

Running head: QUALITY AND SAFETY OF INTERMITTENT INTRAVENOUS
INFUSIONS

QUALITY AND SAFETY OF INTERMITTENT INTRAVENOUS
INFUSIONS

By

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Abstract

Problem: Intermittent intravenous infusion (III), also referred to as a secondary infusion or intravenous piggyback, is a common but complex process with safety risks in medication errors, infection, and residual medication management. Almost all patients receive IV therapy in acute care hospitals. III is a method frequently used to deliver IV medications, usually with the assistance of a smart pump. Little evidence exists to guide nursing practice with III. Available literature reports issues with poor nursing practice, errors, and limited knowledge by the nurse.

Aims: This quality improvement study addressed the following questions.

1. What are the frequencies and types of III medication errors?
2. What are the frequencies and types of infection risks observed in III administration?
3. What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?

Methods: An observational technique, framed in Donabedian's Structure, Process, and Outcome Model, was used to collect data in a large level one trauma center in the Midwest. Medications, fluids, tubings, smart pumps, and eMAR documentation were assessed with an adapted observation checklist tool initially developed by a multidisciplinary group from Brigham and Women's Hospital in Boston, MA.

Pertinent findings: A total of 102 patients with 117 III medication administrations were assessed. Medication errors of unauthorized fluids, incomplete

drug library within the smart pump, wrong concentrations and rates, and incomplete patient name labeling were found. Of the observed infusions 110 (96%) had between one to six medication errors each. Of the 102 patients, 77% had one to four infection risks from inappropriate end cap coverings of the IV tubing and incorrect or absent date labeling of tubing and fluids. In regard to residual volume, 56% of the 104 completed infusions had medication remaining in the IV bag or tubing chamber at completion of the infusion via the smart pump.

Conclusions: This study identified medication errors, infection risks, and residual volume in the administration of III. Although relatively few errors were immediately harmful, the potential for poor patient outcomes or more serious harm exists. The results of this study will serve as a baseline for quality improvement and future education.

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To my wonderful family,
my husband, David
my daughters, McKenzie and Shelby
and my parents, Gary and Soni
for their constant love and support.

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Chapter I

Introduction

Intermittent intravenous infusion (III) also referred to as a secondary infusion or intravenous piggyback (IVPB) is a common clinical practice but is deceptively complex in regard to patient safety with risks in medication errors, infection, and residual medication management (Claus, Buyle, Robays, & Vogelaers, 2010; Fan et al., 2014; Hadaway, 2007; Hoefel, Lautert, Schmitt, Soares, & Jordan, 2008; Nunnally & Bitan, 2006; Peterfreund & Phillip, 2013). Little evidence exists to guide nursing practice in this multifaceted and pervasive procedure (Infusion Nurses Society, 2011; Marschall et al., 2014; O’Grady et al., 2011; Peterfreund & Phillip, 2013). There is evidence of reduced quality and safety including errors, yet there is limited understanding of proper techniques and standardized processes (Institute for Safe Medication Practice, 2007; Nunnally & Bitan, 2006; Vanderveen & Husch, 2015). This study investigated the quality and safety of III administration.

Observations in the adult acute care setting of a large level one trauma hospital were used to report the frequency of medication errors, infection, and residual management in current nursing practice. The results of this study may be used to guide future policy and systems improvement for the organization specifically related to education for practicing nurses and nursing students.

Background

In the acute care setting, 90 percent or more of patients require intravenous (IV) fluids or medications, clearly establishing the importance of III in nursing’s work and the need for high quality and safe care (Alexander, Corrigan, Gorski,

Hankins, & Perucca, 2010; Baranowski, 1995). Maki, Kluger, and Crnich, (2006) report, in the last 30 years, the variety and number of intravascular devices have greatly increased in the United States. More recent estimates indicate there are more than 300 million peripheral IV catheters and seven million central vascular catheters sold in the United States yearly (Hadaway, 2010). Through these devices, patients receive infusates consisting of medications, fluids, blood, nutrition, and or electrolytes by three main methods: continuous or intermittent infusions and bolus administration (Potter, Perry, Stockert, & Hall, 2013; Taylor, Lillis, Lynn, & LeMone, 2015). This study investigated the quality and safety of III administration.

Changes in the technology of electronic infusion devices or smart pumps have stimulated recent interest in identifying quality and safety issues with III (Nunnally & Bitan, 2006; Trbovich, Pinkney, & Easty, 2010). Researchers investigating new drug protocols which involve III are realizing the administration set and pump may affect their outcomes and suggest methods to deal with these issues be clearly identified (Claus et al., 2010; Kontny et al., 2012). Practitioners in anesthesia, (Lovich, Doles, & Peterfreund, 2005; Peterfreund & Phillip, 2013) emergency department (Greggie & Moore, 2007) and neonatal and pediatric settings (Anh, Norris, & Charles, 2006) have also identified issues with the complexity of delivery of medications with III.

More recently, researchers in Canada implemented a multi-phase research project regarding multiple IV infusions of which secondary infusions or III are a primary theme. From their work, risk factors have been identified with some recommendations regarding secondary infusions (Cassano-Piche' et al., 2012; Fan et

al., 2014). When administering III, the infusions tasks are particularly prone to error because of additional cognitive demands placed on the nurse. The researchers also identified high risks for errors when the task is not well standardized, has many associated failure modes, and the failures are not easily detected. All are common issues with III (Cassano-Piche' et al., 2012).

Medication errors. It is considered best practice to administer III via infusion pumps that include Dose Error Reduction Software (DERS) commonly known as smart pumps (Taylor et al., 2015). Pedersen, Schneider, & Scheckelhoff (2015) report that the largest hospitals in the United States (greater than 600 beds) are using smart pumps at 100 percent. Overall, 80 percent of all U.S. hospitals use smart pumps which have more than doubled since 2005 (32 percent use of the devices). Through a systematic review of the literature Ohashi, Dalleur, Dykes, & Bates (2014) found that smart pumps decrease but do not totally eliminate programming errors. All the studies reviewed reported that certain types of errors continued after implementation of the smart pumps (Ohashi et al., 2014). Some errors smart pumps cannot correct are related to III in the programming and monitoring (Trbovich et al., 2010). It remains the nurse's responsibility to correctly select the correct drug name and concentration from the DERS, and select or enter the correct time frame or rate per hour to be infused. If the wrong drug is selected from the drug library or a workaround is performed to bypass the safety mechanism, no warnings will be issued, and failure is not easily detected unless patient symptoms related to the medication error appear. If the III is delivered through a secondary administration set, the III

must be hung significantly higher than the primary bag with most smart pumps. The secondary tubing must be attached to the primary line above the pump, the clamp must be opened, and the nurse must make sure the pump is pulling from the III bag rather than the primary bag. If the above steps are done incorrectly, the errors are only detected by careful observation from the nurse (Cassano-Piche' et al., 2012).

Infection risks. Contamination risks are unique in III when compared to continuous infusions. Continuous IV infusions are expected to stay connected to the patient's intravascular device during the entire time of therapy and therefore represent a closed system (Infusion Nurses Society, 2011). For this reason, the Center for Disease Control and Prevention [CDC], (2015) currently recommends continuous administration sets are changed no more frequently than every 96 hours. The difference in III is that the administration set is repeatedly disconnected and reconnected to the IVD via a needleless connector. This frequent manipulation is thought to increase the risk of contamination at the catheter hub, needleless connector, and the male luer end of the tubing (Infusion Nurses Society, 2016). In 2007 the Institute of Safe Medication Practice (ISMP) issued a safety alert informing hospitals of poor practices of the aseptic technique by nurses in the delivery of III. The alert stated nurses were leaving administration sets uncapped between dosing intervals. For these reasons, research performed on infection outcomes on continuous administration sets cannot be generalized to intermittent administration sets and the Infusion Nurses Society (INS) recommends that III administration sets be changed every 24 hours (Infusion Nurses Society, 2011). The CDC makes no

recommendation for III administration sets based on a lack of evidence (O'Grady et al., 2011).

Residual volume. Ensuring the complete administration of III and therapeutic success is a vital part of medication administration by the nursing team (Burke, 2005; ISMP, 2013). When healthcare providers prescribe medications, they anticipate the complete dose will be administered (Weeks, 2012) and it is assumed the IV route is a suitable way to ensure rapid and proper delivery of a prescribed medication (Kontny et al., 2012). Residual volume is one issue interfering with complete dosing with III. Residual volume is defined as the amount of fluid or medication left in the IV administration set when the III bag is empty (Infusionnurse, 2015). A variety of factors can influence the residual volume: the infusion device, the type of administrations set, and procedures used to prime and flush the line at the beginning and end of the medication administration (Kontny et al., 2012). It has been documented that residual volume was never delivered to the patient and discarded (Chan, 2013), or delivered at the next infusion interval in a possible degraded state (Hoefel, Lautert, Schmitt, Soares, & Jordan, 2008). Plagge, Golmick, Bornand, and Deuster (2010) report as much as 32 percent of the intended dose may be lost as residual volume even when the drip chamber is empty on the administration set. Claus et al. (2010) report a 40 percent loss of medication due to residual volume in III with medication bags of 50 milliliters. There is a lack of evidence on best practice regarding residual volume, and it is managed multiple ways, often incorrectly (Chan,

2013; Hoefel et al., 2008; Peterfreund & Phillip, 2013; Wotton, Gassner, & Ingham, 2004).

Local Problem

Over the past few years, nursing faculty working with students in a large level one trauma hospital began to notice differences in the administration and maintenance of III among nursing staff throughout the hospital. Faculty expressed concern as to whether III was being consistently administered according to best practice related to safety procedures, infection control, and residual medication management. Policies and education materials available did not address all the complexities of III, and there seemed to be a lack of best practice guidelines to address all the issues with III.

The literature notes a high prevalence of intravenous devices (Maki et al., 2006), smart pump use (Pedersen et al., 2015), and medications administration errors by the IV route (American Society of Health-System Pharmacists [ASHP], 2008; Hicks & Becker, 2006; Husch et al., 2005; Keers, Williams, Cooke, & Ashcroft, 2013). This literature along with faculty observation leads to the assumption that investigating quality and safety of III should be a high priority for healthcare organizations, nursing, and patients. Cognitive demands on nurses involved with III place the patient at risk for errors from human factors. Smart pumps while providing safety features to decrease errors have the unintended consequence of administration set errors, potential programming errors, plus issues with residual medication within the tubing (Cassano-Piche' et al., 2012). The increased manipulation and potential

contamination issue of the intermittent administration set place the patient at risk for a hospital-acquired infection (Infusion Nurses Society, 2016). Fundamental nursing textbooks address III, but not to the level of complexity required to address the multifaceted issues at the bedside related to smart pump programming and residual volume management (Potter et al., 2013; Taylor et al., 2015). Because of this complexity, it is essential for institutions to monitor the administration of III to identify if there are areas to improve in safety, infection control, and residual management.

Purpose

The purpose of this study was to investigate the current quality and safety of III administrations at an 886 bed; level one trauma hospital in Springfield, Missouri. The study results are the first step in collecting baseline data on medication errors, infection risks, and residual volume management for quality improvement and education regarding the process of III. This information may be used for future quality improvement decisions, plus education development for practicing nurses and nursing students.

Project Questions

This study addressed the following questions regarding patient quality and safety.

1. What are the frequencies and types of III medication errors?
2. What are the frequencies and types of infection risks observed in III administration?

3. What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?

Theoretical Framework

An integral step in the research process is the selection of a theory or conceptual model to use as a research framework. The research framework will provide a frame of reference and organization to the study and help describe the problems to be solved and questions asked (McEwen & Wills, 2014). Fitzpatrick (1998) stated that theories can propose approaches to clinical problems and develop clinical practice protocols. LoBiondo-Wood and Haber (2010) consider the use of a framework as a step toward generalizing the findings from research studies to groups other than the one studied. With these attributes in mind, Donabedian's structure, process, outcome model was chosen for guiding the study in determining prevalent practices in III administration.

Avedis Donabedian proposed a model for quality assurance over 40 years ago that is still used today. He transformed the thinking about health systems in regards to quality care and has been honored all over the world with awards plus foundations, libraries and research centers named in his honor. Born in 1919 in Beirut, Lebanon, his family fled the area to avoid the Armenian holocaust. Growing up in Palestine he experienced social and political turmoil which he referred to throughout his life. By 1944 Avedis had acquired a medical degree and practiced as a family physician in Jerusalem and Beirut. In 1954 he moved to Boston and attended Harvard to obtain a master's degree in public health. In 1961 he was recruited by the School of Public

Health at the University of Michigan where he stayed for 28 years. Donabedian's 1966 article "Evaluating the quality of medical care", in the *Milbank Memorial Fund Quarterly*, is where he first introduced the Structure, Process, and Outcome Model. This model is one of the best-known frameworks in health service research (Best & Neuhauser, 2004).

In determining priorities in patient welfare monitoring Donabedian (2003) states, "select what is frequent, grievous, and correctable" (p. 40). The administration of III is a procedure that frequently occurs in acute healthcare settings (Fan et al., 2014; Hadaway, 2007) and the literature lists many errors surrounding III, some having dire consequences regarding patient conditions (Cassano-Piche' et al., 2012; "ISMP Medication Safety Alert," 2007; Nunnally & Bitan, 2006; Vanderveen & Husch, 2015). The present study provides local baseline data regarding III in nursing practice and will guide future actions in medication safety, infection prevention, and residual management.

Donabedian (2003) reports a triad approach to assessing the quality of clinical care: structure, process, and outcome. These are not attributes of quality but rather types of information that a researcher may gather and then decide the value of the quality. There is a predetermined relationship among the three approaches with each approach affecting the next. Structure influences process and process influences outcome (Donabedian, 2003).

Structure is the category designating the conditions in which care is provided. This includes the facilities and equipment, number of human resources and

organizational characteristics. Structures are usually easy to observe, measure, and can have a direct effect on outcomes as well as process. However, at times it may be difficult to link a strong relationship with quality of care (Donabedian, 2003).

Examples of structure in the present study include the healthcare facility, the adult medical-surgical floors included in the study, III administration sets, electronic medication administration record (eMAR) in the EHR, and smart pumps.

Donabedian (2003) defines process as the activities that represent health care and are usually provided by health care providers, patients, and their families. When compared to structure process is more directly related to quality. Donabedian (2003) states that “quality of care” can be interchangeable with “quality of the process of care.” This relationship formed in advance states that certain processes will result in desirable outcomes (Donabedian, 2003). Administration of III is a nursing activity that falls within process. Process includes the elements related to III safety, specifically detecting medication errors, infection risks, and residual volume management. In the proposed study the aims are to identify prevalent practices of the process of III within the medical, surgical units of the hospital.

Outcome is the change that occurs both wanted and unwanted in patients that can be credited to health care. More simply, an outcome is a result of antecedent care (Donabedian, 2003). Due to the descriptive nature of this study, the outcomes are the results of the process data collected via observation.

