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# Medication Error Reporting to Improve Patient Safety

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Medication Error Reporting to Improve Patient Safety

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at Eastern Kentucky University

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Abstract

In 2006, the Institute of Medicine estimated that 1.5 million preventable adverse drug events occur in healthcare facilities annually (Institute of Medicine, 2006). Each ADE adds approximately $8,750 per hospital stay (Institute of Medicine, 2006). In 2017, the Food and Drug Administration (FDA) estimated that 1.3 million people are injured annually from medication errors (Agency for Healthcare Research and Quality, 2017). For the purposes of this project, all Registered Nurse staff on the Medical-Surgical unit were mandated to participate in an education targeted at medication error reporting, the importance of reporting, and a demonstration of inputting an error into the database. Participants were asked to complete a four-page survey titled; "Nurses' Perceptions of Medication Errors". The tool was divided into seven different domains, addressing various questions pertaining to medication error reporting. Domains one (causes of medication errors), two (medication errors committed over a period of 12 months), and five (reporting errors) were found to be clinically, but not statistically significant. Domains three (barriers to reporting medication errors) and four (factors increasing the participants' chances of reporting) were found to be both clinically and statistically significant post educational intervention.

Keywords: medication error reporting, medication safety, punitive culture, likelihood to report errors, medication education, and methods to reduce medication error reporting.

**Signature Page**

MEDICATION ERROR REPORTING TO IMPROVE PATIENT SAFETY

Table of Contents

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apologize for the many bad moods, and missed events. I love you all and appreciate the

encouraging words, texts, funny memes, and laughs along the way.

Medication Error Reporting to Improve Patient Safety

Error reporting is essential to identify within the healthcare system. It is through identification of system-wide errors that safety nets can be put in place to prevent a similar event occurring in the future. One prospective study demonstrated that 12 Intensive Care Units (ICU) had a 39.2% adverse event rate, with a denominator of 3,611 patients (Garrouste, et al., 2008). The study also resulted a 22.7% rate for patients that experienced more than one adverse event during their hospitalization (Garrouste, et al., 2008). The researchers during this study defined "adverse event" as any event that was a result in an error that reached the patient but may or may not have caused harm; including medication errors. The mean number of adverse events was 2.8 events per patient, with a range of adverse events from 1-26 (Garrouste, et al., 2008). Another study was conducted years later by several of the same researchers and they found that medical errors in the ICU were mostly related to medication administration errors (Garrouste-Orgeas, et al., 2010). Within this study, fourteen medical errors were selected for review, medication errors being one of those. The most common medical error in the ICU was insulin administration errors. It was reported that there were 185.9 insulin-related errors out of 1,000 patient days of insuin treatment. Of these insulin-related errors, 58 of them required additional clnical treatment or intervention after the error was idenitified (Garrouste-Orgeas, et al., 2010).

**Problem Description**

Medication error reporting is essential for identifying and preventing system errors. An "Adverse event" is any event that was a result in an error that reached the patient but may or may not have caused harm; including medication errors. An "adverse drug event (ADE) is specific to medications. Several studies have shown that most of the adverse events for hospitalized patients resulted from a medication error(s). Reporting a medication error allows for a root cause to be

determined and system-wide processes to be put into place in order to prevent the same scenario from occurring repeatedly. Errors are often not reported as a result of the staff being fearful of retaliation, or the reporting process being too time consuming.

In 2006, the Institute of Medicine estimated that 1.5 million preventable adverse drug events occur in healthcare facilities annually (Institute of Medicine, 2006). Each ADE adds approximately $8,750 per hospital stay (Institute of Medicine, 2006). In 2017, the Food and Drug Administration (FDA) estimated that 1.3 million people are injured annually from medication errors (Agency for Healthcare Research and Quality, 2017).

Identification of all error types allows root causes to be determined and system errors to be addressed (Agency for Healthcare Research and Quality, 2017). Without understanding the underlying reason as to why the errors are occurring, healthcare leaders cannot put safety nets in place to prevent patient harm. Being aware of the errors that are occurring will also allow the facility leadership to be more proactive, rather than reactive in error prevention.

## Available Knowledge

The literature search conducted for this project yielded several results. Two of the studies were in support of anonymity for the person reporting an error, and recommended making the error reporting tool easy to use for the staff. One of the studies researched the effect of rewards on increasing error reporting by recognizing the staff that reported an error. This method also supported increased reporting for the department studied.

There were weaknesses/limitations noted for the articles reviewed. Only 1 of the studies had a theoretical framework that was utilized to provide a foundation for the research. All 4 studies had a small sample size in comparison to a stronger Level 1 research study. The majority of the studies reviewed utilized raw numbers for data reporting, rather than statistical testing that

would have strengthened the data. A review of the literature was conducted to identify barriers in error reporting, and potential strategies to increase error reporting. The literature search yielded many results supporting error reporting and a non-punitive culture. For the purposes of this project, six research studies will be discussed.

VanOyen, et al. (2006) investigated effective strategies to increase medication error reporting within Delnore Community Hospital in Illinois. The cross-sectional study began by developing a Medication Event Team (MET). The team was designed to analyze and promote a non-punitive culture at the facility. The MET team designed two tools to increase error reporting (a short form for near-misses and a medication event tool). All medication events were analyzed by the MET team based upon event type (ordering, dispensing, transcription, and administrative error types). Focus groups were conducted with nurses and pharmacists regarding their personal feelings about error reporting. Multiple barriers were identified regarding medication error reporting from analysis of the focus group data. Barriers included inaccessibility of the error reporting forms, reports were deemed punitive in nature, and error reporting was considered too time consuming. The MET team developed two tools and implemented education to improve the error reporting rate. Medication error reporting increased from 14 reports pre-intervention to 72 per month post-intervention.

Conerly (2007) conducted a cross sectional study to increase near-miss reporting and the reporting of adverse events. The setting for this study was a Women's Hospital in Baton Rouge, Louisiana. The sample included all staff employed within the facility (n=800). Data analysis included error reporting before and after the educational intervention. The analysis consisted of assessing the raw numbers of incidents reported. In 2000, 45 incidents were reported. In 2001, there were 87 reports generated. In 2002, there were 99 reports. In 2003, 103 reports were

entered. In 2004, there were 97 reports made. In 2005, there were 87 error reports. An analysis of

the annual employee survey regarding their opinion of a just culture was also examined pre and

post intervention. The intervention was multifaceted in that rewards (thank you cards, employee

recognition) were provided when error reports were completed. Results were favorable post

intervention. Error reporting did not increase, but a safety culture was reported from the

employee annual survey post intervention from the employees. Although the incidents reported

did not increase, benefit was seen from a perspective of the staff feeling a less punitive culture.

