvement goals that are consistent with customer demands and enterprise strategy.
- Measure the current process and collect relevant data for future comparison.
- Analyze to verify relationship and causality of factors. Determine what the relationship is, and attempt to ensure that all factors have been considered.

- Improve or optimize the process based upon the analysis using techniques like Design of Experiments.
- Control to ensure that any variances are corrected before they result in defects. Set up pilot runs to establish process capability, transition to production and thereafter continuously measure the process and institute control mechanisms.

A hospital in Illinois recently focused on using process improvement as the major means for reducing medication administering errors. Using the DMAIC methodology, the hospital was able to reduce their medication order entry errors to 0.04 per bed (Benitez et al., 2007). Tools such as VOC (Voice Of Customer) and QFD (Quality Function Deployment) provided the team with a systematic way of identifying tasks within a process that needed to be streamlined and improved.

The VOC is a process in which a “customers” needs are identified and organized into a structure which allows for the requirements to be prioritized (Appendix E). The customer helps determine the importance of each need in relation to other needs and the overall desired outcome. Involving those that are the most impacted by the process creates joint ownership and helps improve the chances the new solution will be successfully adopted. The QFD matrix is used to take the customer’s needs from the VOC and transform them into actionable and prioritized goals. In the case of the hospital, the QFD was used to create the design requirements for the new processes that were being implemented.

Using the DMAIC methodology assures that a team not only assesses how computerized technology might improve a process but how the process itself can reengineered to provide better results.

6.4 Decision Support Systems

Using the Nebeker study, the prescribing, administering and monitoring stages of the Medication Use System harbored the majority of the errors responsible for the preventable ADE's. All of these three stages rely heavily on a clinician's knowledge and experience rather than the automation or streamlining of tasks. This is clearly detailed in the results shown in Figure 3 where the hospital studied had extensive computer system integration but lacked decision support functionality with drug dosage, selection and monitoring capability.

Examples of decision support systems include solutions such as infusion smart pumps and databases which provide best practice information. However, like any program, decision support systems are only effective when used. Literature has shown that many systems are not utilized due to a false perception of risk, difficulty in using the system itself, and failures to update necessary drug library databases when errors are identified (ISMP, 2007). The main objective of all decision support systems is to reduce patient care variability and provide clinicians with the most up to date information. While many people may believe that these types of systems do not allow for the individualized thinking and action that is so highly coveted within the health care industry, the main objective should be to reduce the variances in care received between the best and worst clinician.

7 Future Research

Mandatory reporting of all preventable ADE's carries the greatest opportunity for disrupting the health care industry. Several industry agencies have expressed that the mandatory reporting of errors would only serve to reduce the quality of care provided to the public. In addition, it has been expressed that providing error data to the public is a poor way of communicating the level of care that can be expected at a particular facility. However, there is a lack of quantitative data that supports many of these statements.

In response to a California law that was recently passed which will mandate the reporting of all Adverse Drug Events; Kasey Thompson, director of patient safety for AHSP comments "When a medication error results in death or injury, it is very difficult for a facility to sweep it under the rug. But using medication errors to compare facilities is problematic. And to use the information to publicly embarrass hospitals could have a chilling effect on reporting and the creation of the kind of database of errors that could improve safety." (Sipkoff, 2006).

It would be beneficial to study states where mandatory reporting programs currently exist in an effort to determine the impact on reporting frequency. In addition, the relationship between the repercussions of failing to report a preventable ADE and observed reporting rate should be examined. This information would help determine the necessary punitive system required to obtain the level of reporting to improve the public health care system.

The majority of the recommended solutions would have substantial costs attached to their implementation. For example, a highly integrated computerized system with decision support capability can run approximately \$5 million for community sized hospitals and in excess of \$20 million for very large medical centers (USA Today, 2006).

