A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a neonatal intensive care unit in upcoming maternal & new-born electronic health record

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MSc. in Health Informatics 2017

DECLARATION

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

Signed: _____

Anu Garg

July 6, 2017

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ABSTRACT

Introduction

Medication errors more frequently occur in a neonatal intensive care setting, and most of these errors occur during the administration phase of medication use process (MUP) (Krzyzaniak and Bajorek, 2016). Administration errors during continuous intravenous infusions especially high-risk infusions can be detrimental to already sick individual in the critical care unit (Alanazi *et al.*, 2016). Several health information technologies (HIT) are emerging to intercept these errors. However, implementation of these technologies brings changes in clinical workflow due to lack of integration with existing systems that eventually increase the clinicians' workload and lead to unintended consequences. The national system -Maternal and newborn electronic health record (EHR) will be implemented in the study unit in the last quarter of 2017. This dissertation aimed at appraising the clinical workflow at the administration phase of high-risk infusions in upcoming maternal and newborn EHR in a simulated environment.

Study design and methods

Clinical simulation method was utilised to identify the type of potential errors and the severity to cause potential harm, that could arise due to change in the clinical workflow in upcoming maternal and new-born EHR. Thirty-one simulation sessions were conducted in March- April 2017. The nurses working in the NICU, Rotunda Hospital, participated in the study. Participants were asked to retrieve the information from the computer screen, cross-checked against medication protocol, prepare syringe labels and program the pump. Data was collected using mixed method approach. Quantitative data was gathered on set forms to identify errors at the administration phase. Qualitative data was collected in the form of a post-simulation survey to explore the perceptions of the participants about the administration process. The researcher observed the simulation session to gain the insight of administration process.

Results

Out of 155 prescription orders, thirty-one prescription orders had either programming error (n=11, 7%) or wrong labelling parameters (n=12, 7.7%) or both programming error and wrong labelling parameter (n=8, 5.2%). All the syringe labels had one or more missed labelling parameters. 89% of all the programming errors belongs category 'C' and category 'D' on NCC-MERP index of medication errors. More than half (52.6%, n=10, N=19) of the infusion orders with programming errors led to more than ±10% deviation from the prescribed dose, and 77%(n=7, N=10) of these deviations were due to programming wrong concentration. Further, logistic regression analysis showed that increase in labelling errors increases the likelihood of programming errors.

Conclusion

Taken together, these results suggested that the changes (need of computation of concertation and preparing syringe labels) in the workflow at the administration phase of high-risk infusions in future EHR primed to serious errors that can be detrimental in the real clinical setting. This study strongly suggested to include concertation in the prescription order, and either has printed syringe labels or standard labelling template to enhance patient safety. Further research is required to evaluate the clinical workflow in a real clinical setting using the actual system.

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ABBREVIATIONS

ABA	An Bord Altranais
ACSQHSC	Australian Commission on Safety and Quality in Health Care
RANP	Registered Advanced Nurse Practitioner
CDSS	Clinical Decision Support System
CPOE	Computerised Patient Order Entry
DERS	Drug Error Reduction Software
GEP-HI	Good Evaluation Practice in Health Informatics
HITs	Health Information Technology
IOM	Institute of Medicine
IV infusion	Intravenous infusion
ISMP	Institute for Safe Medication Practices
MN-CMS	Maternal and Newborn Clinical Management System
MUP	Medication use process
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
Pdf	Portable document format
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SIP	Smart infusion pump

GLOSSARY

Automated dispensing cabinet: It is an automated cabinet made up of a touch screen monitor and keyboard, with various other secure storage spaces connected to it (i.e. refrigerator).

Barcode Medication Administration (BCMA): BCMA is an inventory control system that uses barcodes to prevent human error at the administration phase by ensuring that "five rights" are confirmed- right patient, right medication, right dose, right time, and right route of administration.

Clinical workflow: Clinical workflow is a directed series of steps comprising a clinical process that 1) are performed by people or equipment/computers and 2) consume, transform, and produce information where patient outcomes count as information.

Cognitive walkthrough: The cognitive walkthrough is a usability evaluation method in which one or more evaluators work through a series of tasks and ask a set of questions from the perspective of the user (Wharton *et al.*, 1994)

Computerised patient order entry (CPOE): A system in which prescriber places the order electronically, with the orders transmitted directly to the recipient. A CPOE with clinical decision support system (CDSS) prevents the errors at the prescribing stage, dispensing stage and transcribing stage by ensuring standardised, legible and complete orders.

Environment fidelity; Environment fidelity concerns the extent to which physical characteristics of the real-world environment (beyond the training equipment) are realistically represented in the simulation (Dahl *et al.*, 2010)

Equipment fidelity: Equipment fidelity refers to the extent to which the appearance and feel of real tools, devices, or systems (hardware and soft-ware) is replicated for simulation participants to operate on (Dahl *et al.*, 2010)

Error of Commission: An error which occurs as a result of an action taken (National Steering Committee on Patient Safety (Canada), 2002).

Error of omission: An error which occurs as a result of an action not taken (National Steering Committee on Patient Safety (Canada), 2002).

Functional Fidelity: Functional Fidelity describes the degree to which the simulation reacts like "the real thing," that is, that it provides realistic responses to the tasks and actions executed by the participant (Dahl *et al.*, 2010).

Hawthorne effect: Hawthorne effect is defined as the effect where people in studies change their behaviour because they are watched (Andale, 2016).

High-risk infusions: High-risk infusions are drugs that bear a heightened risk of causing significant patient harm when used in error and may lead to devastating complications for patients (ISMP)

Human Factors: Study of the interrelationships between humans, the tools they use, and the environment in which they live and work

Labelling error: Labelling error is defined as incomplete or inaccurate information in the syringe labels

Medical Error: an act of omission or commission in planning or execution that contributes or could contribute to an unintended result (Grober and Bohnen, 2005).

Medication Errors: 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 health care professional, patient, or consumer (NCC-MERP, 2017).

Smart Infusion Pump (SIP) / Drug error reduction system (DERS): An infusion pump equipped with IV medication error-prevention software that alerts operators when a pump setting is programmed outside of pre-configured limits.

Task fidelity: Task fidelity describes the degree to which tasks involved in the actual environment for a given domain are replicated in the simulation (Dahl *et al.*, 2010).

CHAPTER 1 INTRODUCTION

> *"There is no direct way to reduce errors or harm. Instead, errors are reduced when the conditions of work (i.e., the work system) positively shape the way that healthcare professionals (HCPs) perform cognitive work; harm is reduced when the conditions of work allow HCPs to perform well under challenging or disruptive conditions."* (Karsh *et al.*, 2006)

In late 1999 "To Err is Human: Building a Safer Health System" the landmark report by the Institute of Medicine (IOM) spurred the awareness in the health industry about medical errors and the urgent need to develop more reliable health system (Kohn *et al.*, 2000). However, even after several years since the publication of the report, the 2nd report by IOM "*Crossing the Quality Chasm*" stated that the expected improvements had not been achieved yet (Chuo and Hicks, 2008). Medication errors account for half of medical errors, and the majority of them are preventable (Agency for Healthcare Research and quality, 2015). Fortunately, most of them either do not reach patients or cause actual harm (Aspden *et al.*, 2007, p.38). According to a recent report by FDA, (2016), medication error leads to at least one death every day in the United States. Amongst all health care facilities, the incidence of medication errors is highest in neonatal intensive care units (NICU) (Krzyzaniak and Bajorek, 2016). Nearly half of medication errors in NICU occur during the administration phase of medication use process (Krzyzaniak and Bajorek, 2016; Stavroudis *et al.*, 2010).

During the last few decades, health information technology (HIT) has managed to curtail medical errors and to enhance patient safety (Ammenwerth and Rigby (eds.), 2016, p.196). Adoption of electronic health records (EHR) is gaining momentum worldwide with the aim to minimise medical errors, augment workflow efficiency and guarantee patient safety (Mack *et al.*, 2016). However, design and implementation of any health information system (HIS) play a critical role in the success. Poor design and inappropriately implemented systems can increase the difficulty of already complex health care settings, and that can result in unintended adverse consequences

further damaging patient safety (Harrison *et al.*, 2007). Furthermore, organisations must keep in mind that HIT is a technical system of computer and software that operates in a complex sociotechnical system that includes a collection of various IT systems already in operation within an organisation and consists of people that operate the system and work processes (Borycki and Kushniruk, 2010). Nevertheless, it is imperative to prospectively evaluate these technologies in a simulative environment to detect potential unintended errors so that health care organisation can anticipate and if possible, correct before going live (Sittig and Singh, 2010).

The Irish health system is in the process of implementing a maternal New-born-electronic health record (EHR) in nineteen Irish maternity hospitals known as the MN-CMS (Maternal and New-born clinical management system). As the researcher is a neonatal nurse and has an interest in medication safety in a neonatal unit, this study was proposed to evaluate the clinical workflow for administering high-risk infusions in a neonatal intensive care unit (NICU) in the new maternal and new-born EHR. The following section will describe medication use process (MUP), its complexity in the context of the neonatal intensive care environment and the changes in the clinical workflow in upcoming maternal and new-born EHR.

1.1 MEDICATION USE PROCESS AND ITS COMPLEXITY

Medication use process (MUP) is a complex and multifaceted process and encompasses several phases and involvement of numerous people at different stages (see Figure 1.1.a). It is a cyclic process which starts with the evaluation of the patient's medical history and clinical condition and ends with monitoring the effects and side effects of administered medications and re-evaluation. Every step of the MUP is error prone as it involves several users (patient, doctors, nurses and pharmacists), equipment (smart infusion pumps, computer, syringes and barcode scanner) and systems (e-prescription, computer patient order entry (CPOE)) (Karavasiliadou and Athanasakis, 2014).

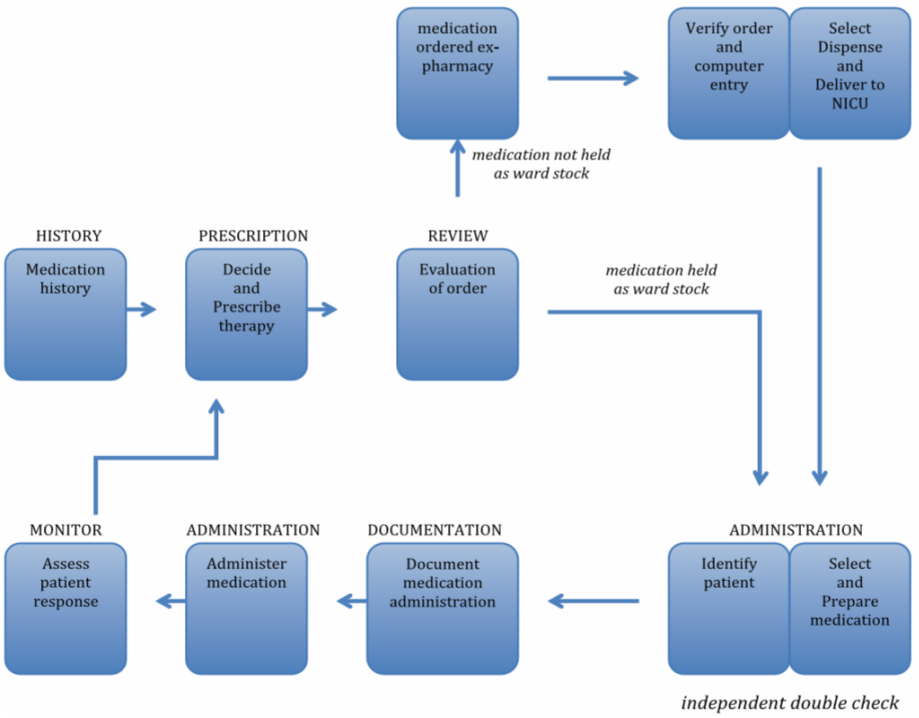

Figure 1.1.a Medication use process

The next section explains the different phases of MUP and various HITs utilised to ameliorate potential errors at each phase.

1.1.1 Prescribing phase

In the prescribing phase, the prescriber writes the medication order after evaluating patients' medical history and clinical condition using his or her expertise. Evidence from published research demonstrated that the majority of errors occur at this stage of the MUP and if not detected resulted in death (Bates and Slight, 2014). Furthermore, this applies in ICU environments where the changes are often made at the patient's bedside. Infants in NICU and a paediatric setting are among the sickest and most complex patient populations, receiving large numbers of potentially dangerous and untested medications(Krzyzaniak and Bajorek, 2016).

Prescribing errors consists of wrong drug, wrong dose, wrong units, wrong route of administration, error relating to the frequency of administration and missing patient information (Krzyzaniak and Bajorek, 2016). CPOE, e-prescribing with or without clinical decision support systems (CDS) has been exploited to address these errors (Santesteban *et al.*, 2015). Nevertheless, unintended errors have been reported while prescribing using these technologies due to the poor human- machine interface, for instance, the prescriber chose the wrong drug, wrong route of administration or wrong concentration from the drop down menu (Cheung *et al.*, 2014). Thus, it is mandatory to have regular audits, teaching and evaluation of these HIT.

1.1.2 Dispensing Phase

Drug dispensing involves the preparation, packaging, labelling, record-keeping and transfer of a prescription drug to a patient or an intermediary who is responsible for the administration of the drug. It should be done by the pharmacist and should only be taken by the nurse/midwife in exceptional circumstances after reviewing the order against set medication guidelines (An Bord Altranais (ABA), 2007). For infusion therapy, the dispenser prepares or uses readymade solutions per the prescribed order. However, there is potential for a transcribing error to occur especially with hand- written prescriptions. Electronic prescription systems and CPOE have been utilised to reduce the risk of illegible or missing information (Santesteban *et al.*, 2015). Nurses usually prepare medication infusions in emergency or intensive care units after reviewing the order. Some prescription errors are identified in the reviewing process during the dispensing phase. Automatic dispensing technology has been utilised to lessen the errors at this stage (Dib *et al.*, 2006). In the study unit, the nurses prepare the prescribed medication.

1.1.3 Administration phase

Adminnnistttration phase is the last phase where medication error can be intercepted before reaching the patient. Nurses usually administer the prescribed medicine and to ensure medication safety at the administration phase of MUP. Nurses adhere to six rights of medication administration: Right patient, Right Drug, Right dose, Right time, Right route of administration

and Right documentation. Continuous intravenous (IV) infusion constitutes the delivery of medicine within a large drug volume at a constant rate over a prescribed period. Syringe drivers should be used to ensure the safe delivery at the prescribed rate (Health Service Executive, 2013, p.14). Programming the pump is critical to safe and accurate medication delivery, and wrong programming can lead to fatal medication errors. As a result, Flynn and colleagues (2003) proposed right programming should be considered as a seventh right of medication administration. Nevertheless, inaccurate and incomplete labelling is also a recognised risk for safe administration of medication (Strbova *et al.*, 2015). In some health care organisations, pharmacy applies a barcode to the medication after preparation and then dispenses it to the unit. The nurse then scans the barcode and checks patient identification and prescription order and then administers medication. However, in the study unit, the nurse prepares all intravenous infusions and labels the syringes. To address medication safety issues in the study unit, smart infusion pump (SIP) technology with drug error reduction software (DERS), a drug library and e-prescription software linked to a label printer for six high-risk infusions was initiated in 2016 as a pilot project. The results of the pilot project demonstrated the significant reduction of medication errors at the administrative phase.

1.1.4 Documentation and Monitoring phase

In this phase, nurses document the administered drug, time of administration and any side effect of the drug in the patient record. Nurses should monitor the patient's reaction to the drug, advise the prescriber of the need to adjust the dose based on clinical condition and response particularly in an ICU setting and simultaneously document all the changes in the patients' medical record.

1.2 COMPLEXITY OF NICU ENVIRONMENT AND VULNERABLE NEONATAL POPULATION

Medication errors occur more frequently in certain areas like intensive care units and emergencies which may be due to high use of multiple drugs. Figure 1.2.a describes a typical dynamic NICU environment where several things happen at the same time such as new admissions, ward rounds, changing care plans, airway management activities and several medical personnel are involved. Moreover, certain populations like neonates and paediatrics are more vulnerable to medication errors as the drug doses depend on their daily weight and age which necessitates additional attention and expertise from the prescribers (Krzyzaniak and Bajorek, 2016).

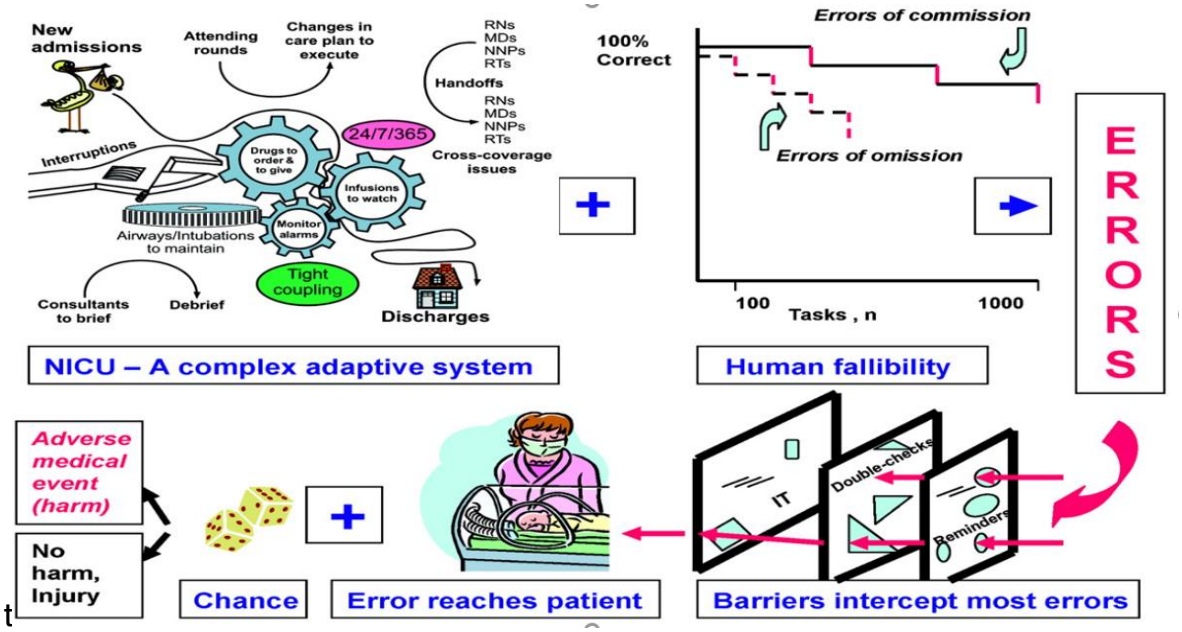

Figure 1.2.a Depicts the complexity of NICU environment and chances of errors

Furthermore, lack of evidence of the effect of drugs in a neonatal population and their inability to metabolise certain drugs due to the immaturity of the liver and kidney makes it an arduous task for the prescribers (Kieran *et al.*, 2014; Laforgia *et al.*, 2014). Santesteban *et al.*, (2015) point out that intra-venous infusions are riskier than other forms of medication administration. Due to this complex environment, errors of commission and omission are

more prevalent in NICU (Krzyzaniak and Bajorek, 2016). However, reminders, double-checking and IT system are being put in place to intercept these errors before they reach the patient (Keers *et al.*, 2014; Ohashi *et al.*, 2013; Krzyzaniak and Bajorek, 2016).

1.3 EXPECTED CHANGES IN CLINICAL WORKFLOW

Successful implementation of an EHR relies on the integration of the system into the current clinical workflow. Poor integration with existing systems can lead to unintended consequences which in turn can be catastrophic to patient safety (Harrison et al., 2007). In September 2017, a national Maternal and New-born EHR is to be implemented in the study site which aims at increasing patient safety by automating several clinical processes and providing easy access to patient information on demand. However, the current prescription and syringe label printer will not be integrated into the future EHR. Consequently, the three-step administration process in the current workflow will become five step process in the MN-CMS (see Table 1.3.A). Key changes that will be required are as follows:

Retrieval of information from the system:

In the new EHR, the nurses will access the prescription from the computer screen and will check it against the built-in protocols. Whereas in the existing process the nurse has the prescription information written on a drug chart.

Calculation of concentration of the infusion:

Currently, the concentration of prescribed infusion is stated on the prescription, but in the new EHR, the nurse must compute the prescribed concertation.

Preparing the syringe labels:

The label printer is currently integrated with an electronic prescribing system and the prescriber prints the syringe labels and prescription at the same time. As the label printer will not be integrated in the new EHR, the nurse will be preparing handwritten syringe labels.

Table 1.3.A Comparison of clinical workflow at the administration phase of high-risk infusion in current system and Maternal and new-born EHR

Current clinical workflow	Clinical workflow in Maternal and new-born EHR
Step1: Crosscheck the information on the printed prescription labels with the medication protocol. Step 2: Prepare the infusion and apply the printed syringe label Step 3: Program the infusion pump as per prescription	Step 1: Retrieve the information from the system Step 2: Crosscheck with the medication protocol and calculate the prescribed concentration. Step 3: Prepare the syringe labels Step 4: Prepare the infusion and apply the syringe label Step 5: Program the infusion pump as per prescription

1.4 RESEARCH QUESTION

The research question is

> "Will the introduction of the new clinical workflow contain in the MN-CMS impact on medication safety during the administration phase of high-risk infusion in NICU?"

1.4.1 Objectives of the study

To prospectively evaluate the clinical workflow and patient safety issues related to administration of high-risk infusions in a NICU using a clinical simulation technique in maternal and new-born EHR.

Measurable outcomes:

1. Type of potential errors in the drug administration process in the system.

2. Error rate per 100 infusions at the drug administration process in maternal and new-born EHR.

3. The severity of errors in terms of potential to cause harm.

1.5 OVERVIEW OF RESEARCH

Patient safety organisations (AHRQ, 2016) recommended the evaluation of HITs in a simulated environment before their deployment in a real clinical environment. Therefore, the research question was addressed through a mixed method approach to appraise the clinical workflow and identify patient safety issues at the administrative phase of high-risk infusions in the Maternal and New-born EHR in the simulated environment. As it was a simulation study, the evaluation of whole administration process of MUP for high-risk infusions was outside the scope of this study. For this reason, the researcher only examined some steps of the administration phase; retrieving information from the system, cross-checking against the medication protocol, preparing syringe labels and programming the infusion pump.

This research was used to identify the potential type, number and severity of medication errors at the administrative phase of high-risk infusions in maternal and new-born EHR due to change of clinical workflow. Eventually, it will help the organisation to plan any necessary measures to ensure patient safety when the Maternal and New-born EHR goes live in September 2017.