     Jeddi & Atoof (2015) conducted a descriptive, cross-sectional study focused on designing

a conceptual model for reporting medical errors. The study was conducted with a basic

questionnaire with three answer options (agree, disagree, no opinion). The questionnaire

consisted of 20 questions, and to validate the questionnaire a split-half method was utilized

(alpha level 0.76 was noted). Each question included within the questionnaire was evaluated and

re-evaluated by several experts, and put through three rounds of validity. Any questions that did

not pass the test, were eliminated from the questionnaire. This process established face validity.

     All results were tallied according to the participants' responses.  Thirteen (43.3%) of the

participants stated that the reporter should remain anonymous. Twenty-six (86.7%) stated that

the error should be reported as soon as possible after the event. Eighteen (60%) stated that they

disagree that the person who made the error should be punished. Seventy percent of the

participants preferred an internet-based error reporting system, as opposed to paper. The study

concluded that education of the importance of error reporting was a necessity to increase

reporting by staff. Only 54.8% of the staff were aware of the method to which they were

supposed to report a medical error, and only 39.5% were aware of what types of errors to report

per the participant questionnaire. Keeping the reporter anonymous was favorable amongst the participants and all participants agreed that medical errors should be analyzed to identify trends.

Walpola, et al. (2017) investigated the effects of an educational intervention for intern Pharmacists and if patient safety and error reporting improved as a result. Within this study, four domains of patient safety and error reporting were measured. The four categories consisted of addressing errors, questioning behaviors, blaming the individual, and reporting errors. An ANOVA and paired t-test were performed to test post-intervention effectiveness. Post-intervention, the ANOVA results were as follows: addressing errors, $F_{(2,188)} = 7.99$, $p < 0.001$; questioning behaviors, $F_{(2,199)} = 6.11$, $p < 0.003$; blaming the individual, $F_{(2,188)} = 12.17$, $p < 0.001$; reporting errors, $F_{(2,188)} = 8.43$, $p < 0.001$. The paired t-test results were as follows: addressing errors, $t_{(94)} = 4.30$, $p < 0.001$; questioning behaviors, $t_{(94)} = 3.57$, $p = 0.001$; blaming the individual, $t_{(94)} = 4.87$, $p < 0.001$; and reporting errors, $t_{(94)} = 4.58$, $p < 0.001$. Both the ANOVA and the paired t-tests showed substantial improvement and sustainment (Walpola, Fois, McLachlan, & Chen, 2017). This study demonstrated a statistically significant relationship between education regarding patient safety and error reporting and improvement with addressing errors, having a questioning attitude, and reporting errors post-education.

Costello et al. (2007) also researched a pharmacist-led medication safety team to which the intervention consisted of an educational component, as well as the development of a new tool for reporting. This research study was broken down into three phases. Phase one consisted of data gathering regarding medication error reporting. Phase two and three consisted of instating an educational offering, and development of the new tool. Post-intervention, error reporting increased significantly, as well as the severity of the errors reported decreased. Total errors reported in phase one began at 11 reports, and by phase three, 75 reports were made. Out of the

categories studied (nursing, pharmacy, attending physician, and dietician), nursing had the most

substantial increase in overall reported medication errors (eight reports for phase one and 46

reports for phase three), and followed by pharmacy (zero reports for phase one and 23 reports for

phase three). For phase one, the severity decreased by 46%. Phase two decreased by 8%, and

phase three decreased severity by 0%. Near miss reporting also increased throughout the phases

of this study. Near miss reporting increased from 9% in phase one to 51% in phase three

(Costello, Torowicz, & Yeh, 2007).

A qualitative study was conducted by Hung, et. al., (2016) to which they linked the

nurse's attitudes towards reporting of medication errors. The aim of this study was to link under

reporting and a causal factor. Of the 596 staff nurses surveyed, the findings were conclusive that

nurse manager attitudes were a predictor and linked to staff nurse willingness to report

medication errors (Hung, Chu, Lee, & Hsiao, 2016).

Lu, et, al., (2013) conducted a study that consisted of a randomized control trial in 2009.

232 staff nurses amongst 21 hospitals were provided a sixty-minute educational in-service that

was developed by the researchers centered on high alert medication safety (Lu, et al., 2013). The

study consisted of a pre-test of 20 questions regarding high alert medications, the educational

intervention, and then a six-week post intervention test. The pre-test consisted of a 75.8% (mean;

n=232) correct answer rate (Lu, et al., 2013). The post-test showed statistically significant

improvement in nursing knowledge regarding high alert medications for the intervention group

(n=113) (pre versus post; 77.2 + 15.5 vs. 94.7 + 7.6; paired t= 10.82, p<0.0001). There were no

changes noted in the control group (Lu, et al., 2013). These results show a direct link between

education and improvement of nursing knowledge base for high-risk medications.

Several database searches were completed utilizing CINAHL, EBSCO, Cochrane database searches utilizing keyword searches: medication error reporting, medication safety, punitive culture, likelihood to report errors, medication education, and methods to reduce medication error reporting.

**Theoretical Framework**

Kurt Lewin was a Gestalt social psychologist that is widely known for developing the Change Management Theory in the 1940's (Kaminski, 2011). The purpose of Lewin's theory was to create "planned change" (Lewin, 1951). The theory is used widely to implement sustainable change. The theoretical foundation guiding this project was Kurt Lewin's "Change Theory." Lewin's Change Theory can be applied to "Medication Error Reporting to Improve Patient Safety" project because each phase of the theoretical framework is applicable to the progress of the project.

The FFA theory has several concepts. The first concept is that Lewin's "planned change" as it relates to the Change Management theory would be accomplished by moving through three phases; unfreezing, change, and refreeze (Lewin, 1951).

The unfreezing phase consists of the individuals recognizing a need for change Within the "unfreezing" phase, Lewin theorized that previous thinking or mindset can be changed if the parties involved are willing to recognize the need for change. For the purposes of the project, this phase encompassed the Medical Surgical staff bringing concerns forward to their leader requesting training and the need to focus on error reporting.

The "change" phase consists of making a change. Within the "change" stage, either the individual or the group can transition into the change. This stage is also called the "movement"

or "transition" phase as well. This phase was utilized to implement education targeted at medication safety and error reporting.

