

## Research Article

# Ensuring Safe Medication Administration through Direct Observation

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## ABSTRACT

**Background and Objectives:** A medication administration process was examined within a university affiliated pediatric hospital. Areas for future improvement will be identified in order to enhance medication practices and ensure the safety of patients during a medication administration.

**Methods:** To evaluate the effectiveness of the medication administration process in regards to patient safety and quality assurance, a direct observation study of inpatient units was conducted. The outcomes of this study address labeling medication, patient identifiers, the Five Rights of medication administration, the use of nursing staff worksheets, double checks, and the presence of distractions and interruptions during the medication administration process.

**Results:** From the 60 observations, information was collected and then analyzed both quantitatively as well as qualitatively.

The numerical outcomes are shown in the following graphs and the data are discussed at length. The data identify areas where improvements can be made to ensure safe medication administration.

**Conclusions:** This study provides a first step towards making quality changes to ensure the safety of patients during a medication administration. In order to draw more conclusive results, collection of data would need to take place over a prolonged period of time with a sample population proportionate to the institution.

**Keywords:** medication errors, medication administration errors, patient safety, quality assurance

**Abbreviations:** eMAR: electronic Medication Administration Record; MAR: Medication Administration Record; MRN: Medical Record Number

## Background and objectives

Ensuring safe medication administration is a complex and multi-factorial system involving nursing and pharmacy. Often the evaluation of it depends solely on risk reports to identify process improvement needs. Alternative methods such as trigger tools and direct observation can add to the body of knowledge without relying on a single method. One is well aware of the Five Rights of medication administration but in reality it is unknown if they indeed occur.<sup>1</sup> A study by Antonow found that 62.1% of medication errors were prevented at the dispensing/delivery phase but the likelihood of prevention decreased in the later stages of the medication administration process.<sup>2,1</sup> (Figure 1)

In the pediatric population, medication errors are usually attributed to nursing staff; in a study of 190 nursing administration errors, 57% were due to “omission, wrong infusion rate, and wrong time”<sup>1</sup>. However, nursing staff are also the most likely health care professionals to catch errors before they occur. Kopp’s study indicates “24 of the 110 (22%) potential adverse drug events (ADEs) were intercepted, primarily by nursing personnel (88%).”<sup>2</sup> This becomes significantly important as medication administration errors rates

are higher in the pediatric patient population compared to adult patient populations. A Sentinel Event Alert about preventing pediatric medication errors, published by the Joint Commission, cited dosing errors as one of the root causes because of “weight based dosing calculations, fractional dosing, and the need for decimal points.”<sup>3</sup> Error rates detected by direct observation

Five Rights of Medication Administration Were the Five Rights of medication administration utilized?

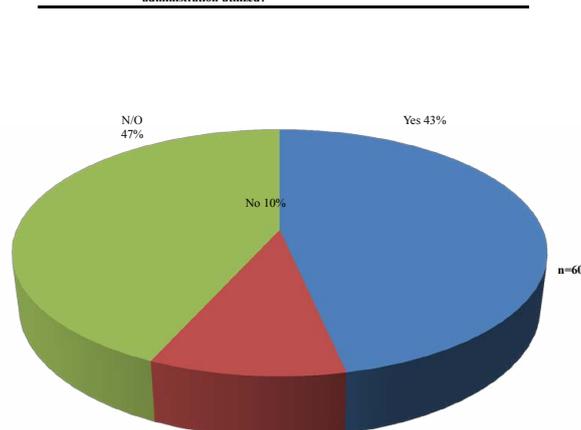


Figure 1: Medication Labeling Graph.

studies have varied reported error rates. In the Buckley study, the type of error documented as the most common (wrong dose) with 26.2% yet in other studies, using similar direct observation methods, found the error to occur infrequently with only 1.2%.<sup>4</sup>