1. The frequencies and types of III medication errors.
2. The frequencies and types of infection risks observed in III administration.

3. The frequencies of residual volume and types of administration techniques used to manage residual volume.

This outcome information is baseline data as the first step of quality improvement, plus information to guide education development for practicing nurses and nursing students.

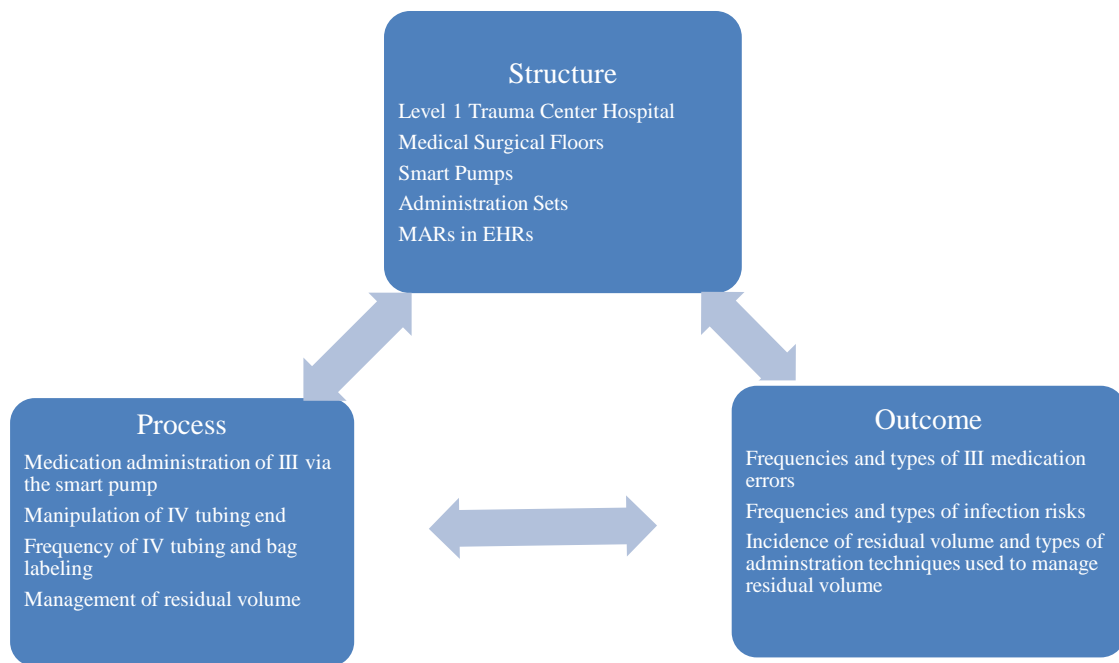


Figure 1. Framework for study utilizing Donabedian's Model

Definitions

Intermittent intravenous infusions. Intermittent intravenous infusions (III) are defined as the “administration of intravenous medications or solutions at prescribed times” (Infusion Nurses Society, 2011, p. S104). Other terms used in the literature for III are secondary infusion or IVPB related to the manner in which they are given. Intermittent intravenous infusions administer medications over a short,

safe period of time through all types of intravenous devices (IVD) such as central line catheters, peripherally inserted central catheters, and short peripheral catheters. The infusions can be delivered via gravity or smart pump. This infusion is followed by an automatic return to a continuous infusion when completed, or the administration set can be disconnected and the intravascular device flushed and locked (Alexander, Corrigan, Gorski, Hankins, & Perucca, 2010). This method of medication delivery has several advantages, such as avoiding an additional IV insertion and reducing the nurse's workload when the primary infusion resumes automatically (Fan et al., 2014).

Administration sets. Administration sets also termed IV tubing are “a device to administer fluids from a container to a vascular access device” often included with administration sets are add-on devices defined as “an additional component such as an inline filter, stopcock, y-site, or needleless connector that is added to the administration set or vascular access device” (Infusion Nurses Society, 2011, p. S101). This study will investigate two main administration sets, primary and secondary and two delivery methods, intermittent or continuous. Medications delivered by III can be infused through a primary administration set (See figure 2) where the III medication is the primary fluid and the administration set is primed directly with the medication. Primary administration sets are usually primed with a volume of 15-27 ml of fluid and are between 60-110 inches long. Different manufacturers may vary and specific information can be found on each product package (Infusionnurse, 2015). If continuously infusing the administration is left

continuously connected to the patient's IV site and the administration set change requirements are no more frequent than 96 hours (O'Grady et al., 2011).

Secondary administration set (See figure 3) are most commonly only 30- 36 inches long and require less than 10 ml to prime (Alexander, Corrigan, Gorski, Hankins, & Perucca, 2010). Secondary sets are not used alone to deliver I.V. The secondary administration set is connected to a primary administration set thus the name intravenous piggyback (IVPB). The primary and secondary set together can now be used to deliver fluids and medications either continuously or intermittently. If either administration set is disconnected from the access site, then this set becomes an intermittent administration set and is replaced every 24 hours due to increased risk of contamination. After each disconnection, the tubing end must be protected with a new dead-end cap (Infusion Nurses Society, 2016).

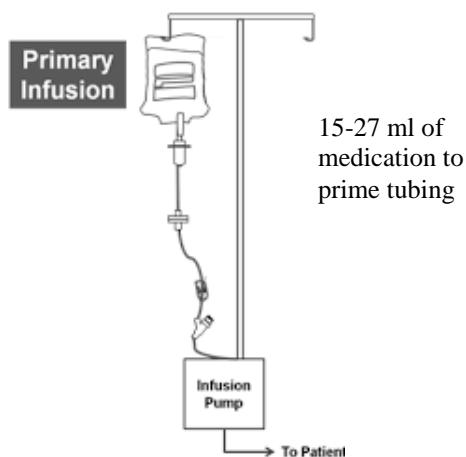


Figure 2. Primary Administration Set (Colvin, 2011)

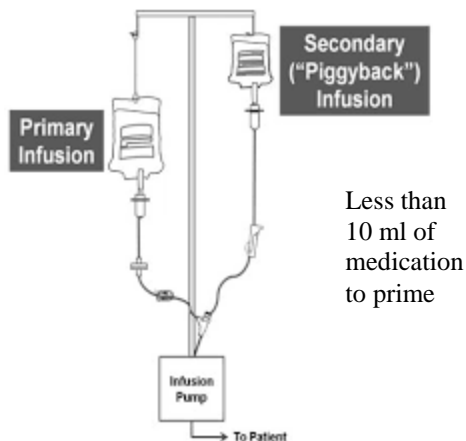


Figure 3. Secondary Administration Set (Colvin, 2011)

Safety risks with III. Safety according to the *Oxford English Dictionary*

Online is defined as “being protected from or guarded against hurt or injury; freedom from danger.” Other definitions listed include: “a deliverance or rescue from peril, a means of instrument of safety; protection, safeguard, and quality of being unlikely to cause hurt or injury; the quality of not being dangerous to presenting risk” (“Safety,” 2013). The Quality and Safety Education for Nurses (QSEN) website defines safety as “the process of minimizing risk of harm to patients and providers through both system effectiveness and individual performance” (Quality and Safety Education for Nurses, n.d.). Using these definitions of safety with the literature surrounding III there is potential patient harm from medication errors, catheter-related bloodstream infections, and excessive or inappropriate residual volume.

Medication errors. Medication errors pose a significant threat to patient safety as the most common error in health care (Aspden, Wolcott, Bowden, & Cronenwett, 2007; Kohn, Corrigan, & Donaldson, 2000). In an ethnographic study

Jennings, Sandelowski, and Mark (2011p. 1441) used the words from experts in the field of safety in the following definition for medication errors, “Errors are defined as unintended acts including those of omission whereby a necessary action is not taken, commission whereby an incorrect action is taken (Leape, 1994), and near misses, or events that could have resulted in bad consequences, but did not (Reason, 1997, p. 118)”. In a systematic literature review of medication definitions, Lisby, Nielsen, Brock, & Mainz (2010) found only 45 articles from 203 relevant studies included a generic definition of medication errors including 26 different forms of definitions. This multiplicity and inconsistency in defining medication errors, as well as a lack of definitions in a majority of articles supports the need for the application of standardized terminology. The most common definition used in 17 of the articles was developed by National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP; Lisby et al., 2010). The council urges medication error researchers to utilize the following definition to improve the quality and consistency of medication error findings. Therefore, the following definition from NCC MERP will be used to define medication errors in the study.

A medication error is 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 professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution,

administration, education, monitoring, and use. (National Coordinating Council for Medication Error Reporting and Prevention, 2016, p. 1)

Infection risks with III. Handwashing, administration set changes, cleaning the hub or needleless connectors and no touch aseptic techniques are all part of the 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections (O’Grady et al., 2011). Due to the nature of this study, the risk for infection was evaluated through manipulation of the administration set in the treatment regime of III. According to the Infusion Nurses Society (2016), III administration sets should be changed every 24 hours when they are repeatedly disconnected and reconnected between dosing intervals. There is a heightened risk of contamination at the spike end, catheter hub, needleless connector, and the male luer end of the administration set which can raise the potential for catheter-related bloodstream infections (Infusion Nurses Society, 2016). The Infusion Nurses Society (2016) and IOM (2007) also identify the common practice of looping as a risk for infection. Looping is defined as attaching the open male luer end of the administration set to a port on the same administration set. To prevent unnecessary disconnection for gown changes Cassano-Piche’ et al. (2012) recommend that all hospitals use snap gown sleeves. Also important is to attach a new sterile covering to the administration set’s male luer end after each intermittent use (Institute for Safe Medication Practice, 2007). Observation of tubing and bag labeling determined compliance with bag and administration set changes. Observation of the management of the luer end was

identified to determine prevalent practices. No distinction was made between central lines, peripherally inserted central lines and short peripheral intravenous catheters.

Residual volume management. Residual is defined as the amount of fluid or medication that is left in the IV administration set when the III is completed (Infusionnurse, 2015). There are a variety of factors that can influence the residual volume. These factors include the infusion device, the type of administrations set, and procedures used to prime and flush the line at the beginning and end of the medication administration (Kontny et al., 2012).

Assumptions

In 1999, The Institute of Medicine concluded that medical errors are mainly the result of system failures rather than the fault of individuals. A culture of safety was sought with the patient in the center. The assumption is that we have bad systems rather than bad people. It is the assumption of this study that nurses practice with a beneficence and nonmaleficence goal in mind. Their intent is to provide safe quality care to the patients whose care they are entrusted and to cause no harm. This investigation of III administration is focusing on both positive methods as well as risk factors. It is assumed that nurses are familiar with the smart pumps and both primary and secondary III administration sets. Patients may have existing administration sets that may be used or need new administration sets. Using Donabedian's model the study investigated structure and process with III for a baseline to improve outcomes.

Significance for Nursing

In a recent ethnographic study by Jennings, Sandelowski, & Mark (2011) medication administration was found to encompass the entire day rather than just

being a single nursing function. They identified that the number of medication doses per day is more than double that which policy groups have identified in the past. Medication administration is inseparable from other intervention the nurse provides during the day. In spite of its frequent occurrence the medication process is poorly understood and potentially lethal (Jennings et al., 2011). Even with the advances in safety technology medication errors continue to be the most common mistake in healthcare and IV medication is the route of many of the most severe of these errors related to their immediate bioavailability (Hicks & Becker, 2006). These aim at the heart of healthcare, where nurses have the responsibility to do good and no harm (Mayo & Duncan, 2004). Present-day IV therapy is multifarious and can be high risk by nature (Waterson, 2013). The complexity of III present opportunities for errors to occur (Cassano-Piche' et al., 2012). Investigating the administration of III will provide a baseline for quality improvement. This information may be used for future policy and systems improvement for organizations plus educational decisions for practicing nurses and nursing students and all healthcare employees involved in the process of medication administration.

Summary

Delivering medications via III is a common but complex process with factors involving safety, with risks in medication errors, infection control, and residual management (Claus, Buyle, Robays, & Vogelaers, 2010; Fan et al., 2014; Hadaway, 2007; Hoefel, Lautert, Schmitt, Soares, & Jordan, 2008; Nunnally & Bitan, 2006). Almost all patients receive IV therapy in acute care hospitals (Alexander et al., 2010;

Baranowski, 1995) with III a common method to deliver IV medications usually with the assistance of a smart pump (Pedersen et al., 2012). Little evidence exists to guide nursing practice with III (Infusion Nurses Society, 2011; Marschall et al., 2014; O'Grady et al., 2011). Literature which does exist reports issues with poor nursing practice, errors, and limited knowledge by the nurse (Cassano-Piche' et al., 2012; "ISM Medication Safety Alert," 2007; Nunnally & Bitan, 2006; Vanderveen & Husch, 2015). While working with students in a large acute care hospital nursing faculty noticed variances in how staff nurses administered and maintained III. Policies and education materials available did not address all the complexities of III. This observation along with a review of the research literature regarding IV medication errors and III prompted research questions regarding the prevalence of safety, infection control, and residual management of III.

Chapter II

Literature Review

Purpose

This study investigated the quality and safety of nursing practice in III administrations. Identifying errors and risks with the process of III is the first step in quality improvement and will serve as a baseline for quality improvement and education.

Study Questions

The present study addresses three main areas of patient safety as identified from the literature related to medication errors, infection control, and residual volume management. Observation of the electronic health record (EHR) and IV equipment of

patients receiving III was used to collect data for a descriptive study. This technique identified quality and safety practices nurses employ when administering III and will address the following questions.

1. What are the frequencies and types of III medication errors?
2. What are the frequencies and types of infection risks observed in III administration?
3. What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?

Search Strategy

Health care literature was searched using the years from January 2005 to August 2017. Databases used included CINHL Complete, Cochrane Database of Systematic Reviews, Joanna Briggs Evidence-Based Practice, MEDLINE, ProQuest Dissertations and Thesis, and Google Scholar. Initial articles were found with combinations of the following keywords: ‘intermittent intravenous infusion’ OR ‘secondary infusion’ OR ‘intravenous piggyback.’ Another focus of the paper was medication safety” OR “medication errors” with III, so these terms were used in combination with the different terms for III. Since III are administered primarily by smart pump an additional search using key words of: ‘smart pump’ OR ‘intravenous smart pumps’ OR ‘infusion pumps’ AND ‘secondary medication administration’ OR ‘intravenous piggyback’ OR ‘intermittent intravenous infusions’. Residual volume identified as a consequence of III was searched to gather additional information on this topic. Keywords used were: ‘residual volume’ OR ‘dead volume’ OR dead space

in combination with III. In this same theme the terms: ‘intravenous flush’ OR ‘intravenous carrier fluid’ OR ‘intravenous flush amounts’ AND ‘secondary medication’ OR ‘intermittent IV infusions’ OR ‘intravenous piggyback’ were searched. For infection control related to III, another combination of keywords were used to retrieve articles: ‘infection control’ OR ‘infections’ OR ‘infection prevention’ AND ‘intermittent intravenous infusions’ OR ‘secondary infusions’ OR ‘intravenous piggybacks’. Additional searches were used with keywords: ‘infection control’ AND ‘intravenous lines infections’ AND ‘intravenous administration set changes’. All searches were limited to papers written in English and peer-reviewed. Research literature was identified first, and then literature reviews, case reports, abstracts, and proceedings were included to obtain a broad understanding of the subject matter. Relevant websites including the Institute for Safe Medication Practices (ISMP), CDC, and The Joint Commission were searched for smart pump information. References of relevant articles were hand searched to obtain landmark research and additional literature completed before 2005.