The final phase is the "refreezing" phase, which encompasses making the change sustainable. The "refreezing" stage was designed to implement the planned change. This phase consisted of implementing a plan for sustainability. Diagram 1.0 depicts a visual diagram of Lewin's Change Management Theory.
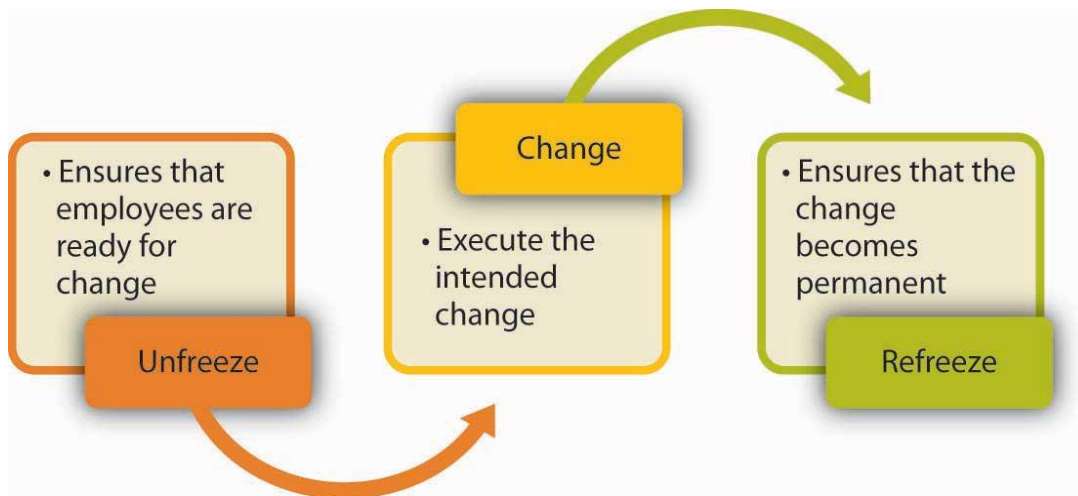


Diagram 1: Depiction of Lewin's Change Management Theory.

## Specific Aims

The intent of this project was to implement medication safety and error reporting education for all Registered Nurses on the Medical-Surgical unit. The outcomes were to increase medication error reporting, address the staff perception of medication errors, and identify barriers to error reporting. Staff were educated on the purpose and importance of error reporting and the basic principles of medication safe practices specific to high-risk medications (per the facility policy) to increase near-miss medication error reporting rates, while an overall increase in medication error reporting was desired.

## Context

Medication errors can result in no harm or effect on the patient, but they can also result in serious harm or death. Medication errors can cause strain and emotional stress to the nursing staff that experienced the error as well. Many barriers exist that prevent staff members from reporting medical errors, specifically medication errors. Some of these barriers include: the report may be utilized in a punitive manner, the act of reporting is time consuming, and the reporting process often lacks anonymity (VanOyen Force, et al., 2006). A cross-sectional study was conducted by Amrollahi et, al., (2017) regarding 1278 nurses working in three different teaching hospitals in Iran. This study focused on the nurses' perception as to why errors are not always reported and the barriers related to reporting (Amrollahi, Khanjani, Raadabadi, Hosseinabadi, Mostafaee, & Samaei, 2017). The study concluded that the majority of medical errors, including medication errors, are not reported due to "management-related factors" surrounding utilizing error reporting in a punitive manner from a leadership perspective (Amrollahi, Khanjani, Raadabadi, Hosseinabadi, Mostafaee, & Samaei, 2017). 67.6% of the study participants reported that they feel as though the manager focuses on the nurse who experienced the medication error as opposed to the reason for the error (Amrollahi, Khanjani, Raadabadi, Hosseinabadi, Mostafaee, & Samaei, 2017).

The consequence of not reporting medication errors is that the errors could continue to occur. Each medication error made has the potential to lead to severe or permanent harm to the patient. Nurses have a responsibility to ensure the patient is kept safe from harm, this includes safe and accurate medication administration. Medical errors, to include medication errors, was reported to be responsible for 98,000 American deaths and was named as the eighth leading cause of death (Institute of Medicine (US) Committee of Health Care in America, 2000). 7,000

16

of these 98,000 deaths were attributed to medication errors (Institute of Medicine (US) Committee of Health Care in America, 2000).

## Interventions

Saint Joseph East has experienced many high-risk medication errors on the Medical-Surgical unit over the past five years. To reduce these types of errors, the administrative team was in support of targeted medication error education. The project leader and facility leadership were in alignment for this project.

The project occurred on a 34 bed Medical-Surgical unit located within a 217 bed licensed acute care hospital. The target population consisted of all Registered Nurses that are employed on this unit. The project was chosen in conjunction with the facility President and Chief Nursing Officer based upon the lack of medication error reporting house-wide, but especially on the Medical-Surgical unit. The nursing leader of the Medical-Surgical unit requested medication error reporting education as a result of a staff meeting where the Registered Nurses voiced concerns about not understanding the need or importance of error reporting. There were many stakeholders for this project. The President, the Chief Nurse, the Quality Director, the staff, and the patients were stakeholders that had a vested interest in the project outcome.

The target population for this project were all Registered Nurses on the Medical-Surgical unit of Saint Joseph East. Participation in the educational intervention was considered a condition of employment, but survey pre and post survey completion was voluntary. The stakeholders for this project included the nursing staff working on Medical-Surgical unit, nursing leadership for the unit and the facility, and the patients receiving direct care.

The Eastern Kentucky University Institutional Review Board (IRB) approval was granted on March 21, 2018. The project implementation plan consisted of numerous meetings with the

Medical-Surgical nursing leader and Chief Nursing Officer to discuss the project plan. A

mandatory staff meeting was posted by the nursing leader two weeks in advance of the

determined implementation date. The project leader posted a flyer alerting the nursing staff about

the project and date of the mandatory intervention (March 21, 2018). The project leader also

emailed a copy of the project cover letter, as well as the educational flyer to all Registered

Nurses on the Medical-Surgical unit informing them of the mandatory attendance. The nursing

staff education occurred via a PowerPoint presentation that lasted approximately 30 minutes in

length and allowed for staff questions. The PowerPoint focused on medication safe practices and

the importance of error reporting. The PowerPoint was developed by the project leader and

presented to the nursing staff during a mandatory staff meeting. Prior to the educational

intervention, a pre-survey was given via an envelope along with the project cover letter. The

Project Leader reviewed the cover letter with the participants at the beginning of the educational

meeting and answered any existing questions. Each individual that volunteered to participate in

the project, completed the survey and returned the survey to the Project Leader in the envelope

provided. The four-page survey, titled, "Nurses' Perceptions of Medication Errors" developed by

Dr. Mary Jo Maurer (2010). Ten minutes was allotted for survey completion. To preserve the

confidentiality of each participant; all participants were instructed to identify a four-digit code

using their mother's birth month and day.  Two digits for the month and two digits for the day.