The first stage of the research involved the review of current literature related to HITs utilised to prevent medication errors in neonatal and/or paediatric populations and their impact on patient safety. The literature review also aided in identifying the reasons behind the failure of HITs.

The second stage involved preparation and conduction of simulation sessions to identify potential medication errors at the administrative phase of high-risk infusions in the Maternal and new-born EHR and their severity in term of potential to cause harm. The survey was conducted to explore the perceptions of end-users regarding the change in the workflow in the MUP associated with the new EHR.

Following the simulation session data was analysed. The findings of the study are presented in Chapter 4, page no 442. Conclusions were drawn culminating in suggestions for the organisation to consider before the EHR is implemented in September 2017 to improve patient safety.

1.6 OVERVIEW OF DISSERTATION

Chapter 1 presented the dissertation topic, the motivation behind the research, research questions and introduced the research undertaken.

Chapter 2 details the findings of the literature review. The review presents the use of HITs to reduce medication errors, the benefits and risk of the interventions, reasons behind the failure of interventions and suggestions for successful implementation of HITs.

Chapter 3 describes the study design and research methodologies. This chapter explains the research question, aims and objectives and research approach utilised to answer the question. The discussion includes a description of the study duration and setting, sampling method and ethical considerations.

Chapter 4 presents the results of the study. The type of errors and the severity of potential errors that were identified are presented. Additionally, key findings of the post-simulation survey were summarised.

Chapter 5 evaluates and analyse the results of the study. The results of the study are discussed to answer the research questions and to reflect on the literature review.

In chapter 6, the study results are reflected upon, strengths and limitations of the study are discussed, and areas for future research are identified.

CHAPTER 2 LITERATURE REVIEW

This chapter presents a review of current, published scientific evidence of the impact of health information technology on medication errors in neonatal and paediatric patients and the methodology used to extract the literature.

2.1 AIM OF THE LITERATURE REVIEW:

The search was conducted to identify studies that showed the impact of various interventions especially health information technology on the medication errors in paediatric/neonatal populations.

2.2 METHODS

2.2.1 Search Strategy

A systematic search was conducted using several scientific databases namely. Scopus, Science Direct, PubMed and CINHAL complete. The keywords “smart infusion pumps”, “electronic patient records”, “medication errors”, “electronic health record” and “interventions used to reduce medication errors” were used to identify relevant literature published in the English language between 2010-2017. Using current time frame assured the retrieval of up-to-date information regarding the selected topic.

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram was utilised to systematically select papers for inclusion (Liberati *et al.* 2009). Figure 2.2.a on the next page presents the methodological approach adopted to extract the literature. Out of retrieved (n=272) articles, only 23 articles were included for final review.

2.2.2 Selection criterion

The following criteria were used to extract the relevant literature.

Study Type:

Empirical studies describing quantitative, qualitative and mixed-method studies were included for the examination. Other papers such as editorials conference proceedings, reviews, case studies and opinions were excluded

from the final review. Peer reviewed articles written in English language articles were considered.

Scope

Studies describing interventions used for reducing medical errors in the paediatric population and neonatal units in the hospital settings were included. Further, the studies describing both adult and paediatric or neonatal population were also included for the review. However, the studies in an ambulatory setting or adult only were excluded. The majority of research studies originated either from the USA or Europe. Very few studies were identified from Asia or Australia. One possible explanation for this may be US government initiative of promoting HITs to enhancing patient safety.

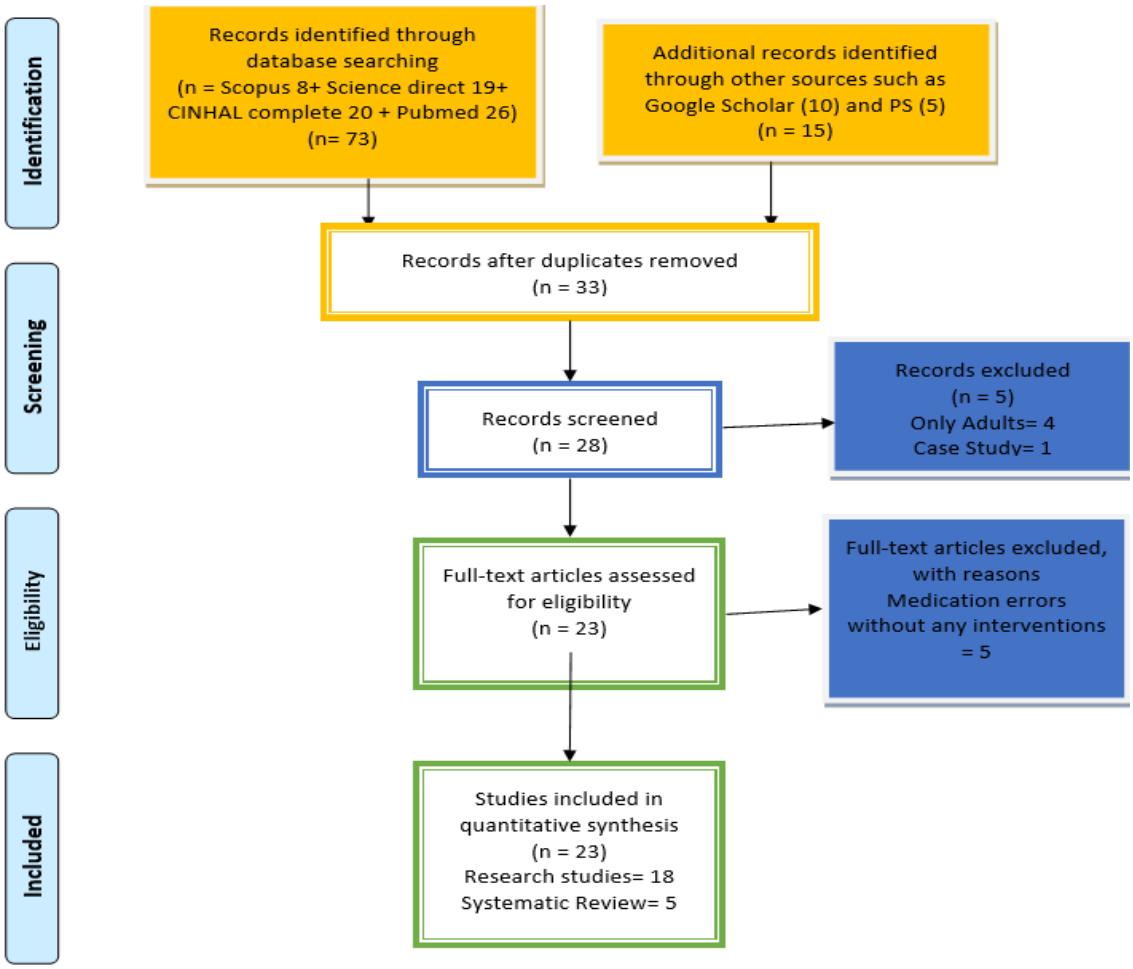

Figure 2.2.a Methodology approach to extract the literature

Data Extraction

Data were extracted using Microsoft Excel spreadsheet as a data collection form. A similar form was employed by Berdot *et al.*, (2016). The data collection form included the characteristics of the study (author name, publication year, type of study, origin of study, methodology used), type of interventions used (type of HIT used, educational and training), study area (paediatric unit, neonatal unit), outcome (type of errors, severity of errors and percentage of errors) and source of measurement outcome (pump logging data, voluntary reporting system, electronic reporting system and audits). No study author was contacted for additional data.

Data Analysis:

Given the heterogeneity in the methodology used as well as the use of different measuring outcome techniques, the researcher did not perform a meta-analysis. All the findings were analysed and assessed discretely.

Limitation of literature:

Heterogeneity amongst the identified literature decreases the generalizability of the results due to the utilisation of different definitions for errors as well as reporting of near-miss errors. There is a paucity of published studies that were conducted in a NICU setting.

2.3 OVERVIEW OF RESULTS

2.3.1 Study Characteristics

Study Design:

Eighteen out of twenty-three retrieved studies were research studies others were systematic studies. Nearly half of the studies used pre and post-intervention effect on medication errors. Only two were comparative studies in which one study compares the prescribing system in two different health information systems (Westbrook *et al.*, 2011) and second one compares the error rate due to the use of the system by two separate set of users (paediatric nurses and emergency nurses) (Yamamoto and Kanemori, 2010). Only two included studies were randomised control trials (RCTs) (Trbovich *et al.*, 2010; Yamamoto and Kanemori, 2010).

In eight of the studies data was collected retrospectively (Pawluk *et al.*, 2016; Stultz and Nahata, 2015; Guérin *et al.*, 2015; Cheung *et al.*, 2014; Westbrook *et al.*, 2013; Hennings *et al.*, 2010; Stavroudis *et al.*, 2010; Samaranayake *et al.*, 2012) and only seven studies took the prospective approach of data collection (Manrique-Rodríguez *et al.*, 2016, 2014c; Campino *et al.*, 2016; Russell *et al.*, 2010, 2015; Pang *et al.*, 2011; Chedoe *et al.*, 2012) . Three of eighteen studies were conducted in the simulative environment (Sowan *et al.*, 2010; Yamamoto and Kanemori, 2010; Trbovich *et al.*, 2010), and all the other included studies have been carried out in the real clinical environment.

The data collection techniques varied among the studies with direct observation the most commonly adopted approach (n=8) (Manrique-Rodríguez *et al.*, 2016; Campino *et al.*, 2016; Russell *et al.*, 2010; Bergon-Sendin *et al.*, 2015; Manrique-Rodriguez *et al.*, 2013; Russell *et al.*, 2015; Pang *et al.*, 2011; Chedoe *et al.*, 2012). Direct observation is considered the most appropriate method to identify medication administration errors, as it identifies the largest number and full range of errors compared with chart review and self-reporting. However, observational studies are susceptible to a potentially high risk of bias due to Hawthorne effect (Andale, 2016). Eight studies utilised incident reporting data mostly included voluntary reporting in nature which includes both electronic and paper-based reporting techniques (Pawluk *et al.*, 2016; Stultz and Nahata, 2015; Santesteban *et al.*, 2015; Li *et al.*, 2015; Guérin *et al.*, 2015; Cheung *et al.*, 2014; Stavroudis *et al.*, 2010; Samaranayake *et al.*, 2012). One study collected the data using an incidence reporting system integrated with the electronic medical record (Li *et al.*, 2015). Other methods used were pump logging data (n=3) (Manrique-Rodríguez *et al.*, 2014c; Hennings *et al.*, 2010; Cousins *et al.*, 2013).

2.3.2 Setting and demographic:

The majority of the research studies (n=16) were carried out in a single centre. Only one study was conducted at various institutions (Cheung *et al.*, 2014), and one study was conducted across two institutions (Westbrook *et al.*, 2013). Of the included studies, only five were focused solely on the neonatal intensive care unit (NICU) (Campino *et al.*, 2016; Santesteban *et*

al., 2015; Guérin *et al.*, 2015; Bergon-Sendin *et al.*, 2015; Chedoe *et al.*, 2012), and six studies focused only on the paediatric intensive care unit (PICU) (Manrique-Rodríguez *et al.*, 2016; Stultz and Nahata, 2015; Russell *et al.*, 2010; Manrique-Rodríguez *et al.*, 2014c, 2014a; Russell *et al.*, 2015). Two studies included both PICU as well as adult unit (Hennings *et al.*, 2010; Yamamoto and Kanemori, 2010), and only one study included both PICU and NICU (Maaskant *et al.*, 2015a). In one study, research was carried out in several settings including the PICU, NICU, Adult ICU and general wards (Cheung *et al.*, 2014).

2.3.3 Types of interventions used

Types of interventions studied to see the impact on medication errors were Smart Infusion Pump (SIP) technology with inbuilt drug library, CPOE, Bar-coding, automatic dispensing and training and education. The majority of the studies (n=17) investigated the SIP technology with or without other intervention. Twelve studies investigated the impact of CPOE on medication errors. Most of the studies mentioned the impact of two or more interventions. However, only two studies investigated the impact of integration of two or more health technology with EMR on the medication errors (Li *et al.*, 2015; Russell *et al.*, 2010)

2.3.4 Impact of interventions

Error rate

Fifteen out of twenty-three studies showed the positive impact of interventions on the error rate. However, some studies showed mixed results of interventions (Russell *et al.*, 2010; Maaskant *et al.*, 2015a; Ohashi *et al.*, 2014). On the other hand, a couple of studies found no significant impact of interventions on the error rate (Guérin *et al.*, 2015; Sowan *et al.*, 2010). Several studies (n=7) reported the reduction of programming errors and human errors, which are most common error when infusion pumps are used (Manrique-Rodríguez *et al.*, 2016; Russell *et al.*, 2010; Bergon-Sendin *et al.*, 2015; Keers *et al.*, 2014; Hennings *et al.*, 2010; Russell *et al.*, 2015; Trbovich *et al.*, 2010). Nonetheless, only two studies examined the discrepancies between programmed dose and prescribed dose (Russell *et al.*, 2010, 2015)

and revealed that there is a reduction in programming error, but it was not statistically significant. Hence, standalone SIP technology can reduce the risk of programming out of safe range, but there is still a probability of discrepancies between programming dose and prescribed dose with the use of SIP.

Error type

Nearly one-half of errors occur at either prescribing stage, or administration phase of medication process (Santesteban *et al.*, 2015; Stultz and Nahata, 2015; Cheung *et al.*, 2014) and One-half of those errors were related to IT system (Stultz and Nahata, 2015). On the contrary, (Stultz and Nahata, 2015) reported only 1.6% of total errors were related to IT system. The most common cause of medication error was the weak interface between the system and human (Santesteban *et al.*, 2015).

Error severity

Researchers used different methods to measure the severity of errors. Thus, it was difficult to analyse the result.

2.4 DISCUSSION OF FINDINGS

2.4.1 Benefits of interventions used to reduce the medication errors

Several interventions have been investigated in the literature to intercept the medication errors at different stages of medication process. HITs such as CPOE, e-prescription, SIP and BMCA have been utilised more often than automatic dispensing that might be due to the high incidence of errors at prescription and administrative stage of a medication process (Maaskant *et al.*, 2015b; Santesteban *et al.*, 2015). The majority of institutions introduced two or more interventions at the same time for instance CPOE and SIP or SIP, CPOE and BMCA (Santesteban *et al.*, 2015), SIP, CPOE, BMCA and automatic dispensing (Manrique-Rodríguez *et al.*, 2016; Samaranayake *et al.*, 2012; Cheung *et al.*, 2014).

CPOE aided in intercepting prescription errors related to illegible writing or incomplete information and calculation errors (Sowan *et al.*, 2010; Yamamoto and Kanemori, 2010). Furthermore, it would intercept more errors if it is interfaced with EHR and Clinical decision support system that directs all the relevant information related to patient and drug to the system (Santesteban *et al.*, 2015).

Smart infusion pumps have been widely used in intercepting dosing, wrong rate and programming errors at the administrative stage that leads to a diminution of adverse drug event rates (Manrique-Rodríguez *et al.*, 2014b). However, SIP technology reduced the error by applying soft and hard limits to abet the errors but did not eliminate the error (Ohashi *et al.*, 2014 Santesteban *et al.*, 2015). Guérin *et al.*, (2015) examined the administration error rate pre and post implementation of SIP technology and used adverse event reporting system to identify the error rate. They did not find any reduction of administration errors rate by SIP technology in a maternity hospital. However, the main weakness in their study was the use of adverse incident reporting data for determining the error rate which is under-reported most of the times due to voluntary in nature (AHRQ, 2014).

2.4.2 Negative impact of interventions used on medication errors

Discrepancy Between programmed dose and prescribed dose

Smart infusion pump can only alarm the user about the changes programmed outside the limits, but errors in entering the weight, drug concentration and dose within the range is outside the scope of SIP detection. Thus, such errors could be easily missed when the error rate is measured using pump log data without integrated patient data (Sowan *et al.*, 2010). Russell *et al.*, (2015) investigated the difference between the prescribed dose on CPOE and programmed pump using observation and detected 42.4% inaccuracies in the observed Iv fluid administration. However, the study failed to detect the origin of the error. Trbovich *et al.*, (2010) conducted a simulation study to compare if a nurse can detect a planted administration error using traditional pump vs. smart infusion pump vs. smart infusion pump integrated

with barcode technology. They revealed no difference in error detection rate between traditional pump and SIP. Interestingly, they noticed more errors recovery when SIP technology was integrated with barcode technology which confirms that integration of SIP, CPOE with BCMA is needed to increase medication safety (Trbovich *et al.*, 2010). Hennings *et al.*, (2010) evaluated the use of SIP technology in adult intensive care and paediatric intensive care and revealed that there were 1.68 times more likely to intercept programming errors in paediatric populations than in adult populations. The authors of this study suggest that the most likely explanation for these findings is the use of weight and age-based doses in paediatric populations (Hennings *et al.*, 2010).

Inability to intercept errors:

Retrospective analysis of medication errors reported by voluntary reporting and reporting using rule triggering revealed that despite extensive use of HIT to intercept medication errors, medication errors were still prevalent particularly at prescribing phase (27-49.3%) and at the administration phase (53-64%) that reach patients (Stultz and Nahata, 2015). Likewise, Santesteban *et al.*, (2015) reported that half of medication errors occur during the administration phase. Another study by Cheung *et al.*, (2014) reported more prescribing errors reach the patient, and the prescribing errors were more severe than errors at the administration. However, the majority of those errors did not cause any harm to the patient. Furthermore, Russell *et al.*, (2015) found highest errors rate with the intravenous fluid administration in comparison to other forms of medication administration. Thus, it is imperative to appraise these technologies, especially when used for high-risk infusions.

Change of workflow

Implementation of any HIS brings change in clinical workflow. Russell *et al.*, (2015) analysed the impact of an interface between CPOE and Pharmacy system on the order and infusion pump discrepancies and revealed that there were more omitted discrepancies on the CPOE which was unexpected. Following the review, they uncovered that practice had been influenced as a result of delays of prescribed medications from the pharmacy. In an

attempt to circumvent this, clinicians started to prescribe in advance i.e. the day before surgery. However, it was not always needed and was then recorded as omitted and thus an error in the system. Likewise, Westbrook *et al.*, (2013) also reported an increase of prescribing error rate due to change of workflow at the prescribing phase and some of these errors were severe enough to endanger patient safety. The evidence from these studies suggests that it is essential to evaluate the clinical workflow before implementation of any IT system.

2.4.3 Reasons behind failure of interventions

In the preceding section, the limited benefits of standalone SIP technology in intercepting administration errors was described. This section presents the available literature that described the rationale behind the failure of SIP technology to mitigate administration error rates.

Lack of integration

DERS and SIPs technology have reduced the error rate by preventing programming of dose outside set safety limits (Keers *et al.*, 2014; Ohashi *et al.*, 2014). However, the SIP technology alone cannot prevent the manual programming errors. For example, if there is no integration between CPOE/ EMR and SIP, the infusion pump will not have any information about the prescription order. If nurse programs the wrong drug or wrong concentration or wrong dose but within safety limits, the infusion pump will infuse whatever is set which can be fatal for the patient in the critical care unit. Ohashi *et al.*, (2013) evaluated the cause for administration errors associated with an infusion pump and identified human programming errors like the selection of wrong drug or typing wrong information as one of the common reason for a programming error. Vanderveen and Husch, (2015) suggested having a closed loop medication systems in which all the medication safety system such as EMR, pharmacy system, smart infusion pump, CPOE, BCMA and automatic dispenser will be integrated to enhance medication safety (see Figure 2.4.a).

Figure 2.4.a Integrated closed loop medication safety system (A system of systems) Source: Vanderveen and Husch, (2015)

Gerhart *et al.*, (2013) examined the impact of a closed-loop medication safety system named intravenous clinical integration (IVCI) system at Well-Span Health on patient safety. The HITs in the IVCI system are interconnected with bi-directional interfaces that facilitate the flow of required information from the CPOE to the infusion pump. The nurse also receives the alert on EHR in the case of new order. Then nurse scans the prepared infusion from the automatic dispenser delivered by the pharmacy using BCMA to confirm positive identification and right drug. After scanning the pump and confirming the patient details and drug using BCMA, the nurse start the infusion. The pump then automatically sends the information back to the EMR. This system also provided visibility of pump data with real-time clinical information (Gerhart *et al.*, 2013). This study revealed that the IVCI improved the patient safety by reducing the medication errors for high-risk infusions, freed up the nursing time and increased the staff efficiency. Un-fortunately, few hospitals have such systems and building these closed loop medication system is a challenging task.

Inappropriate use

HITs are devised to safeguard the MUP and increase patient safety. However, inappropriate use of HITs like overriding the alarms and bypassing the technology (use the SIP with drug library but actually program the pump without using drug library on the pump) have been reported especially during the initial phase of introduction of technology by Ohashi *et al.*, (2014) and Bergon-Sendin *et al.*, (2015). Similarly, Stultz and Nahata (2015) analysed the use of HITs such as CPOE and SIP to detect the origin of error and revealed that the majority of the IT preventable errors still exist due to inappropriate use (such as override, bypasses) of technology by different healthcare professionals at various phases of MUPs. This study also reported that the inappropriate use at prescribing phase and administration phase led to severe errors that have the potential to cause patient harm. Manrique-Rodríguez *et al.*, (2014b) examined the implementation process to ascertain the reasons that lead to inappropriate use of SIP technology. They revealed the following: slow upload and update of data on the systems forced the nurses to reprogram the infusion pump without using the safety software, lack of training of nursing staff led to incorrect profile or standard concentration of the drug selection.

Human- machine interaction

Human-machine interactions like choosing the wrong drug, dose or route of administration were main causes of CPOE and prescription error (Cheung *et al.*, 2014; Westbrook *et al.*, 2013; Samaranayake *et al.*, 2012).

Hardware problems

There were very few problems with the actual interface with IT systems like print out. However, lack of information on the printout can lead to serious medication administration error (Cheung *et al.*, 2014).

2.4.4 Steps to make the intervention successful

The following section explores the literature to identify steps involved in making the intervention successful. Review of the literature identified the evaluation, education and training and customisation of the systems which are discussed below.