A medication administration error is defined as a “deviation from the prescriber’s medication order as written on a patient’s record, manufacturers’ preparation, administration instructions, or institutional policies/procedures” on medication administration.<sup>5</sup> A review of direct observational studies on medication administration errors identified a median error rate of 19.6% of total opportunities for error. The wrong time, medication omission, and wrong dosage were the three most common medication administration errors. The authors in the Keers study note bar-code medication administration (BCMA), computerized prescriber order entry, educational packets, and different drug distribution systems have shown a decrease in the rate of medication administration errors.<sup>5</sup>

Elganzouri and colleagues found nurses averaged 15 minutes on each medication administration. The administration included the preparation, retrieval, administration and documentation. Based on the study’s results, it is apparent there are opportunities for interruptions to the medication administration process. The observational study included a rural, urban and an academic hospital and represented both electronic and paper based ordering and documentation.<sup>6</sup> The direct observation studies done by Keers et al, in adult and pediatric medical/surgical intensive care units, found that one preventable error occurred for every five doses of medication administered. Errors occurred in each stage of the medication administration process. Wrong dose, wrong time, wrong technique and extra doses were medication administration errors observed in the studies.<sup>5</sup> In both direct observation studies conducted by Buckley et al and Kopp et al, proximal causes identified in the administration stage included slips and memory lapses, lack of drug knowledge, rule violations, preparation errors, faulty dose checking, infusion pump problems and faulty interaction with other services. Slips and memory lapses were identified as the most common cause of medication administration errors.<sup>2,4</sup>

In this process improvement project, the team undertook a direct observation study of the medication administration process in our pediatric population. The University of Michigan Health System opened a new pediatric hospital, C.S. Mott Children’s Hospital, prior to the study. The direct observation study was formulated in an attempt to observe medication passing in the new facility with increased Omnicell® locations, different access to nursing stations, and the historical use of nursing worksheets. Nursing worksheets had previously been utilized as an organization tool for nurses. These were used, prior to the implementation of computerized physician order entry, to prioritize medication administration. The mission of the study was to bring awareness and educational initiatives to the nursing staff members. Additionally, the team intends to identify and analyze the different steps of the medication administration process for further improvement.

## **METHODS**

### **Setting**

This 24-day direct observational study took place at the

University of Michigan’s C.S. Mott Children’s Hospital—a 198-bed inpatient institution—between September 10<sup>th</sup>, 2012 and October 12<sup>th</sup>, 2012. This length of time was chosen to allow the students to observe each of the eight pediatric nursing units on at least three different occasions, with the exception of two units only being observed twice. A risk management student observer from the Office of Clinical Safety visited each of the selected inpatient units between 8am and 10am during morning medication administration; each time observing multiple patients’ medication administration.

The demographic of patients varied among the eight units. The patients observed were both male and female patients between the ages of 11 days to 68 years old; the average patient age was four years. One of the observed units houses pediatric hematology/oncology and bone marrow transplant (BMT) patients. Adult BMT patients are also admitted to this unit, resulting in the observation of medication administration to 10 patients over the age 18.

An observation form was utilized during the observation time period and consisted of questions to be answered during each medication administration, as reference during the observation time period. The questions on the form were based on issues identified in our voluntary Patient Safety Reporting System reports (i.e. contributing factors identified in medication administration errors). In addition, nursing feedback obtained at our pediatric medication safety meeting was used to supplement the questions/metrics deemed valuable to measure during the observation.

The institution utilizes the electronic Medication Administration Record (eMAR) for information regarding medication tasks. Therefore, it is standard of practice for nursing staff that documentation will occur in the eMAR system. The student observer was instructed to observe the nursing staffs’ many uses of the eMAR. Medications on the inpatient floors are stored in several medication rooms located throughout the floors as well as in locked cabinets by the patients’ bedside.

In addition, student observers were informed of the uses of the unit-specific Omnicell® supply cabinets and bedside medication cabinets. The Omnicell® supply cabinets contain medications such as narcotics, analgesics and protocol or algorithm-based medications. These cabinets also contain medications for emergency situations. Bedside medication cabinets are utilized for storing scheduled patient medications.