If either number is a single digit a leading zero should be added.  For example, the four-digit

code for January the 5th would be 0105.  An instruction sheet was given to each participant prior

to survey completion. After two weeks, the participants were asked to complete post-education

survey utilizing the same confidentiality elements as the pre-survey. Two weeks' post-

educational intervention, the RN staff will be given the "Nurses' Perceptions of Medication

Errors" developed by Dr. Mary Jo Maurer. The cover letter was reviewed again, and voluntary

participation was reinforced.  Participants were reminded of the 4-digit code used for the pre-

survey. All data pertaining to medication error reporting was entered into SPSS for analysis

using the four-digit code for data pairing. No identifying information participant or patient

information was included.

### Study of the Interventions

The approach chosen to assess the impact of intervention was raw number incident report

comparison (pre and post educational intervention), and increased knowledge about medication

error reporting. An analysis of the pre and post survey results established an increased awareness

with causes of medication errors, medication errors committed over a defined timeframe, barriers

to reporting, and increased factors that influence medication error reporting.

### Measures

Education regarding the importance and value of incident reporting increases error

reporting. Costello, Torowicz, & Yeh (2007) conducted a study that demonstrated a positive

correlation between education and increased medication error reporting. Pharmacy

representatives led a safety team specific to medication error-reporting (Costello, Torowicz, &

Yeh, 2007). Error reporting within this study increased six-fold overall post intervention,

demonstrating increased error reporting post education. Error reporting will consist of all

reported errors to include near-miss reporting.

The instrument for this project consisted of a four-page survey regarding nurse perception

of medication errors. The tool is titled, "Nurses' Perceptions of Medication Errors" and was

developed by Dr. Mary Jo Maurer. The tool focused on seven areas; contributing factors to

medication errors, experiences with medication errors, barriers to reporting medication errors,

factors increasing the likelihood of reporting medication errors, communication of medication errors, helpfulness of medication administration technology, and nurse demographics and characteristics (Maurer, 2010). Only four of the six domains were considered relevant to this project: causes of medication errors, experiences with medication errors, barriers to reporting, and error reporting.

Face validity of the tool was determined by comprehensive review of the literature, and content validity was determined per expert panel (Maurer, 2010). There were four experts that reviewed the tool to determine validity that had expertise in this particular field of study (Maurer, 2010). In order to determine reliability of the tool, Dr. Maurer conducted a convenience sample of nine registered nurses for pilot testing and reliability. The tool was given to the nine nurses in two intervals; two weeks apart. The Cronbach Alpha demonstrated tool reliability in all categories during the pilot testing. The Cronbach Alpha for "causes of medication errors" was 0.78, "barriers to reporting" was 0.77, "factors likely to increase reporting" was 0.79, "communication of errors" was 0.99, and "technology utilized to decrease errors" was 0.63 (Maurer, 2010).

Education success was measured by an increased knowledge base/perception for the nursing staff, and an increase in medication error reporting. For the purposes of the incident reports, a raw number was calculated pre and post educational intervention. The pre-survey was provided immediately prior to the educational intervention. The post-survey will be administered 14 days post intervention. The number of incident reports before education and training was assessed, and then was reassessed post intervention. All medication-related incident reports are maintained in a database managed at the facility level. The database was accessed via the facility Risk Manager, and all patient names blinded for the purposes of this project. All study

participants were also instructed to complete the complete the demographic portion of the four-page survey tool.

**Analysis**

Domain One:

Domain one addressed how often a specific primary cause of a medication error occurred utilizing a Likert scale (1- Never to 5-Always). Inquiry of nurse calculating dosages of medications, interruptions, short staffing, high acuity patients, total hours worked, hostility within the workforce, and clinical knowledge base were all questions addressed within the survey.

A paired samples t-test (two tailed) was conducted to analyze the mean difference between pre and post survey scores. The eta squared value was .08; indicating a moderate effect and clinical significance. The p-value was not found to be statistically significant. Of the questions asked, I have highlighted those that were found to be the most relevant. Nursing knowledge regarding medications being administered, interruptions during med pass, unclear policies, short nursing staff, and incomplete medications orders were all found to be majority causes for medication errors.

Table 1.0 refers to the most relevant questions within domain one. 41.7% of respondents stated that the nursing knowledge of the medication being administered were "sometimes" a cause of errors, 25% stated that this was the cause "most of the time" or "always". Over half of the respondents stated that interruptions during medication administration were "most of the time" or "always" the cause of medication errors (refer to Table 1.0). 66.7% of respondents stated that being short staffed with Registered Nurses was the primary cause of medication errors

"sometimes"; whereas 33.3% stated "most of the time."

Table 1.0: Depicts domain one and the most relevant questions to this project pertaining to causes of medication errors.

Domain Two:

Domain two targeted the experience the participant's had with medication errors over the past 12 months. There were 3 questions asked in total; how many medication errors did they or a colleague make over the past 12 months that resulted in harm to a patient, how many medication errors over the past 12 months that did not cause harm, and how many medication errors were reported over the past 12 months?

For domain two, specific to questions one and two, the p value was not found to be statistically significant, and the eta squared was found to not be clinically significant either. For question three, the question pertains to how many errors to staff reported within the last 12 months. For this question, the p value was not found to be statistically significant, but the eta squared was .27, indicating a large effect and clinical significance. Refer to Table 2.0 for details regarding mean, standard deviation, t and p values.

Table 2.0: Depicts medication errors that did not cause patient harm.

Domain Three:

Domain three included questions pertaining to barriers of reporting medication errors. Examples of these barriers are how other nurses will perceive the person who reports an error, blame, reporting is too detailed and time consuming, and retaliation of reporting. The p value was .000, with an eta squared of .70; indicating a large effect. Barriers to reporting medication errors were found to be clinically and statistically significant. The mean increase for this domain was 5.75.

Table 3.0: Depicts barriers to reporting medication errors; domain three.

Domain Four:

Domain four included questions pertaining to factors that increase the chance that staff would report medication errors. This domain section utilized a five point Likert scales with scores ranging from 7-35. Examples of these factors include: if any of the five rights of medication administration (right patient, drug, dose, time, or route) were violated, if the reporting process was anonymous, if there was patient harm, if there were benefits to reporting (improved practice, increased accountability), if the nurse had no fear of retaliation, and if the physician/nurse relationship was positive. The p value of 0.17 was found to be statistically significant, and the eta squared was .41 indicating a large effect and clinical significance.