SIP technology enables the reduction of medication administration errors. However, these technologies need continuous evaluation (Berdot *et al.*, 2016). Ideally, evaluation should be done in real time by integrating SIP, EMR, CPOE and pharmacy system (Guérin *et al.,* 2015). Ohashi *et al.*, (2014) suggested upgrading drug libraries, developing standardised drug libraries, decreasing the number of unnecessary warnings, and developing stronger approaches to minimise workaround is essential to improve the appropriate and safe use of technology. Bergon-Sendin *et al.,* (2015) demonstrated that the implementation of SIP along with Random safety audits improves the appropriate use of technology. According to Hennings *et al.,* (2010), root cause analysis can make SIP technology safer Integration.

Education and training

Several studies reported better and improved utilisation of HITs to reduce medication errors by increasing training and education of the staff (Stultz and Nahata, 2015; Westbrook *et al.*, 2013; Berdot *et al.*, 2016). A systematic review by Keers *et al.*, (2014) reported a significant decline in medication error rates with the use of a simulation training session, lecture and practice based training session in comparison to a direct observation method of training.

Customisation of system per the unit policies

IT systems should be developed per specific population (ISMP, 2009). Using CPOE without CDS may not bring a significant difference to medication error rate rather it may increase the errors due to low sensitivity (Maaskant *et al.*, 2015a).

2.5 LIMITATION OF THE LITERATURE REVIEW

There is an insufficient body of literature available which examined the impact of HITs on administration errors along with the origin of errors. Moreover, there was heterogeneity between the definition of administration errors and data collection techniques which lessen the significance of reported findings.

2.6 SUMMARY

Health information technologies such as SIP, COPE, BCMA are emerging to alleviate the occurrence of medication errors at different stages of medication use processes. However, a lack of integration between these technologies and inappropriate use can lead to serious medication errors. The administration phase of the medication process is the last opportunity for capturing medication errors and avoiding medication them to reaching the patient. Moreover, customisation of the technologies as per unit policies and developing better human-computer interfaces is essential to ensure patient safety. The introduction of any HITs at ward level leads to change of clinical workflow that can cause medical errors and endanger patient safety. Thus, it is imperative to evaluate these clinical workflows before deploying any HITs so that the organisation can take essential steps to eliminate or reduce the risk of errors and enhance patient safety.

2.7 CONCLUSION

This chapter presented a review of current published research findings that enabled the researcher to identify available HITs to make MUP safer and their impact on the patient safety. This review also presented the ways described in the literature for successful implementation of HITs.

The next chapter delineates the research methodology and the study design utilised to answer the research question.

CHAPTER 3 RESEARCH METHODOLOGY

As the literature review in the previous chapters enlightens the importance of evaluation of clinical workflow before deploying any HITs to ensure the patient safety via identifying, eliminating or reducing the risk of medical errors. Therefore, the researcher decided to evaluate the clinical workflow at the administration phase of high-risk infusions in MN-CMS. This chapter describes the research methodology and rationale behind chosen methodology.

3.1 INTRODUCTION

HITs are snowballing to facilitate efficient, safe and timely patient care and to ease the work of clinicians (Mack *et al.*, 2016). However, inadequate and poorly designed interfaces escalate the cognitive workload of clinicians (Harrison *et al.*, 2007). According to Magrabi *et al.*, (2016), this negatively impacts on the usability, and it does not allow the users to complete their tasks efficiently. Consequently, it can instigate unintended errors, changes in clinical workflow, decreased efficiency and it can also lead to wastage of resources, actual harm and patient death (Ammenwerth and Rigby, 2016). Therefore, it is critical to evaluate HITs before deploying in the real clinical setting. The evaluation in health informatics is defined as

> *"An act of measuring or exploring properties of a health information system (in planning, in development, in implementation, or in operation), the result of which informs a decision to be made concerning that system in a specific context."* (Ammenwerth *et al.*, 2004)

3.2 RESEARCH QUESTION

As speculated in section 1.3 the deployment of the maternal & new-born EHR will bring the changes in the clinical workflow at the administration phase of high-risk infusions in the NICU at the study unit.

The research question is

> "Will the introduction of the new clinical workflow contain in the MN-CMS impact on medication safety during the administration phase of high-risk infusion in NICU?"

3.3 AIMS AND OBJECTIVES OF THE STUDY

The aim of the study is to prospectively evaluate the clinical workflow and patient safety related to administration of high-risk infusions in a NICU using a clinical simulation technique in maternal & new-born EHR. The specific objectives are:

1. Type of potential errors in the drug administration process in the system.
2. Error rate per 100 infusions at the drug administration process.
3. The severity of errors in terms of potential to cause harm.

3.4 DEFINING THE QUESTION

To answer the research questions and ensure the validity and reproducibility of the study, it is imperative to define the different types of medication error at the administration phase that will be used for this study. Next section states the definitions used to describe a different type of errors at the administration phase of high-risk infusions.

3.4.1 Programming errors:

A programming error in this study is defined as any deviation in programming pump parameters from the prescribed infusion order. **Error! Reference source not found.** *s*tates the operational definitions of the different type of programming errors.

Table 3.4.A Operational definitions for programming errors

Error Type	Definition
Wrong concentration	An amount of medication in unit of solution is different from the prescribed order
Wrong dose	The dose of prescribed medication is different from the prescription order
Wrong weight	Programmed weight is different from the prescription order
Wrong rate	Programmed infusion rate in the infusion where drug library is not available is different from the prescription order

3.4.2 Labelling errors

Labelling error is defined as incomplete or inaccurate information in the syringe labels. After comparing labelling parameters recommended by Australian Commission on Safety and Quality in Health Care (ACSQHSC), (2015); ISMP, (2010); Larsen, (2005) (explicitly designed for neonatal population) and currently printed syringe labels used in the NICU, a total of 16 labelling parameters were identified to be included on syringe labels (see Appendix A). After consultation with the Registered Advanced Nurse Practitioner (RANP) and clinical pharmacist, fourteen parameters were included in the final analysis which were further divided into two categories: Essential labelling parameters (which must be on the labels to ensure medication safety) and Non-essential labelling parameters (which should be on the label)(see Table 3.4.B). As this is a simulation study, expiry date was excluded from the labelling parameters as the participants were not provided with actual drug. Drug amount and drug volume were put together as both parameters provide almost same information.

Table 3.4.B Labelling parameters included in the study for final analysis

No	Essential labelling parameters		Non-essential labelling parameters
1	Patient's Name	10	Starting dose
2	Weight	11	Start rate of infusion
3	Drug Label	12	Route
4	Concentration	13	Dose range
5	Drug volume/drug amount	14	Signature
6	Diluent Added		
7	Preparation date		
8	Preparation time		
9	Hospital no		

3.4.3 Categorisation of identified errors:

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) provided the index to categorise the medication error per harm (NCC-MERP, 2001). There are main four categories: No error; Error no harm; Error harm; Error, a death which is further divided into nine categories from 'A' to 'I' (see Figure 3.4.a). As it is a simulation study, errors were categorised from A to D only. Programming errors were discretely examined for the potential harm and categorised from category A to D and were reviewed by RANP and Clinical pharmacist. A criterion used for categorising the labelling errors is described in (see Table 3.4.C).

Table 3.4.C Criteria used for categorising labelling errors on NCC-MERP index

Error category	Criteria
A	Incomplete label with missing only non-essential parameters
B	Incomplete label with missing essential parameters
C	Syringe label with wrong information/missing essential labelling parameter and has category 'C' programming error
D	Syringe label with wrong information/with missing essential parameter and has Category 'D' programming error

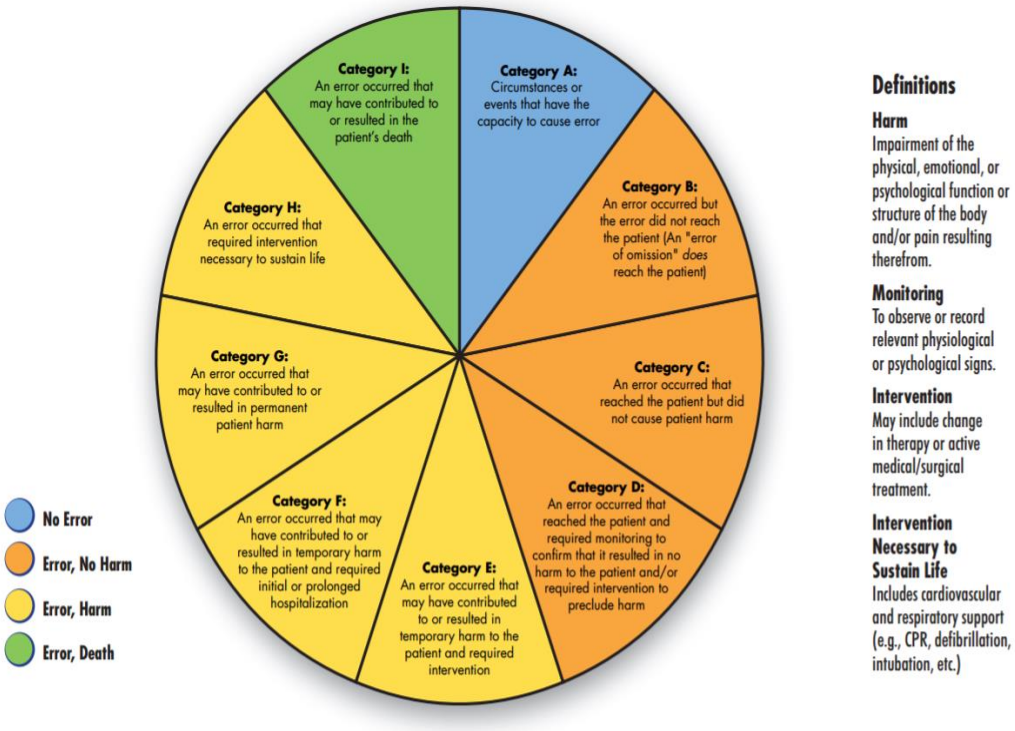

Figure 3.4.a NCC-MERP index to categorise medication errors (Source: NCC-MERP, 2001)

3.5 RESEARCH DESIGN

Designing an evaluation study is similar to peeling an onion where the answer to a question leads to another question at the next level and decisions made at every level primes to actual planning of a scientific evaluation study in health informatics (McNair, 2016). A rigorous approach based on scientific method is indispensable to perform a scientific evaluation study and secure an appropriate level of evidence (McNair, 2016). Further, the method of performing a scientific evaluation of a HIT hinges on the purpose of evaluation and the timing of the project (Marcilly *et al.*, 2016).

Expert evaluation is typically carried out in a laboratory setting at the starting or formative stage of a health information system to verify the functionality of the system (McNair, 2016). Experts usually use heuristic evaluation methods and cognitive walkthrough. This type of evaluation is known as formative evaluation.

User testing and simulation methods are carried out with real end-users in a controlled environment where the researcher observes the end-users interacting with the HIT performing a specific task. User testing usually takes place in a lab/office whereas simulation is carried out in real or realistic settings that provide the ecological validity to the evaluation. These evaluation studies aim at identifying any safety issues and unintended errors due to technology and end-user interaction in a specific environment. This type of evaluation is known as summative evaluation (McNair, 2016).

Post-market surveillance is the highest possible fidelity evaluation method to identify usability flaws and system errors in the post-implementation period. Evaluation is done through observation, feedback survey, interview or reviewing incidents reports or system logging data. This type of evaluation provides insight to unintended use of technology and workaround behaviours. A simulation study can be either a computer-based simulation or a clinical simulation. A computer-based simulation is used in the early stages of development of an information system for optimisation, safe engineering, modelling, and examining the effects of human systems whereas a clinical simulation is used in the later stages, and it involves real end-users enacting

in the realistic clinical scenario (Borycki *et al.*, 2010, pp.31-32). It brings humans in the loop and assesses the health information system that aids in uncovering the sociological aspect of socio-technical interaction such as the effect of an information system in different clinical context, its efficiency, user satisfaction (Jensen *et al.*, 2015). Thus, clinical simulation is considered as a rigorous method of evaluation of user interface in comparison to the other types of usability evaluations (Jensen, 2016). As the system under evaluation is in pre-implementation stages, and the researcher aims at evaluating clinical workflow and identifying unintended errors at the administration phase of high-risk infusions, the researcher decided to conduct a clinical simulation study.

A scientific theory and rigorous approach are crucial for enhancing the credibility of an evaluation study (Ammenwerth *et al.*, 2004). Hence, the researcher opted to adopt the methodological approach to conducting clinical simulation described by Jensen *et al.*, (2015) which is garnered from twenty clinical simulation studies aimed at evaluating and optimising clinical information system before deploying them in real clinical practice. Overall the methodological approach described by Jensen *et al.*, (2015) comprises of four phases 1.Purpose, 2. Planning, 3. Preparing and 4. Performing. Each phase has some steps to conduct a clinical simulation study (see Figure 3.5.a)

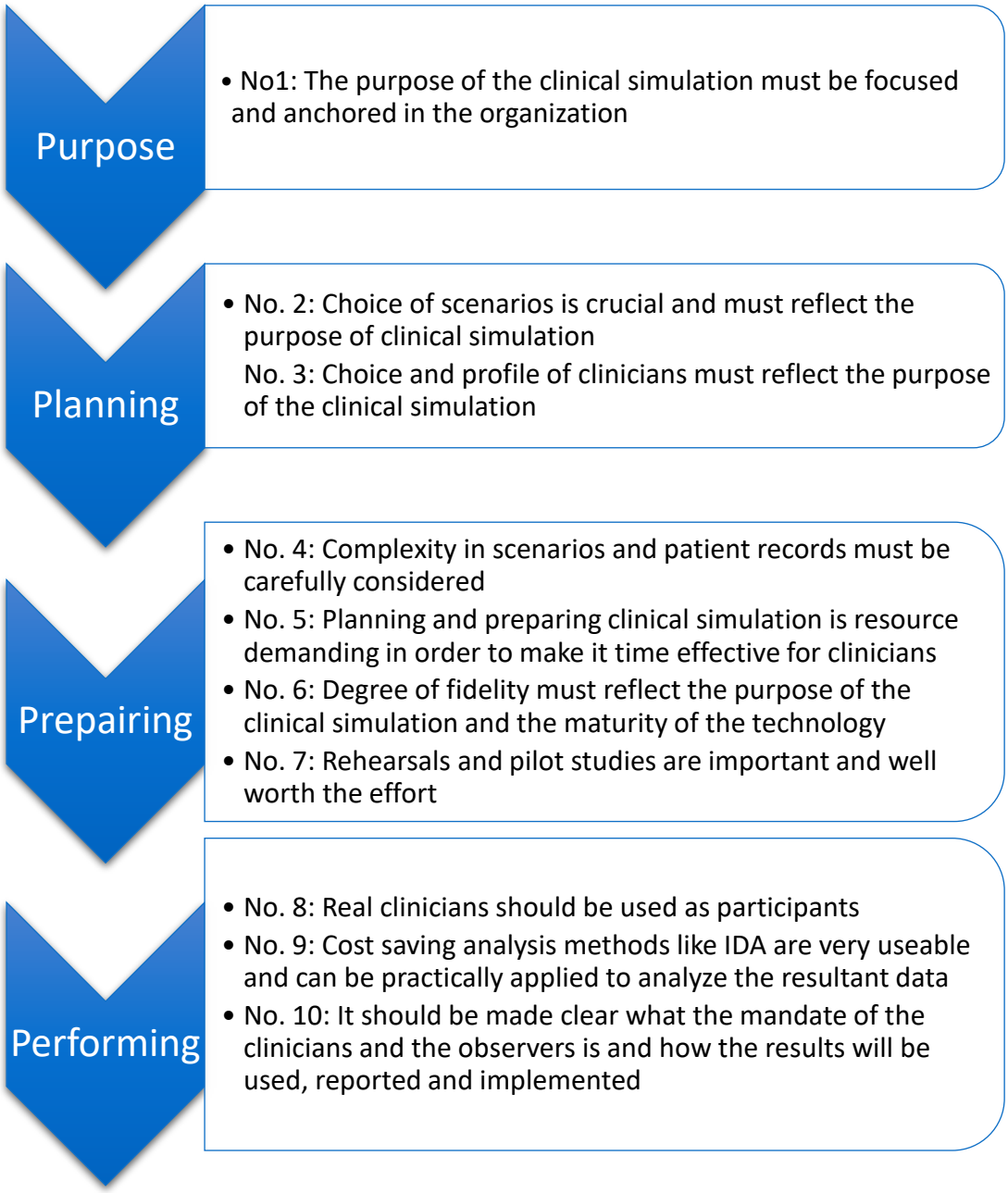

Figure 3.5.a Methodological Approach for clinical simulation (adapted from Jensen et al. (2015))

3.5.1 Purpose

The purpose of an evaluation study guides almost all the study design decisions. Therefore, the purpose of the study should be clearly delineated at the preliminary stage, and it should signify the necessity of the study (guidelines for good evaluation practice in health informatics (GEP-HI) by (Nykänen *et al.*, 2011). The Maternal and new-born EHR will be deployed at the study site in September 2017, and one of the aims of the system is to ensure medication safety. Hence, given the complexity of NICU environment (described in section 1.2) and medication use process (outlined in section 0) and the inherent increased risk of medication errors in neonatal population, the main purpose of this study is as follow:

1. To prospectively evaluate the clinical workflow and risks to patient safety associated administration of high-risk infusions in a NICU in Maternal and new-born EHR.

2. To identify the type of potential errors in the drug administration process in the system.

3.To measure the error rate per 100 infusions at the drug administration process.

Further, such prior information will offer insight to the organisation decision-makers of the impact of changes arising from the introduction of Maternal and new-born EHR on patient safety issues related to high-risk infusion at the administration phase. Consequently, an organisation can take proactive decisions such as better customisation of technology that fits clinical context or interventions like training and support to mitigate any patient safety risk before the deployment of the system (Borycki *et al.*, 2010, p.34).

3.5.2 Planning

The researcher planned and defined the scope of the study to accomplish the purpose of the study identified in the first phase. The first step in planning a simulation study involves the choice of scenarios for inclusion. The scenarios should reflect the typical tasks in a small fraction of the clinical work practice and cover the parts of the workflow affected by the

new technology (Jensen *et al.*, 2015). In the current study, each participant was given a prescription of five infusion orders on the computer screen. The participant retrieved the information from the computer screen and cross-checked the prescription with the clinical protocol. If the prescription order was correct; each participant made syringe labels and programmed the drug in the infusion pump. Each participant repeated the same procedure for five infusion orders.

The next crucial step in planning the simulation is the choice and profile of clinicians involved which should reflect the purpose of the clinical simulation. As best practice to ensure medication safety, in the real world of clinical practice, two registered nurses are involved in the administration phase for double-checking of the prescription especially for the administration of high-risk medications as recommended by (An Bord Altranais (ABA), 2007, p.11). However, a pragmatic approach was considered due to a shortage of staff. Thus, only one registered nurse working in NICU per simulation session was included as a participant who will be a real end-user of the Maternal and new-born EHR. Given the short timeframe, it was decided to conduct thirty simulation sessions.

3.5.3 Preparing

Preparing phase includes writing up the scenarios, recruiting the appropriate users of the system and preparing for clinical and technical set up for the planned simulation session (Jensen *et al.*, 2015). The first step in this phase is to create a complex clinical scenario that mimics real clinical practice. Careful consideration has been taken to create ten scenarios based on the actual clinical settings. Each scenario included prescription orders for five high-risk infusions for two patients. The prescription order generated from the Maternal and new-born EHR consist of frequently used six high-risk medications namely, morphine, insulin, dopamine, adrenaline, vasopressin and milrinone. As the unit is in the process of developing a drug library for high-risk medications, the drug library for adrenaline, vasopressin and milrinone was not available at the time of the study. Where the drug library was unavailable, the participants were asked to programme the prescribed infusion rate to deliver the medication as prescribed. Initial scenarios were

drafted onto the Excel spreadsheets which were reviewed and finalised by a clinical pharmacist (see Appendix B).

Once the clinical scenarios were agreed steps were taken to ensure, the simulation exercise was not burdensome regarding the time taken to complete. With this in mind, screen shots of prescription orders as well as the nurse's view of the prescription were generated using the training module of the Maternal & new-born EHR. The screenshots were arranged in portable document format (pdfs) per planned ten scenarios with necessary details (see Appendix C.).

The realism and acceptance of a degree of fidelity of simulation set up which must reveal the purpose of clinical simulation (Ammenwerth and Rigby (eds.), 2016, p.156). Simulation acceptance model by Dahl *et al.*, (2010) described the four types of fidelity under main two headings physical fidelity and psychological fidelity (see Figure 3.5.b).

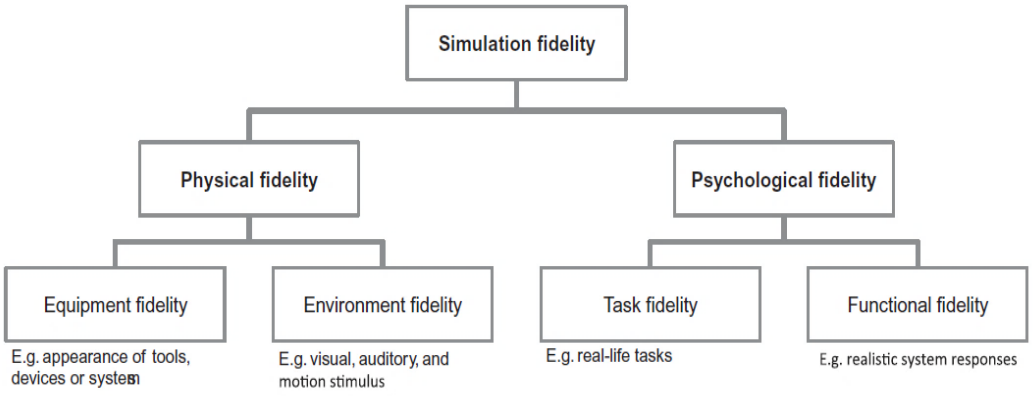

Figure 3.5.b **Types of simulation fidelity (Dahl et al., 2010)**

Equipment fidelity was high in the designed study as the equipment used such as infusion pump, and computer screen were similar to those used in the real clinical setting. Similarly, high environment fidelity was attained as the simulation sessions were conducted in an environment analogous to the clinical setting. Likewise, the task fidelity was at a high level in the designed study as the task performed in the clinical simulation was reflective of real

clinical activity performed by healthcare professionals. However, the functional fidelity was not as high as the researcher did not use the real clinical information system. However, in an effort to improve functional fidelity, an electronic prototype of the system was created in the form of pdfs to demonstrate the concept.