### **Definitions**

According to the institution’s medication administration policy, a medication administration can be defined as “the provision of medications by authorized personnel...in a manner that assures proper patient and medication identification, documentation of medication administration in the medical record.” This policy was used as a reference for the student observers conducting the observations.<sup>7</sup>

### **Medication Process & Data Collection**

The observation form presents sixteen questions specifically focused on the critical steps that nursing staff members adhere to during a medication administration. The medication observation form was created by the research team and was further refined

to accurately reflect the sequence of events during a medication administration. In addition to the original responses of “Yes”, “No” and “N/A” listed on the form, a column titled “N/O” (not observed) was created to account for the incidences where the student observers were only able to observe a fraction of the medication administration. Furthermore, for questions 2, 3, 4, 7, 8, 9, 11, 12, 15 and 16, “N/A” would not be an applicable answer since the reasonable choices are simply “Yes”, “No” or “N/O”.

Nurse Managers were notified of the planned observation days and to the purposes of the observational study. In order to more accurately portray an everyday medication administration, Nurse Managers and the observed nursing staff were unaware of the specific questions included on the observation form. Once the student observers arrived at their assigned inpatient unit, the Charge Nurse or Nurse Manager would assign the student observer to a member of the nursing staff or a designated nursing station to observe. Thereafter, when the nursing staff member planned to begin a medication administration, the nursing staff would alert the student observer, and the student observer would proceed to either the medication room or the patient’s room with their assigned nursing staff. During the two-hour observation period, the student observer was encouraged to observe as much of the medication administration process as the situation permitted.

For further analysis of the collected data, six of the sixteen questions on the observation form became a primary focus where the concern for patient safety was the highest. The six questions dealt with issues related to the following medication administration’s areas: labeling medication, two patient identifiers, the Five Rights of medication administration, the use of worksheets, double-checks and presence of distractions or interruptions during the medication administration process. (Figure 2 and 3)

**RESULTS**

**Data**

Microsoft Access was used to record and analyze the responses from the data collection sheets. The data graphs can be found in Figures 4 through 8.

Distractions or Interruptions  
Was there a distraction or interruption during preparation or administration?

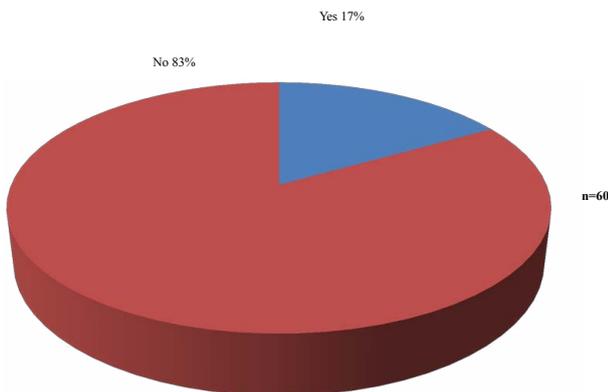


Figure 2 : Patient Identifiers Graph.

There were 60 medication administration observations in total. In all 60 of the observations, the nursing staff who administered the medication either had a RN or BSN degree, or was a nurse trainee who was under the supervision of a registered nurse. On several occasions, nursing staff members were observed multiple times with different patients; however, nursing staff names were not documented during the study for privacy reasons so the exact number of nursing staff observed cannot be determined. There were a total of 57 patients whose medication administration was observed; three patients were observed twice.

The total number of observations for each of the eight units was dependent on how many nursing staff members were observed. The mean number of observations was 7.5 with a range of 8; the least amount of medication administrations observed on a unit was 3 and the most observed was 11.

**Key Questions**

As mentioned in the Methods section, 6 of the 16 questions on the observation form were identified as “key questions” after the observational study. These questions (5, 7, 11, 13, 14 and 15) highlighted areas of concern that are vital to patient safety and quality of care. These six questions are represented graphically in Figure 4 through 8.

Distractions or Interruptions Follow-Up  
Was the distraction or interruption avoidable?