Table 4.0: Depicts factors that increase the chance of nursing reporting a medication error.

Error Reports:

 The raw numbers of medication error reports did increase by 50% over the two week time span, with near miss reporting increasing as well. No near miss medication reports were filed 2 weeks prior to the educational intervention. Four reports from 3/7/18 to 3/21/18 with eight reports from 3/22/18 to 4/5/18. Four error reports were classified as near miss reports.

## Ethical Considerations

 No ethical considerations were noted during the duration of this project.

## Summary

 Data analysis was completed by utilizing an appropriate statistical software package, SPSS. The demographic data was analyzed and consisted of four questions (age, total years of nursing experience, years of experience on the specific unit, and length of employment at the facility). A paired t-test will be utilized to compare the pre and post-survey data.

## Interpretation

 Domains three and four were considered both statistically and clinically significant. This was not surprising in that these sets of questions are focused on the physical act of error reporting, and communicating about the error if one should occur. The educational intervention demonstrated how to report an error within the hospital database, as well as the importance of reporting errors to the facility, patient, and physician. Since this information was addressed directly through the intervention, it was expected to have these areas significant.

Domains one, two, and five were found to be clinically, but not statistically significant. Domain 1 addresses the perception of reporting. Domain two focuses on their previous experiences with reporting medication errors. Domain five focused on technology such as barcode scanning. These domains were found to be unusual elements to be found as clinically significant two weeks post intervention. When the findings were reviewed with the nursing leader of the unit, I was informed that she addressed the importance of medication error reporting, and the ease in which it takes to input a report. I believe I can attribute some of the positive outcomes for these domains to repeated reinforcement and a visible support and focus by the study participant's direct nursing leader.

## Limitations

The sample size was small for this study, but all participants completed both the pre and post educational survey. An area of opportunity for future studies would be the need to evaluate areas other than home department to assess intervention effectiveness. For the purposes of this agency's incident reporting system, the department that generated the error would be the attributing department within the incident report. If the error originated in Pharmacy, such an incorrect dose being delivered to the Medical-Surgical department, the Med-Surgical nurse would attribute that near miss to Pharmacy, and therefore Med-Surgical would not have this report within their totals.

## Conclusions

The purpose of this project was to increase awareness regarding reporting medication errors, as well as increasing the number of medication errors. The overall response to the education provided was positive from the staff participating. If the facility wishes to continue the program,

education refreshers specific to reporting medication errors would need to be provided

throughout their employment to reinforce the need for reporting medication errors.

## Funding

There were costs associated with this project. Each nurse on the Medical-Surgical unit

required mandatory attendance for the educational intervention, which took approximately 30

minutes to complete. There were 12 nurses that participated in the project, with the average

salary of $27.00/hour. The nursing staff wishing to participate were also asked to complete a pre

and post-survey, which accounted for approximately thirty minutes' total. The total estimated

cost for nursing staff participation was $472.50 (35 participant's x average salary of $27/hour x

50 minutes). The incident report data was manually pulled for the Medical-Surgical unit. The

Risk Analyst pulled this data. Her approximately rate of pay was $22.00/hour, and this data

abstraction took approximately one hour. The total anticipated cost for the project was $492.50.

References

Agency for Healthcare Research and Quality. (2017, March 1). *Adverse events, near misses, and errors*. Retrieved from AHRQ: https://psnet.ahrq.gov/primers/primer/34/adverse-events-near-misses-and-errors

Amrollahi, M., Khanjani, N., Raadabadi, M., Hosseinabadi, B., Mostafaee, M., & Samaei, S. E. (2017). Nurses' perspectives on the reasons behind medication errors and the barriers to error reporting. *Nursing & Midwifery*, 132-136.

Baratto, M., Pasa, T., Cervo, A., Dalmolin, G., Pedro, C., & Magnago, T. (2016). Cluture of patient safety in the hospital setting: An integrative review. *Journal of Nursing*, 4126-4136.

Baulcomb, J. S. (2003). Management of change through force field analysis. *Journal of Nursing Management*, 275-280.

Costello, J. L., Torowicz, D. L., & Yeh, T. S. (2007). Effects of a pharmacy-led pediatrics medication safety team onmedication-error reporting. *American Journal of Health-System Pharmacy*, 1422-1426.

Garrouste, O. M., Timset, J., L., S., M., T., C., A., F., P., . . . J., C. (2008, July). Impact of adverse events on outcomes in intensive care unit patients. *Critical Care Medicine*, 2041-2047.

Garrouste-Orgeas, M., Timsit, J., Vesin, A., Schwebe, C., Arnodo, P., Lefrant, J., . . . Soufir, L. (2010). Selected medical errors in the intensive care unit: Results of the IATROREF study: Parts I and II. *American Journal of Respiratory Critical Care Medicine*, 134-142.

Hsaio, G., Chen, I., Yu, S., Wei, I., Fang, Y., & Tang, F. (2010). Nurses' knowledge of high-alert medications: Instrument development and validation. *Journal of Advance Nursing*, 177-190.

Hung, C., Chu, T., Lee, B., & Hsiao, C. (2016). Nurses' attitude and intention of medication administration error reporting. *Journal Clinical Nurse*, 445-453.

Institute of Medicine (US) Committee of Health Care in America. (2000). *To Err is Human: Building a Safer Health System.* Washington: National Academies Press (US).

Kaminski, J. (2011, March). Theory applied to informatics – Lewin's change theory. *Canadian Journal of Nursing Informatics*, 1-5.

Lee, T.-T. (2006). Adopting a personal digital assistant system: Application of Lewin's change theory. *Journal of Advanced Nursing*, 487-496.

Lewin, K. (1951). *Field theory in social science; selected theoretical papers.* (H. &. Row, Ed.) New York: D. Cartwright.

Lu, M., Yu, S., Chen, I., Wang, K., Wu, H., & Tang, F. (2013). Nurses' knowledge of high-alert medications: A randomized controlled trial. *Nurse Education Today*, 24-30.

McGarry, D., Cashin, A., & Fowler, C. (2012). Child and adolescent psychiatric nursing and the 'plastic mans': Reflections on the implementation of change drawing insights from Lewin's theory of planned change. *Contemporary Nurse*, 263-270.