According to Jensen *et al.*, (2015), rehearsals of scenarios, the clinical set up, technical set up, test data implemented in the information system and data collection before the actual simulation session make the process time effective. Therefore, an initial rehearsal was carried out using the drafted pdfs in an empty room within NICU to match the real clinical setting. This rehearsal benefitted in modifying the pdfs, and corresponding clinical medication protocols were added along with prescription pdfs. The rehearsal also facilitated the appraisal of the clinical and technical set up as well as the data collection process. Modified pdfs included the linked clinical medication protocol which forced the participants to switch in-between to look for medication protocol like the actual clinical information system. It helped in enhancing the task fidelity of the planned simulation. Overall, the designed study has attained nearly high fidelity.

3.5.4 Performing

Performing phase of clinical simulation consists of conducting actual simulation with the participants (Jensen, 2016). This phase involves three steps; 1. Introduction, 2. Simulation, and 3. Debriefing. Introduction phase included a brief description of the system and activity to be performed during the simulation session. Ammenwerth and Rigby (eds.), (2016, p.156) state that extent of training before the simulation depends on the purpose of evaluation. Participants were already aware of medication use processes in the current study as a part of their current practice. Hence, a standardised reference guide for the simulation procedure (see Appendix D) and a brief introduction was provided to the participant just before the clinical simulation. Participants were also informed that the purpose of the simulation was an evaluation of the system and not their practice as recommended by Jensen *et al.*, (2015).

After a brief introduction of the simulation procedure and environment, the participants performed the real activity. The participants were made comfortable during the session. The researcher observed the activity of the participant from the other side of the room. The researcher stayed in the room in the initial part of simulation session to facilitate the use of technology. After completion of a simulation session, participants were asked to complete the post-simulation survey (see Appendix E) which was completely optional. The questionnaire must reveal the purpose of the study and should contain questions concerning efficiency and satisfaction concerning simulation scenarios. The post-simulation feedback survey comprised of three questions to gather relevant demographic information, eight questions about participant's perception of the system's safety and degree of difficulty (using a Likert-style) and two open-ended question about their perception of the simulation session and suggestions to improve the information system under evaluation.

To create high fidelity simulation, it is essential to include the clinicians who are familiar with the current practice. Hence, the registered nurses who are currently working in the NICU were invited for the study. However, the clinician who was involved in the development of maternal and new-born EHR project at the time of the study was excluded. Extensive experience with the testing of the system can lead to personal bias which can affect the output of the evaluation study (Jensen *et al.*, 2015). It is recommended that there should be an adjoining room to the simulation room separated by glass window to observe and instruct the participants during the session. However, there is no such facility in the research site, therefore, taking a pragmatic approach a room within the unit was used as a simulation room. The researcher observed the participant from the far side of the room to reduce Hawthorne effect.

The final step in the simulation studies is to make the participants aware of what is expected of them during the session and how the results will be used, reported or implemented (Jensen, 2016). A participants' information leaflet (see Appendix F) containing brief information about the motivation and purpose of the study, the simulation session and reporting of the results, was provided at least 24 hours before they decided to participate in the

study. Further consent (see Appendix G) was obtained before the simulation session.

3.6 CONTEXT AND STUDY SETTING

An evaluation study using a clinical simulation method should be conducted in the realistic setting of the unit where the technology is to be deployed reflecting the real clinical setting. The neonatal intensive care unit, Rotunda Hospital, Dublin was chosen as the study site as maternal and new-born EHR is planned to be deployed in the Rotunda hospital in last quarter of 2017. The participants have kept away from the clinical duties for the duration of the simulation session.

3.7 STUDY POPULATION

A high-fidelity evaluation study must involve real end-users of the technology (Sligo *et al.*, 2017). For this reason, registered nurses working in NICU at the time of the study were identified as the eligible participants as they will be the end-users of the Maternal and new-born EHR and will be involved in the process under investigation.

Inclusion criteria:

Nurses or midwives employed by the Rotunda Hospital but not working in NICU.

Exclusion Criteria:

All other than nurses working in the NICU, Rotunda Hospital were excluded from the study.

3.8 SAMPLING

3.8.1 Sampling method

Convenient sample method which is a nonprobability sampling method was chosen for this study to achieve the purpose of the study.

3.8.2 Justification for sample size

The sample size was chosen as a pragmatic approach given the staffing constraints and current workload in the NICU. After the discussion with the supervisor at the site, it was decided to have 100-150 prescription orders in 25-30 simulation sessions, and one participant per simulation session.

3.9 Ethical Approval process

Before conducting the research, it is indispensable to consider a number of factors such as any harm to participants/system during the study, confidentiality and participant/organisation privacy.

3.9.1 Ethical consideration

The study involved the interaction between a system and the participant at the time of simulation session. Measures were taken by the researcher to protect the participants from harm. As a pragmatic approach, simulation sessions were conducted while the participants were at work to facilitate recruitment. The participants were informed a day before the simulation session. However, some planned simulation sessions were postponed due to increased clinical activity and the researcher made sure that the study did not affect the clinical work and patient safety. Recruited participants received information leaflet, and informed consent was obtained before the session. The participants were informed that they could withdraw from the study at any point.

3.9.2 Confidentiality

No identifiable data related to participants was collected during the study. To maintain confidentiality, all the data was stored on the secure hospital network in a NICU folder that is accessed through password protected computer. Hard copies of data were kept in a researchers' safe locker in NICU, Rotunda Hospital.

3.9.3 Ethical approval

A research proposal (see Appendix H) was submitted to the research ethical committee of the Rotunda hospital in Nov 2016. Minor changes were made

as suggested by the committee, before re-submission. After receiving written ethical approval from both the Rotunda hospital (see Appendix IAppendix H) and Trinity College, Dublin's School of Computer and Statistics Research Ethics Committee (see Appendix J), the simulation sessions were conducted.

3.10 Recruitment of participants

Recruiting participants for research involving human subject is an exigent task and necessitates a number of activities such as identifying eligible participants, explaining the study to potential participants, and recruiting adequate desired sample based on study goals and design, obtaining informed consent, maintaining ethical standards and retaining participants until completion of the study (AHRQ, 2016). A recruitment flyer (see Appendix KAppendix H) was displayed on the unit notice board to inform potential participants of the research project and inviting participation. The researcher also approached potential participants and explained the study briefly to facilitate recruitment. Participant information leaflet was provided to the interested end-users, and informed consent was obtained.

3.11 Data collection and analysis

Given the socio-technical nature of information systems, only multidimensional analysis can draw the 'whole picture' in the evaluation of a health information system. Due to the complexity of this relationship, a mixed method approach was adopted as it leads to a holistic investigation of the health information system (Ammenwerth and Rigby (eds.), 2016, p.102). Mixed method research is defined as a

> "*research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry.*"
>
> (Tashakkori and Creswell, 2007)

In the current study, the researcher collected both qualitative and quantitative data. During the simulation session, the researcher captured the data via observation which enabled the researcher to describe the interaction between

the system and the users to carry out the mentioned task using the technology in question. Additionally, the quantitative data were collected on the labelling sheet (see Appendix L) which helped to capture and quantify the number of labelling errors or discrepancies during the administration process. Programming data was captured using pump logging data after the simulation session on the pump logging data collection sheet (see Appendix M) to identify programming errors at the administration phase. Participants feedback about the simulation session was collected using a post-simulation feedback survey (see Appendix D). All the data was then transferred onto an excel spreadsheet.

Descriptive analysis of the data was performed using IBM SPSS Statistics 24 data analysis software to identify the number of errors per 100 infusions, type of errors and degree of severity of errors at the administrative phase using Maternal & new-born EHR prototype. Binary logistic regression analysis was performed to identify if there is any statistically significant relationship and to answer the following questions.

Does the age, NICU experience and frequency of use of drug library have an influence on the occurrence of programming errors (yes vs. no)?

How does the probability of occurrence of programming error at the administration phase of MUP change for every additional missed or wrong labelling parameters per infusion order?

Does time taken at the administration phase of MUP influence on the occurrence of programing errors (yes vs. no)?

Does lack of drug library have an influence on the occurrence of a programming error (yes vs. no)?

3.12 SUMMARY

This chapter described the research methodology adopted to answer the research question. A mixed method approach was considered as the appropriate method to evaluate the clinical workflow in Maternal and new-born EHR at the administration phase of high-risk infusions in NICU. This chapter also presented the rationale behind the adopted approach. The following chapter will impart the results of the research.

CHAPTER 4 RESULTS

This chapter presents the results of research conducted using the methodology described in Chapter 3 to answer the research question (see Chapter 1 section1.4.)

4.1 INTRODUCTION

Thirty-two simulation sessions have been carried out to measure the error rate and degree of severity of errors at the administration phase using maternal & newborn EHR. However, one simulation session was not included in the final data analysis as it was interrupted due to the clinical work situation. The first section of this chapter describes demographic characteristics of the participants. The total number of errors and type of errors identified during simulation session at the administration process will be presented. The second section will introduce the categorization of errors per the degree of the severity. The last part describes findings of a qualitative analysis of a post-simulation survey that details the perception of participants regarding the clinical workflow at the administration phase.

From a total population of 75 registered nurses working in NICU at the study site, thirty-two registered nurses participated in the research study. However, one session was interrupted as the participant was required at the workplace to resume clinical responsibilities. Only the data collected in completed simulation sessions were included in the final analysis.

4.2 DEMOGRAPHICS OF THE PARTICIPANTS

Table 4.1.A showed the frequency distribution and relative frequency distribution of included participants' demographic characteristics. The majority of the participants were above 40 years of age. More than half of the nurses had more than sixteen years of experience, and nearly two-third of the participants used drug library at least once a week. However, all the sample population had attended the training session for using drug library as part of in-service education.

Table 4.2.A Shows demographics of participants

CHARACTERISTICS	FREQUENCY (N=31)	RELATIVE FREQUENCY IN PERCENTAGE (%)
Age group		
20 -30 years	3	9.7
31-40 years	8	25.8
41-50 years	12	38.7
over 50 years	8	25.8
Experience in NICU		
0-5 years	7	22.6
6-15 years	7	22.6
16-25 years	9	29.0
>25 years	8	25.8
Use of drug library		
Never	4	12.9
1-2 times per month	9	29.0
once a week	5	16.1
Most days	13	41.9

4.3 POTENTIAL ERRORS AT THE ADMINISTRATIVE PHASE

This section of the report describes the type and number of potential errors identified at the administrative phase of medication process. The study examined a total of 155 prescription orders for potential errors at the administration phase in the simulated environment. Figure 4.3.a portrays the deviation of essential and non-essential labelling parameters, wrong labelling parameters as well as programming errors per prescription order. Out of 155 prescription orders, thirty-one prescription orders had either programming error (n=11) or wrong labelling parameters(n=12) or both programming error and wrong labelling parameter (n=8). There were few programming errors (n=22, 14.2%, Mean=0.14, N=155, range=1-2) and few wrong labelling parameters (n=22, 14.2%, Mean=0.14 N=155, range=1-2). However, there were numerous labelling deviations (n=722, Mean= 4.65, N=155, range=1-8) when compared to the labelling standards. Almost all syringe labels had more than one deviation per syringe labels (Figure 4.3.a).

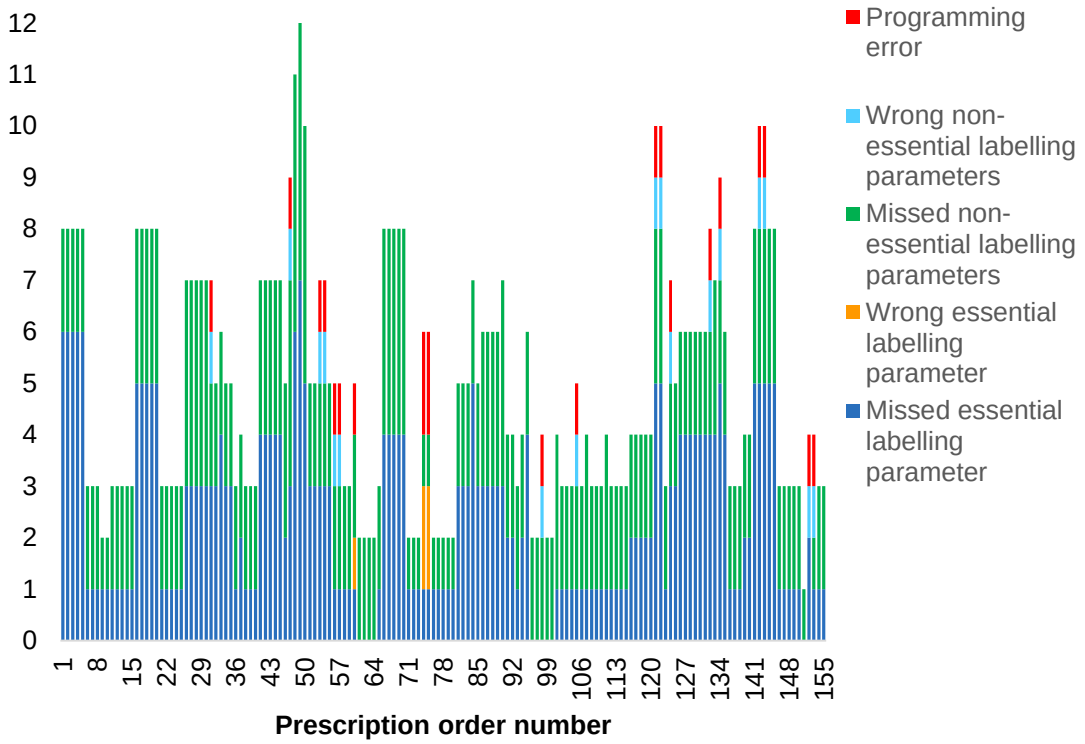

Figure 4.3.a Number of labelling deviations and programming errors per prescription order

4.3.1 Types of errors at Programming stage

Out of N=155 prescription order, twenty-two different types of programming errors were identified in 12.3% (n=19). Figure 4.3.b represents the percentage distribution of identified programming errors. Three (15.8%) of a total of nineteen prescription orders had two programming errors per prescription order. Wrong concentration (31.6%, n=6) and wrong weight (31.6%, n=6) were the most frequent errors at the programming stage. There were only three prescription orders (15.8%) in which an inaccurate infusion rate was programmed.

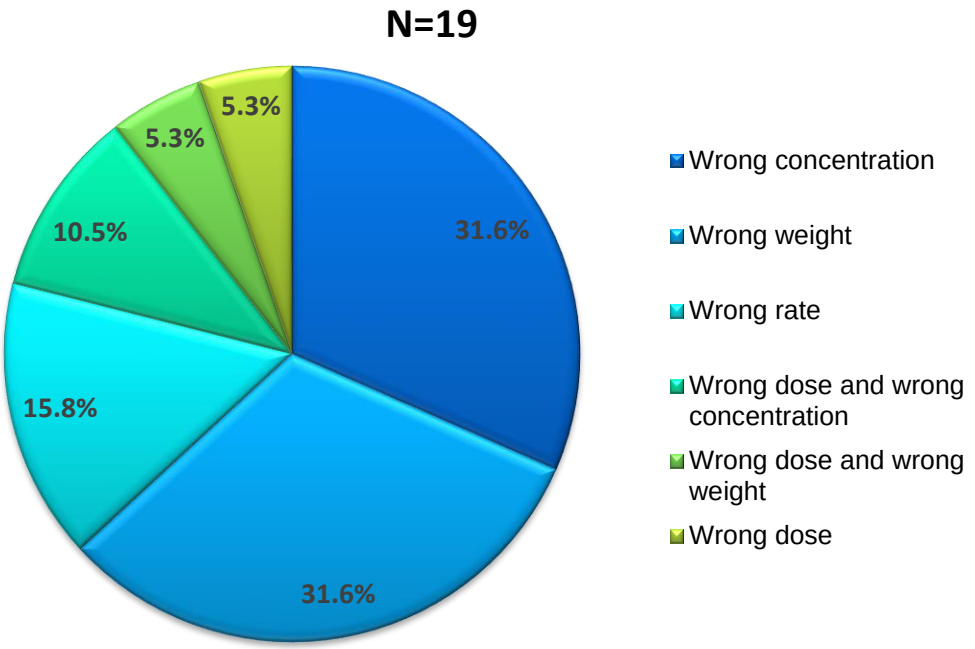

Figure 4.3.b Depicts percentage distribution of different type of errors at programming stage

4.3.1 Deviation from prescribed dose due to different types of errors at programming stage

Figure 4.3.c portrays the percentage deviation from the prescribed dose in 19 prescription orders with programming errors. It is visible in Figure 4.3.c programming wrong concentration led to biggest deviation in six prescription orders. In prescription order no 52, 53, 43, 44, 45, programming wrong concentration preceded to nearly 100 percent deviation from the prescribed dose. Furthermore, programming wrong weight in prescription order no 132 and the wrong dose in prescription order no 5 resulted in 40 percent more drug dose administered than the prescribed dose.

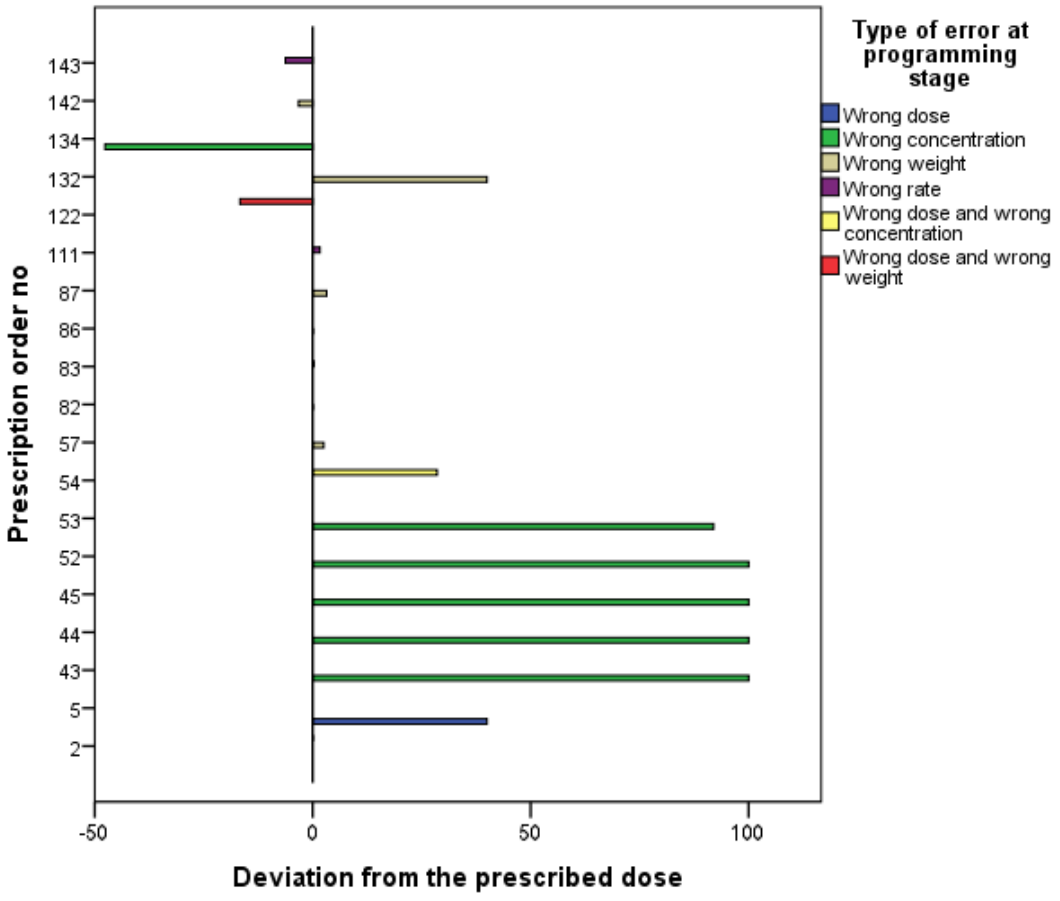

Figure 4.3.c Shows percentage deviation from the prescribed dose in 19 prescription orders with programming errors and type of error at programming stage

4.3.2 Types of errors at labelling stage

Most syringe labels have some deviation, and it varied across all the syringe labels. Table 4.3.A shows the frequency distribution of labelling parameters.

Table 4.3.A Frequency distribution of labelling parameters (N=155)

N=155	Essential labelling parameters		Non-essential labelling parameters	
	Missed	Wrong	Missed	Wrong
Sum	369	5	353	17
Mean	2.4	0.03	2.3	0.11

Only 6.5% (n=10. N=155) of syringe labels had all the nine essential labelling parameters mentioned in Table 3.4.B. Concentration (55%, n=85, N=155) and weight (49%, n= 76, N=155) were the most common missed labelling parameters out of nine essential labelling parameters (see Figure 4.3.d). There were very few wrong essential labelling parameters (3%, n=5) and only three syringe labels had the wrong essential labelling parameters

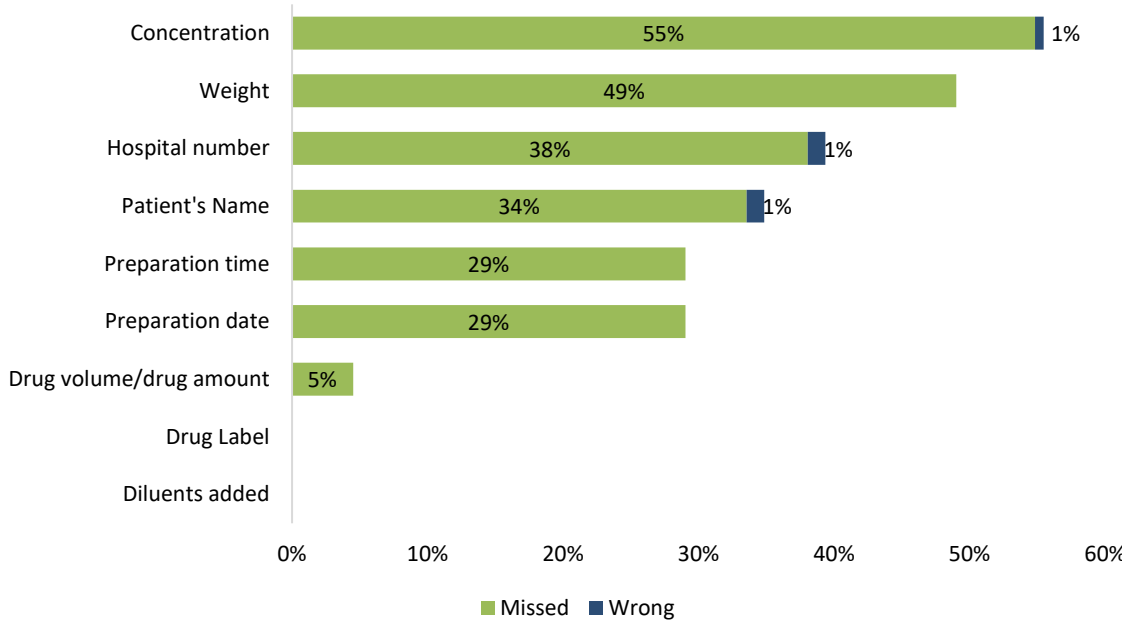

Figure 4.3.d A stacked bar graph presents the percentage distribution of missed and wrong essential labelling parameters (N=155)

4.4 CATEGORISATION OF ERRORS AS PER THE SEVERITY

Figure 4.4.a and Figure 4.4.b portrays the percentage distribution of programming errors and labelling errors as per NCC-MERP index for categorisation of medication errors. The majority of programming errors (89%, n= 17) belongs to category 'C' and 'D' whereas only 11% (n=17) of total labelling errors belongs to category 'C' and 'D'.