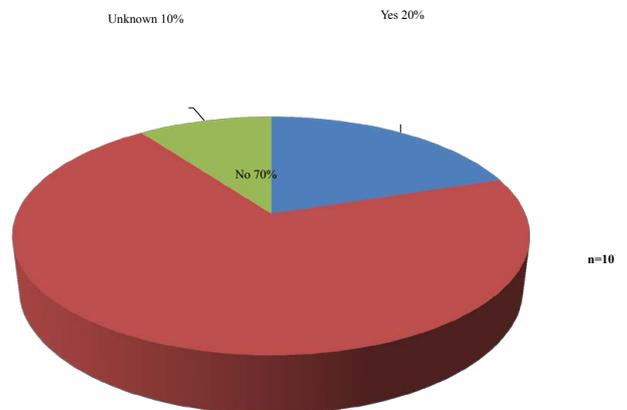


Figure 3 : Five Rights of Medication Administration Graph.

Medication Labeling  
The medication was labeled throughout process?

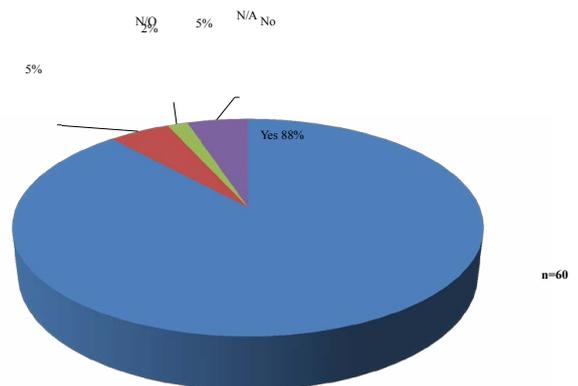


Figure 4 : eMAR Documentation Graph.

## Labeling Medication

Question 5 addresses whether or not the medication was labeled throughout the medication administration process, from preparation to administration. At the institution, if the medication is not administered immediately, the medication label is required to have the “name of the medication, dose or amount, and the expiration date (when not used within 24 hours) and expiration time (if expiration is less than 24 hours)”. 88% (53/60) of the medication administrations that were observed had the correct labeling while 5% (3/60) were labeled incorrectly (i.e. name and date of medication were missing). In 2% (1/60) of the observations, the student observers did not observe the medication labeling therefore, they were not able to confirm or deny whether or not the medication was labeled correctly. In another 5% (3/60) of the observations, the labeling of the medication was not necessary (N/A) because the medication was administered immediately from the medicine cabinets located in the patients’ room.

## Patient Identifiers

Question 7 quantifies whether or not two patient identifiers were used prior to the administration of medication. According to institution’s policies, the patient’s identity needs to be confirmed, prior to critical tasks, using two different “identifiers”. These two identifiers can be any two of the following: patient full name, date of birth, or registration number (this is the same as the Medical Registration Number [MRN]). All three of the identifiers are included on the Positive Patient Identifier band that is required to be on the patient at all times. The nursing staff administering the medication often utilizes the identification band to obtain the two patient identifiers. 65% (39/60) of all patients were correctly identified using two identifiers while 17% (10/60) were not. In 18% (11/60) of the observations, the patient identification step of the process was not observed (N/O). The identification process was not observed during the 11 medication administrations due to a variety of reasons; most frequently due to contact precautions, requiring students to remain outside the room during the medication administration, and the patient being too young to verbalize their name and birthdate and their caregiver was not present.(Figure 5)

## The Five Rights of Medication Administration

Question 11 was framed in regards to the Five Rights of Medication Administration: verifying the “Right Patient”, “Right Medication”, “Right Dose”, “Right Route” and “Right Time”.<sup>1</sup> All Five Rights need to be completed prior to every medication administration. In 47% of all observations, all Five Rights were completed and verbalized with the student observers before administration. In 10% of the observations, one of the Five Rights was not met. The percentage of not observed responses, 43%, was almost equivalent to those where the Five Rights were completed.

10% of the responses for question 11 were “no” – therefore, six observations had at least one of the Five Rights missing. The comments for all six observation forms with a “no” response were queried to display which Right was unmet in each instance.

In all six of the observations (100%), the unmet “Right” was “Right Patient”.