It would be beneficial to understand the financial impact these solutions would have on a hospitals ability to continue to provide patient care and the incremental costs that would be passed on to the consumer. The U.S. hospital system is run by public companies that are in business to make reasonable returns on their investments. If the costs of systems to reduce errors make the business environment unprofitable, you could see an already strained health care system become even weaker. In any case, the costs of these systems need to be balanced with an acceptable level of risk that the public is willing to accept.

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Appendix A – Online Public Survey

Survey Methodology

The following survey was sent via email to approximately 300 people. Of the approximately 300 people who received the survey, 173 answered all five questions.

Question 1

In a hospital, how many medication errors per day do you think a single patient is subject to?

Errors	Respondents	Percentage
0	125	72.25%
1	35	20.23%
2	8	4.62%
3	0	0.00%
4	5	2.89%
5	0	0.00%
	173	100.00%

Question 2

In a hospital, specific to your care, how many medication errors per day would you accept before seeking another hospital to obtain health care services from?

Errors	Respondents	Percentage
0	71	41.04%
1	94	54.34%
2	8	4.62%
3	0	0.00%
4	0	0.00%
5	0	0.00%
	173	100.00%

Question 3

How many times were you aware that there was an error made in the type or dose of medication given to you?

Errors	Respondents	Percentage
0	130	75.14%
1	25	14.45%
2	9	5.20%
3	9	5.20%
4		0.00%
5		0.00%
	173	100.00%

Question 4

Have you ever inquired about your doctor or hospitals level of care being offered?

	Respondents	Percentage
Yes	103	59.54%
No	70	40.46%
	173	100.00%

Question 5

**What types of medication errors do you think should be reported to the public by a hospital?
(U.S. News Ranking Reports, Board Certifications, Medical School)**

Error Type	Respondents	Percentage
Preventable Death	145	83.82%
Causing Permanent Impairment	143	82.66%
Any Error Requiring Additional Treatment	112	64.74%
Any Medication Error	73	42.20%

Appendix B – Pyxis MedStation

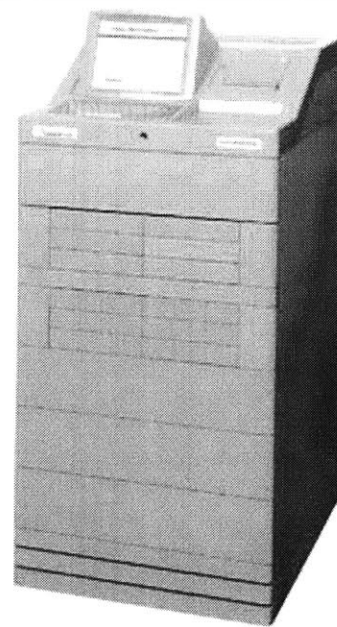
Pyxis MedStation automates the distribution, tracking, management and security of medications and drives improvements in quality and efficiency.

Proven to reduce chances of medication errors, Pyxis MedStation supports safe, efficient medication dispensing in patient care areas.

Saves nursing and pharmacy time, providing more time for clinical patient care

- Helps increase patient safety
- Supports timely administration of medication
- Controls which medications users can access
- Supports JCAHO and regulatory compliance
- Increases charge and cost capture

MedStation consists of a touch screen computer attached to a number of modules for drug storage in specially designed, compartmentalized drawers. Users log in using the touch screen and once authenticated, they can access patient profiles showing the med list for each patient. Drawers are opened for med removal by simply selecting the desired med on the med list.



Pyxis MedStation

Appendix C – Alaris Pump

The Alaris pump is a modular point-of-care infusion device that integrates infusion, patient monitoring and clinical best practice guidelines in a single platform for optimal outcomes. The modules provide flexibility in managing to the unique needs of the specific patient while maximizing asset utilization.

It consists of a main control module (a.k.a. PC) and up to four different modules plus a bar-code scanner that can be connected to the main control unit. Each pump is associated to a patient in a room and can be automatically programmed by simply scanning the medication.