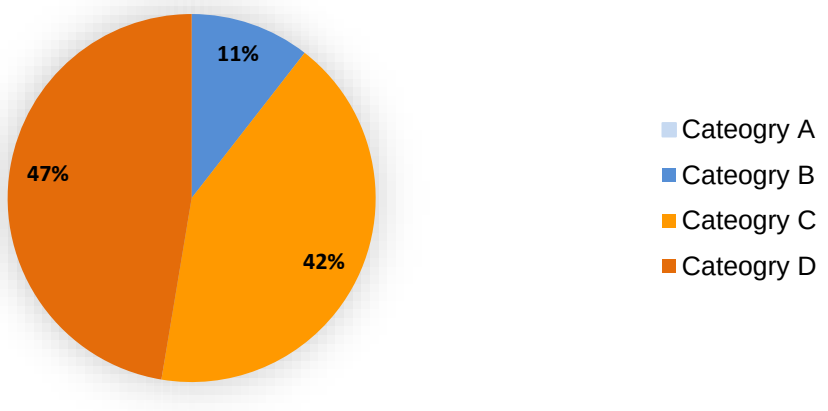

Figure 4.4.a Percentage distribution of programming errors (N=19) as per NCC-MERP index

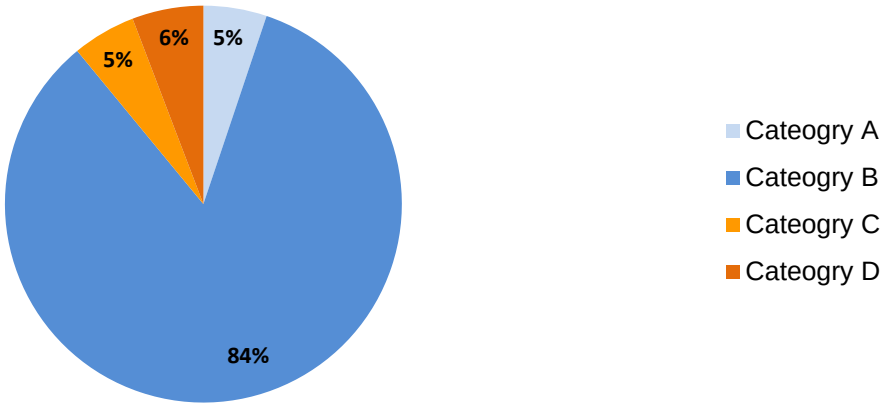

Figure 4.4.b Percentage distribution of labelling errors (N=727) as per NCC-MERP index

Table 4.4.A and Table 4.4.B presents the description of the programming errors more than ±10% and less than ±10% deviation from the prescribed dose respectively. Dopamine (n=6) is the most common high-risk infusion with programming error followed by morphine (n=4) and insulin (n=4). Further, out of nineteen prescription orders with programming errors, more than half of the prescription orders had more than ±10% deviation from the prescribed dose. Dopamine (n=3), morphine (n=3) and insulin (n=4) were the most common infusions with more than ±10% deviation from the prescribed dose, and 70% of them had wrong concentration programmed.

Table 4.4.A Categorisation and description of programming errors with more than ±10% deviation from the prescribed dose

Prescription order no	Drug name	Programming error	Prescribed	Programmed	Deviation from prescribed dose (%)	category
132	Dopamine	Wrong weight	0.5 kg	0.7 kg	40	**D**
52	Dopamine	Wrong concentration	3000 mcg/ml	1500 mcg/ml	100	**D**
45	Dopamine	Wrong concentration	3000 mcg/ml	1500 mcg/ml	100	**D**
5	Morphine	Wrong dose	7 mcg/kg/hour	10 mcg/kg/hour	40	**D**
43	Morphine	Wrong concentration	100 mcg/ml	50 mcg/ml	100	**D**
122	Morphine	Wrong dose Wrong weight	8 mcg/kg/hour 0.78 kg	8.33 mcg/kg/hour 0.6 kg	-16.67	**C**
53	Insulin	Wrong concentration	0.2 unit/ml	0.1 units/ml	92	**D**
44	Insulin	Wrong concentration	0.2 unit/ml	0.1unit/ml	100	**D**
134	Insulin	Wrong concentration	0.1 unit/ml	0.2 unit/ml	-47.62	**D**
54	Insulin	Wrong dose Wrong concentration	0.02 unit/kg/hour 0.1 units/ml	0.05 units/kg/hour 0.2 units/ml	28.57	**D**

Table 4.4.B Categorisation and description of programming errors with less than ±10% deviation from the prescribed dose

Prescription order no	Drug name	Programming error	Prescribed	Programmed	Deviation from prescribed dose (%)	category
143	Adrenaline	Wrong rate	0.16 mls/hour	0.15mls/hour	-6.25	**C**
142	Dopamine	Wrong weight	0.78 kg	0.76 kg	-3.23	**C**
2	Dopamine	Wrong dose Wrong concentration	10mcg/kg/min 1500 mcg/ml	5 mcg/kg/min 3000 mcg/ml	0	**C**
87	Dopamine	Wrong weight	0.78 kg	0.79 kg	3.22	**C**
86	Morphine	Wrong weight	0.78 kg	0.79 kg	0	**B**
82	Fentanyl	Wrong weight	3.98 kg	4.0 kg	0	**B**
57	Fentanyl	Wrong weight	3.9 kg	4 kg	2.56	**C**
83	Vasopressin	Wrong rate	2.99 mls/hour	3 mls/hour	0.33	**C**
111	Milrinone	Wrong rate	0.59 mls/hour	0.6 mls/hour	1.69	**C**

Mean time taken to prepare one syringe label and program the pump was 9.21±2.64 (Range=12, min=6, max=18). The results of cross-tabulation of different demographic categories and time taken per infusion order are portrayed in Figure 4.4.c. The majority of participants (77%, n=24, N=31) took 5-10 minutes to complete the process. The participants belong to age group 20-30 years spent less time than the other age groups. Further, participants with 6-25 years of NICU experience completed the process quicker than other groups. Participants with no experience with drug library spent more time than the participants with some experience of using drug library.

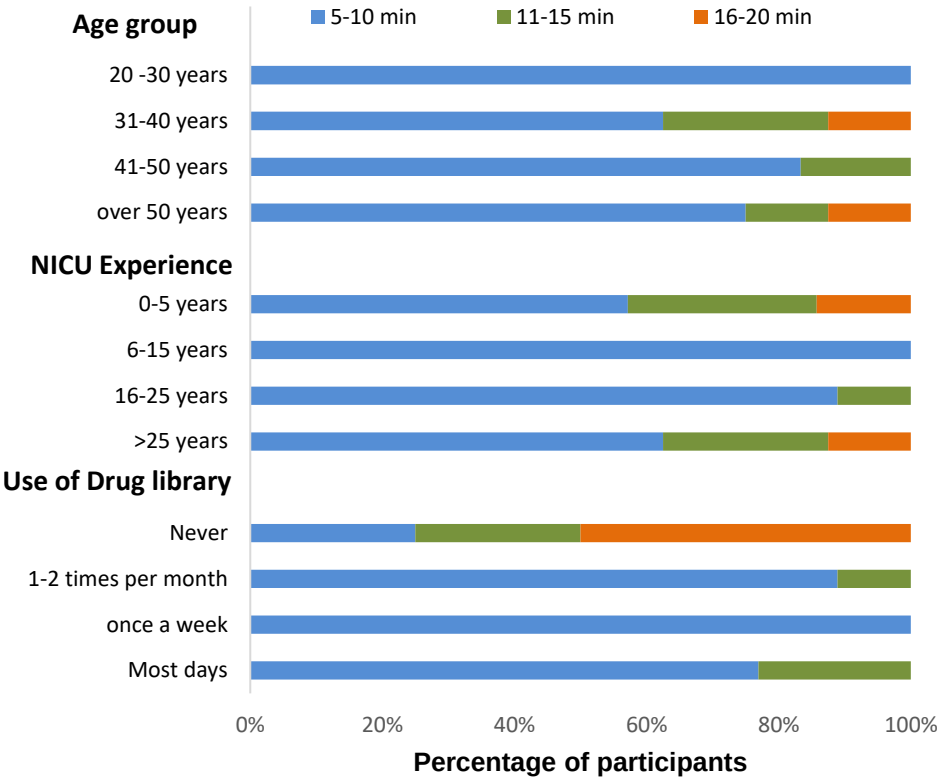

Figure 4.4.c Result of cross-tabulation of different demographic categories and time taken per infusion order

4.5 RESULTS OF LOGISTIC REGRESSION ANALYSIS

Binary logistic regression analysis was carried out to predict if there is any statistically significant relationship between demographics of participants and the likelihood of occurrence of programming errors (see Figure 4.5.a**Error! Reference source not found.**). Participants aged between 31-40 years are less likely to have programming error when compared to age group 20-30 years (odds=0.12, 95% C.I. lower 0.02 and 0.90). However, no statistically significant relationship was found in the occurrence of a programming error between more NICU experience and less NICU experience. Similarly, there was no statically significant difference in the likelihood of a programming error

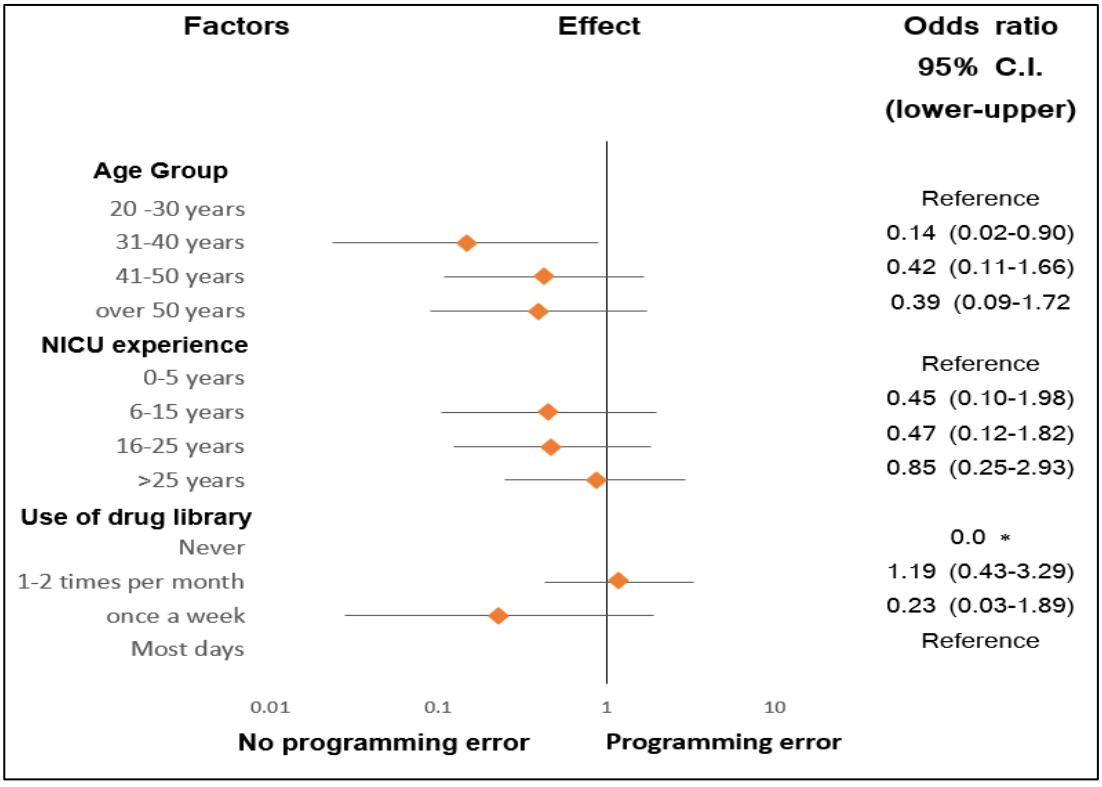

Figure 4.5.a shows the results of binary logistic regression analysis to predict likelihood of programming error as per different demographic factors

◆ represents odds ratio and — denotes upper and lower C.I. for odds ratio

* the value <=0 is not plotted in forest plot

in participants with never/less use of drug library and frequently use of drug library.

Figure 4.5.b shows the results of binary logistic regression analysis for the prediction of a programming error in case of missing or wrong labelling parameters. The chances of occurrence of a programming error increase with an additional wrong labelling parameter and missing non-essential labelling parameter. There was not any statistically significant relation between other labelling deviations and the likelihood of programming error.

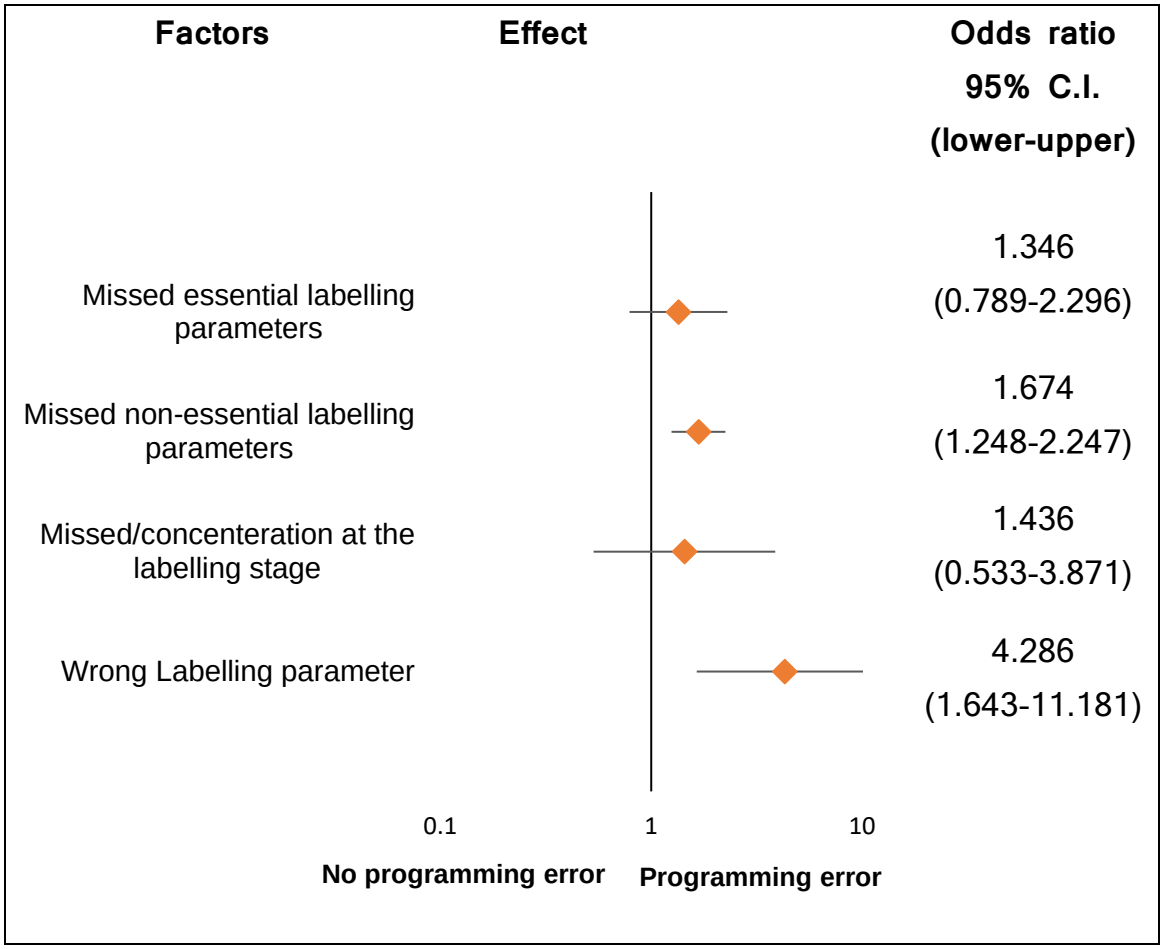

Figure 4.5.b shows the results of binary logistic regression analysis to predict likelihood of programming error due to missing/ wrong labelling parameters.

◆ represents odds ratio and — denotes upper and lower C.I. for odds ratio

* the value <=0 is not plotted in forest plot

Figure 4.5.c presents the results of binary logistic regression analysis to show the effect of drug library availability and time taken per infusion order on the likelihood of programming error. There was no statistically significant relationship of non-availability of drug library on the occurrence of a programming error. Furthermore, there was no statistical difference in the likelihood of programming error in case of participants taking additional time to prepare a label and program the pump.

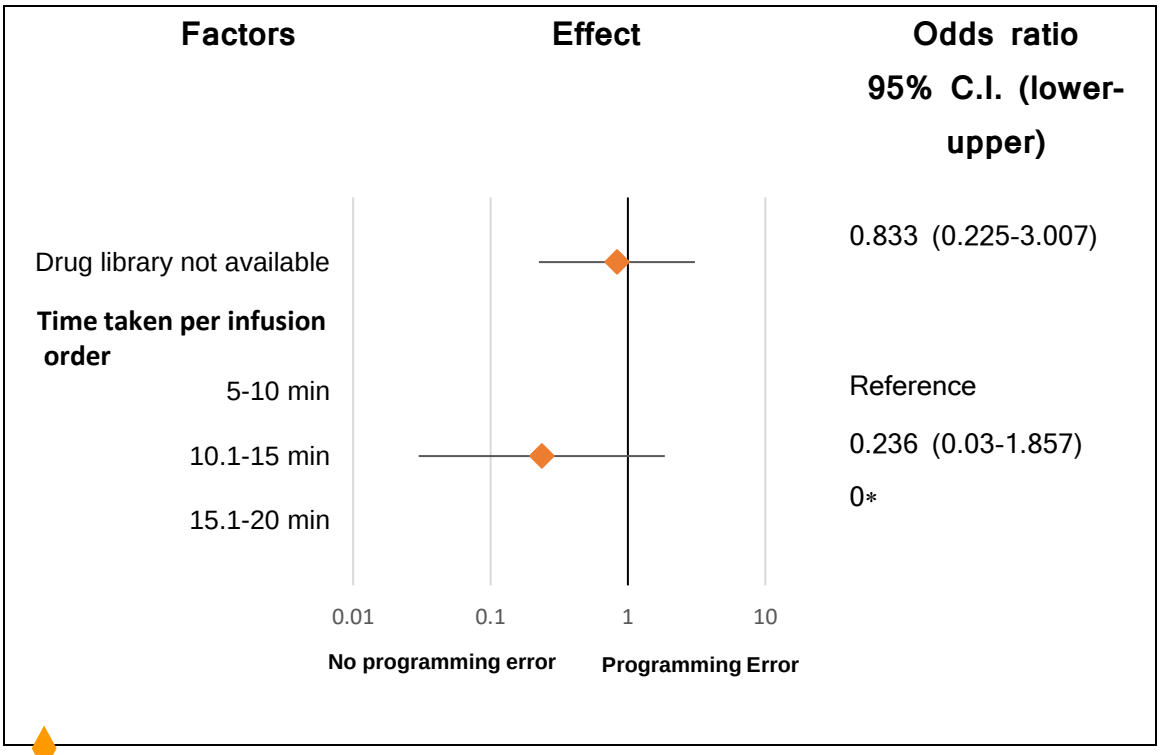

Figure 4.5.c shows the results of binary logistic regression analysis to predict likelihood of programming error due to drug library availability and time take per infusion order.

Represents odds ratio and — denotes upper and lower C.I. for odds ratio

* The value <=0 is not plotted in forest plot

4.6 POST-SIMULATION FEEDBACK SURVEY

This section will present the findings of a post-simulation survey that contains three questions related to demographics, eight Likert-style items on a scale of five from strongly agree to strongly disagree and two open-ended questions. Statistical analysis related to demographics is presented in the first section of this chapter (see section 4.2). Therefore, data from the remaining items on the questionnaire are presented in this section.

The researcher divided the questions into two subcategories for the analysis: 1) Questions related to the degree of difficulty of the administration process (Likert item no 4, 7, 9 & 11);

2) and Questions related to the safety of the administration process (Likert item no 5, 6, 8 & 10) (see Appendix D). The researcher will present the frequency of responses to each statement in percentage.

4.6.1 Perception of participants about the easiness of the administration process in maternal & new-born EHR

Error! Reference source not found.Error! Reference source not found. shows the responses of the participants to the statement- "overall the administration

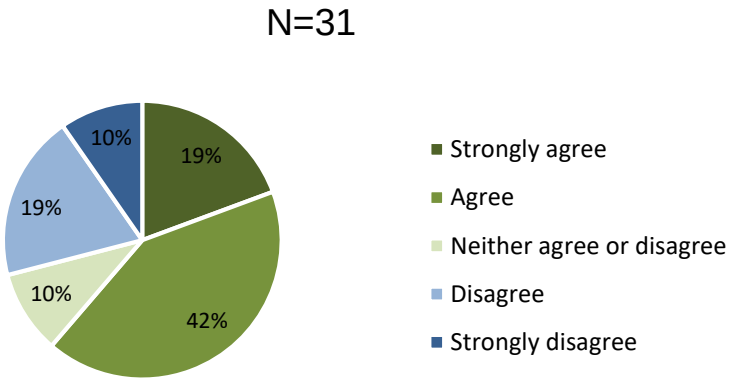

Figure 4.6.a Depicts frequency distribution (%) of responses to questions related to easiness of process of overall administration process in Maternal and new-born EHR

process in Maternal & new-born EHR is easy to implement". It indicates that the majority of the participants (62.4%, n=19) agreed/ strongly agreed that the steps of the administrative process examined in the study would be easy to implement in the real clinical scenario.