## eMAR Documentation

Although question 12 was not identified as a key question, two follow-up questions stemmed its content: “Did nursing staff immediately document the medication given on the MAR (eMAR) after administration?” The original results for question 12 yielded 91.7% of nursing staff (51/60) immediately documented the medication on the MAR, 6.7% (4/60) did not, and on one occasion it was not observed.

From the 4 observations forms with “no” responses, the comment section was analyzed for comments regarding the timing of the documentation if it wasn’t immediate. Two possible outcomes were decided on as responses to this question: “delayed” or “not entered during observation”. It was discovered that of the 4 observations, 50% had delayed documentation and 50% were not documented during the time of the student observers’ observations.

Of the 4 responses from question 12 that indicated the medication administration was not immediately documented in the eMAR, the team questioned whether the corresponding nursing staff used a personal worksheet instead of the eMAR to document. The 4 observation forms were collected and the corresponding response from question 13 was recorded. Furthermore, it was determined in those 4 observations forms that the medication administration was not immediately documented in the eMAR because the respective nursing staff was using personal worksheets.(Figure 6)

## Nursing Staff Worksheets

Question 13 refers to whether or not the nursing staff referred to a personal worksheet as a schedule for patient medications. It is preferred that nursing staff members utilize the electronic medication schedule in the eMAR instead of transcribing the medication schedule on a separate piece of paper. Using a hand-made worksheet is a static way of keeping track of medication schedules whereas the eMAR provides flexibility, fluidity, and real-time updates on medication dosages, times, routes, etc. 57% (34/60) of the nursing staff utilized personal worksheets while 28% (17/60) did not. In 8% (5/60) of the instances, it was not

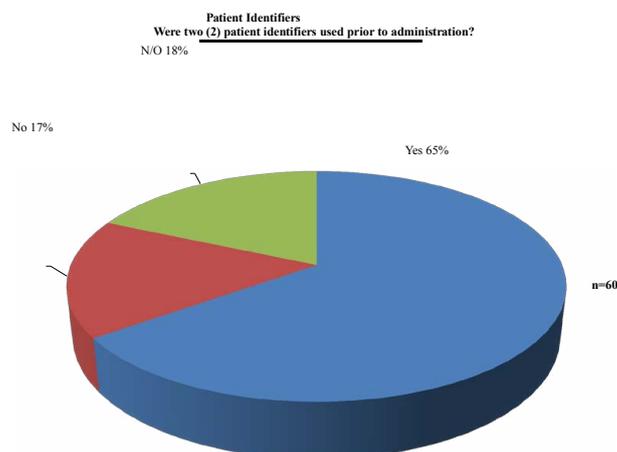
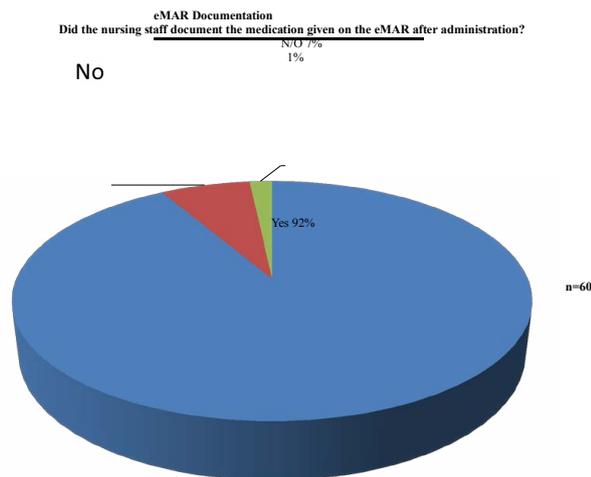


Figure 5: Nursing Staff Worksheet Graph.



**Figure 6: DOUBLE-CHECKS GRAPH.**

observed (N/O) whether or not a worksheet was used and in 7% of instances the use of a worksheet was not applicable (N/A).