Medication Errors

Medication errors continue to be the most common error in healthcare and IV medication administration is the route of the most serious. Particularly vulnerable to this complex issue is the nurse’s role in medication administrations, at the point of care, where errors are least likely to be intercepted before delivery to the patient (Aspden, Wolcott, Bowden, & Cronenwett, 2007). Information from United States Pharmacopeia’s (USP) Medmarx database from 2002-2006 reported that parenteral

medications errors were nearly three times as likely to cause harm as other medication errors. The majority (79%) of harmful or lethal errors reported to Medmarx during this four year time period involved the IV route, and 58 percent occurred during the administration period (ASHP, 2008). High usage compounds the significance of the issue with more than 90 percent of hospitalized patients requiring IV fluids or medications (Alexander et al., 2010; Baranowski, 1995). Researchers in Canada recently conducted 12 ethnographic field studies at 10 Ontario hospitals in regards to multiple intravenous infusions, the complexity, and resulting patient safety risks. One of the safety themes identified from the field studies was secondary infusions. Recommendations for hospitals resulted from the study, and the following were aimed specifically for secondary infusions:

1. When initiating a secondary medication infusion (often referred to as a “piggyback” infusion), nurses should verify that the secondary infusion is active and that the primary infusion is not active by viewing the activity in both drip chambers. Full drip chambers should be partially emptied to restore the visibility of drips.
2. Continuous high-alert medications (Institute for Safe Medication Practices Canada, 2005) should be administered as primary infusions. Continuous high-alert medications should not be administered as secondary infusions.
3. Secondary infusions should be attached to primary infusion sets that have a back-check valve. If infusions sets without back check valves are also available on the unit, multiple strategies should be employed to ensure the

types of tubing available are easily differentiated and the likelihood of a mix-up is minimized (Cassano-Piche, Fan, & Easty, 2012, p. 37).

Smart pump technology. In an attempt to decrease IV programming errors smart pump technology was introduced. While infusion pumps have been utilized in hospitals since the 1960s, only in the last decade have they become “smart” (Vanderveen, 2005). For the first 30 years, pumps infused fluids and medications according to the programmed rate set by the nurse and had few safety mechanisms. Nurses operated solely on their expertise to manually calculate and enter the rate of infusion (Giuliano, 2015; Giuliano, Richards, & Kaye, 1993). Today, infusion pumps are called smart pumps, a term devised by the Institute for Safe Medical Practices (2002) because of their advanced capabilities. They provide instant drug administration information at the point of care (Flynn Makic, 2015). This information is provided through a computer chip that allows a drug library and dose error reductions systems (DERS) to assist the nurse in calculating and administering the correct medication dose. The drug library contains the most commonly used IV medications decided by each institutions health systems pharmacy or interdisciplinary team. The DERS alerts the nurse if dose calculations exceed or minimizes the normal dosing limits. The alerts are articulated as either a hard stop which cannot be bypassed by the nurse or a soft stop which will still allow the user to proceed after the alert has been acknowledged (Institute for Safe Medication Practice, 2002). Currently, smart pumps are considered the industry standard for IV medication safety (Harding, 2012 & Taylor et al., 2015). The American Society of Health System

Pharmacists (ASHP) reported 100 percent of the largest U.S. hospitals, greater than 600 beds, were using smart pumps in 2014. Overall 80 percent of all U.S. hospitals are using smart pumps which have more than doubled since the first survey in 2005 reported 32 percent of hospitals were using these devices (Pedersen et al., 2015).

Errors persist. Unfortunately, new technology does not always completely resolve old problems, and sometimes the technology comes with new problems (Ash, 2004; Bates et al., 1999; Setliff, 2015). The United States Food and Drug Administration (FDA) statistics report that, between 2005 and 2009, more than 56,000 infusion pump incidents were reported, including 710 deaths. This data included all types of environments, manufacturers, and infusions. It included pump malfunctions along with human error (U.S. Food and Drug Administration [FDA], n.d.). Specifically regarding errors with III and smart pumps, Nunnally and Bitan (2006) searched the Manufacturer and User Facility Device Experience (MAUDE) database of the FDA 2003-2004 for a segment of their research. Of 137 reported cases with the keywords smart pumps and piggyback they found 30 relevant reports. Incorrect administration set up was a causative factor in all instances. Over infusion represented the majority of errors with 19 cases. Nine cases reported under infusion. One case described a simultaneous infusion and another described a mixing in the medication bags. Additional works by several authors discuss errors that cannot be corrected with the use of the smart pump alone. Studies addressing errors specifically related to III and smart pumps identified the following: unauthorized drug administration (Osashi et al., 2013; Rothschild et al., 2005, Schnock et al., 2017), III

bag height errors (Cassano-Piche' et al., 2012; Husch et al., 2005), labeling errors (Husch et al., 2005, Ohashi et al., 2013; Schnock et al., 2017) and clamped intravenous lines (Cassano-Piche' et al., 2012; Ohashi et al., 2013).

Conflicting results. The research both supports and refutes the value of smart pumps in preventing adverse events (Hertzel & Sousa, 2009 & Ohashi et al., 2014). Using the pump correctly and acknowledging soft and hard alerts can intercept and prevent medication dosing and rate errors as cited in the following studies.(Husch et al., 2005; Ohashi et al., 2013; Mansfield & Jarrett, 2013; Pang, Kong, DeClifford, Lam, & Leung, 2011; Trbovich et al., 2010). Unfortunately, the positive results found in these studies are all heterogeneous in research methodology and outcomes making it difficult to statistically summarize the findings (Ohashi et al., 2014). No significant effect on medication errors were found in a randomized controlled trial by Rothschild et al. (2005). Nuckols et al. (2007) also determined that smart pumps were unlikely to reduce preventable errors, but their study methodology reviewed patient health records only to determine errors. They did not utilize smart pump logs or observe smart pump use. A recent retrospective study evaluated the impact of smart pumps on reported errors in a 500 bed hospital in Canada. Over a three year span there was no significant difference in errors (Guerin et al., 2015). Nunnally & Bitan (2006) specifically examined III with smart pumps with multiple methods. They found through smart pump log files that III are a common practice and safety features of the pumps were rarely used. In addition they studied a smart pump laboratory simulation exercise with 19 experienced nurses. The simulation findings

had a high failure rate with only 16 percent of the 38 pump scenarios judged highly efficient. Limitations of the study were that three of the four smart pumps were new to the nurses and they had no prior experience with them. The physician researchers were surprised by findings that there was no confusion between primary and III infusion settings. They found it disturbing that nurses chose not to use the call back option when III completed and returned to the primary infusion rate (Nunnally & Bitan, 2006). Interestingly Fan et al. (2014) lists this same process as an advantage to III infusion. Nunnally and Bitan (2006) refute that smart pumps make III simpler and safer and recommend infusing III either by gravity alone or through a second pump with primary tubing.

Compliance with drug library. Literature reviews on smart pumps clearly state compliance with utilizing the drug library is crucial in the ability of smart pump's to prevent errors (Hertzel & Sousa, 2009 & Ohashi et al., 2014;). In early studies by Husch et al. (2005) and Rothschild et al. (2005), little evidence in error reduction was found with smart pumps, but compliance with the drug library was also low. Rothschild et al. (2005) identified a system problem regarding pump configuration which made it easier for nurses to bypass the drug library rather than use it. Later Nuckols et al. (2007) found that smart pumps prevented only four percent of identified medication errors in their study. They felt this low rate may be related to poor drug library development. Barriers still exist that cause non-compliance and workarounds which can compromise patient safety (Wulff, Cummings, Marck, & Yurseven, 2011). The ISMP has identified several reasons

why nurses may circumvent the drug library. The explanations include lack of a current drug library, alerts which are not credible, low perception of risk, additional work and time pressures, clinical emergencies and an environment that encourages workarounds (Institute for Safe Medication Practices, 2007). Early in the use of smart pumps Wetterneck et al., (2006) identified the importance of consulting nurses in the development of drug libraries. They reported high compliance rates with the safety features of smart pumps when intensive training was provided, and nurses were allowed input into the design of the drug libraries so that it matched clinical practice. Smart pumps were never designed to replace the nurse's critical thinking ability but to be a tool to increase safety (Hertzel & Sousa, 2009). Research on nursing perception supports that nurses feel smart pumps improve safety and increase their self-confidence in the delivery of safe medication administration (Eckel, Anderson, Zimmerman, Szandzik, & McAllister III, 2006; Rosenkoetter, Bowcutt, Khasanshina, Chernecky, & Wall, 2008).

Continuous quality improvement. The ability of the smart pump to track and provide relevant data to support continuous quality improvement programs may be its most valuable attribute (Snodgrass, 2005). The pump software automatically logs data on all medications, programming events, and alerts (Mansfield & Jarrett, 2013). Bates (2007) and Keers et al. (2013) both address that health care providers and leaders must ensure iterative changes are made with new devices. Multiple studies address that to truly encourage a safe patient culture pump log data must be continuously monitored and updates made within the pump library, hard and soft

alerts, and the healthcare system as the data suggests (Manrique-Rodriguez et al., 2013; Mansfield & Jarrett, 2013; Skledar et al., 2013; Trbovich, Cafazzo, & Easty, 2011).

Infection Risks

Administration sets. Administration set changes, is part of the 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections (O'Grady et al., 2011). The literature on intravenous administration sets changes exclusively addresses continuous infusion. Intermittent tubing that is disconnected from the patient and used at set intervals is either not mentioned or intentionally excluded. Intermittent tubing is manipulated on both ends numerous times within a 24-hour period, so the chance of contamination is high (Hadaway, 2007). In a study by McDonald, Banerjee, and Jarvis (1998) children with an increased bloodstream infections rate were more likely to receive III. Infection rates returned to baseline when administration sets were replaced every 24 hours rather than every six days. The CDC makes no recommendation for replacement intervals for intermittent tubing related to a lack of evidence (Centers for Disease Control and Prevention, 2015). The Infusion Nurses Society (2011) recommends a conservative approach to tubing change of every 24 hours in the absence of research with intermittent tubing changes.

Most of the research on intravenous (IV) tubing changes was done during the 1970's- 1990. A Cochrane updated review identified 16 studies involving 5001 participants. The studies started comparing the tubing changes of continuous infusions at 24 vs. 48 hours and continued with decreasing the frequency to 96 hours.

The review concluded that tubing may be left in place up to 96 hours without increasing the risk of infection (Ullman et al., 2013). More recent studies are exploring the risks and benefits of 168 hours between tubing changes (Rickard et al., 2015)

Arterial lines. Arterial catheters involve frequent manipulation for blood analysis which can lend to the risk of contamination similar to III administration sets. Research has been done with arterial sampling lines used in intensive care units. Initially, these lines were thought to pose low risk of infection, but more recent studies refute this claim. These studies often compare the newer closed systems to the older method of stopcock for retrieving blood samples. The closed systems reported a lower bacterial contamination from the intraluminal fluid and similar lower contamination at the catheter tip. When comparing tubing and accompanying equipment changes with arterial lines, there was limited evidence to support more frequent changes decrease infection (Daud, Rickard, Cooke, & Reynolds, 2012; Oto et al., 2012).

Intravenous fluids. Intravenous fluid hang time and its relationship to infection risk is another closely related question being currently researched. Similar to intermittent tubing changes the traditional change time for continuous IV fluids has been 24 hours (Alexander et al., 2010). In a cross-sectional study, Rickard et al. (2009) found no relationship between fluid hang time and colonization of infusates. At the study site, IV fluids and tubing were used until treatment ended. Infusates and tubing were used in a range of one to eight days with the median usage time of 34

hours. Over 18 months 264 samples were collected, and seven (2.7%) showed growth. There were no infusate related bloodstream infections. What makes this study unique is it included intermittent lines within the sample. The author mentions intermittent infusions that had been disconnected, capped, hung at the patient's bed when not in use and then reconnected. The author also mentions some patients in the sample group had their lines discontinued when showering, but no number is given of this sample representation. It is important to note that 77 percent of the IVs were discontinued at 48 hours. A small number less than 20 IVs continued for 96 hours (Rickard et al., 2015).

Residual Volume

There is a beginning appreciation for the complexity of III medications identified by specialty groups in health care. In surgery and critical care, it is a common practice for a second infusion to join the primary infusion as an III. Due to the nature of secondary medications in these areas it is often critical that the medication is delivered to the bloodstream quickly, dosage adjustments are done swiftly, and medications are stopped promptly when the effect is no longer needed (Peterfreund & Phillip, 2013). Affecting the delivery time is the concept of dead volume. Dead volume is sometimes used interchangeably with residual volume defined as the space between the beginning of the secondary infusion into the primary fluid pathway and the point of exit from the infusion into the bloodstream (Lovich et al., 2005). Through mathematical and lab experiments Lovich et al. (2005) determined that large variations in the delivery rate of medications occur related to

the interactions of the administration set dead volume, secondary drug flow rate, and the primary carrier fluid rate. Their mathematical and experimental models predicted a lag time in initiation, change, and cessation of secondary drugs. Even the side port and how the administration sets were connected had an impact on medication delivery time.