Figure 4.5.b portrays the responses to the statement related to the of the process at different stages of the administrative process. Nearly 84% participants were strongly agreed/agreed that programming the infusion pump was easy whereas only 48% participants agreed/strongly agreed that labelling the syringe was easy. About 64% participants reported that transcribing the prescription was easy.

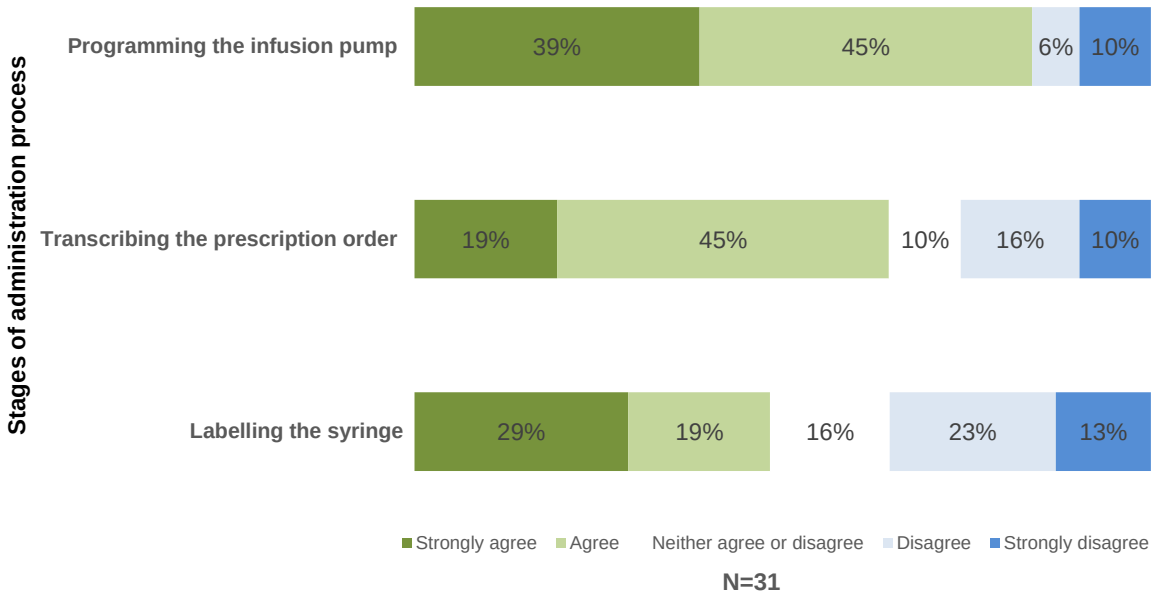

Figure 4.6.b Depicts frequency distribution (%) of responses to questions related to easiness of process at different stages of administration process

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4.6.2 Perception of participants about the safety of the administration process in maternal and new-born EHR

This section presents the findings of the responses of questions related to the safety of the steps of the administration process examined in the study. About two-third of the participants (67.8%) of the participants were agreed/ strongly agreed with the statement that the steps of the administration phase examined in the study are safe to implement in real clinical scenario (see Figure 4.6.c).

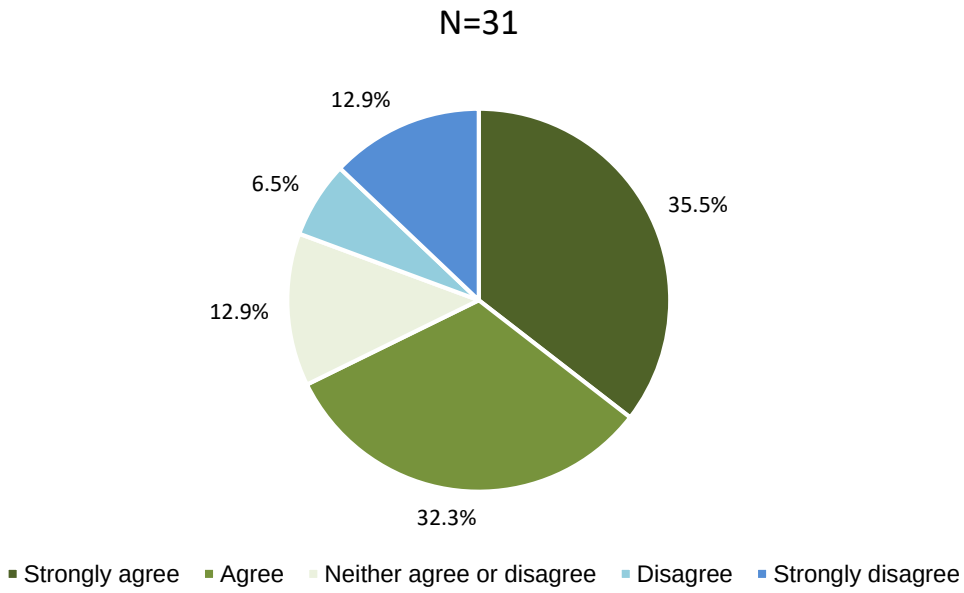

Figure 4.6.c Shows the responses to an item- overall the administrative process in maternal and new-born EHR is safe to implement in real scenario

The majority of participants were agreed/ strongly agreed that the programming the pump (84%) and transcribing the prescription order (62%) are safe in maternal and new-born EHR. However, only 48% of the participants felt that the labelling the syringe is safe in maternal and new-born EHR (see Figure 4.6.d).

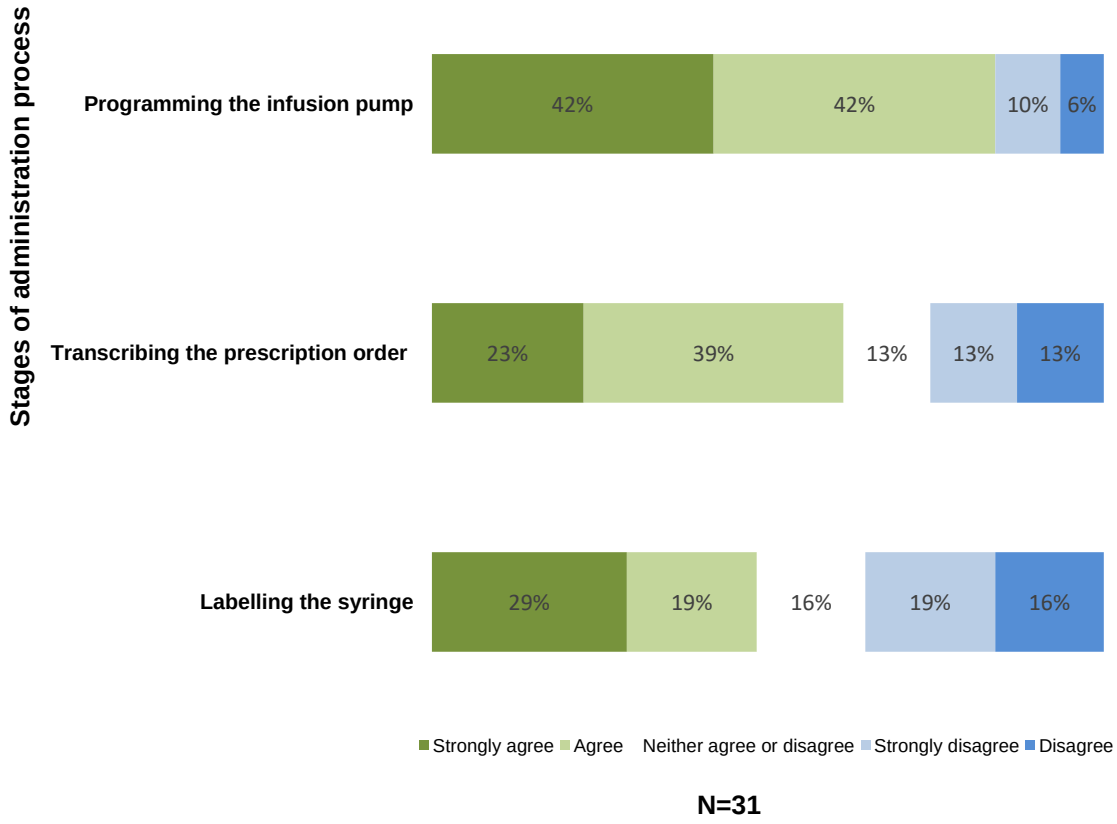

Figure 4.6.d Depicts frequency distribution (%) of responses to questions related to easiness of process at different stages of administration process

4.6.3 Perception of the participants about the simulation session and the administration process

Table 4.6.A shows participants perception of the simulation session. Only two third of the participants responded to the question (64.5%, n=20). More than one-third of participants (38.7%, n=12) reported that they were concerned about the clarity of the prescription order especially the starting dose and concentration in the order. One fifth of the participants mentioned the necessity of practice and concentration to avoid errors (19.4%. n=6). Few participants (12.9%, n=4) also mentioned the screen display (small font size height of monitor) and needed to switching from one screen to another to check the prescription order as circumstances that can cause errors in the administration process.

Table 4.6.A Perception about the simulation session and process

Responses	PERCENTAGE OF PARTICIPANTS (N=31)
Unclear about content prescription order like starting dose, concentration of infusion	**38.7**
Need practice and concentration	**19.4**
Display problems like font size, height of monitor and need of switching from one screen to another screen	12.9
Enjoyed the simulation session	12.9
Difficulty in labelling process	9.7
No response	35.5

Participant's suggestions to improve the administration process in Maternal and newborn EHR are listed in Table 4.6.B. More than half of the participants (51.6%, n=16) felt that printed labels or standard label template can decrease the errors at the labelling stage of the administration process. Further, nearly one-third of the participants (32.3%, n=10) suggested some amendments to prescription order like adding concentration, drug volume, highlighting starting dose and patients' details.

Table 4.6.B Participant's suggestions to improve the administration process in Maternal & New-born EHR

SUGGESTIONS	PERCENTAGE OF PARTICIPANTS (N=31)
Printed labels / standard template for labels	**51.6**
Amendments to prescription like adding concentration, highlighting starting dose and patient's details, adding volume of drugs and area for nurses to acknowledge the dose	**32.3**
Need for full drug protocols	9.7
Practice session	9.7
Prepared by pharmacy	6.5
Display suggestion like large font size, one drug at a time	6.5
Double checking with another person	3.2
No response	19.4

4.7 FINDINGS OF OBSERVATION DURING SIMULATION SESSION

The majority of the participants were not sure of the prescribed dose, and they confused the default start dose with the prescribed dose. Interestingly, the majority of the participants utilised most of their time to the process of calculating the concentration, and they were confused about the prescribed concentration. Initially, nearly half of the participants did not recognise that they must find the concentration before programming the pump. Almost all the participants took more time to finish their first prescription order than the subsequent orders.

4.8 SUMMARY

This chapter presented the results of the study. Changes in the clinical work-flow in Maternal and newborn EHR at the administrative phase of high-risk infusions led to programming errors and labelling deviations in the simulated environment. Programming errors were less frequent, but the majority of these errors caused more than ± 10% deviation from the prescribed dose. Further, more than half of the programming errors fall in category 'C' and 'D' (i.e. error but no harm) on the NCC-MERP index. Binary logistic regression analysis was portrayed to predict the factors that can increase the likelihood of programming errors and revealed that every increase in labelling deviation could increase the risk of occurrence of a programming error. Lastly, the researcher presented the findings of post-simulation survey and observations made during a simulation session.

The next chapter will appraise and discuss the results of the study to answer the research questions and to reflect on the present literature.

CHAPTER 5 DISCUSSION

This chapter aspires to evaluate and analyse the results presented in the previous chapter to answer the research questions stated in section 1.4 and to reflect on the literature review.

5.1 INTRODUCTION

Before interpreting the results of the study, I would like to reiterate the goal of this study which is to evaluate the clinical workflow in upcoming maternal & new-born EHR at the administrative phase of high-risk infusions in NICU and identify patient safety issues.

5.2 TYPES AND NUMBER OF IDENTIFIED MEDICATION ERRORS

Ohashi *et al.*, (2013) investigated the medication administration errors and reported that programming errors and labelling errors are prevalent even after the introduction of SIP technology. Similar to Ohashi *et al.*, (2013), when compared with labelling standards, numerous labelling deviations (n=722) were discerned in the current study which could pose a risk to patient safety in real scenarios.

There are very few studies identified in the literature that investigate the discrepancy between programmed dose and prescribed dose. Russell *et al.*, (2010) reported 24% discrepancies in programming when compared to the prescription orders. Whereas, this study found only 12% discrepancies in the programming and only half of those discrepancies led to more than ±10% deviation from the prescribed dose. It is critical to know how and why these discrepancies occur so that necessary steps can be taken to make the MUP safer. There are very few evidence in the literature that explained the reason behind these discrepancies. The next section will analyse these errors against the changes in clinical workflow to identify the cause behind these discrepancies.

5.3 ANALYSIS OF IDENTIFIED RISKS AGAINST CHANGE IN CLINICAL WORKFLOW AND POTENTIAL RISK TO PATIENT SAFETY

Human factors engineering research acquainted that an increase in cognitive workload as a consequence of changes in workflow enhances the risk to patient safety (Harrison *et al.*, 2007). The following were three main changes identified in the clinical workflow of administration process of high-risk infusions in the upcoming EHR identified;

1. Retrieving information from the system,
2. Computing the prescribed concentration, and
3. Preparing syringe labels (see Table 1.3.A).

5.3.1 Effect of change in the process of retrieving information from the system

Given it is the first exposure to the proposed MN-CMS, most of the participants perceived the retrieval of information was easy and safe (Figure 4.6.b and Figure 4.6.d). That was evident in the analysis of actual data collected during the session as 87.7 % percent of the participants retrieved the right information from the system in the simulation session. Wrong concentration programmed or labelled was not considered an information retrieval error as these are mainly due to wrong computation rather than information retrieval. After excluding those infusion orders with the wrong concertation programmed or labelled, only nineteen infusions had wrong information programmed (n=12) or labelled (n=19).

The participants needed mainly five parameters from the system to program the infusion: prescribed drug, working weight, prescribed dose, drug amount and rate of infusion. Fourteen programming parameters in thirteen prescription order were not programmed as prescribed. After a thorough analysis of the programming errors, it was found that the actual reason for the discrepancy was rounding off rather than retrieval of information (see Table 4.4.A and Table 4.4.B) and all of these proceeded to less than ±10% deviation from the prescribed dose which can be considered as clinically insignificant. Like Ohashi

et al., (2013) and Manrique-Rodríguez *et al.*, (2014a), this study also found programming of wrong parameter 'weight' and 'dose' in the rest of eight infusions. The detailed analysis of programming errors by Ohashi *et al.*, (2013) revealed that human programming error like selecting the wrong drug and pushing a key to change the number, of errors was the common reason for a programming error. Likewise, in the current study, there is probability that participants may have erroneously pressed the key while programming the infusion. For example in the prescription order no 86 and 87, the participant might have pressed the key one extra time and programmed weight 0.79 instead of 0.78. In the current study, only half of those errors (n=4) caused clinically significant deviation from the prescribed dose but there is probability that nurses can select the wrong drug or from the drug library that can lead to significant deviation from the prescribed dose. Thus, one can say that it is less likely that any change in the information retrieval process would pose a clinically significant risk to patient safety.

5.3.2 Effect of the need of computation of prescribed concentration

The next change in the clinical workflow of high-risk infusions administration process is the necessity of calculation of the prescribed concentration which can increase the cognitive workload on the nurses (Trbovich *et al.*, 2013). However, during the simulation session, many of the participants did not recognise the need to calculate the concentration until they started programming the infusion. One explanation for this finding may be due to the change in the prescription parameters in the upcoming system as the prescribed concentration is already mentioned on the prescription labels in the existing system.

In this study, only 6.3% (n=8) of all the prescription orders (N=127) with drug library option, had the incorrect drug concentration programmed (see Table 4.4.A &Table 4.4.B). Discrepancies related to the wrong concentration except one (prescription order no 2) led to more than ±10% deviation from the prescribed dose which is clinically significant and carries the risk of real harm to the patient in the actual setting. Though there was no deviation from the prescribed dose in prescription order no 2, it cannot be ignored as it presents

wrong clinical information. In this scenario, the clinician can think the patient is getting 5 mcg/kg/min of dopamine as displayed on the pump but the patient will be receiving 10 mcg/kg/min. Particularly in situations where the patient has not improved, and the clinician decides to increase the dose, it could have a detrimental effect. Furthermore, all the prescription orders with a programmed wrong concertation error led to more than 90% deviation from the prescribed dose in this study. These were categorised as category 'D' errors (i.e. error with no harm) on NCC-MERP index in the study as there was no involvement of the patient. However, if these errors reach the patient in a real scenario, these can lead to category 'E' to 'I' on the NCC-MERP index (i.e. error and harm/death). Hence, these study findings confirmed that the increased need for computation at the administration phase of high-risk infusions could increase cognition workload that has potential to enhance the risk to patient safety in the real settings.

5.3.3 Effect of preparing syringe labels

Incomplete or inaccurate labelling of high-risk infusions in intensive care unit is recognised risk factor for patient safety (ACSQHSC, 2015). The nurses working in the study unit will be preparing hand-written syringe labels for high-risk infusions due to the lack of integration of future EHR with the current label printer. As these are continuous infusions and prepared for 24 hours, syringe labels are the way vital information about the infusion characteristics are communicated. U.S. Food and Drug Administration, (2015) also recommends the checking of syringe labels and programming parameters at the change of shifts to ensure patient safety at the administration phase. Moreover, there are frequent changes made in infusion rate of high-risk infusions in the intensive care unit depending on the condition of the patient. In that case, incomplete or inaccurate information on the labels can increase the risk of errors occurring greatly (Ohashi *et al.*, 2013).

Incomplete labelling of IV infusions had been reported previously by Ohashi *et al.*, (2013). Similarly, this study also found that almost all the labels had one or more missed parameters. Further, it is apparent in Figure 4.3.d that concentration and weight were the most common missed parameters out of

all the vital parameters which are compulsory to cross-check the setting of the infusion pump during the change of shift and to change the dose of the infusion. However, one can only speculate so as to the clinical significance of these errors, but the incomplete labelling could adversely affect clinical decision making and can probably cause inappropriate changes in therapy and clinician uncertainty about drug administration.

The results of binary logistic regression analysis shown in Figure 4.5.b indicates that every increase in labelling errors enhances the risk of occurrence of a programming error. Additionally, more than half of the participants also felt that the labelling the syringe is neither easy nor safe (see Figure 4.6.b and Figure 4.6.d) and suggested that the unit should have printed labels or a standard template (see Table 4.6.B). Above discussion confirmed that preparing syringe labels in the simulation session enhances the error rate at the labelling stage which can negatively impact patient safety. Moreover, it is more time-consuming as well. This study showed that the average time taken per infusion to complete the whole process was 9.21±2.64 minutes which can be significantly cut by the introduction of printed labels or standard template in upcoming EHR.

5.4 Analysis of errors in administration process relation to the demographics

Few studies reported that the age, NICU experience and knowledge of the use of drug library could significantly reduce the risk of medication errors (Westbrook *et al.*, 2011). However, on the contrary to previously reported findings by Westbrook *et al.*, (2011), this study did not find any statistically significant relationship between NICU experience and occurrence of a programming error. The results of logistic regression analysis found that the nurses aged between 31-40 years are less likely to have a programming error in comparison to nurses aged between 20-30 years. Whereas, there was no statically significant difference in the occurrence of programming errors in other age-groups (see Figure 4.5.b). Further, the study also examined the availability of drug library and time taken per infusion order and the likelihood of occurrence of programming error but could not able to find any statistically significant

relationship. However, it is more likely in a real clinical setting that if the system could make these processes less time-consuming, the nurses could able to concentrate more important activities in the critical area.

5.5 SUGGESTIONS TO IMPROVE THE ADMINISTRATIVE PROCESS IN MATERNAL AND NEW-BORN EHR

Real end-users input plays a vital role in improving the clinical workflow in any system (Sligo *et al.*, 2017). Although, the participants perceived the steps of the administration process examined in this study as safe and easy. They suggested some changes to make the process more efficient in real clinical settings. For example, nearly half of the participants in this study intimated that having printed labels or a template would increase efficiency and reduce the difficulty. Further, one-third of the participants also proposed adding the concentration parameter in the prescription as well as highlighting the start dose in the prescription order. Other potentially better practice suggestions included having practice sessions, preparation of high-risk infusions by the pharmacy and double checking with another person to reduce the risk of errors.

5.6 SUMMARY

The discussion of the results of the study in the above sections revealed that the changes in the clinical workflow in upcoming Maternal and new-born EHR could potentially increase the risk to patient safety. The need to calculate the drug concentration in the proposed new work-flow led to increased programming errors that could be detrimental to the patient. The results of this study suggest that the lack of integration of a label generation process (i.e. linked label generation and printing) can pose a risk to patient safety, especially in the intensive care setting. However, the identified risks can be reduced by modifying prescription orders (adding concentration and highlighting the starting dose) and integrating label printer with the upcoming EHR.

5.7 CONCLUSION

This chapter discussed the results of the study to answer the research question which was the evaluation of clinical work-flow at the administration phase of high-risk infusion in upcoming maternal and new-born EHR to identify potential errors and consequently estimation of potential risk to cause patient harm. This chapter also presented the end-users' suggestions to make the clinical workflow more efficient.

The next chapter will impart the strengths and limitations of the study. The chapter will also inform the reader about dissemination of findings, the implication for the organisation to improve quality and recommendation for future research.

CHAPTER 6 CONCLUSION

The concluding chapter outlines the strengths and limitations of the research study, identifies areas for future research along with the implications for the organisation in improving the quality of patient care and avoiding medication errors. The researcher concludes the chapter with a reflection on the research process.

6.1 INTRODUCTION

While all research studies have strengths and limitations, this section describes the strengths and limitations of this study.

6.1.1 Strengths of the study

The first strength of this study is the research methodology utilised to answer the research question that enabled the researcher to design a near to high fidelity simulation study. The simulation environment offered some unique benefits. It allows the researcher to examine the administration process of high-risk infusion in great details, in a standardised environment and allowed to involve the real end-users of upcoming EHR in the study unit. This methodology enabled the research to identify the types of errors that could occur with severe consequences should they be repeated in the real world of clinical practice. Another benefit of this approach was that the errors could be made safely as no patient involved and learning can still occur. Additionally, due to mixed method approach utilised for data collection in this research enabled the researcher to identify the reason for errors which have not previously mentioned in the literature.