### Double-Checks

Question 14 reviews continuous infusion guidelines. Before continuous infusions of medications are started or administered or when there is a change to the syringe or bag of continuous medication infusion, the administering nursing staff member must have another nursing staff member “double-check” to verify that all information on the infusion pump is correct. For question 14, 15% of all necessary infusions were double-checked by an additional nursing staff member while 5% were not double-checked. In 70% of the observations, double-checks were not required as either an intravenous infusion was not initiated, a medication dose was not changed, or a new bag was not hung. In 10% (6/60) of the observations the double check was not observed (N/O).

### Distractions and Interruptions

Question 15’s topic sought to determine how prominent distractions and interruptions were during the medication administration process. In 83% of the medication administrations observed, there were no distractions or interruptions. However, 17% of the observations had a distraction or an interruption during the administration.

Datum from this question was analyzed further; after the observation was complete, responses were reviewed to determine if the distractions or interruptions that took place during the observations were avoidable. Examining data for this question required looking back at the 10 observations that had an interruption or distraction and classifying the response based on the corresponding comments. An avoidable distraction or interruption was considered to be a task or situation that could have waited until after the medication administration. An unavoidable distraction or interruption was considered an unforeseeable event that halts the medication administration process; for example, an unavoidable distraction could be a change in the status of the patient, or medical teams coming into the room during a medication administration to do their daily rounds. Of the 10 observations with interruptions or distractions, 20% were considered avoidable [after the fact], 70% were considered

unavoidable [after the fact] and 10% could not be classified and remained unknown.

## DISCUSSION

### Labeling Medication

For the purpose of this pediatric medication administration observation study, the student observers were directed to observe if nursing staff labeled the medication throughout the process. The student observers found that the majority of the nursing staff labeled the medication prior to administration. After reviewing the data, only 5% of the observations showed medications labeled incorrectly. For the student observers observing, it became apparent that the practice of nursing staff is not reflective of the institution’s policy. In a number of observations the nursing staff made an attempt to label the medication, but not all the recommended information was included. For example, the patient name was not included but the drug name was.

A medication container or syringe should be labeled at all times in order to prevent administering the wrong medication to the wrong person. Moreover, moving to a barcoded system of medication administration would help to validate the Five Rights of Medication Administration; that is, ensuring that patients receive the “Right Drug, the Right Dose, the Right Patient, the Right Route, and at the Right Time.” (Frederico, 2011) By implementing such a system, there is less room for human error and the barcoded system would serve as a double-check for administered medications. This would also give a more accurate portrayal of when medications are administered and would aid in the documentation process.

### Patient Identifiers

Two patient identifiers are required to be confirmed, prior to critical tasks including medication administration, to verify a patient’s identity. A preferred method of identifying patients has yet to be defined and leaves the two identifiers used up to the nursing staff’s discretion.

50 of the 57 patients observed were under the age 18, some only days old. This patient population can make patient identification challenging for nursing staff. As discussed previously, in some observations the patient was too young to verbalize their name and date of birth. In other instances, the child was sleeping and a caregiver was not present to verify the identity of the patient. In these instances nursing staff needed an alternative method to verify the patient’s identity, using the Positive Patient Identifier (PPI) band instead. These wrist bands are to be kept on the patient at all times and were often used to confirm patient name, birthdate, and medical record number, which was then compared to the electronic medical record.

However, in some observations the PPI band was not observed directly on the patient but instead on the patient’s bed or basinette. This practice could result in incorrect patient identification if the PPI band is the only form of patient identification. If the patient can advocate for themselves or a caregiver is present, having the patient state his or her name and their date of birth to the nurse verbally was the most effective and reliable form of patient identification.

During one of the observations, a nursing staff member made a suggestion to improve the patient identification step in the medication administration process. The eMAR utilized at the University of Michigan provides only the patient's name and medical record number on the medication page. The nurse recommended adding the patient's date of birth to the medication page in the eMAR as well, which would allow the nursing staff to confirm patients' name and date of birth seamlessly in the eMAR medication page.