Anesthesia. A dangerous situation identified by Bowman, Raghavan, & Walker (2013) involving residual volume is anesthesia drugs left in the dead space of lines after surgery. The dead space in the IV cannula can range from 0.1ml to 0.3ml and then when needle-free injections ports and extension sets are added the residual dead space can be significant in potent anesthesia medications. If residual medication is not properly flushed within the operating room, late paralysis may occur in patients in settings outside the safety of the operating room when fluids or other medications are started within the same IV. Another vulnerable situation occurs when anesthesia is induced using a rapid sequence induction with an additional IV which remains unflushed. Both of these situations stress the importance of complete medication delivery at the time they are intended with adequate flushing of the lines and cannulae (Bowman, Raghavan, & Walker, 2013)

Neonatal populations. Pediatrics and especially premature neonates are particularly susceptible to issues from residual volume related to low flow rates and volumes (Van der Eijk, Van Rens, Dankelman, & Smit, 2013). In an in vitro study by Anh et al. (2006), four different medications were delivered in a method identical to that used in the neonatal intensive care nursery. The administration sets used had a

total volume of 1.5 ml. Medication samples were collected after administering the medication volume and then flushing each administration set twice with 1.5 ml of normal saline. After the first 1.5ml flush following the medication delivery only 53 percent of phenobarbitone and 60 percent of caffeine were delivered via the administration set. Higher amounts of the other two medications were delivered with gentamicin at 92 percent and 99 percent of Vancomycin after the 1.5ml flush. The second normal saline flush of 1.5ml increased caffeine delivery to 103 percent and 82 percent for phenobarbitone. The model demonstrated that the smaller volume amount of medication needed a larger flush volume. Caffeine with a volume of 0.25ml needed an additional 2.03 ml flush to deliver 95 percent of the dose, while Vancomycin with a dose of 5.45 ml only needed 0.24 ml normal saline flush. For clinical practice the authors proposed a universal flushing protocol of 2ml after all 4 medications predicting that this would deliver at least 90 percent of each dose (Anh et al., 2006).

Extended infusions of antibiotics. A few researchers exploring the advantage of extended infusion of piperacillin-tazobactam and meropenem are yet another group who have identified the importance of residual volume (Lam, Bhowmick, Gross, Vanschooneveld, & Weinstein, 2013). Maddox, DeBoer, & Hammerquist (2014) state with the rapidly rising rates of resistant bacteria and the decreasing number of new antibacterial drugs approved for market disease specialist are reevaluating methods to administer IV antibiotics. In an article describing flushing techniques for residual volume Weeks (2012) makes a similar assertion. She

reports that ensuring the full dose of an III is delivered is an equally important task for the nurse as checking the dose before administering and that suboptimal antibiotic dosages may lead to poor efficacy and treatment failure plus encourage appearance of antibiotic-resistant bacteria. In a literature review on extended piperacillin-tazobactam Lam et al. (2013) found two studies out of 19 discussed incomplete administration resulting from residual volume. Of the two studies, Claus et al. (2010) identified the issue most thoroughly regarding small volume bags of 50ml and smart pump characteristics. They found every replacement of the administration set resulted in a 40 percent loss of the antibiotic or subsequent degraded medication infusion at the next administration if the line was not flushed fully. The study used the Alaris smart pump system and administration sets with a residual volume of 24ml. Claus et al. (2010) recommended either increasing solution volumes or using administration sets (microbore tubing) with minimal dead space if the tubing residual exceeds 10 percent of the infused volume. The second study by Xamplas et al. (2010) automatically utilized 100ml bags rather than 50ml bags to decrease the amount of residual drug volume in the administration set. A European study by Plagge et al. (2010) found comparable results with several different antibiotic III and residual volumes. When the medication was finished infusing and fluid remained in the administration drip chamber the remaining residual volume was found to contain between 47 percent of a 50ml bag and 25 percent of a 100ml bag. When the medication was administered until the drip chamber was completely empty the remaining residual volume was 32 percent for 50ml and 15 percent for 100ml. The

study suggested infusing medications until the drip chamber was empty and increasing to 100ml bags whenever possible (Plagge et al., 2010).

Clinical trials. Kontny et al. (2012) reported results from a study analyzing pharmacokinetics. The authors identified in clinical drug trials priming and flushing issues are avoided to allow for precise definition of dosing. Administration sets are prefilled with the drug only. The infusion bags are overfilled with drug so the infusion can run until the required drug amount is administered which is determined by the flow rate rather than the volume of the system. When the correct drug amount is administered the bag and administration set is discarded. In clinical practice, these are not practical or safe options due to large amounts of waste and potential exposure of toxic medication to nursing. So in clinical practice, many variables exist. The authors reported the drip chamber of the administration set can be filled with different amounts of fluid. They found that flushing the line with one time the residual volume resulted in less than 5 percent drug loss. Even larger variability in the loss was suggested in slow infusion rates and small infusion volumes (Kontny et al., 2012).

Nursing. Experienced nurses intuitively understand the issue of residual volume within an IIV administration set (Claus et al., 2010; Lovich et al., 2005) but nursing research has been limited in regard to complete dosing with only one research article that described a pinching technique of the tubing by the nurse to ensure 99% of the infusing was administered (Thoele, Piddoubny, Ednalino, & Terry, 2018). Mostly anecdotal information is given regarding how to handle residual volume with a primary fluid to flush after an IIV is complete (Alexander & Zomp, 2015; Idea, 2009;

Weeks, 2012). Weeks (2012) lists the following practice to ensure complete dosing when using a smart pump. First, prime the primary tubing with the required volume for the tubing utilizing normal saline in a 250ml bag. A 250ml bag of solution is superior to 50 or 100ml bags because constantly opening the system to hang a new bag increases the risk of contamination. Second, hang the secondary infusion in the usual piggyback fashion into the primary line. After the secondary medication has infused, flush the primary line with normal saline to ensure the full dose of medication is delivered, and no medication is left in the tubing. This same procedure is practiced in two large acute care facilities described by Alexander and Zomp (2015).

Implementation of the flushing procedures requires orders by providers for the saline. In two prevalence studies regarding IV medication errors, Ohashi et al. (2013) and Schnock et al. (2017) found unauthorized medications as a frequent error. Over half of those errors were related to normal saline, running at a keep vein open rate without a provider order. They found that nurses commonly use normal saline to hang with a secondary bag without obtaining an order. This could be considered a significant risk. Any medication that does not follow the usual path through the electronic medical administration record (eMAR) bypasses safety features regarding right medication. They suggest normal saline be automatically ordered via technology with any secondary IV medication in the eMAR.

Literature Review Summary

The literature related to III is fragmented and nominally found in many different areas. Minimal research has been done to completely address all the issues of III (Alexander & Zomp, 2015; Infusion Nurses Society, 2011; Marschall et al., 2014; O’Grady et al., 2011; Peterfreund & Phillip, 2013; Thoele et al., 2018). Smart pumps have decreased errors in medication delivery when the drug library is utilized correctly and hard, and soft alerts are acknowledged, but problems still exist with mechanical aspects of the procedure (Husch et al., 2005; Nunnally & Bitan, 2006; Trbovich et al., 2010). Manipulation of the III tubing places the patient at increased risk for contamination but III has been neglected in the research related to administration set changes (O’Grady et al., 2011; Infusion Nurses Society, 2011). Anecdotal literature (Institute for Safe Medication Practice, 2007) and research (Husch et al., 2005; Ohashi et al., 2013; Schnock et al., 2017) report policies regarding administration set changes and labeling may not be well followed. Residual volume and flushing of III have been identified by different researchers as affecting complete dosing of medications, but no standardized guidelines exist (Anh et al., 2006; Bowman et al., 2013; Claus et al., 2010; Lovich et al., 2005). Due to this complexity, it is important to identify current nursing practice in hospitals regarding the delivery of III. This will determine if nurses are delivering the entire dose of III, utilizing all safety processes available, without exposing the patient to risk of infection from the administration process. This knowledge of current practices can then be used for quality improvement projects and nursing education.

Chapter III

Methodology

Problem and Study Questions

Delivering medications via III is a common but complex process with factors involving safety with risks in medication errors, infection control, and residual management (Claus, Buyle, Robays, & Vogelaers, 2010; Fan et al., 2014; Hadaway, 2007; Hoefel, Lautert, Schmitt, Soares, & Jordan, 2008; Nunnally & Bitan, 2006). Almost all patients in acute care hospitals receive IV therapy (Alexander, Corrigan, Gorski, Hankins, & Perucca, 2010; Baranowski, 1995) with III a common method to deliver IV medications usually with the assistance of a smart pump (Pedersen et al., 2015). Little evidence exists to guide nursing practice with III (Infusion Nurses Society, 2011; Marschall et al., 2014; O’Grady et al., 2011). Available literature reports issues with poor nursing practice, errors, and limited knowledge by the nurse (Cassano-Piche’ et al., 2012; “ISM Medication Safety Alert,” 2007; Nunnally & Bitan, 2006; Vanderveen & Husch, 2015). While working with students in a large acute care hospital, nursing faculty noticed variances and lack of compliance with policies on III administration. Institutional policy on III at the study site (see Appendix A), the *User Manual: Alaris System with Guardrails Suite MX* (CareFusion, 2015), and fundamental texts (Potter et al., 2013; Taylor et al., 2015) do not address all the complexities of III. This observation along with a review of the research literature regarding IV medication errors and III prompted research questions regarding the prevalence of safety, infection control, and residual management of III. The study will address the following questions.

1. What are the frequencies and types of III medication errors?
2. What are the frequencies and types of infection risks observed in III administration?
3. What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?

Design

An observational technique, framed in Donabedian's model of structure, process, and outcome, was used to collect data. Data was collected using direct observation of patients receiving III, the accompanying equipment, and the EHR. Many studies over the years have found observation to be efficient and accurate when studying issues involving medications and safety technology (Flynn, Barker, Pepper, Bates, & Mikeal, 2002; Meyer-Masseti et al., 2011).

Setting

The study occurred in an 886 bed, level one trauma hospital in Springfield, Missouri. Ten adult acute care medical and surgical units were utilized. All intensive care units, pediatric and neonatal units, the emergency department, and the operating room were excluded due to differences in smart pump use. In the emergency and operating room, it may be appropriate to not use the smart pump for III. In the pediatric and neonatal area, III are given routinely with a syringe versus a small bag. The intensive care units were excluded related to high patient acuity but could be a valuable population to study with III.

Population

Adult patients receiving III on ten medical and surgical units, during the days of data collection composed the population for the observational study. These patients were identified by III administration sets and smart pumps visible in the room. The total patient census on the units combined was 270 patients, but not all of the patients were receiving III.

Sample

The observation sample consisted of inpatient adult males and females who showed physical evidence of receiving III on the days the data were collected. Vulnerable populations which include individuals who are pregnant, prisoners, handicapped, mentally disabled or economically or educationally disadvantaged were included in the data if they were a patient on the surveyed units. The literature suggests exclusion of these populations when assessing the standard of care may be deemed unethical (Ogrinc, Nelson, Adams, & O'Hara, 2013).

Measurement

Data were collected with an observation tool developed by researchers at Brigham and Women's Hospital in Boston Massachusetts and supported through the Association for the Advancement of Medical Instrumentation (AAMI) /Carefusion foundation (Ohashi et al., 2013) (see Appendix B for original tool). The tool, based on a previous study by Husch et al. (2005), was developed using a participatory design approach by a multidisciplinary team and validated with data collection (Ohashi et al., 2013). Since its' initial use, the tool continues to be used to identify errors and practice deviations (Bates, 2015; Ohashi et al., 2014; Schnock et al., 2017).

With permission from Komoto Okashi Schnock (see Appendix C email correspondence) the checklist tool was adapted to collect additional data on infection and residual volume. Two items were not included from the original tool related to the procedure of the observational study. Omissions of III and delay or wrong time were not included in the revised checklist. The observation of the eMAR with currently scanned meds makes it difficult to determine if the medications are delayed. Our direct observation at one point in time made it difficult to determine if a medication was truly omitted or given after the observation period. The adapted checklist tool can be found in Appendix D.

Operational definitions for medication errors, infections risks, and residual volume are listed below in Table 1, 2, and 3 respectively.

Table 1.

Definition of medication errors for data collection
<ol style="list-style-type: none"> 1. Wrong dose – the correct medication but the dose is different from the prescribed order in the eMAR. 2. Wrong rate – a different rate is seen on the pump from that prescribed in the eMAR and/or drug library. This data was only collected on medications that were currently infusing. 3. Wrong concentration – an amount of medication in a unit of solution that is different from the order in the eMAR. 4. Wrong medication – a different fluid/medication as documented on the IV bag and/or label is being infused compared with the order in the eMAR. 5. Known allergy – medication is prescribed/administered despite documentation in the eMAR of patient having a known allergy to the medication or class. 6. Patient identification error – patient either has no ID band on wrist or information is incorrect. 7. Unauthorized medication – fluids/medications are being administered, but no order is present in the eMAR. 8. Expired medication- the expiration date or time of the medication /fluids has passed. 9. Secondary administration set errors:

<p>A. Bag height- the secondary bag is not significantly higher than the primary bag fluid level. This data was only collected on medications that were currently infusing</p> <p>B. Clamp – the secondary clamp is found clamped during administration. This data was only collected on medications that were currently infusing.</p> <p>C. Connection – the secondary administration set is connected below the pump.</p> <p>D. High alert medication – the secondary administration set is connected to a high alert continuous medication.</p> <p>10. Smart pump or drug library not used – smart pump is not used, or smart pump is used and drug library is not utilized determined by lack of drug name observed on smart pump screen. This data was only collected on medications that were currently infusing.</p> <p>11. Pump setting error – setting programmed into the pump is different from the prescribed order. This data was only collected on medications that were currently infusing.</p>
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Table 2.

Definition of infection risks for data collection
<p>1. Incorrect tubing end management is defined as tubing disconnected from the patient and left uncapped, looped unto itself, covered with a syringe cap, or other method besides utilizing the approved end cap. This data was only collected on medications that were not currently infusing</p> <p>2. Incorrect administration set changes was determined by administration set labeling which is absent, incorrect or indicates the tubing has hung longer than policy indicates.</p> <p>3. Incorrect primary bag changes was identified through bag labeling and/or documentation in the eMAR which is absent, incorrect or indicates the bag has hung longer than policy indicates.</p> <p>4. Infection and safety risks related to increased tubing disconnection from patient or tubing removal from pump was measured by number of patients wearing gowns without snap or tie type sleeves.</p>

Table 3.

Definition of residual volume incidents and management for data collection
<p>1. The incidence and type of fluid administered continuously or as a flush bag with III administration.</p> <p>2. The frequency and type of administration set used to deliver the III.</p>

3. Frequency of residual volume on completed III infusions utilizing primary administration sets. This data was only collected on medications infusions that were completed.
 - A. Fluid still in the bag.
 - B. Fluid still in the chamber.
 - C. Fluid still in the tubing above the pump.
 - D. Fluid visible only below the pump.A negative response is indicated by fluid still in the bag or chamber.
4. Frequency of residual volume on completed III infusions utilizing secondary administration sets. This data was only collected on medications infusions that were completed.
 - A. Fluid still in the bag.
 - B. Fluid still in the chamber.
 - C. Fluid still in the tubing above the y site.
 - D. Fluid visible only in primary tubing.A negative response is indicated by fluid still in the bag or chamber.

Procedure

Data were collected by the primary investigator and two research assistants (RA). Each RA held a master's degree was an experienced nurse with more than 20 years' experience, and was very familiar with the settings of the Alaris smart pump and the EHR of the hospital. Carthey (2003) states that research in other industries has shown that data collectors with good domain knowledge can make consistent and meaningful observations. All data collectors participated in the organization of the checklist tool. The two RAs participated in practice observation with the checklist tool before the study period. To maintain inter-rater reliability, the primary investigator was always one of the pairs collecting data.