VanOyen Force, M., Deering, L., Hubbe, J., Anderson, M., Hagemann, B., Cooper-Hahn, M., & Peters, W. (2006, January). Effective strategies to increase reporting of medication errors in hospitals. *The Journal of Nursing Administration*, 34-41.

Walpola, R. L., Fois, R. A., McLachlan, A. J., & Chen, T. F. (2017). Evaluating the effectiveness

of an educational intervention to improve the patient safety attitudes of intern

pharmacists. *American Journal of Pharmaceutical Education*, 1-7.

Appendix A: Statement of Mutual Agreement

**EKU**® Eastern Kentucky University
Department of Baccalaureate and Graduate Nursing
Doctor of Nursing Practice Program

## Statement of Mutual Agreement for DNP Project

The purpose of a Statement of Mutual Agreement is to describe the agreement between a designated clinical agency and the DNP student regarding the student's DNP project.

### I.    General Information

Student Name: Dianna Madden

Project Title:   Increasing Medication Error Reporting to Improve Patient Safety

Agency: Saint Joseph East

Agency Contact: Deb Bryant, CNO

### II.    Brief description of the project

Quality Improvement Project:

Error reporting is essential for identification and resolution of problems within the healthcare system. It is through identification of system-wide errors that safety nets can be put in place to prevent a similar event occurring in the future. Garrouste, et al. (2008) found 12 Intensive Care Units (ICU) had a 39.2% adverse event rate, with a denominator of 3,611 patients. Additionally, 22.7% of patients experienced more than one adverse event during their hospitalization (Garrouste, et al., 2008). Adverse event was defined as any event that resulted in an error that reached the patient but may or may not have caused harm, including medication errors. The mean number of adverse events was 2.8 events per patient, with a range of adverse events from 1-26 (Garrouste, et al., 2008). A more recent study by Garroute-Orgeas, et al. (2010) found that medical errors in the ICU were mostly related to medication administration errors. The most common medication administration error in the ICU was insulin administration. The authors reported that there were 185.9 insulin-related errors out of 1,000 patient days of insuin treatment. Of these insulin-related errors, 58 of them required additional clnical treatment or intervention after the error was idenitified (Garrouste-Orgeas, et al., 2010).

There are several types of errors that exist. A near miss event is an error that was identified before reaching the patient (Agency for Healthcare Research and Quality, 2017). A near miss is defined as "an unsafe situation that is indistinguishable from a preventable adverse event except for the outcome. A patient is exposed to a hazardous situation, but does not experience harm either through luck or early detection" (Agency for Healthcare Research and Quality, 2017). These types of events are especially important to report to put action into place to prevent future déjà vu or repeat events. Serious safety events are events where severe or permanent harm is the result of an error. Identification of all error types allows root causes to be determined and system errors to be addressed (Agency for Healthcare Research and Quality, 2017). Without understanding the underlying reason as to why the errors are occurring, healthcare leaders cannot put safety nets in place to prevent patient harm. Being aware of the errors that are occurring will also allow the facility leadership to be more

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Department of Baccalaureate and Graduate Nursing
Doctor of Nursing Practice Program

Prior to the implementation Saint Joseph East gives permission to the Eastern Kentucky

University IRB.

**IV. Required Signatures:**

Dianna S. Madden    2/23/18
_____    _____
Student                     Date

Donna J. Coley    2/23/18
_____    _____
DNP Project Advisor         Date

Deborah Bryonus    2/23/18
_____    _____
Agency Representative       Date

Appendix B: Permission to Use Tool

**Madden, Dianna S**

| | |
|---|---|
| **From:** | Maurer, Mary Jo <mmauer@lourdes.edu> |
| **Sent:** | Monday, January 15, 2018 2:04 PM |
| **To:** | Madden, Dianna S |
| **Subject:** | RE: Permission to Medication Error Reporting Tool |
| **Follow Up Flag:** | Follow up |
| **Flag Status:** | Flagged |

**CAUTION:** This email is not from a CHI source. Only click links or open attachments you know are safe.

Absolutely, use the tool! Good Luck! We will be starting our DNP program at Lourdes this Summer!

Mary Jo Maurer PhD, RN

**From:** Madden, Dianna S [mailto:DiannaMadden@sjhlex.org]
**Sent:** Monday, January 15, 2018 10:07 AM
**To:** Maurer, Mary Jo <mmauer@lourdes.edu>
**Subject:** Permission to Medication Error Reporting Tool
**Importance:** High

Good Morning,

I am a DNP student at Eastern Kentucky University. I am currently working on my Capstone project centered around medication error reporting. Your tool was very inspiring and I was hoping to be granted permission to utilize it in my research? I appreciate your consideration.

Thank you!

*Dianna S. Madden, MSN, RN*
Director of Quality and Risk Management

Saint Joseph East
150 North Eagle Creek
Lexington, KY 40509

O: 859-967-5106
C: 859-361-7326

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## Appendix C: Survey Tool

**Nurses' Perceptions of Medication Errors**

**Directions:** Please complete each of the following items according to the instructions. Your responses will be confidential. Do not put your name on this survey.

**Definition of Medication Error:** *For the purpose of this survey, medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare profession.*

| 1. | How often are each of the following a primary cause of medication errors? (please rate) | Never | Rarely | Sometimes | Most Of The Time | Always |
|----|------|------|------|------|------|------|
| A. | Nurse must calculate the dose of the drug. | | | | | |
| B. | Nurse knowledge of medication being administered. | | | | | |
| C. | Interruption during medication pass. | | | | | |
| D. | Unclear policy and procedures regarding medication administration. | | | | | |
| E. | Short RN staff. | | | | | |
| F. | Nurse caring for high acuity patients. | | | | | |
| G. | Nurse works more than 12 hours in one shift. | | | | | |
| H. | Nurse works more than 40 hours in one week. | | | | | |
| I. | Incomplete medication order. | | | | | |
| J. | Nurse not familiar with unit environment. | | | | | |
| K. | Nurse has limited clinical knowledge. | | | | | |
| L. | Hostile work environment. | | | | | |
| M. | Other (please specify and rate) _____ | | | | | |

2. Please identify your experiences with medication errors (please circle number).

A. How many medication errors did you or a colleague make during the past 12 months that resulted in harm to a patient?

0    1    2    3    4    5    6    7    8    9    10    Over 10

B. How many medication errors did you or a colleague make during the past 12 months that did not harm the patient?

0    1    2    3    4    5    6    7    8    9    10    Over 10

C. How many medication errors were reported over the past 12 months? (please fill in)
1. Medication errors that caused harm _____.
2. Medication errors that did not cause harm _____.