### The Five Rights of Medication Administration

In 43% of the observations done, the Five Rights were not observed. The lack of verbalization between the student observers and nursing staff, when the nursing staff was verifying the Five Rights as well as the two patient identifiers during the medication administration process, made the observations very difficult. Without verbal confirmation that the nurse checked both identifiers and all Five Rights, the student observers could not confirm nor deny whether or not either was completed. The student observers were instructed to simply observe the medication administration process and not actively participate. Therefore the nursing staff could have mentally checked the two patient identifiers and all Five Rights but the student observers could not determine this. Thus, multiple instances for both questions had to be documented as not observed (N/O).

### Nursing Staff Worksheets

The student observers concluded that 57% (34/60) of the nursing staff observed utilized personal worksheets while 28% (17/60) did not. The remainder of observed nursing staff either did not use a worksheet or did not use a worksheet for the purpose of administering a medication. Suffice to note, the nursing worksheets appear to be used as a prioritization tool or task list; the worksheets were not being used to officially document the administration of medication, as this is done in the eMAR. The reason why over half of the observed nursing staff appeared to prefer to use their own worksheet as opposed to solely using the eMAR was not investigated during this study. This yields questions, which should be posed, during further research, to determine specific explanation of staff preferences. If worksheets are determined by nursing leadership to be a best practice in medication administration, the utilization of a standard worksheet across the institution will force standardization of practice. (Figure 7)

### Double-Checks

In 3 (or 5%) of the 60 observed medication administrations, the nursing staff did not perform double-checks for patients who had continuous medication infusions. There could be several contributing factors that could have caused the three observed instances to occur. For example, the workflow that is practiced and advocated throughout the institution might not readily allow the first nurse enough time to notify a second nurse that a double-check is needed. Or in another case, the second nurse who agreed to perform the double-check could have been busy with his or her own patient, made a mental reminder to perform the double-check, but afterwards forgot to perform the needed double-check. The institution will be looking at technology and function to help support double-checks and decrease the

impact in workflow. The lack of adherence to the double-checks on continuous medication infusions is consistent with the Institute for Safe Medication Practices (ISMP) assertion that independent double-checks are undervalued and misused. ISMP suggests that independent double-checks should be reserved for very select high-risk tasks or specific high-alert medications. Use of independent checks on all high-alert medications or all continuous infusions often cause the check to be a routine task and lose its importance. (ISMP, 2013) (Figure 8)

### Distractions and Interruptions

There are several different situations where there were unavoidable distractions and interruptions that delayed the medication administration process. In one instance, there was a change in the patient's physical status, which caused for an unavoidable delay in the medication administration. Specifically, the patient's unexpected low blood glucose was given first priority and the nursing staff immediately proceeded to stabilize the patient. The medication was never administered during the time the student observer was present on the unit. Situations such as a change in the patient's mental or health status typically should take precedence over the administration of a regularly scheduled medication.

The student observers who observed the unavoidable and

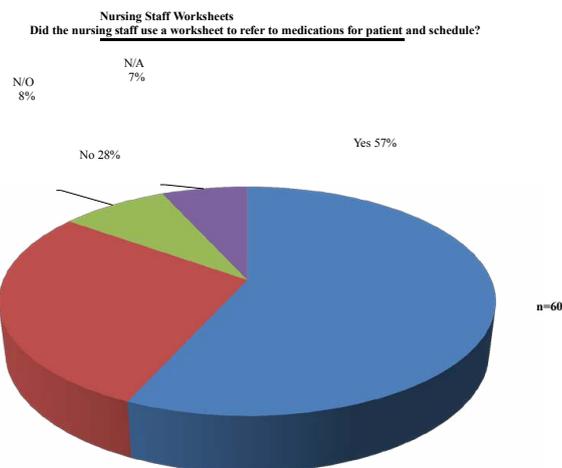


Figure 7: Distractions or Interruptions Graph.