On each unit, a pair of data collectors knocked and entered each patient room. Data were collected on patients with III administration sets visibly hanging within the room. The III were either infusing or in-between dosing intervals. Some direct observations data were obtained when the III was infusing or when the infusion was

completed, but a majority of the data was collected regardless of infusion status. The procedure for III is to leave the tubing and empty bag hanging until the next dosing interval occurs (Potter et al., 2013; Taylor et al., 2015). This allowed the data collectors to collect data at any time period and without the constraints of direct observation of the nurse administering the medication.

Data collection occurred on the day shift until all units were surveyed, a total of six days. Each patient included in the study was informed that we were reviewing the IV medication to ensure safety and quality. The patient could refuse to have their eMAR, IV medication, equipment, and person observed at any point of the observation. No patients refused the observations.

Any discrepancy was researched via the physician's order sheet and patient assessment within the EHR. Discrepancies or errors were reported to the primary and/or charge nurse for appropriate action. To determine the severity of errors observed the NCC MERP harm index (see Appendix E) was utilized with agreement reached by all data collectors in level of severity.

Data Analysis

The results were analyzed as frequency and different types of medication errors, infection risks, and residual volume. Error rates (percentages) were calculated on the corresponding sample size of each category. See Table 4 for how data was analyzed.

Table 4.

Calculation of frequencies and percentages
Question: What are the frequencies and types of III medication errors?

<p>Total number and frequency of medication errors observed in two main categories:</p> <ol style="list-style-type: none"> 1. Medication Delivery Errors - wrong dose, wrong rate, wrong concentration, wrong medication, known allergy, patient identification error, unauthorized medication, expired medication, secondary administration set errors, smart pump or drug library not used, pump setting error. 2. Labeling Medication Errors – patient name absent or incorrect on primary fluid, primary tubing, III medication or III medication tubing 	<p>Frequencies of medication errors by type and error rate (percentage).</p> <ol style="list-style-type: none"> 1. Percentages calculated as the number of identified errors per the sample size. Sample sizes vary by number of : <ol style="list-style-type: none"> a. observed medication administrations. b. number of infusing medications and fluids. c. number of completed medications. d. number of primary fluids hanging. e. number of patients. 2. Percentages calculated as the number of labeling errors per the number of: <ol style="list-style-type: none"> a. primary fluid and tubing present b. III medications and tubing present.
<p>Question: What are the frequencies and types of infection risks observed in III administration?</p>	
<p>Total number and frequency of infection risks observed in three different areas.</p> <ol style="list-style-type: none"> 1. Inappropriate end cap coverings- looping, syringe cap covering or left exposed. 2. Date Labeling Errors- incorrect or absent date labels on tubing or fluids. Labels indicating expired tubing and/or fluid. 3. Non-recommended gowns or tops worn by patients. 	<p>Frequencies of infection risks by type and rate (percentage).</p> <ol style="list-style-type: none"> 1. Percentages calculated as the number of inappropriate end cap coverings per the number of completed III observed. 2. Percentages calculated as the number of incorrect, absent, or expired date labels per the number of: <ol style="list-style-type: none"> a. primary fluid and tubing present. b. III medications and tubing present. 3. Percentage calculated as the number of non-recommended gowns identified per the number of patients observed.

What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?	
<p>Total number and frequency of residual volume presence and management.</p> <ol style="list-style-type: none"> 1. Number and type of administration sets – primary or secondary. 2. Number and type of primary fluid – continuous or flush bag. 3. Residual fluid level after infusion completed – fluid in the bag, chamber or tubing. 	<p>Frequencies of residual volume and administration techniques used to manage residual volume by type and rate (percentage).</p> <ol style="list-style-type: none"> 1. Percentage calculated by number of administration sets per number of III. 2. Percentage calculated by number of primary bag per number of III. 3. Percentage calculated by level of residual volume per number of administration sets.

Protection of Human Services

The problem, research questions, and design were presented to the nursing research council of shared governance within the hospital and they supported the need for the study (see Appendix F for the complete letter). Institutional review board approval was secured from Case Western Reserve University and Mercy Springfield (see Appendices G and H). The quality improvement project did not present any physical, psychological, social or legal risks beyond what was reasonably expected in daily life or in routine medication administration.

Summary

With IRB approval from Mercy Hospital Springfield and Case Western Reserve University, an observational study was implemented by the three data collectors (PI and two RAs) described earlier. Donabedian's model of structure, process, and outcome provided the theoretical framework for the study. Structured observation of patients receiving III, the accompanying equipment, and EHR was collected with an adapted checklist tool initially developed by Ohashi et al. (2013).

Three variables consisting of medication errors, infection risks and management of residual volume were identified from the literature and represent safety risks in III. The study occurred on ten medical-surgical units in an 886 bed, level one trauma hospital. The sample consisted of inpatient adult males and females who showed physical evidence of receiving III on the day's data were collected. The results provide guidance for future quality improvement and nursing education.

Chapter IV

Results

Sample

Ten medical-surgical units were surveyed. On these units, 102 (35%) of a possible 290 inpatients had a total of 117 medications hanging, as some patients had more than one secondary or primary administration set visible. Nine (8%) of the III medications were infusing at the time of observation. The remaining 108 (92%) medications were in-between dosing intervals.

Study Questions

Although some questions related only to medications that were infusing or completed, most of the survey could be answered regardless of the infusion status. Percentages were calculated on the appropriate denominator and will be visible in the tables or narrative.

Study Question 1: What are the frequencies and types of III medication errors?

Medication Errors

Of 117 III hanging, we found 290 medication errors. More errors were possible than the number of medications because each medication could have up to

21 medication errors. One hundred ten medications (94%) had one to six errors observed. Medication error rates varied depending on number of medications and number of medications infusing or completed. Overall there were 1,924 errors possible and an overall error rate of 15%.

No errors were observed for 12 variables. Of the 290 total medication errors, the different errors were grouped into two main categories. One hundred twenty-five (8%) errors from a possible 1,482 were listed as medication delivery errors and further described in Table 5. One hundred sixty-five errors (37%) of a possible 442 were labeling errors and further described in Table 6.

Table 5.

Medication Delivery Errors

Type of delivery error	Possible Errors	Actual Errors	Error Rate
1. Unauthorized medications	104	57	55%
2. Drug library incomplete	117	44	38%
3. Wrong concentration	117	15	13%
4. Wrong rate	9	5	56%
5. Drug library not used correctly	45	4	9%
6. Wrist band incorrect	117	0	0%
7. Expired medications	117	0	0%
8. Incorrect medication order	117	0	0%
9. Wrong drug	117	0	0%
10. Wrong dose	117	0	0%
11. Allergy to medication	117	0	0%
12. High Alert med as primary	104	0	0%
13. Connected below the pump	104	0	0%
14. Smart pump not utilized	117	0	0%
15. Med channel not correct	45	0	0%
16. Clamp not open	9	0	0%
17. Height does not allow dripping from secondary bag	9	0	0%
Total numbers of medication delivery errors	1482	125	*varying sample size, so percentages will not equal 100

Drug library incomplete. All medication names were listed within the smart pump's drug library, but the dose and volumes were not always present for the nurse

to select and had to be manually entered. Each time a medication was not listed fully in the drug library it was counted as incomplete.

Wrong concentration. Errors in this category included medications orders with either missing or different concentrations listed in the eMAR when compared to the concentration listed on the medication bag label. Concentration is defined as the number of milligrams or dose unit per milliliter of solution. Fourteen of the fifteen medication orders had no concentrations listed in the eMAR for the nurse to compare. Only the dose was listed. One medication had a different volume in the bag when compared to the eMAR. The medication bag listed Vancomycin 1500mg in 300ml while the eMAR listed 1500mg in 250ml.

Wrong rate. Nine secondary medications were currently infusing during the time of data collection. The remaining medications were either infusing the primary continuous fluids or in between dosing intervals. Of these nine infusing medications, five (56%) were infusing at a rate different than that listed in the eMAR or the drug library.

Unauthorized primary fluids. Over half of the 104 primary fluids were hanging without an order. All of these were normal saline bags of varying volume size.

Drug library bypassed. Of the 45 infusing medications or primary fluids, all were infusing via the drug library except for four (9%). These four were primary fluids, and the basic infusion was selected rather than the preferred IV fluid guardrail option.

Labeling errors. A large group of errors were related to the hospital labeling policy. This policy requires medication bags, fluid bags, and all tubing to have a patient name label attached. See Table 2 to describe types and frequencies of labeling errors.

Table 6.

Medication Labeling Errors – Missing Patient Name

Type of labeling error	Possible Errors	Actual Errors	Error Rate
18. Pt. name missing on III tubing	117	64	55%
19. Pt. name missing on primary fluid bag	104	45	43%
20. Pt. name missing on primary tubing	104	31	30%
21. Pt. name missing on III medication	117	25	21%
Total number of labeling errors	442	165	*varying sample size, so percentages will not equal 100

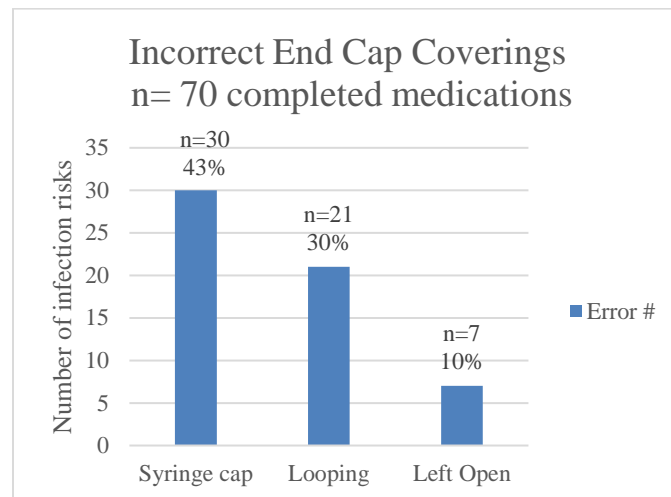
Study Question 2: What are the frequencies and types of infection risks observed in III administration?

Infection Risks

Infections risks numbered 228 (46%) for the 102 patients observed. Each patient could have up to five infection risks. The number of infection risks totaled 497 and was calculated on the number of patients, number of medications, number of completed medications and number of primary bags and tubing. Seventy-nine patients (77%) had one to four safety risks each. These numbers included end caps that were not correctly covered, incorrect or absent dates on the tubing and bags, plus any patients in sleepwear that necessitated additional disconnection and thus potential contamination risk of the open IV end.

End cap. Fifty-eight of 70 administration sets (83%) were found with inappropriate end cap coverings. These administration sets were not connected to the patient and were in-between dosing intervals. We observed looping the tubing back onto another port of the IV tubing, capping the male luer end of the administration set with the cap from a saline flush syringe or leaving the tubing open and dangling from the IV pole. The frequencies of these three types of inappropriate coverings can be seen in Figure 4.

Figure 4.



Outdated tubing and fluid. Altogether more than half of the primary fluid bags and tubing were not dated. Fifty-two primary fluid bags of 104 (50%) had no date and no documentation in the eMAR. Primary fluid tubing was only slightly better with 46 missing dates of 104 tubing (44%). The tubing connected to the medication had 69 missing dates of 117 possible (59%). When the date was absent, it was difficult to tell if the primary bags and tubing were expired, so they were rated as absent only. Bags and tubing that were labeled with dates that were past their

replacement date were rated as clearly expired. Some tubing was labeled with the incorrect date tag, every 96 hours label versus 24-hour change label and these were categorized as incorrect. If the tubing was labeled incorrectly but also clearly expired, then it was counted as clearly expired only. See Table 7 for specific infection risks related to missing fluid and tubing dates.

Table 7.

Infection Risks Related to Date Labeling

Type of Labeling Error	Possible Errors	Actual Errors	Error Rate
1. Medication tubing date absent	117	51	44%
2. Primary fluid date absent	104	49	47%
3. Primary tubing date absent	104	24	23%
4. Medication tubing date incorrect	*117	16	14%
5. Primary tubing date incorrect	*104	16	15%
6. Primary tubing clearly expired	*104	6	6%
7. Primary fluid clearly expired	*104	3	3%
8. Medication tubing clearly expired	*117	2	2%
Total number of labeling errors	325	167	*varying sample size, so percentages will not equal 100
*multiple options for labeling errors but each tubing counted as one error, so sample only counted once			

Patient gowns. Three of 102 patients (3%) were wearing pajamas that would necessitate the nurse to either disconnect the tubing from the patient or remove the medication tubing from the smart pump and reprogram the pump in order to bath or change the sleepwear. This was considered an infection risk due to the probability of disconnection during the gown change. The remaining patients were all wearing snap gowns which are easily changed around an intravenous line on a smart pump.

Study question 3: What are the frequencies of residual volume and what types of administration techniques are used to manage residual volume?

Residual Volume

Residual volume was determined by the presence of fluid at levels within the administration set and bag. The medications had to be finished infusing for this observation. Of the 104 completed medication tubing observed none were completely empty. Eighty-nine percent or 104 of the 117 medications were infused with secondary administration sets along with either a primary infusion or flush bag. Only 13 (11%) of III were infused via primary administration sets. Table 8 summarizes the level of residual medication in both secondary and primary administration sets.

Table 8.

Residual Fluid Level after Infusion

Level of Medication Fluid	Secondary Fluid Level	Secondary Fluid Level Percentage n=98	Primary Fluid Level Number	Primary Fluid Level Percentage n=12
1. Fluid remains in the bag	31	32%	3	25%
2. Fluid remains in the drip chamber	24	24%	2	17%
3. Fluid remains in the tubing above the pump	43	44%	6	50%
4. Fluid only in the tubing below the pump	0	0%	1	8%
Total	98	100%	12	100%

Chapter V

Discussion

This study investigated current quality and safety in III administrations at an 886 bed; level one trauma hospital in Springfield, Missouri. The study results are the first step in collecting baseline data on medication errors and infection risks, plus the incidence and management of residual volume. The strengths and weakness of the results may be used for future quality improvement decisions, plus education development for practicing nurses and nursing students.

Positive Findings

Many positive findings were a result of the data collection in regards to medication errors. Several categories from the survey had no errors or no risks to patient safety. No allergies to any of the medications were found. There was a smart pump available in every room in which secondary medications were visible. Every patient had an identification wristband intact with their correct name. The medication name and dose were always correct in the eMAR, and there was an order for every secondary medication. We found no expired medications. On infusing medications, all were connected above the pump and in the correct channel of the smart pump. The secondary clamp was open with an appropriate head height to allow dripping from the secondary chamber. No high-risk medications were infusing with a secondary medication.