| 3. Please rate how much of a barrier each of the following are: | Major Barrier | Moderate Barrier | Minor Barrier | Not A Barrier |
|---|---|---|---|---|
| A. At our facility the blame is put on the individual rather than looking at the system as a potential cause of the error. | | | | |
| B. Others will think nurses are incompetent. | | | | |
| C. Nurses think most errors are not important enough to report. | | | | |
| D. If something happens to the patient due to a medication error, the nurse will be blamed. | | | | |
| E. Reporting is too detailed and time consuming. | | | | |
| F. Nurses are afraid of a reprimand if they report a medication error that is made. | | | | |
| G. Nurses are afraid of the consequences that may result if they report a medication error. | | | | |
| H. If an error is prevented before it reaches the patient (near miss), it is not necessary to report. | | | | |
| I. Please specify other barriers to reporting medication errors (please rate). | | | | |

| 4. How likely would the following factors increase your chance of reporting a medication error that you or someone else made? (please rate) | Highly Likely | Likely | Undecided | Unlikely | Highly Unlikely |
|---|---|---|---|---|---|
| A. If any of the 5 rights (right patient, drug, dose, time, route) of medication administration were violated. | | | | | |
| B. If the reporting process was anonymous. | | | | | |
| C. If the patient was harmed or potentially could have been. | | | | | |
| D. If there are benefits to reporting such as the prevention of future errors, improved practice, or increased accountability. | | | | | |
| E. If the nurse had no fear of retaliation in the work environment. | | | | | |
| F. If the nurse had a positive relationship with the supervisor/clinical manager. | | | | | |
| G. If the nurse had positive professional relationships with physicians on the unit. | | | | | |
| H. Please specify other factors that would increase your probability of reporting a medication error (please rate). | | | | | |

| 5. | Please rate your agreement or disagreement with the following statements. | Strongly Agree | Agree | Undecided | Disagree | Strongly Disagree |
|---|---|---|---|---|---|---|
| A. | Medication errors should be reported to the patient when they occur. | | | | | |
| B. | Medication errors should be reported to the patient's family, when the patient is not capable of understanding what has occurred. | | | | | |
| C. | Medication error report cards for hospitals should be published for the public to review. | | | | | |

| 6. | How helpful has the following technology been in decreasing medication errors in the facility in which you work? (please rate) | Very Helpful | Helpful | Slightly helpful | Not Helpful at All | Not Sure | Do Not Have This |
|---|---|---|---|---|---|---|---|
| A. | Barcode medication administration | | | | | | |
| B. | Computerized physician order entry | | | | | | |
| C. | Automated medication dispensing | | | | | | |
| D. | "Smart infusion pumps" | | | | | | |

**NURSE DEMOGRAPHICS AND CHARACTERISTICS: (please check mark)**

1. Gender: ___ Female ___ Male

2. Race/Ethnicity (please indicate the background you most identify with):
   ___ African American ___ Hispanic ___ White
   ___ Asian/Pacific Islander ___ Native American/Alaskan Native
   ___ Other (please specify)_____

3. Age _____ (years)

4. Check highest level of education:
   ___ Diploma in Nursing ( 2 or 3 years )
   ___ Associate Degree in Nursing ___ Master Degree in Nursing
   ___ Bachelor Degree in Nursing ___ Other (please specify)_____

5. Do you currently have national certification in a clinical specialty? ___ Yes ___ No
   Certification Specialty: _____

6. Number of years of clinical experience since graduation? _____ years

7. How many years has it been since you attended any pharmacology continuing education?
   ___< 1 year ___1 ___2 ___3 ___4 ___5 ___6 ___7 ___8 ___9 ___10 or more

8. How was pharmacology taught in your undergraduate nursing program?
___ Formal pharmacology course     ___ Pharmacology integrated throughout curriculum
___ Other (please specify) _____

9. What is your work schedule?     ___ Full-time     ___ Part-time     ___ Per diem

10. Which shift do you work?
___ 12 hour shift day          ___ 12 hour shift night          ___ rotate 12 hour shift
___ 8 hour shift day           ___ 8 hour shift evening         ___ 8 hour shift night
___ Rotate 8 hours day/eve     ___ Rotate 8 hours day/night     ___ Rotate 8 hours eve/night
___ Other

11. As a registered nurse how long has it been since your mathematical skills have been formally tested
(e.g. in-house continuing education, skills review)?
___ < 1 year     ___ 1-2 years     ___ 3-4 years     ___ 5 years or more     ___ Never

12. How frequently do you work more than 12 hours in one day?
___ Never     ___ 1-2 times in 2 week period     ___ 3-4 times in 2 week period
___ 5 or more times in 2 week period     ___ Other (please specify)_____

14. I would feel safe being a patient in the hospital that I am currently working. (Please circle one)
Strongly Agree     Agree     Undecided     Disagree     Strongly Disagree

15. When you are working in clinical practice, do you normally (Check only one):
___ Work in the same clinical practice setting
___ Work as part of the float pool
___ Work various hospitals and different floors (from an outside agency)
___ Work on a long-term assignment, several months or more (from an outside agency)
___ Other (please specify) _____

16. The size of the hospital I am currently working in would be classified as:
___ Fewer than 100 beds (small)          ___ 100-299 beds (medium)     ___ 300 plus beds (large)
___ Do not work in hospital

17. My primary place of employment is outside the hospital setting:
___ Extended Care facility              ___ Office type setting
___ Community Health setting            ___ Hospice
___ Other: _____              ___ I do work in a hospital

18. If working in a hospital the type of unit/area most often worked is: (choose only one response)
___ Medical          ___ Surgical          ___ Medical/Surgical          ___ Step-down
___ Obstetrics       ___ Pediatrics        ___ Pediatric ICU             ___ Neonatal ICU
___ Adult ICU        ___ Psychiatric       ___ Long term care unit within the hospital
___ Other (please specify): _____

---

*Thank You for participating in this National Nursing Study!*

Appendix D: Educational Flyer

INCREASING MEDICATION ERROR REPORTING TO IMPROVE PATIENT SAFETY –
Dianna Madden

# Saint Joseph East
# Improving Patient Safety through
# Reporting Medication Errors

Participation in the medication error reporting education is mandatory as a condition of your employment. However, participation in the project is voluntary. You will be asked to complete a survey form prior to the mandatory education and approximately two weeks post-education. The survey is titled; Nurses' Perceptions of Medication Errors. The survey will take approximately 10 minutes to complete at the beginning and at the conclusion of the project.