Alaris Pump

Appendix D– National Quality Forum Guidelines

SERIOUS REPORTABLE EVENTS

Surgical Events

- Intra-Operative or Immediately Postoperative Death in an ASA Class I Patient.
- Surgery Performed on the Wrong Body Part
- Surgery Performed on the Wrong Patient
- Wrong Surgical Procedure Performed on a Patient
- Unintended Retention of a Foreign Object in a Patient after Surgery or Other Procedure

Product or Device Events

- Patient Death or Serious Disability Associated with Intravascular Air Embolism that Occurs while being Cared for in a Healthcare Facility
- Patient Death or Serious Disability Associated with the Use of Contaminated Drugs, Devices, or Biologics Provided by the Healthcare Facility
- Patient Death or Serious Disability Associated with the Use or Function of a Device in Patient Care in which the Device is Used or Functions Other Than as Intended

Patient Protection Events

- Infant Discharged to the Wrong Person
- Patient Death or Serious Disability Associated with Patient Elopement (Disappearance)
- Patient Suicide, or Attempted Suicide, Resulting in Serious Disability while being Cared for in a Healthcare Facility

Care Management Events

- Artificial Insemination with the Wrong Donor Sperm or Wrong Egg
- Death or Serious Disability Associated with Failure to Identify and Treat Hyperbilirubinemia in Neonates (Kernicterus)
- Maternal Death or Serious Disability Associated with Labor or Delivery in a Low-Risk Pregnancy while being Cared for in a Healthcare Facility

- Patient Death or Serious Disability Associated with a Hemolytic Reaction due to the Administration of ABO/HLA-Incompatible Blood or Blood Products
- Patient Death or Serious Disability Associated with Hypoglycemia, the Onset of which Occurs while the Patient is being Cared for in a Healthcare Facility
- Patient Death or Serious Disability Associated with a Medication Error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient Death or Serious Disability due to Spinal Manipulative Therapy
- Stage 3 or 4 Pressure Ulcers Acquired after Admission to a Healthcare Facility

Environmental Events

- Any Incident in which a Line Designated for Oxygen or Other Gas to be Delivered to a Patient Contains the Wrong Gas or is Contaminated by Toxic Substances
- Patient Death or Serious Disability Associated with a Burn Incurred from Any Source while being Cared for in a Healthcare Facility
- Patient Death or Serious Disability Associated with an Electric Shock while being Cared for in a Healthcare Facility
- Patient Death or Serious Disability Associated with a Fall while being Cared for in a Healthcare Facility
- Patient Death or Serious Disability Associated with the Use of Restraints or Bedrails while being Cared for in a Healthcare Facility

Criminal Events

- Abduction of a Patient of Any Age
- Any Instance of Care Ordered by or Provided by Someone Impersonating a Physician, Nurse, Pharmacist, or Other Licensed Healthcare Provider
- Death or Significant Injury of a Patient or Staff Member Resulting from a Physical Assault (i.e., battery) that occurs within or on the Grounds of the Healthcare Facility
- Sexual Assault on a Patient within or on the Grounds of the Healthcare Facility

Appendix E– VOC (Voice of Customer)

Nurses' need	Defined as:	Hierarchy
Quick access	Available immediately for printing (less than one minute).	2%
	Less than three steps to access the document.	2%
Quick pharmacy turnaround time	Less than two hours.	38%
	Fax of order available in real time.	7%
Provide history of meds	Able to see all medications for the entire patient stay.	2%
	Able to see medication start and stop dates.	2%
Portable/mobile	Nurse should not need to go back to station for document.	2%
Check on MAR	Serve to double check all orders in medication administration record (MAR).	12%
	Medications sort in the same way as MAR.	7%
Trustworthy	At least 95% accurate the first time.	19%
	Consistency in order entry by all pharmacists.	7%

Source: Benitez, 2007