Medication Errors

A total of 290 (15%) medication errors of a possible 1,924 were observed by data collectors. The types and percentages of medication errors found are similar to

medication error findings by Ohashi et al. (2013) and a multihospital study by Schnock et al. (2017). These studies respectively developed and utilized the tool adapted for this study. More errors occurred than number of patients (n=102) or number of medications (n=117) because each patient and/or medication could have multiple errors. All the medication errors observed reached the patients, but data collectors decided that no error rated higher than NCC MERP category C. Category C is defined as errors unlikely to cause harm despite reaching the patient (National Coordinating Council for Medication Error Reporting and Prevention, 2016) See Appendix E for complete definitions on NCC MERP. It should be noted that since this was an observational study at one point in time, it is not known to the data collectors if subsequent harm occurred to the patients at a later date as a result of errors.

Labeling errors. Patient names on 100% of tubings, fluids and medications are part of the hospital policy on medication administration. This policy was implemented after a fluid bag was reconnected to the wrong patient after being disconnected between dosing intervals. Without patient identifiers on the tubing or fluids, it can be difficult to quickly determine ownership of different fluids and tubing. We found this policy to be widely violated throughout the units observed as we found 165 (37%) errors of a possible 442 related to just labeling. Other studies in the literature have reported similar results with labeling errors (Husch et al., 2005, Ohashi et al., 2013; Schnock et al., 2017). Parts of this name labeling policy are relatively new within the last two years, and nurses may not understand or value its

significance. It is policy that all medications are scanned before administration as an identity safety feature. But if IV fluids are disconnected for showers and ambulation, there is no scan before reconnection and thus name labels become an even more imperative safety function. According to the Infusion Nurses Society (2016), infusions should not be routinely disconnected when prescribed for continuous use, but this practice has been observed in Mercy Springfield and is reported in the literature (Duncan, Warden, Bernatchez, & Morse, 2018; Rickard et al., 2015). Labeling and routine disconnections may need to be further studied in regards to nurse's knowledge, perception of significance, and solutions.

Labeling is another step in the administration process and requires that labeling occur on two sets of tubing and a primary bag. A fourth label is needed when medication is dispensed from the Omnicell and has to be retrieved and labeled manually by the nurse. It was not part of the study to identify why errors occurred but missing patient names from the medications could be attributed to medications from the Omnicell or medications delivered with the patient label on an outer box or bag that is removed and discarded prior to administration. The III tubing was the tubing most frequently missing the patient name label. It is a short tubing connected to the primary tubing, and the nurse may not feel an additional label is needed. Methods for increased efficiency for the nurse in this process may be helpful. Missing patient names on the primary fluid bag were the second most frequent error. Since this is a relatively new process for the nurse, additional education on the rationale for its significance may be needed.

One potentially critical error was a patient identification error related to the medication label. This error reached the patient and was attributed to the wrong patient name on the medication label. Two patients, in the same room had an identical medication and dose ordered. The patient in bed one received bed two's medication. The patient wristband and medication had been scanned, but the system is designed to scan the medication rather than the patient label on all medications besides insulin pens. Insulin pens scan procedures are different. Pens are scanned twice, once for the medication and once for patient name label on the pen. This is to ensure that each patient's pen is only used for that particular person. This two-medication scan could have prevented this particular error, but labels currently do not exist to support this method. The error was reported to the patient's nurse, and charge nurse. Neither patient was injured or missed a dose, but the potential for harm is present when the patient's name is not visualized on the medication label.

Wrong rate. We found five medications infusing at different rates than ordered. One of these errors could be identified as good nursing judgment and others as flaws in the system. One incorrect rate was the situation of a 91-year-old patient receiving 1000 mg of Vancomycin in 200 ml of fluid. The eMAR order was for 200 ml per hour. The nurse had manually set the pump at 100 ml per hour. This deviation is likely an example of clinical reasoning by the nurse; as a 91-year-old heart or vein may not tolerate 200 ml in one hour. Deviations as these should be included in hospital policy or within the eMAR to help guide novice nurses in the quest for quality patient care. The other four errors demonstrate system problems. One

Gentamicin order listed the infusion rate at 204 ml per hour in the eMAR. The pump was infusing at 198 ml per hour while the bag was labeled to run the medication over 30 minutes, which calculates to 100 ml per hour for the 50 ml volume.

A second situation involved albumin in a 100ml vial. No directions for rate of infusion were listed either in the eMAR or pump. Gahart, Nazareno, and Oretaga (2018) list the rate of infusion for albumin at 1-2 ml per minute. The nurse had programmed the rate at 66 ml per hour.

The final two wrong rate medications had switched to the primary flush rate while still infusing the III, indicating a difference in the volume in the bag with the volume programmed within the smart pump. One medication was Vancomycin which depending on the dose comes in a variety of concentrations, and it would be conceivable that the nurse might select the wrong concentration. The other medication, Cefazolin 1000mg/100ml, was a new concentration for the hospital. Since hurricane Maria hit Puerto Rico last September Cefazolin and Ceftriaxone were coming in both 50ml and 100ml bags. This shortage is not unique to Mercy Springfield and is causing concern at many hospitals (L'Altrelli et al., 2018). The 50 ml bag was the original concentration and was within the drug library of the smart pump. Concentrations of the medications in 100ml were not a part of the drug library and had to be manually entered.

Drug library and wrong concentration. An incomplete drug library within the smart pump necessitates the need for the nurse to manually enter the medications dose and volume increasing the chance of error. Varying concentrations between the

medication bag, eMAR and drug library is confusing and could be difficult for the novice nurse to determine when it was acceptable to deviate from the eMAR prescription or drug library.

The safety literature strongly supports standardization and collaboration among health care providers. Cassano-Piche et al. (2012) list the complexity of secondary medication administration and recommend the use of standardization to limit errors. In 2007 ISMP listed maintaining current drug libraries and credible alerts as necessary for patient safety. Wetterneck et al. (2006) recommended the importance of nursing involvement in the design of drug libraries so it matches clinical practice. On a broader note, literature and key organizations related to interprofessional collaboration continue to support the importance of healthcare providers such as nursing, medicine, and pharmacists working together (Institute of Medicine [IOM], 2015; Interprofessional Education Collaborative [IPEC], 2017; Scarsi, Fotis, & Noskin, 2002) but this collaboration is often poorly implemented or lacking in education (Dornan et al., 2009; Wilson, Palmer, Levett-Jones, Gilligan, & Outram, 2016; Zwarenstein, Rice, Gotlib-Conn, Kenaszkuk, & Reeves, 2013). Collaboration between nursing and pharmacy could improve the medication system in regard to errors in these areas. An interprofessional committee of nurses from patient units, infection control, quality management and patient safety, pharmacists, and hospitalists could bring input from their areas and discipline to develop an approach to identify and resolve issues with III administration. This committee should analyze

the methods of drug library updates, barriers, and propose solutions. It will be essential for hospital leadership to support solutions identified financially.

Unauthorized primary fluids. Unauthorized primary fluids represented the most numerous of the administration type medication errors. All errors were related to normal saline used as a flush bag. The nursing practice council developed a policy encouraging the use of a flush bag but requires a provider order for the primary fluid. The flush bag was used but without the order. Previous studies reported the same type of error (Husch et al., 2005; Ohashi et al., 2013; Schnock et al., 2017). Without an order, the saline does not show up in the eMAR so there is no patient documentation or charge for the fluid. Collaboration between medicine, nursing and pharmacy is needed to address this issue. A possible solution could be a nurse driven protocol that provides easy and immediate order access for the saline flush bag in appropriate patients and guidance to seek consultation in patients at higher risk for fluid volume overload.

Infection Risks

Multiple labeling errors were seen in regard to date. On completed medications, between dosing intervals, the male luer end of the administration sets was not well managed with a variety of inappropriate coverings. Patient gowns observed were a positive result in regard to low infection risk with 97% of patients wearing gowns with easy access in relation to their IV's.

End cap coverings. The large number of inappropriate end caps observed was concerning. We observed looping the tubing back onto another port of the IV tubing,

capping the male luer end of the administration set with the cap from a saline flush syringe or leaving the tubing open and dangling from the IV pole. The literature has long supported using sterile end caps with growing evidence to support disinfection caps (Duncan, Warden, Bernatchez, & Morse, 2018; Institute for Safe Medication Practices, 2007; Paparella, 2017; Voor in 't holt et al., 2017). Mercy Hospital in St. Louis, a part of the Springfield Mercy network, has used disinfected caps as part of a bundle for peripheral IVs to decrease the rate of primary bloodstream infections from 0.57 infections per 1000 patient days pre intervention to 0.11 infections per 1000 patient days (Duncan et al., 2018) and this, along with education, may be an option to resolve the poor end cap maintenance and should be further evaluated and discussed by the Nursing Practice Council.

Outdated tubing and fluid. Expert opinion states that outdated tubing and fluid places the patient at risk for infection (Centers for Disease Control and Prevention, 2015; Infusion Nurses Society, 2016;) but there is a lack of high level evidence to support these statements (O'Grady et al., 2011). Current evidence questions the relationship between infections a longer hang time (Duncan et al., 2018; Zhang, Cao, & Marsh, 2016). But regardless of hang time, tubing and fluid need to have a system for labeling with the date and patient name. As this issue was common, addressing this issue at the system level through shared governance at the nursing practice council would be an important next step.

Residual Volume

A disconcerting number (56%) of medications still had fluid in the bag or fluid in the chamber of the administration set. The importance of emptying the chamber of medication for complete dosing is noted by several different researchers. Previous studies have found that up to 47 percent of the medication may be lost to residual volume when the medication chamber is not empty (Claus et al., 2010; Plagge et al., 2010; Xamplas et al., 2010).

A positive finding was a high volume (87%) of medications were infused using a secondary administration set and continuous infusion or flush bag as the carrier. This is the same technique recommended in the literature to ensure complete dosing (Alexander & Zomp, 2015; Idea, 2009; Weeks, 2012).

Why were there so many medications with fluid still in the bag and chamber? Possible reasons for the incomplete dosing could be attributed to differences in volumes actually in the bag and what is listed in the eMAR and drug library. Pharmacists may not appreciate the effect a change in volume will have on complete dosing at the bedside when reconstituting medications in the pharmacy. Collaboration between pharmacy and nursing to appreciate the role each profession has to play in complete dosing could be beneficial in addressing this problem. Another possible reason may be related to the pump and bag heights when administering III. For all the advancements in technology, III still primarily infuses based on a gravity system. This study did not measure the specific pump and fluid heights, but all III infusions were higher than the primary bag and infusing

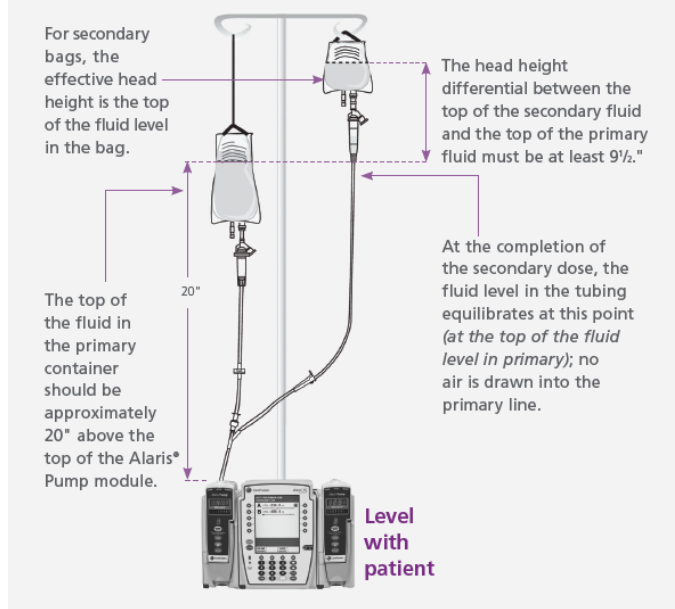
medications were dripping from the secondary bag with the clamp open. This may not be enough to ensure complete dosing. According to CareFusion (2015), the III will stop dripping from the secondary bag when the III fluid volume is at the same level as the primary fluid. Therefore, depending on the height, size, and volume inside of the primary bag the III may need to be at varying heights to infuse all the medication. The height of the nurse and IV pole may even affect the dosing, since administration of III depends on gravity. A nurse of shorter stature may need to first, lower the IV pole to hang the medication and second, fully extend it high enough to prevent a loop in the secondary tubing. Although it was not data collected, few if any secondary administration sets were hanging straight without a dependent loop as shown in Figure 5. Nurses may not be aware of these exact height differences and the effect they have on complete dosing. Education for nurses regarding the importance of height differential could decrease residual amounts. Education on loops could follow the example for preventing dependent loops in urine drainage systems in the prevention of catheter-acquired urinary tract infections (Danek, Gravenstein, Lizdas, & Lampotang, 2015). Recognition of this problem by CareFusion and other smart pump companies could improve the technology so that gravity was no longer a factor needed for complete dosing. Finally, the problem could be attributed to the reliance on the features of the smart pump. The usefulness of the smart pump is to use the drug library for safety, so when it does not deliver the entire medication the nurse may not recognize this as incomplete dosing. Literature on residual volume was scarce and difficult to find so this topic is not well known and attributes to the

problem. The literature was scattered among anesthesia (Bowman et al., 2013), clinical trial researchers (Kontny et al., 2012; Lam et al., 2013), critical care (Lovich et al., 2005; Perterfreund & Phillip, 2013), pediatrics (Anh et al., 2006), and oncology (Thoele et al., 2018). Each study used different terms and methods to measure or manage residual volume. No tool was found to measure residual volume at the bedside. Further research, assessment, and education through interprofessional groups needs to take place to address complete dosing.

Figure 5.

Recommended head height differential

A. Appropriate head height differential positioning for secondary bags



Recommendations

If necessary, use additional hangers to lower the primary container to achieve the minimum 9 1/2" head height differential.

(CareFusion, 2015)

Theoretical Model

Donabedian's Structure, Process, and Outcome Model provided a frame of reference and organization for the study. Each portion of the model provided guidance of what to include from a rather large body of literature on medication errors, infection risks, and residual volume. Structure provided guidance on which types of floors would be included in the survey, what equipment would be observed and how the EHR would be reviewed. The model assisted in developing the study questions on types and frequencies of medication errors, infection risk, and residual volume management in process and outcome. Donabedian (2003) described his model as linear: structure, process, and outcome. The researcher would argue it be used more as a continuous, cyclic, and inter-related process. Recommendations from the results (outcome) suggest interprofessional teams (structure) as a place begin to find solutions to the system problems (process) identified. The model was useful and simple to use and is recommended for future quality improvement studies.