The Irish health system is moving from paper records to electronic health records. However, it is critical to evaluate the clinical workflow of error-prone processes before implementation. This study demonstrated the feasibility of a clinical simulation method to assess the clinical workflow of high-risk processes before deployment of a new system which will help the organisation to improve the processes before go-live. The qualitative data collected illuminated end user's feelings and perceptions of the changed workflow and valuable yet

insightful suggestions to improve the process which is critical for the successful implementation of any system.

6.1.2 Limitations of the study

While all research studies, to some degree, will suffer from limitations, this section outlines the limitation of this study. Firstly, due to time constraints, the study only examined some steps of the administration phase of MUP, and there is a chance of errors occurring at the other steps like the preparation and documentation phase of the administration process. Secondly, in real clinical settings, the nurses double check the prescription orders with another nurse that can intercept the errors before they reach the patient whereas due to staffing constraints, this study only involved one nurse per session. However, the participants have kept away from the clinical responsibilities during the simulation session which enabled them to concentrate on the process in this study whereas clinicians can have numerous interruptions during MUP in a real clinical setting which can cause more errors.

Thirdly, the researcher used the mature prototype of the system to examine the clinical workflow rather than the actual system so the effect can be different when using the 'real' system. Nonetheless, this study provided baseline data to examine the effect of interventions used so as to improve the system in the future. Data collected using observation can be subject to the Hawthorne effect resulting in changed behaviour that was not reflective of the real clinical scenario. Finally, this was the first time participants were exposed to the system which can lead to more errors that can be mitigated with more exposure, practice and education sessions before implementation.

6.2 Recommendation for future research

As this study looked at only a few steps of the administration phase of high-risk infusions using a prototype in a simulated environment future research should examine the whole MUP in a real clinical environment using the actual system. Like this study, the researcher recommends evaluation of error-prone processes in a simulated environment to identify the potential risk to patient safety. Once the MN-CMS has been implemented and embedded, it would be beneficial to look at the number or medication errors and compare both to the number of actual errors before the EHR and during the simulation sessions.

6.3 Implication for organisation management and quality

The researcher recommends the closed loop medication system as described in Figure 2.4.a to mitigate the risk of identified error in the study at the administration phase of high-risk infusions in MUP. However, as the study unit is very near to implementing the Maternal and new-born EHR and there is insufficient time to do. However, the researcher recommends that some changes in the prescription order like the addition of concentration and highlighting starting dose to decrease the cognitive workload on the nurses should be strongly considered. Such changes have the potential to reduce the risk of medication errors. Additionally, either a label printer should be integrated with upcoming EHR or a standard template for syringe labels be designed to reduce labelling discrepancies. Finally, the organisation should support the evaluation of clinical workflow around high-risk processes in a simulated environment to identify potential risk to patient safety before implementation of the new systems in the organisation. Education and practice sessions in preparation for the new system can be tailored to highlight the error-prone processes and how they can be avoided.

6.4 Dissemination of findings

A truncated version of the results will be submitted to the neonatal medication safety committee in the study unit that may help the unit to take necessary steps to reduce the identified risk and enhance patient safety. A final copy of the research study will be made available to the organisation and participants if they wish. The researcher hopes to publish the results in a respected journal such as Irish journal of medical sciences and present at local and international conferences.

6.5 Reflections on the research process

This section presents the personal reflection of the research process and lessons learned during the process. It is imperative to select a topic for research that suits as per given time frame. Initially, the researcher decided to evaluate the two error prone phases of MUP (administration as well as prescription), but one of the supervisors advised to narrow down the scope due to the given shorter time frame. Hence, the researcher decided to evaluate only error prone steps at the administration phase of high-risk infusions.

Additionally, it is important to choose the right study design that is suitable for answering the research question. The researcher adopted the evidence-based approach recommended by Jensen *et al.*, (2015) to design clinical simulation study to evaluate the clinical information system. The steps recommended by Jensen *et al.* (2015) helps to identify several issues throughout the process. For instance, this approach suggests performing rehearsal before the actual simulation session to identify any issues. Thus, after the rehearsal session, the researcher modified the prescription pdfs and included the medication protocols as well. The later version impersonates the maternal and new-born EHR as the links of the protocol will be available to the end-users in the real system. Another difficulty faced was the recruitment of participants for the study. However, one of the supervisors advised approaching the participants individually to increase the involvement. The potential participants were personally approached to explain the purpose and benefits of the study and clear the doubts. Overall, the whole research process was challenging, but many lessons were learnt throughout the process, and the experience was gained.

6.6 CONCLUSION

This chapter confers the strengths and limitations of the study along with the implications for the organisation management and recommendation for future research. This study presented the identified potential errors and their severity to cause potential harm during the administration phase of high-risk infusions in upcoming maternal and new-born EHR. The personal reflection was presented to share the experiences and lessons learned throughout the research process.

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APPENDICES

Appendix A. COMPARISON OF LABELLING PARAMETERS

Parameters to be included in the syringe labels	Currently used label	Recommended by ISMP (ISMP, 2010)	Recommended by (Australian Commission on Safety and Quality in Health Care ACSQHSC, 2015, p.18)	Specific for neonatal population (Larsen *et al.*, 2005)
Patient's Name	√	√	√	√
Weight	√			√
Drug Name	√	√	√	√
Concentration	√	√	√	√
Starting dose	√	√		√
Start rate of infusion	√	√		√
Preparation date	√		√	√
Preparation time	√		√	√
Signature	√	√	√	
Hospital number	√	√	√	√
Drug volume	√			
Drug amount		√	√	
Diluent added	√	√	√	√
Route	√	√	√	
Dose range	√			
Expiration date		√		

Appendix B. CLINICAL SCENARIOS FOR CLINICAL SIMULATION

Scenarios to be used for dinical simualtion

	Weight(KG)	RES/Non Restric	Infusion	Dose	Rate of infusion	drug to be added	concenteration
1	0.5	Restricted	Morphine	10	0.1	2.5	50
	0.5	Restricted	Dopamine	10	0.1	150	3000
	0.5	Restricted	Insulin	0.05	0.13	10	0.2
	0.7	Non Restrictive	Insulin	0.02	0.14	5	0.1
	0.7	Non Restrictive	Morphine	7	0.1	2.5	50
2							
	3.9	Non Restrictive	Milrinone	0.5	0.59	10	200
	3.9	Non Restrictive	Fentanyl	1	0.78	250	5
	4	Restricted	Fentanyl	1	0.4	500	10
	4	Restricted	Vasopressin	0.3	0.18	20	400
	4	Restricted	Dopamine	10	0.48	250	5000
3							
	4.3	Restricted	Fentanyl	2	0.86	500	10
	4.3	Restricted	Dopamine	15	0.77	250	5000
	4.3	Restricted	Midazolam	3	0.77	50	1000
	0.9	Non Restrictive	Midazolam	1	0.27	10	200
	0.9	Non Restrictive	Morphine	15	0.27	2.5	50
4							
	0.78	Non Restrictive	insulin	0.02	0.16	5	0.1
	0.78	Non Restrictive	Morphine	8	0.12	2.5	50
	0.6	Non Restrictive	Morphine	10	0.12	2.5	50
	0.6	Non Restrictive	insulin	0.05	0.3	5	0.1
	0.6	Non Restrictive	Dopamine	10	0.24	75	1500
5							
	3.5	Restricted	Dopamine	15	0.63	250	5000
	3.5	Restricted	Milrinone	0.5	0.53	10	200
	3.5	Restricted	fentanyl	2	0.7	500	10
	2.8	Non Restrictive	fentanyl	1	0.56	250	5
	2.8	Non Restrictive	Dopamine	10	0.56	150	3000
6							
	0.5	Non Restrictive	Morphine	10	0.1	2.5	50
	0.5	Non Restrictive	Dopamine	10	0.2	75	1500
	0.5	Non Restrictive	insulin	0.06	0.3	5	0.1
	0.7	Non Restrictive	insulin	0.03	0.21	5	0.1
	0.7	Non Restrictive	Morphine	10	0.14	2.5	50
7							
	4	Non Restrictive	Fentanyl	0.5	0.4	250	5
	3.98	RestrictedES	Fentanyl	2	0.8	500	10
	3.98	RestrictedES	Vasopressin	5	2.99	20	400
	3.98	RestrictedES	Dopamine	10	0.48	250	5000
	3.98	RestrictedES	Adrenaline	0.2	0.48	5	100
8							
	0.78	Non Restrictive	Morphine	10	0.16	2.5	50
	0.78	Non Restrictive	Dopamine	10	0.31	75	1500
	0.78	Non Restrictive	Adrenaline	0.2	0.16	3	60
	3.6	Restricted	Adrenaline	0.2	0.43	5	100
	3.6	Restricted	Milrinone	0.5	0.54	10	200
9							
	0.75	Non Restrictive	Insulin	0.05	0.38	5	0.1
	0.75	Non Restrictive	Morphine	7	0.11	2.5	50
	1.2	Restricted	Morphine	15	0.18	5	100
	1.2	Restricted	Insulin	0.02	0.12	10	0.2
	1.2	Restricted	Dopamine	5	0.12	150	3000
10							
	2.9	Restricted	Fentanyl	1	0.29	500	10
	2.9	Restricted	Vasopressin	3	1.31	20	400
	2.9	Restricted	Dopamine	15	0.52	250	5000
	3.8	Non Restrictive	Dopamine	8	0.61	150	3000
	3.8	Non Restrictive	Fentanyl	1	0.76	250	5

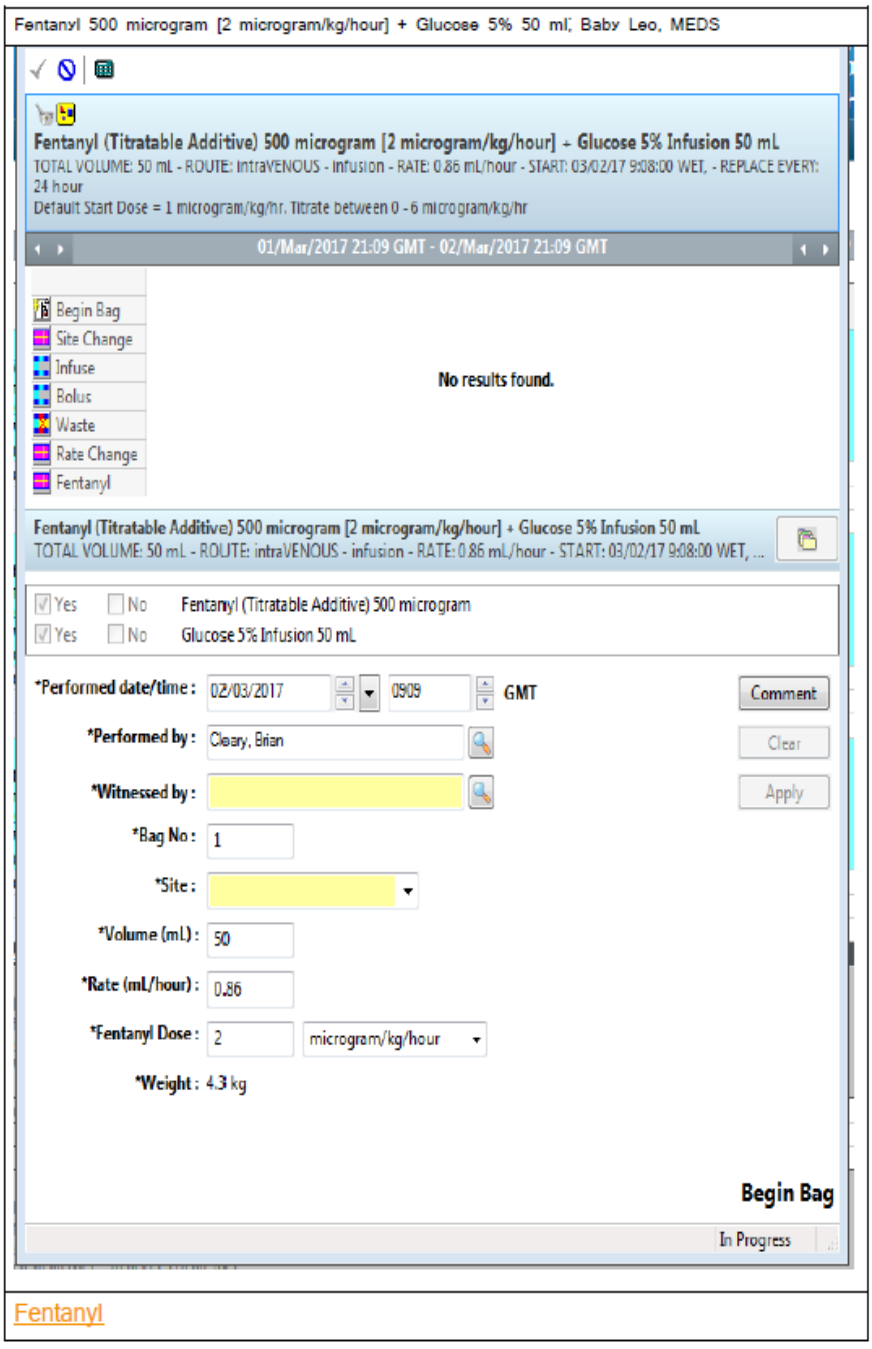
Appendix C. PDF OF INFUSION ORDERS USED

PRESCRIPTION ORDER SHEET

	Name: Baby Leo **MRN**: 432002 **Working weight**: 4.3 Kg Note: Fluid restricted		
A	**Fentanyl (Titratable Additive) 500 microgram [2 microgram/kg/hour]** **Glucose 5% Infusion 50 mL** **TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.86 mL/hour - START: 03/02/17 9:08:00 WET, - REPLACE EVERY: 24 hour** Default Start Dose = 1 microgram/kg/hr. Titrate between 0 - 6 microgra... **Administration Information** Fentanyl Glucose 5%	*continuous*	Fentanyl
B	**DOPamine 250 mg [15 microgram/kg/minute]** **Glucose 5% Infusion 50 mL** **TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.77 mL/hour - START: 03/02/17 9:11:00 WET, - REPLACE EVERY: 24 hour** Default Start Dose = 5 microgram/kg/min. Titrate between 2 - 20 microg... **Administration Information** DOPamine Glucose 5%	*continuous*	DOPamine
C	**Midazolam (Titratable Additive) 50 mg [3 microgram/kg/minute]** **Glucose 5% Infusion 50 mL** **TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.77 mL/hour - START: 03/07/17 15:15:00 WET, - REPLACE EVERY: 24 hour** Default Start Dose = 1 microgram/kg/min. Titrate between 0 - 4 microgram/kg/min **Administration Information** Midazolam Glucose 5%	*continuous*	Midazolam

	Name: *Baby May* ***MRN***: *433032* ***Working weight***: *0.9 Kg* *Note:*		
D	**Midazolam (Titratable Additive) 10 mg [1 microgram/kg/minute]** **Glucose 5% Infusion 50 mL** **TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - STA 03/07/17 15:18:00 WET, - REPLACE EVERY: 24 hour** Default Start Dose = 1 microgram/kg/min. Titrate between 0 - 4 microgram/kg/min **Administration Information** Midazolam Glucose 5%	*Continuous*	Midazolam
E	**Morphine (Titratable Additive) 2.5 mg [15 microgram/kg/hour]** **Glucose 5% Infusion 50 mL** **TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - STA 03/07/17 15:19:00 WET, - REPLACE EVERY: 24 hour** Default Start Dose = 20 microgram/kg/hr. Titrate between 0 - 20 microgram/kg/hr **Administration Information** Morphine	*Continuous*	Morphine