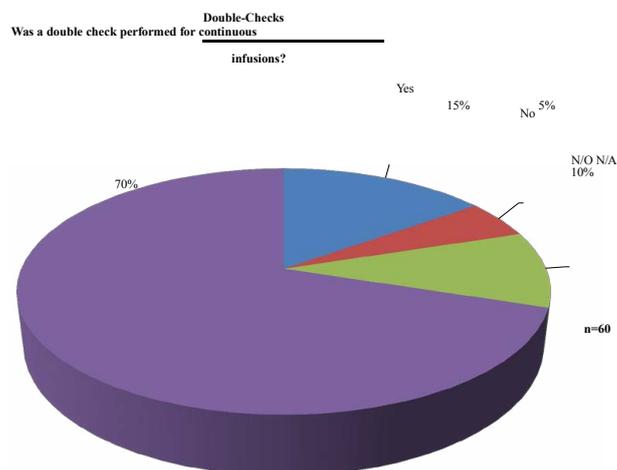


Figure 8 : Distractions or Interruptions Graph.

avoidable interruptions and distractions were vigilant in their observation comments. Several times during the unavoidable interruptions and distractions, the nursing staff continued with the medication administration process with frequent ease. This is referring to when the patient was stable for the medication administrations. Since the nursing staff continued with the medication administration process undisturbed, the nursing staff demonstrates that these distractions and interruptions are normal occurrences happening several times throughout the day. (Figure 9)

**CONCLUSION**

This observational study provides us with many possible areas of improvement which could be addressed to ensure a safe medication administration. This study identified those potential areas to focus on labeling, utilizing patient identifiers, adhering to the Five Rights of medication, using a standardized documentation method, double checking medications, and working around the presence of distractions during the medication administration process. Further research is needed to determine the root causes of these potential problem areas.

The results of this study are of course limited to the willingness of nursing staff to participate, and the observations taken through this study may not accurately portray the institution’s medication administration practice as a whole. Selection bias was not under the control of the study and may have occurred. Furthermore, because this was a direct observational study, the presence of the observer in the room had the potential to change the behavior of the participating nursing staff member.

Regardless of the limitations of a direct observation study, this study provides a first step towards making quality

changes to ensure the safety of patients during a medication administration. Moreover, this observational study highlights the need for a revision in compliance and expectations of nursing staff. However, encouraging increased compliance will not decrease errors altogether; putting hard-stop barriers in place are necessary in order to alleviate the possibility of human error or complacency. This study aims to draw awareness to the need for future policy improvements – such as a barcoding system – to make medication administration and documentation a safer, consistent, and streamlined process.

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**Medication Administration Audit Form**

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Patient MR #: \_\_\_\_\_ Date of Review: \_\_\_\_\_ Time: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Unit: \_\_\_\_\_ Staff: RN Prescriber

Instructions: Fill in the blanks above to its entirety, complete one page for each patient.

Question	Criteria	Yes	No	N/O	N/A	Comments
1.	If there are contact precautions, did staff follow the sign?					
2.	Did the staff use proper hand hygiene before the med pass?					
3.	Did the staff prepare the drugs for only one patient at a time?					
4.	Did the staff open the eMAR & compare the MAR with the medication prior to administration? Where was it done?					
5.	The medication was labeled throughout process, prep to administration? (PO, NG, IV)					
6.	The nurse correctly transported the medication.					
7.	Two (2) patient identifiers used prior to administration? <i>(Patient name, MR# or birthdate)</i> <i>(Note whether identification band is on patient.)</i>					
8.	Medications are opened from the unit dose container at the bedside.					
9.	Did the staff explain to the patient what drugs he/she is being given and their use? <i>(Record anything the patient/parent says related to medications.)</i>					
10.	Did the staff swab port prior to accessing IV line?					
11.	Were the 5 rights of medication administration utilized? If no, circle the unmet right.					Patient Drug Dose Route Time
12.	Did the staff document the medication given on the MAR after administration (immediate or delayed)?					
13.	Did the staff use a worksheet to refer to medications for patient and schedule?					
14.	Was a double check performed for continuous infusions? What medications?					
15.	Was there a distraction or interruption during preparation or administration? <i>Was this avoidable or unavoidable?</i>					
16.	Did the staff provide teaching or answer question(s) to the patient/parent when required?					

N/O = Not Observed; N/A = Not Applicable [boxes are grayed out for questions N/A does not apply to]

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**Figure 9 : Observation Form.**