Limitations

The study was only relevant to Mercy Springfield although many of the findings mirrored results from studies using a similar tool (Ohashi et al., 2013; Schnock et al., 2017). The sample size for infusing medications was small. Data collectors observed nine medications infusing and four flush rates infusing. Thus the majority of observations were on completed medications. We were only able to determine one volume to be infused amount. Consequently, methods other than observation are needed to assess these processes or data collectors would need to

follow the nurse during medication administration and additional days would be needed. Barriers existed, and smart pump log data was not available to data collectors as initially planned. The survey tool was paper and pencil, and implementation would be enhanced with a secure web application for recording the data.

Recommendations

From the study results, many things need to happen to improve the quality and safety of III administration. The study results need to be disseminated to involved health care providers. Interprofessional teams need to be formed to identify and implement solutions. Education needs to be developed to address deficits in the study areas for nursing students as well as practicing nurses. Specific next steps could include the following:

1. Disseminate the results to nursing, pharmacy, and medicine through shared governance and discipline-specific meetings.
2. Develop an interprofessional task force from nursing, infection control, quality management, patient safety, pharmacy and medicine to address the issues of medication errors, infection control and residual volume related to III infusions.
3. Develop education modules for the use in skill introduction and clinical judgment that address issues found in medication errors, infection risk, and residual volume of III.

Conclusions

This study identified types and frequencies of medication errors, infection risks, and management of residual volume with the administration of III. The most significant medication errors were regarding an incomplete drug library within the smart pump and unauthorized saline bags used for flush bags. Medication errors with less incidence included medications infusing at the wrong rate and inconsistent drug concentrations between the medication label, eMAR, and smart pump. While all these errors were listed as causing no harm to the patient the potential for more serious harm exists. All results indicate a need for collaboration between nursing, pharmacy, and medicine to determine a system to reduce the incidence of these errors. Violations of hospital policy on patient name and date labeling were especially frequent. As this issue is so common, addressing the violations at the system level through shared governance would be an important next step.

Specific to infection risks was the management of end caps. Education and the introduction of an easily observed disinfection cap have the potential to decrease the variety of incorrect end caps found currently. As with medication errors, an interprofessional approach will be needed to address the issues.

Residual volume found in a large number of III bags and chambers is potentially the most valuable finding from this study. Incomplete dosing has implications in poor patient outcomes. Additional evaluation is needed to identify reasons for the residual volume with interprofessional collaboration to recognize and implement solutions.

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Appendix A

Mercy Hospital Springfield Intermittent I.V. Medication Administration

Policy



Mercy Hospital Springfield

Manual: NURSING SERVICES

Policy #: 0718

Effective Date: 4/88

Revision Dates: 4/88, 12/89, 9/91, 6/99, 4/03,
04/06, 08/08, 09/10, 9/15

Last Date Reviewed: 9/15

Approved By: Nursing Practice Council

Intermittent I.V. Medication Administration**POLICY**

Medications given per intermittent infusions will be administered by a Registered Nurse or the Licensed Practical Nurse who has successfully completed the Intravenous Fluid Treatment Program as approved by the Missouri State Board of Nursing. Please see policy [#0715 - Intravenous Drug Guidelines](#)- (For Registered Nurse and Licensed Practical Nurse).

DEFINITIONS

Intermittent Infusion with no continuous primary fluid ordered- An intermittent infusion is considered to be an infusion (bag/syringe) containing medication that is administered intermittently and connected and disconnected with each use.

Intermittent Intravenous Piggyback (IVPB) Infusion with ordered continuous primary fluid-A secondary IVPB infusion is an infusion (bag/syringe) containing medication that is administered through the established pathway of a continuous primary intravenous fluid (IVF). Administration is via a smart pump or gravity.

EQUIPMENT

1. Chlorhexidine swab
2. Infusion pump if infusing via Alaris pump
3. Secondary Alaris tubing
4. Primary Alaris tubing if no continuous
5. Fluids (IVFs) infusing.
6. Ready to infuse intermittent medications
7. Normal Saline (NS) or Dextrose 5% in water (D5W) - 250 ml bag if no continuous (IVFs) infusing
8. Alaris Point of Care Unit (PCU) and Alaris Large Volume Pump Module (LVP)

if infusing per pump

9. Gloves

Intermittent Infusion with No Continuous IVF

KEY INFORMATION

- Perform hand hygiene prior to any IV medication administration and put on PPE if indicated.
- 7 rights must always be verified prior to medication administration.
- Ensure patency of existing intravenous (IV) access. If IV appears patent without signs of infiltration and IVF infuses without difficulty, proceed with administration even if no blood obtained with aspiration. Observe closely for signs and symptoms of infiltration during and after administration.
- Primary **intermittent** infusion sets (both primary and secondary tubing) and infusates should be changed every **24 hours** or at any indication of contamination. Ensure that both sets of tubing and infusates are labeled with a patient label and the date, time, and initials of person changing the tubing. Any “add-on devices” that are disconnected with infusion, such as extension sets, filters, and needleless devices should be changed at the time of the administration set.
- Accurate secondary infusion delivery is dependent upon hanging the secondary container sufficiently higher than the primary
- Minimal disconnection of the intermittent medication administration tubing from the primary IV is encouraged.
- When primary intermittent infusion is complete, disconnect tubing from patient and flush catheter per institutional policy. Place sterile cap over exposed end of disconnected tubing and maintain cleanliness.
- Cleanse the IV port with chlorhexidine for 15 seconds prior to accessing any IV port.

PROCEDURE:

1. Ensure patency of existing intravenous (IV) access.
2. Hang a 250 ml NS or D5W bag as the primary fluid using Alaris pump infusion set tubing after scanning the fluids into Epic.
3. See Lippincott for IV priming:
 - a. [IV Priming](#)
 - b. [IV secondary line infusion](#)
4. Program pump.
5. Press “Channel Select”
6. Select guardrail IV fluids.
 1. Select Carrier IV fluid.
 2. Set rate of flush to **rate of secondary medication being administered.**
 3. Set volume to be infused (VTBI) on the Primary Infusion to **25-50 ml.**
 4. Select the “Secondary” button on the main screen, “Guardrail Drugs” will appear.
 5. Select the correct medication and dosage.
 6. Enter the correct duration for drug administration.
 7. Unclamp tubing, including the secondary tubing. **For medication to infuse correctly, ensure that secondary tubing is unclamped.**
 8. Push “Start”. **Witness the dripping of the secondary tubing before leaving the room.** (The pump will deliver the medication and then sound six rapid beeps. The

pump will convert to set flush rate and deliver the 25ml or 50ml flush. The pump will sound continuously upon completion of the flush.)

9. Deliver next medication or place to infusion plug.
To deliver the next medication, hold the secondary tubing lower than primary infusion tubing. Back prime by flushing the remainder of fluid that is left in the secondary set into the now empty secondary bag or bottle. **NOTE:** Hold the secondary bag upright filling drip chamber completely allowing approximately 10 ml fluids to enter the secondary bag/bottle. Discard the secondary medication bag/bottle and hang the medication to be delivered and repeat steps.
10. Saline flush line when medications are complete. Monitor patient for adverse reactions.

Intermittent Intravenous Piggyback (IVPB) Infusion with Ordered Continuous Primary IVF

KEY INFORMATION

- Perform hand hygiene prior to any IV medication administration and put on PPE as indicated.
- Ensure patency of existing peripheral intravenous (IV) access. If IV appears patent without signs of infiltration and IVF infuses without difficulty, proceed with administration even if no blood obtained with aspiration. Observe closely for signs and symptoms of infiltration during and after administration.
- Check compatibility of medication to primary IVF and any additive to the primary IVF.
- Both primary and secondary IVF tubing (for continuous administration) and infusates are to be labeled with a patient sticker and changed and labeled with date, time, and initials of change agent every 96 hours or at any indication of contamination.
- Secondary set is to be left in line with primary tubing with roller clamps closed after each medication administration.
- Cleanse the IV port with chlorhexidine for 15 seconds prior to accessing any IV port.

A. Per Alaris pump as a secondary infusion with ordered primary fluid

1. **Check compatibility of primary fluid with medication.** If incompatible, start new IV access and following above information on *Intermittent Infusion with No Continuous IVF*.
2. If compatible, proceed as follows:
 - a. [IV secondary line infusion](#)
 - b. Program pump.
 - c. Press “add secondary”
Select the correct medication.
 - d. Following the pump cues, enter the correct medication information.
 - e. Unclamp tubing, including the secondary tubing.
 - f. Resume primary infusion.
 - g. To deliver the next medication, hold the secondary tubing lower than primary infusion tubing. Backprime by flushing the remainder of fluid that is left in the secondary set into the now empty mini bag or bottle. **NOTE:** Hold the mini bag upright filling drip chamber completely allowing approximately 10 ml fluids to enter the mini bag/bottle. Replace the discarded medication bag/bottle with the medication to be delivered and repeat steps.
 - h. Monitor patient for adverse reaction.

B. Per Gravity as a secondary infusion with ordered primary fluid

1. Verify rate of administration and calculate drop rate.
2. Check compatibility of primary fluid with medication. If incompatible, start a new IV access. If compatible, proceed as follows:
 - a. Prepare the secondary container by closing the roller clamp on the secondary tubing and spiking the secondary container.
 - b. Swab the top of the Y-site port on the primary tubing with appropriate antiseptic and attach the secondary line to the port.
 - c. To back prime, lower the secondary container to a level below the primary container.
 - d. Open the roller clamp on the secondary tubing.
 - e. Allow the fluid to back prime from the primary container into the secondary tubing.
 - f. Close the roller clamp once the secondary tubing is primed and the drip chamber is two-thirds full.
 - g. Hang the secondary container from the IV pole.
 - h. Use the plastic extension set to hang the primary container lower than the secondary infusion.
 - i. Open the vent on the drip chamber if the secondary container is glass or semi-rigid.
 - j. Using the roller clamp on the primary IVF, adjust drip rate to run at calculated rate ensuring that both primary and secondary roller clamps are open.

When the infusion starts, ensure drops are falling in the secondary drip chamber and no drops are falling in the primary drip chamber prior to leaving the room.

- k. Monitor patient for adverse reaction.
- l. After primary infusion is complete, hang primary bag higher than secondary bag and set drop rate to ordered primary fluid rate.

Resources:

Alexander, MM., Corrigan, A., Gorski, L., Hankins, J., Perucca R. eds. *Infusion Nursing: An Evidenced-Based Approach*. 3rd ed. St. Louis, MO: Saunders/Elsevier; 2010.

Weeks, Karen A. Intermittent I.V. infusions in acute care: Special considerations. *Nursing*. 2012;

42(12);66-68

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<http://www.carefusion.com/search.aspx?q=tip%20sheets>.

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Taylor, C., Lillis, C., LeMone, P., Lynn, P., *Fundamentals of nursing: the art and science of nursing*

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References:

Pharm D, MBA, MHA

Appendix B

Original Tool from Brigham and Women's Hospital in Boston Massachusetts

supported through the Association for the Advancement of Medical

Instrumentation/CareFusion foundation

12/15/2015 10:10am www.projectredcap.org

Confidential

*Smart Pump
Patients/Meds_
postdata2014*

meds

Patient ID

Pump type

General infusion pump

PCA

Syringe

Primary/secondary

Primary Secondary

IV fluids type

Drug name

Concentration

Dose

Continuous dose

Demand dose

Maximum doses

Lock-out interval(minute)

Rate

Current time

Administration start time(current bag/syringe)

(push "now" button)

Smartpump was used
pump

Yes No Connected to the

but the pump is off

Status of IV bag contents

IV bag is empty

Has some contents but intentionally
leave at
bedsideHas some contents, without known
reasons

Drug dictionary used

Yes No Unknown

Is there a drug library for this?

Yes No

Right meds programmed in correct channel /pump Yes

No Unknown

Describe

Is the clamp open?

Yes No N/A

Tubing tagged according to policy

Yes (or tag is not required)

No tag (error) Missing required
information

What is missing?

RN Initial

Start date

Discard date Discard time

Other

(describe what info is missing)

Other details

Label complete

Yes (or label is not required)

No No Label(error)

What info is missing?

Drug name

Dose

Volume Expiration date

Pt's name Pt's location

Hung by Date Time

Other

Describe

(describe what info is missing)

Hospital label matches manufacture label	Yes	No	N/A
Describe	_____		
	(describe what info is missing)		
Patient name on wrist band matches medication label	Yes	No	N/A
Describe	_____		
Expired drug	Yes	No	
Describe	_____		
	(when is the expiration date?)		
Chart Review Below			
Medication orders	Yes	No	
Right drug name	OK	Discrepancy	
Name discrepancy details	_____		
Right concentration	OK	Discrepancy	
Concentration discrepancy details	_____		
Right dose	OK	Discrepancy	
Dose discrepancy details	_____		
Right rate	OK	Discrepancy	
Rate discrepancy details	_____		
Right time	OK	Discrepancy	
Time discrepancy details	_____		
	(when was the scheduled time)		
Allergic to this drug	Yes	No	
Describe	_____		
*Record once for each patient			
Medication ordered that was not administered	Yes	No	
Describe order details	(drug name, dose, rate, time,etc)		

Rating

Discrepancy code (multiple choice)

1. No discrepancy
2. Wrong patient
3. Wrong IV fluids/meds
4. Wrong concentration
5. Wrong dose
6. Wrong rate
7. Delay
8. Omission of IV fluids/meds
9. Wrong channel
10. Wrong info on label(missing info)
11. Oversight allergy
12. Smartpump/IV infusing was not used
13. Unauthorized meds
14. Other

Unauthorized medication details

- Discontinued order
- Missing KVO order
- Verbal order
- No documentation on eMAR/flow sheet
- Unknown

Other discrepancy

NCC MERP harm index

- (A) capacity to cause error
- (B) an error occurred but did not reach the patient
- (C) errors unlikely to cause harm despite reaching the patient
- (D) errors that would have required increased monitoring to preclude harm
- (E) errors likely to cause temporary harm
- (F) errors that would have caused temporary harm and prolonged hospitalization
- (G) errors which would have produced permanent harm
- (H) errors that would have been life threatening
- (I) errors that would likely have resulted in death

Comments _____

Review(BWH use only)

- Need to review by site
- Need to discuss with group
- Exclude from entire analysis
- Incomplete data collection

Appendix C

Email Correspondence for Tool Approval

From: Schnock, Kumiko O. [KSCHNOCK@PARTNERS.ORG]
Sent: Thursday, November 12, 2015 2:23 PM
To: Morrow, Suzie
Cc: Dykes, Patricia C.
Subject: RE: Web based observational tool for IV medications

Hi Suzie,

Sorry for the late reply. Glad to hear that our tool fits your need. Here are responses to your questions.

Is there a possibility to add a few questions to the tool and still maintain the original tool integrity?

Yes, you can modify the tool and add additional questions on Redcap(may need to test the modified tool before conducting the data collection).

Since the tool was developed with REDCap database is it available to view on-line? I've read the development article and the PowerPoint presented by Dr. Bates in March 2015, but I have been unable to find the tool.