# (3/21/18 at 6pm in Med-Surg PT Gym)

# Attendance is required by all Registered Nurses

For any concerns attending this session please contact
Dianna Madden, Primary Investigator.

Appendix E: Instruction Sheet

INCREASING MEDICATION ERROR REPORTING TO IMPROVE PATIENT SAFETY –
Dianna Madden

Instruction Sheet

Unique Four – Digit Numerical Code

To protect the confidentiality and identification of each participant; all participants will be instructed to list a four-digit numerical code unique to them on all of the project documents. The Primary Investigator will not know the unique identifying code of each participant. The four-digit code should be the participant's mother's birthday month and day. Two digits for the month and two digits for the day. If it is a single digit add a leading zero.

For example, if the birth month is December use the digits 12. The same is true if the birthday is a single digit number; add a zero. If the day of the month is the 2nd you would use the double digits of 02. If the birthdate is December, the 2nd the four-digit number would be 1202. Only these four numerical numbers will be placed on all documents used in this project.

Appendix F: Cover Letter

INCREASING MEDICATION ERROR REPORTING TO IMPROVE PATIENT SAFETY
Dianna Madden

Cover Letter
Doctor of Nursing Practice Student
Eastern Kentucky University

Dear Registered Nurse (RN):

My name is Dianna Madden. I am implementing an educational program at Saint Joseph East as a requirement for the completion of my Doctor of Nursing Practice (DNP) degree at Eastern Kentucky University. My work will be guided by my project advisor Dr. Donna Corley. This project is titled Increasing Medication Error Reporting to Improve Patient Safety. The purpose of this project is to increase medication error reporting to find areas of opportunity in order to decrease repeat events.

You are being asked to participate because you are a RN employed by Saint Joseph East. Participation in the medication error reporting education is mandatory as a condition of your employment. However, participation in the project is voluntary. You will be asked to complete a survey form prior to the mandatory education and approximately two weeks post-education. The survey is titled; Nurses' Perceptions of Medication Errors. The survey will take approximately 10 minutes to complete at the beginning and at the conclusion of the project.

There is no known benefit to your participation; however, your participation may help identify ways to reduce medication errors and increase medication error reporting. The Medication Error Reporting program is developed to provide encouragement and support for reporting medication errors. The project will last 2 weeks.

To the best of my knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. The only identified risk is the potential loss of confidentiality. Your confidentiality is important to me and every effort will be made to keep the information you provide confidential. No information that could connect you to the information you provide will be included on any of the survey forms. Only aggregate (group) data will be shared with Eastern Kentucky University faculty, Saint Joseph East administration and in presentation and publication.
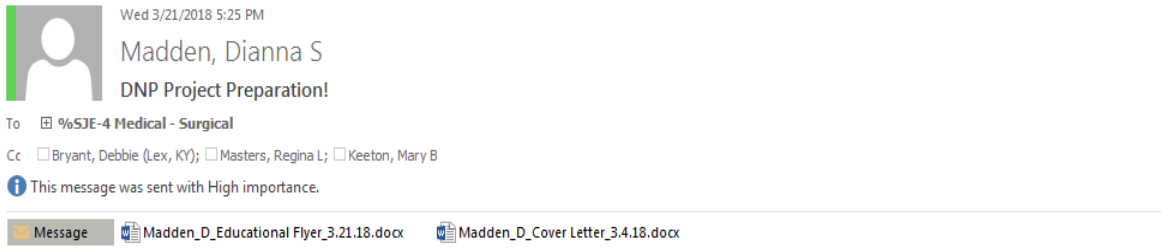
If there are any questions during the project, please reach out to the principal investigator Dianna Madden at (859) 361-7326 or my project advisor Dr. Donna Corley (859) 622-6316.

Thank you for your consideration,

Signature of PI

Appendix G: Email to Participants

Wed 3/21/2018 5:25 PM

**Madden, Dianna S**

**DNP Project Preparation!**

To   ⊞ %SJE-4 Medical - Surgical

Cc   ☐Bryant, Debbie (Lex, KY); ☐Masters, Regina L; ☐Keeton, Mary B

ℹ This message was sent with High importance.

✉ Message   📄Madden_D_Educational Flyer_3.21.18.docx   📄Madden_D_Cover Letter_3.4.18.docx

Good Afternoon!

Hello! I am a Doctorate of Nursing Practice (DNP) student at Eastern Kentucky University. You have been selected to participate in education related to improving patient safety by reporting medication errors. This project will consist of a pre-survey depicting your current knowledge about error reporting and the benefits of doing such reporting, a brief education (via PowerPoint), and a post education survey two weeks later. I have attached a Cover Letter, and flyer regarding the project and your participation. I am really looking forward to working with each of you and having you be a part of my DNP journey!

Thank you in advance and I will see you tonight!

*Dianna S. Madden,* MSN, RN
Director of Quality and Risk Management

Saint Joseph East
150 North Eagle Creek
Lexington, KY 40509

O: 859-967-5106
C: 859-361-7326

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Appendix H: IRB Approval

Reply all |     Delete    Junk |

## IRB Approval Notification: Protocol Number #1498

SP    Sponsored Programs <support@inforeadyreview.com>     Reply all |
Yesterday, 1:57 PM
Madden, Dianna S; Corley, Donna

Inbox

To help protect your privacy, some content in this message has been blocked. To re-enable the blocked features, click here.

To always show content from this sender, click here.

Application
Management

Hello Dianna Madden,

Congratulations! The Institutional Review Board at Eastern Kentucky University has approved your **IRB Application for Expedited Review** for application entitled, **"Increasing Medication Error Reporting to Improve Patient Safety."** Your approval is effective immediately and will expire on 3/20/2019.

**Principal Investigator Responsibilities**: It is the responsibility of the principal investigator to ensure that all investigators and staff associated with this study meet the training requirements for conducting research involving human subjects, follow the approved protocol, use only the approved forms, keep appropriate research records, and comply with applicable University policies and state and federal regulations.

**Consent Forms**: All subjects must receive a copy of the consent form as approved with the EKU IRB approval stamp. You may access your stamped consent forms by logging into your InfoReady Review account and selecting your approved application. Copies of the signed consent forms must be kept on file unless a waiver has been granted by the IRB.

**Adverse Events**: Any adverse or unexpected events that occur in conjunction with this study must be reported to the IRB within ten calendar days of the occurrence.

https://outlook.office.com/owa/?ItemID=AAMkADdiMGUxOGNiLTk0ZTItNDNiOC1iYj...   3/22/2018