Redcap is the free web database developed by Vanderbilt Univ and I think you can get an access from them. Once you get an account, then I can share the original tool. Here you may find more information about the tool.

<http://www.ncbi.nlm.nih.gov/pubmed/24551395>

The setting for my study is medical/surgical units in a large acute care hospital. My sample group is adult patients who are receiving intermittent IV infusions. Some of these patients will also receive continuous fluids. Patients receiving continuous fluids without intermittent infusions would not be included in the study. Would this be a problem?

This is not the problem. You can decide what types of IVs you would like to include for the data collection. For the national wide study we clearly defined inclusion criteria beforehand. We excluded TPN and blood products, but some participating sites include them for their local research. Also we conducted another study only looking at PCA/PCEA pumps. Our tool was designed for adult population in med/surgical and medical ICU and surgical ICU, so perfectly fits.

PCA study

<http://www.ncbi.nlm.nih.gov/pubmed/24943538>

You mentioned interviews and focus groups with nurses in your article. Were you able to do these? I would be interested in the outcomes if you are able to share the information?

Which article did you read?

Most importantly, what is the process to gain permission for the tool and is there a fee associated with its use?

Depending on how much you want us to involve in your study, but if you need us to help to modify the tool or support the study, we may ask you to cover our time. If you just would like to adopt our tool, then we would be fine if you could credit our name or put the reference in your paper so there is any fee for using the tool itself.

Currently we are under the reviewing process of publishing a paper about this study and we can share more details.

Please let me know if you have any further question,

Thank you,

Kumiko

From: Schnock, Kumiko O. [KSCHNOCK@PARTNERS.ORG]
Sent: Monday, November 02, 2015 4:38 PM
To: Dykes, Patricia C.
Cc: Morrow, Suzie
Subject: Re: Web based observational tool for IV medications

Hi Suzie,

I am happy to help you about this. We developed this observation tool as a part of national wide smart pump study founded by AAMI/Carefusion foundation. Actually by using the same tool, researchers in UK, Canada and Finland have replicated our study. The tool was built on Redcap database.

Please let me know if you have any questions or would like to set up a call.

Thank you,
Kumiko

Kumiko O. Schnock, RN, Ph.D.
Division of General Internal Medicine & Primary Care
Brigham and Women's Hospital / Harvard Medical School
Mail: [1620 Tremont Street](#), OBC-3,
[Boston, MA 02120-1613](#)
Tell: [617-525-8898](#) / FAX: [617-732-7072](#)
E-mail: kschnock@partners.org

On Nov 2, 2015, at 7:04 AM, Dykes, Patricia C. <PDYKES@BWH.HARVARD.EDU> wrote:

Hi Suzie,
Congratulations on your research—this is an important area. My colleague Kumiko Schnock led the development of the tool and coordinates use at other sites. I have cc'd her on this message.

Best
Patti

Patricia C. Dykes PhD, RN, FAAN, FACMI
Sr. Nurse Scientist
Program Director, Center for Patient Safety Research and Practice
Program Director, Center for Nursing Excellence
Brigham & Women's Hospital
1620 Tremont Street, 3rd floor
Boston, MA 02120
617-525-3003

From: Morrow, Suzie [<mailto:Martha.Morrow@Mercy.Net>]

Sent: Sunday, November 01, 2015 11:22 PM

To: Dykes, Patricia C.

Subject: Web based observational tool for IV medications

Dr. Dykes,

I am currently pursuing a DNP degree through Case Western Reserve University. For my scholarly project I am investigating nursing practices when administering intermittent IV medications or secondary medications. I am particularly interested in safety and error prevention regarding the intermittent IV infusion via the smart pump and management of residual volume of the intermittent medications. As part of this research I would like to perform an observational study of the process.

I work in a 800 bed acute care hospital in Springfield, MO and we use the Alaris smart pump. We have computerized provider order entry plus bar code medication administration. At this point in time we do not have a closed loop system integrating the smart pump with the BCMA technology.

I have read your article " Development of a Web-based Observational Tool for Detecting IV Medication Errors with Smart Infusion Pumps" and was impressed with your tool development. I have found no other tools in the literature and I would like to utilize your team's tool in my research. Would this be a possibility? Any assistance or advice would be appreciated. Thank you for your time.

Sincerely,

Martha Morrow, MSN, RN, CNE
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Appendix D
**Quality and Safety of Intermittent IV Infusions
 Checklist Tool**

Data number _____
 time _____

Start time _____ End

Observation of Medication and Fluid Variables ME – medication errors, IR – infection risks, RV – residual volume management					V labels
1	IV Medication: (choices for intermittent infusion). If multiple intermittent IV infusions (III) complete a sheet on each one <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Cefazolin 100mg/50ml 2000mg/50 ml Cefipime 1000mg/50 ml 2000mg/50 ml Ceftriaxone 1000mg/50 ml 2000mg/50 ml Cefoxitin 1000mg/50ml 2000mg/50 ml Doxycycline 100 mf/100ml Erythromycin 500mg/100ml 1000mg/100ml Fluconazole 200mg/100ml 400mg/200ml Gentamicin 80mg/50ml 120mg/100ml Imipenem-Cilastin 250mg/50ml 500mg/100ml </div> <div style="width: 45%;"> Levafloxin 250 mg/50ml 500mg/100ml 750mg/150ml Meropenem 500mg/50 ml 100mg/100ml Metronidazole 250mg/50ml 500mg/100ml Piperacillin/tazo 2.25gm/60ml 3.375gm/50ml 3.75gm/65ml Potassium CL 20 mEq/100ml 40mEq/270ml Central line 40mEq/100ml Ciprofloxacin 200mg/100ml 400mg/200ml Vancomycin 1000mg/250ml 1250mg/250ml 1500mg/300ml Other, please list drug and concentration </div> </div>				ME1
2	Is there a drug library for the medication	Yes	No		ME2
3	Patient name on wrist band matches medication label	Yes	No Describe		ME3
4	Medication label present and complete	Yes	No label Incorrect label		ME4
	What is missing from medication label - circle all that apply drug name dose volume expiration date pt's name date time n/a other				
5	Medication expired	Yes	Unknown	No	ME5
6	Primary fluid infusion type	Continuous	Flush Bag	N/A	RV1
7	Patient identification label on primary fluid bag present	Yes	No label	Incorrect patient label	ME6
8	Primary fluid dated correctly	Yes Dated Found in eMAR	No Clearly expired Unable to determine expiration		IR1

9	Patient name label present on primary fluid tubing	Yes	No	N/A	ME26
10	Date label present on primary fluid tubing	Yes No Incorrect	Outdated	N/A	IR5
11	Medication order present -III	Yes	No		ME7
12	Right Drug name - III	Yes	No List discrepancy		ME8
13	Right Dose - III	Yes	No List discrepancy		ME9
14	Right Concentration -III	Yes	No Not listed in eMAR List discrepancy		ME10
15	Right rate – III Only for currently infusing meds	Yes	No	N/A	ME11
16	Allergic to medication	Yes	No		ME12
17	Primary fluid order present	Yes	No	N/A	ME13
18	Primary fluid according to order or policy	Yes	No	N/A	ME14
19	Primary fluid is a high alert medication	Yes	No	N/A	ME15
20	Primary fluid flush bag volume to be infused set according to order or policy Only for currently infusing medications	Yes	No Not currently infusing	N/A	ME16
21	Primary fluid flush bag rate set according to order or policy Only for currently infusing medications	Yes	No Not currently infusing	N/A	ME17
22	Type of administration set use to deliver III	Primary administration set	Secondary administration set		RV2
23	Secondary set tubing connected above the pump	Yes	No	N/A primary tubing used	ME18
24	Patient name label present on secondary tubing?	Yes	No	Incorrect patient label	ME19
25	Date label present on secondary tubing?	Yes	No	Incorrect label (wrong type) Outdated tubing	IR2
26	Smart Pump Used (visible in room with administration set in module, may be infusing or between dosing intervals)	Yes	No		ME20
27	Smart Pump Currently in Use	Yes (running)	No (inbetween dosing intervals)		AM1

28	Drug library in use Only for currently infusing medications	Yes		No		ME21
29	Medications programmed in the correct channel. Only for currently infusing medications	Yes		No		ME 22
30	Clamp is open on secondary administration set when infusing Only for currently infusing medications	Yes		No	N/A Med is primary	ME23
31	The head height differential between the secondary fluid and the primary fluid allows dripping from secondary bag Only for currently infusing medications	Yes		No Describe	N/A No primary fluid	ME24
32	Appropriate end cap is covering the male luer end of the administration set when not in use Only for completed III	N/A	Yes	No – pick option below: Looping Syringe cap used Left open Other: describe		IR3
33	Tubing connected to patient but infusion complete Only for completed III	N/A	Yes	No		ME25
34	Patient attire offers easy access for tubing management through ties, snaps, Velcro,etc? (Only address one time per patient.)	Yes		No Already observed		IR4
35	Secondary Administration Set At completion of the infusion the medication fluid level is? (Observe on completed infusions only. Choose only the highest fluid level option)	Secondary tubing empty Fluid in the secondary administration set tubing Fluid remains in the drip chamber Fluid remains in the bag Inconclusive (back priming may have occurred) N/A				RV3
36	Primary Administration Set At completion of the infusion the medication fluid level is? (Observe on completed infusions only. Choose only the highest fluid level option)	Fluid in the primary tubing below the pump Fluid in the primary tubing above the pump Fluid remains in the drip chamber Fluid remains in the bag N/A				RV4

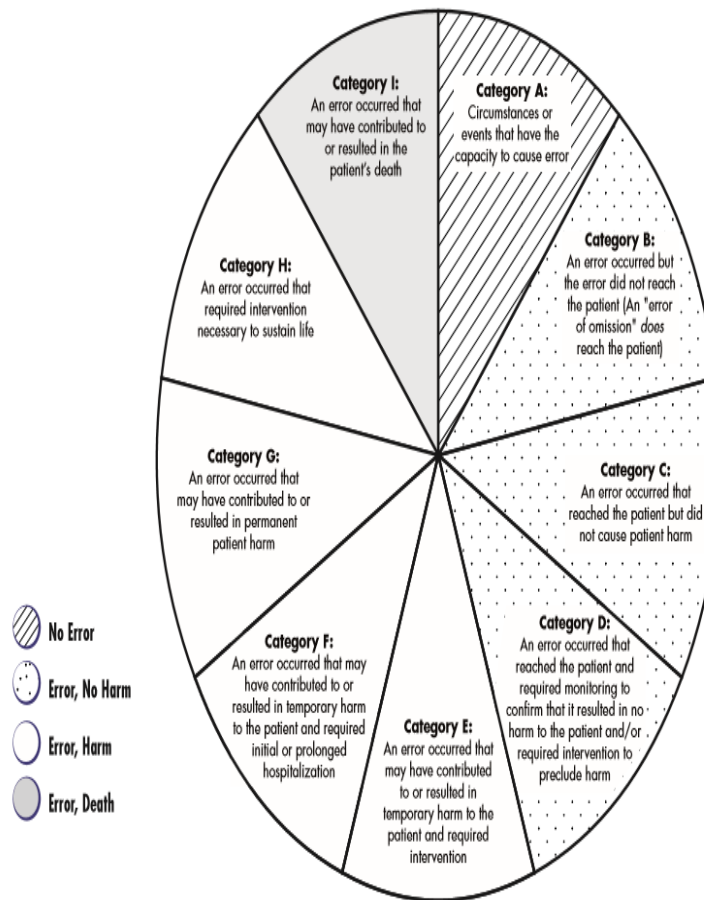
Observation Checklist – adapted from tool developed by national smart pump project team members supported by the Association for the Advancement of Medical Instrumentation and Care Fusion Foundation.

Ohashi, K., Dykes, P., McIntosh, K., Buckley, E., Wien, M., Kreitzman, K., ... Bates, D. W. (2013). Development of a web-based observational tool for detecting intravenous medication errors with smart infusion pumps. *Studies in Health Technology and Informatics*, 192, 1102. <https://doi.org/10.3233/978-1-61499-289-9-1102>

Appendix E

NCC MERP Index

NCC MERP Index for Categorizing Medication Errors



Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention

Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

Appendix F
Letter of Approval from Mercy Research Council




Mercy Hospital
Medical 6B
1235 E. Cherokee
Springfield, MO 65804
unit phone 417-820-2856
fax 417-820-7885
hospital 417-820-2000
mercy.net

To whom it may concern,

Martha Morrow presented her proposed research question and design, in regards to the administration of intermittent IV infusions, to the Research Council of Mercy Hospital Springfield on 2/18/2016. The Research Council supports her pursuit of IRB approval to perform the research regarding intermittent IV infusions.

Sincerely,



Donna Greene, RN
Research Council Chair
Mercy Hospital
1435 S. Cherokee, Springfield, MO 65807
Donna.greene@mercy.net

Appendix G
Case Western Reserve University IRB Approval



NOTICE OF EXEMPTION #2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

CWRU IRB Protocol Number: **IRB-2017-2172**

Protocol Title: ***Quality and Safety of Intermittent Intravenous Infusions***

Responsible Investigator (RI): **Irena Kenneley**

Co-Investigator (CI): **Martha Morrow, DNP (Nursing)**

RI Department: **Case Western Reserve University IBC and SBER IRB -**
NUR - Nursing General

Exemption Date: **12/19/2017**

The CWRU Institutional Review Board (IRB) has deemed the above protocol EXEMPT under 45 Code of Federal Regulations (CFR) part 46.101(b)(2). The IRB will not conduct subsequent reviews of this protocol.

IF YOU WISH TO CHANGE THIS EXEMPTED PROTOCOL IN ANY WAY, YOU MUST SUBMIT AN ADDENDUM REQUEST AND WAIT FOR IRB APPROVAL PRIOR TO IMPLEMENTING ANY PROTOCOL CHANGE.

Any changes to the protocol that put it under the purview of the IRB would require a formal application to, and approval of, the IRB prior to implementation of the change.

Appendix H
Mercy IRB Approval



**ERCY
INSTITUTIONAL
REVIEW
BOARD**

524 N. Boonville
Springfield, MO 65806
phone 417-520-4647
mercy.net

DATE: May 30, 2017

TO: Martha Morrow, MSN, RN, CNE

FROM: Mercy Institutional Review Board

Project Title: [929636-2] Protocol 16-18, "Quality and Safety of Intermittent Intravenous Infusions" Previously named "intermittent Intravenous Infusions: Prevalent Practices"

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPTION

DECISION DATE: May 30, 2017

Thank you for your submission of New Project materials for this project. The Mercy Institutional Review Board has determined this project does not meet the requirement for IRB oversight under the purview of the IRB according to federal regulations.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact Sandy Whittaker at 417-520-4647 or sandra.whittaker@mercy.net. Please include your project title and reference number in all correspondence with this committee.