A Fentanyl



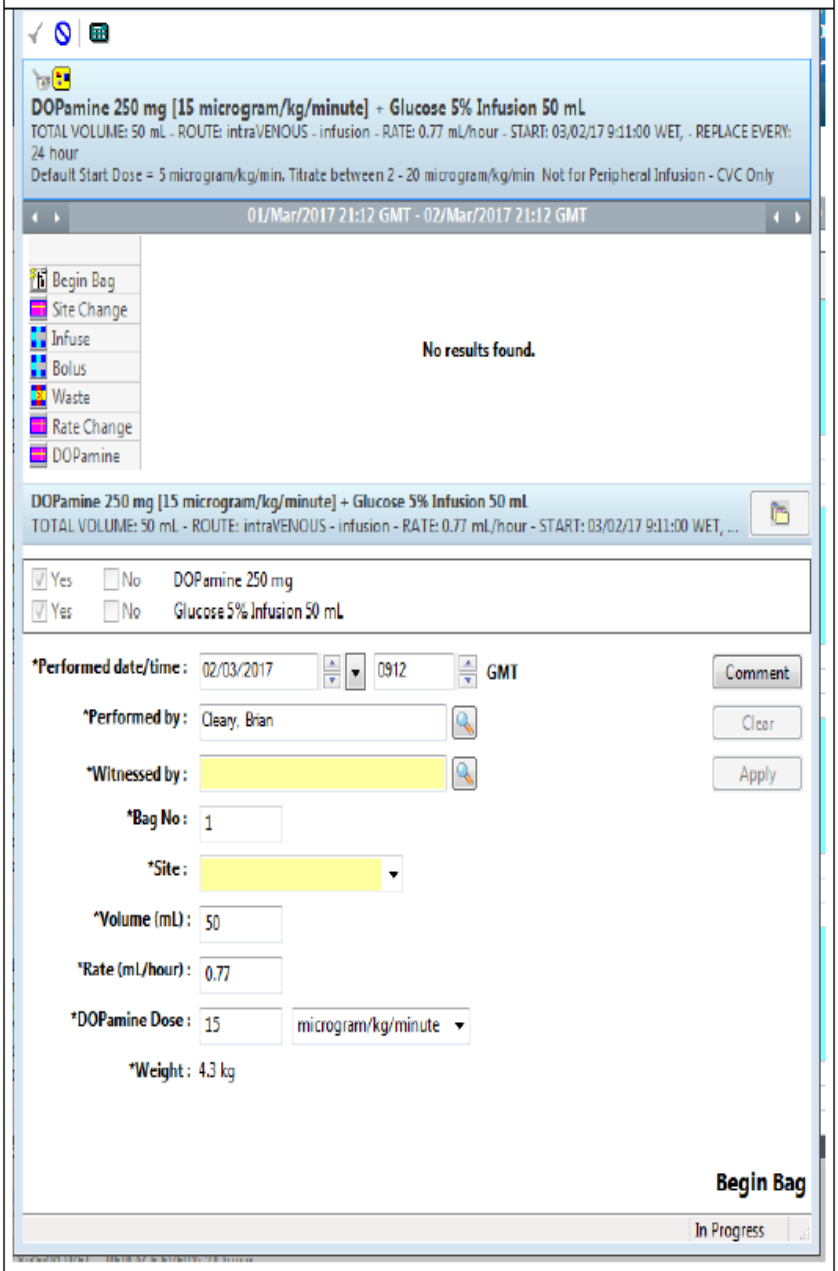
Fentanyl

2

Prescription_order_Sheet

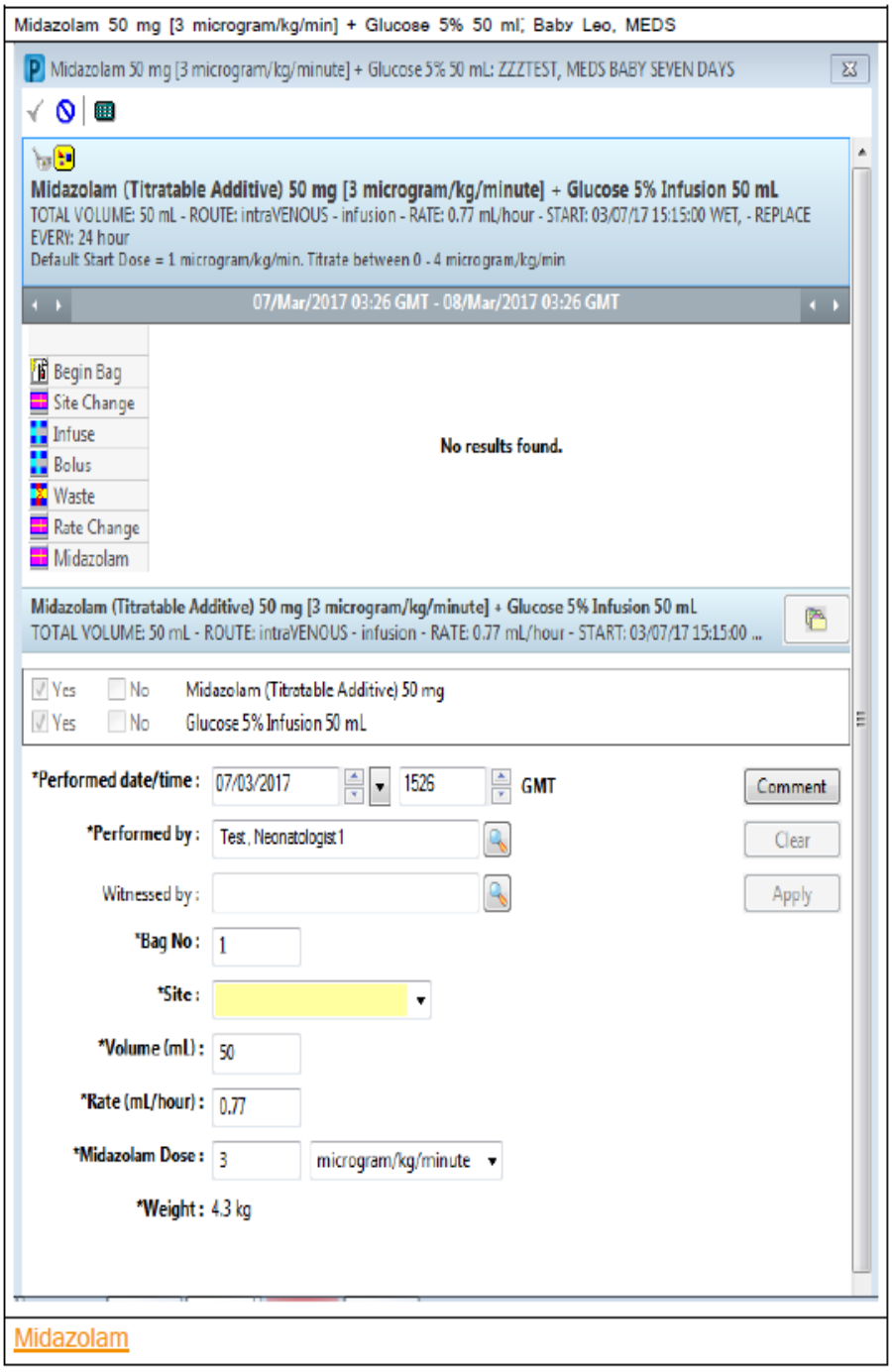
B DOPamine

DOPamine 250 mg [15 microgram/kg/min] + Glucose 5% 50 ml, Baby Leo, MEDS

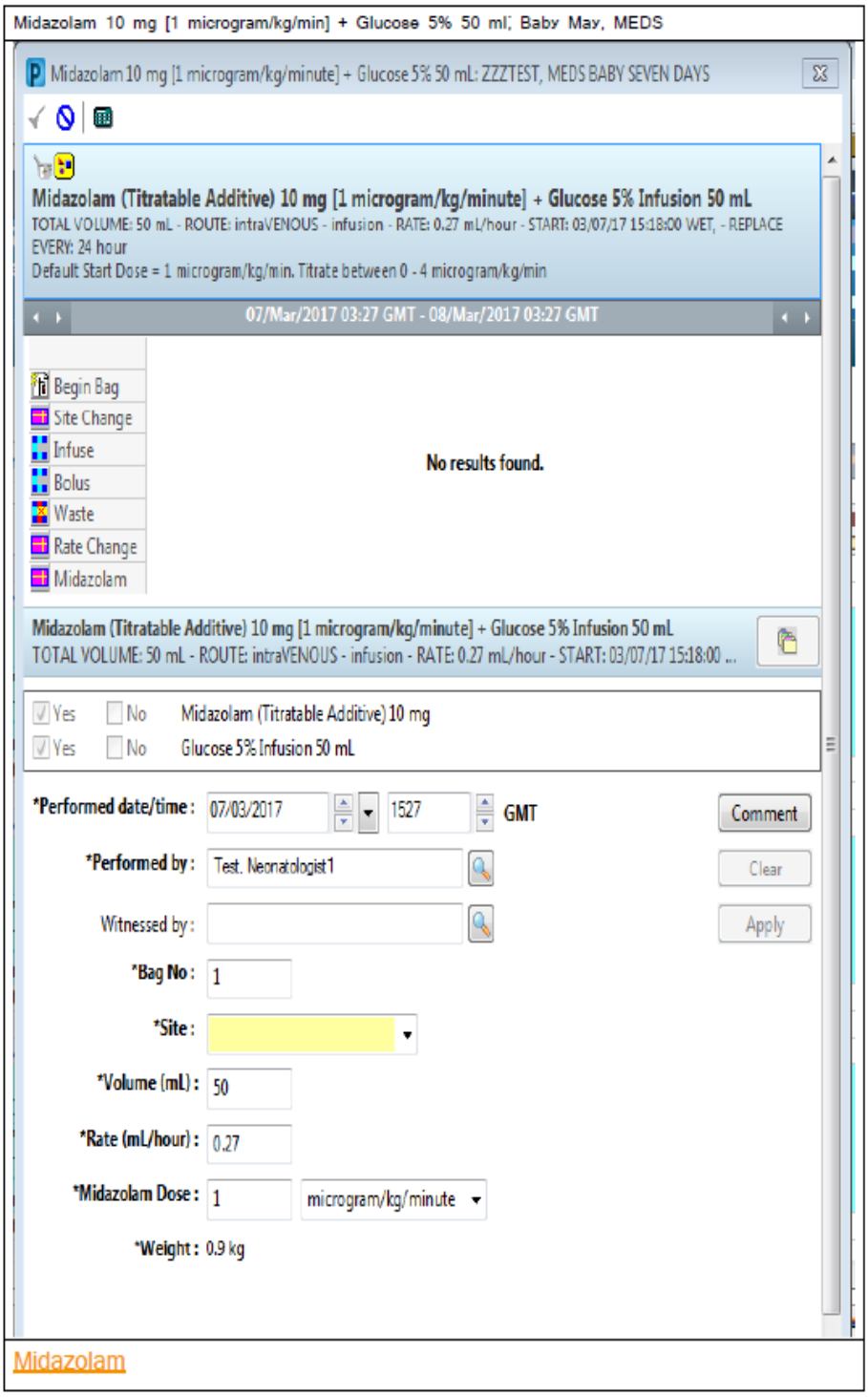


Dopamine

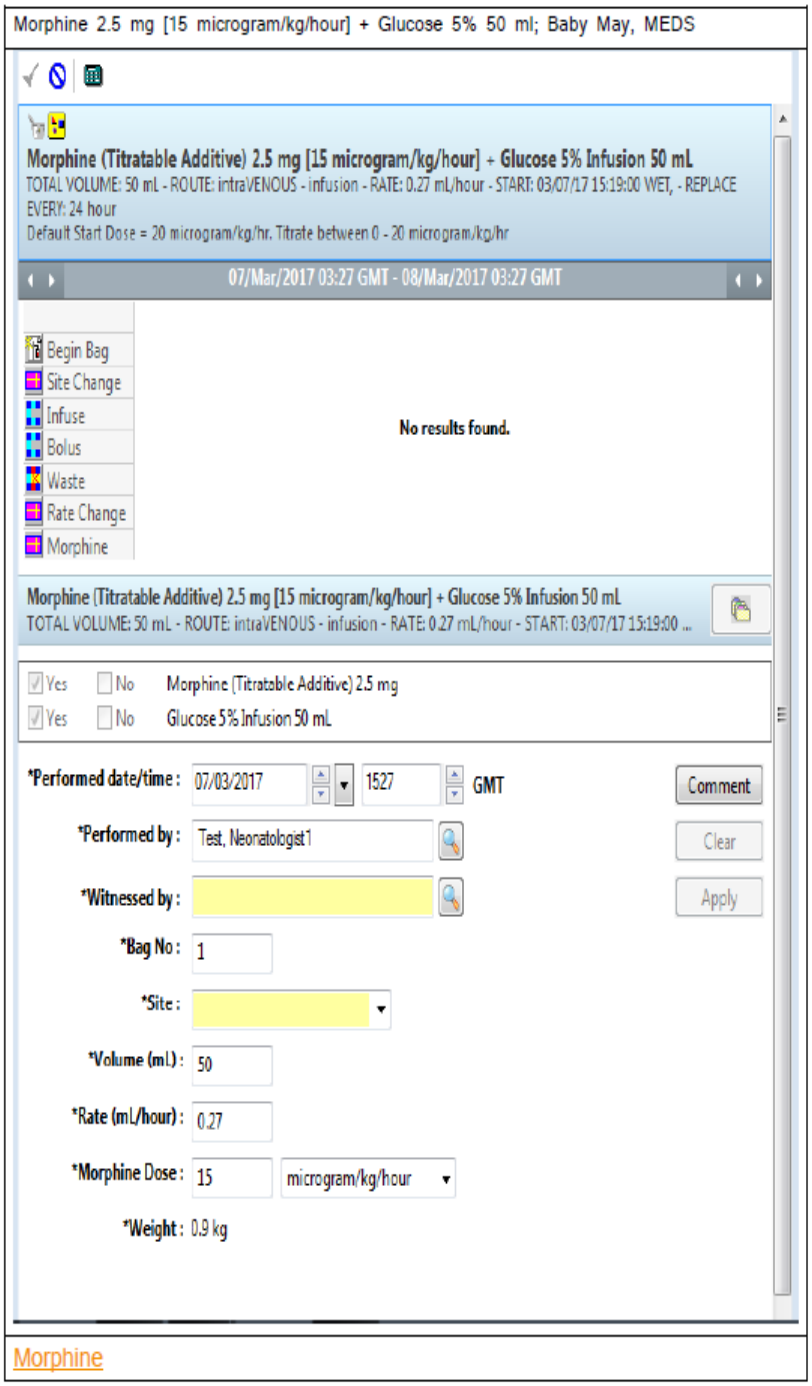
C Midazolam


Midazolam 50 mg [3 microgram/kg/min] + Glucose 5% 50 ml; Baby Leo, MEDS
Midazolam 50 mg [3 microgram/kg/minute] + Glucose 5% 50 mL: ZZZTEST, MEDS BABY SEVEN DAYS
Midazolam (Titratable Additive) 50 mg [3 microgram/kg/minute] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.77 mL/hour - START: 03/07/17 15:15:00 WET, - REPLACE EVERY: 24 hour
Default Start Dose = 1 microgram/kg/min. Titrate between 0 - 4 microgram/kg/min
07/Mar/2017 03:26 GMT - 08/Mar/2017 03:26 GMT
Begin Bag
Site Change
Infuse
Bolus
Waste
Rate Change
Midazolam
No results found.
Midazolam (Titratable Additive) 50 mg [3 microgram/kg/minute] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.77 mL/hour - START: 03/07/17 15:15:00 ...
Yes No Midazolam (Titratable Additive) 50 mg
Yes No Glucose 5% Infusion 50 mL
*Performed date/time: 07/03/2017 1526 GMT
Comment
*Performed by: Test, Neonatologist1
Clear
Witnessed by:
Apply
*Bag No: 1
*Site:
*Volume (mL): 50
*Rate (mL/hour): 0.77
*Midazolam Dose: 3 microgram/kg/minute
*Weight: 4.3 kg
Midazolam

D Midazolam


Midazolam 10 mg [1 microgram/kg/min] + Glucose 5% 50 ml; Baby May, MEDS
Midazolam 10 mg [1 microgram/kg/minute] + Glucose 5% 50 mL: ZZZTEST, MEDS BABY SEVEN DAYS
Midazolam (Titratable Additive) 10 mg [1 microgram/kg/minute] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - START: 03/07/17 15:18:00 WET, - REPLACE EVERY: 24 hour
Default Start Dose = 1 microgram/kg/min. Titrate between 0 - 4 microgram/kg/min
07/Mar/2017 03:27 GMT - 08/Mar/2017 03:27 GMT
Begin Bag
Site Change
Infuse
Bolus
Waste
Rate Change
Midazolam
No results found.
Midazolam (Titratable Additive) 10 mg [1 microgram/kg/minute] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - START: 03/07/17 15:18:00 ...
Yes No Midazolam (Titratable Additive) 10 mg
Yes No Glucose 5% Infusion 50 mL
*Performed date/time: 07/03/2017 1527 GMT
Comment
*Performed by: Test, Neonatologist1
Clear
Witnessed by:
Apply
*Bag No: 1
*Site:
*Volume (mL): 50
*Rate (mL/hour): 0.27
*Midazolam Dose: 1 microgram/kg/minute
*Weight: 0.9 kg
Midazolam

E Morphine


Morphine 2.5 mg [15 microgram/kg/hour] + Glucose 5% 50 ml; Baby May, MEDS
Morphine (Titratable Additive) 2.5 mg [15 microgram/kg/hour] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - START: 03/07/17 15:19:00 WET, - REPLACE EVERY: 24 hour
Default Start Dose = 20 microgram/kg/hr. Titrate between 0 - 20 microgram/kg/hr
07/Mar/2017 03:27 GMT - 08/Mar/2017 03:27 GMT
Begin Bag
Site Change
Infuse
Bolus
Waste
Rate Change
Morphine
No results found.
Morphine (Titratable Additive) 2.5 mg [15 microgram/kg/hour] + Glucose 5% Infusion 50 mL
TOTAL VOLUME: 50 mL - ROUTE: intraVENOUS - infusion - RATE: 0.27 mL/hour - START: 03/07/17 15:19:00 ...
Yes No Morphine (Titratable Additive) 2.5 mg
Yes No Glucose 5% Infusion 50 mL
*Performed date/time : 07/03/2017 1527 GMT
Comment
*Performed by : Test, Neonatologist1
Clear
*Witnessed by :
Apply
*Bag No : 1
*Site :
*Volume (mL) : 50
*Rate (mL/hour) : 0.27
*Morphine Dose : 15 microgram/kg/hour
*Weight : 0.9 kg
Morphine

Neonatal and Paediatric Pharmacists Group
Neonatal Medication Monograph

DOPamine

Dopamine has dose-dependent hemodynamic effects [1]. Low doses are mainly dopaminergic, (increased renal blood flow and urine output). Intermediate doses have dopaminergic and beta$_1$-adrenergic effects (increased renal blood flow, heart rate, cardiac contractility, cardiac output, and blood pressure). At high doses alpha-adrenergic effects begin to predominate (vasoconstriction and increased blood pressure) [1].

MEDICATION SAFETY ISSUES

- Misplacement of the decimal point in the calculation for preparing dopamine infusion was possibly responsible for the death of an infant [2].
- The Institute for Safe Medication Practices (ISMP) classifies dopamine as a high alert medication [1, 3].
- Sound-alike/look-alike issues: DOPamine may be confused with DOBUTamine [1, 3].

USES

To correct the haemodynamic imbalance due to acute hypotension, shock and cardiac dysfunction or failure [4].

PRESENTATION

DOPamine 40mg/ml in a 5 ml ampoule.

DOSAGE

Initially 5-10 micrograms/kg/minute, adjusted according to response (usual dose range: 2- 20 micrograms/kg/minute) [4].

The hemodynamic effects of DOPamine (dose-dependent) should be taken into consideration when selecting the dose of DOPamine, as outlined above.

A dose range should be specified indicating the minimum and maximum doses (in microgram/kg/minute).

RECONSTITUTION

Dilute DOPamine to one of the concentrations recommended in Table 1. Select the appropriate weight band. Then choose between regular or high concentration depending on the neonate's available fluid volume.

Table 1: Regular and high strength concentrations for DOPamine according to the patient's weight

Weight (kg)	DOPamine REGULAR CONCENTRATION	DOPamine HIGH CONCENTRATION (for patients with limited available fluid volume)
≤ 2.5	1,500 micrograms / ml	3,000 micrograms/ml
> 2.5	3,000 micrograms / ml	5,000 micrograms/ ml (CENTRAL administration ONLY)

LL

Prescription order Sheet

Alaris GH Pumps deliver a minimum flow rate of 0.1 ml/hr. The higher concentrations may result in a flow rate which is too low (< 0.1 ml/hr) for the pump to deliver. If the flow rate is below 0.1ml/hour, a lower concentration should be selected to get a flow rate that the pump can deliver. If none of the above concentrations are suitable a 500 micrograms/ml concentration can be used.

Dilution recommendations are provided in Table 2 below.

Table 2: Dilution recommendations for DOPamine concentration solutions

Concentration	Amount to add to the infusion fluid*	Volume to withdraw from the 40 mg/ml DOPamine ampoule	Volume of Infusion Fluid* (final volume in syringe is 50 ml)
500 micrograms/ml	25 mg	0.6 ml	49.4 ml
1,500 micrograms/ ml	75 mg	1.9 ml	48.1 ml
3,000 micrograms/ml	150 mg	3.8 ml	46.2 ml
5,000 micrograms/ml	250 mg	6.3 ml	43.7 ml

* Infusion fluid refers to Dextrose 5%, Dextrose 10% or Sodium Chloride 0.9%, as prescribed

ADMINISTRATION

- Dopamine is administered by continuous intravenous infusion. Refer to the "Alaris® GH Pump Protocol" for instructions on how administer Dopamine using the infusion pump.
- The 5,000 micrograms/ml standard concentration should be administered via central access **ONLY.**
- Always check for incompatibilities when administering medications terminally to lines containing other infusions. DOPamine is NOT compatible with strongly alkaline solutions such as sodium bicarbonate (inactivates DOPamine)[3].
- Ensure that every syringe is appropriately labelled.

SAMPLE CALCULATION

The correct infusion rate will be provided by the infusion pump given that the correct drug **and concentration** are selected and that the correct weight and dose are inserted in the pump. This rate should be checked with that printed on the prescription / syringe label and also manually using the relevant information from the "Neonatal Standard Concentration Infusion Table" as follows:

Drug Name	Weight band	Regular Concentration (RC)	Default RATE (ml/hr) for default start dose (RC)	Default START DOSE	High concentration (HC) for patients with limited available fluid volume	Default RATE (ml/hr) for default start dose (HC)
DOPamine	≤ 2.5 kg	* 500 micrograms/ml	0.6 x Wt (kg)	5 microgram/kg/minute		
		1,500 micrograms/ml	0.2 x Wt (kg)		3,000 micrograms/ml	0.1 x Wt (kg)
	> 2.5 kg	3,000 micrograms/ml	0.1 x Wt (kg)		5,000 micrograms/ml	0.06 x Wt (kg)

* Low concentration for use where flow rates below 0.1ml/hr occur with other concentrations- refer to monograph.

NB: The usual dose range is 2-20 micrograms/kg/minute.

Actual rate (ml/hr) can be calculated using the following formula:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{Prescribed\ Dose\ (Actual\ Dose) x\ Default\ Rate\ (ml\ per\ hour)}{Default\ Start\ Dose}$$

Note: Default rate is calculated by multiplying the default rate constant in the table above by the baby's weight- see sample calculation below:

Dopamine is prescribed for a 2.3 kg baby at a dose of 7 micrograms/kg/minute using a concentration of 1500 micrograms/ml:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{(7\ microgram/kg/minute)\ x\ (0.2\ x 2.3\ kg)}{(5\ microgram/kg/minute)} = 0.64\ ml/hr$$

STORAGE AND SPECIAL PRECAUTIONS FOR HANDLING

- Ampoules are for single use only. Any unused contents should be discarded [5].
- Do not use infusion if discoloured [5, 6].
- Store in original outer container to protect from light. Light protection not required during administration [6].
- Solution is stable for 24 hours after dilution [6].

MONITORING

- Continuous ECG and heart rate monitoring [3]. Continuous blood pressure monitoring if feasible.
- Hourly monitoring of urine output [3].
- Regular renal function and serum sodium and potassium monitoring (particularly during high dose regimens as decreased renal blood flow can occur) [3]
- If given peripherally, choose a large vein and monitor the injection site closely for phlebitis [3, 6]. **The 5,000 micrograms/ml concentration should ONLY be administered centrally.**
- Patients should be closely monitored for any changes in colour of the extremities [3, 6].

ADVERSE EFFECTS

Most common side-effects include vomiting, palpitation, tachycardia, vasoconstriction and hypotension [4].

Dopamine has a short duration of action and most adverse effects respond to stopping the infusion or reducing its rate [6].

REFERENCES

1. UpToDate, *Dopamine: Pediatric Drug Information*. 2015, Wolters Kluwer.
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Neonatal and Paediatric Pharmacists Group (NPPG)
Neonatal Medication Monograph

FentaNYL

Opioid analgesic

MEDICATION SAFETY ISSUES

- FentaNYL may be confused with alfentanil, SUFentanil [1]
- The Institute for Safe Medication Practices (ISMP) classifies fentaNYL as a high alert medication [1]
- Apnoea may occur with rapid bolus injection or with large doses. Peak respiratory depression occurs 5-15 minutes after dosing [2].
- Chest wall rigidity is related to high doses, rapid escalation to moderate doses [2] and rapid intravenous injection [3].
- Naloxone (opioid antagonist) injection and resuscitative equipment should be immediately available [4].
- Abrupt discontinuation following prolonged use may also lead to withdrawal symptoms; taper dose gradually when discontinuing [1].

USES

- To provide continuous analgesia, sedation and respiratory depression in mechanically ventilated neonates in intensive care [3, 4].
- In combination with other medications for intubation – see separate protocol.

PRESENTATION
50 micrograms / ml solution for injection [5].

DOSAGE [1, 4]

- Loading dose: 1-2 microgram/kg over 3-5 minutes, followed by:
- Continuous infusion: usual start dose is 1 microgram/kg/hr.
- Titrate carefully to effect.
- A dose range should be specified indicating the minimum and maximum doses (in microgram/kg/hour). The usual dose range is 0.5 - 2 micrograms/kg/hr [1].

Renal Impairment [4]
Avoid use or reduce dose.

RECONSTITUTION

Loading Dose

- Withdraw the required volume from the 50 micrograms/ml ampoule.
- Dilute this volume up to 2 ml.
- Administer by intravenous injection over 3-5 minutes.

Continuous Infusion

Dilute FentaNYL to one of the concentrations recommended in Table 1. Choose between regular or high concentration depending on the neonate's available fluid volume.

Table 1: Regular and high strength concentrations for FentaNYL (**not** weight-dependant)

FentaNYL REGULAR CONCENTRATION	FentaNYL HIGH CONCENTRATION (for patients with limited available fluid volume)
5 micrograms / ml	10 micrograms/ml

*The 5 micrograms/ml and 10 micrograms/ml concentrations are appropriate for the majority of neonatal infusions. A **minority** of neonatal infusions need to be prepared at different concentrations based on the unique needs of the neonate.*

Alaris GH Pumps deliver a minimum flow rate of 0.1 ml/hr. The higher concentration may result in a flow rate which is too low (< 0.1 ml/hr) for the pump to deliver. If the flow rate is below 0.1ml/hour, the lower concentration should be selected to get a flow rate that the pump can deliver.

Dilution recommendations are provided in Table 2 below.

Table 2: Dilution recommendations for FentaNYL concentration solutions

Concentration	Amount to add to the infusion fluid*	Volume to withdraw from the 50 micrograms/ml FentaNYL ampoule	Volume of Infusion Fluid* (final volume in syringe is 50 ml)
5 micrograms/ ml	250 micrograms	5 ml	45 ml
10 micrograms/ml	500 micrograms	10 ml	40 ml

* Infusion fluid refers to Dextrose 5% or Sodium Chloride 0.9%, as prescribed.

ADMINISTRATION

- FentaNYL is administered by continuous intravenous infusion. Refer to the "Alaris® GH Pump Protocol" for instructions on how administer FentaNYL using the infusion pump.
- Always check for incompatibilities when administering medications terminally to lines containing other infusions.
- Ensure that every syringe is appropriately labelled.

SAMPLE CALCULATION

Example 1: Loading Dose

A loading dose of 1 microgram/kg of fentaNYL is prescribed for a 3 kg baby.

- Dose: 1 micrograms x 3 kg = 3 micrograms.
- Withdraw the required volume from the 50 micrograms/ml ampoule: (3 micrograms x 1 ml / 50 micrograms) = 0.06 ml
- Dilute 0.06 ml (3 micrograms) up to 2 ml; (final concentration is 3 micrograms in 2 ml).
- Administer by intravenous injection over 3-5 minutes.

Example 2: Continuous Infusion

The correct infusion rate will be provided by the infusion pump given that the correct drug **and concentration** are selected and that the correct weight and dose are inserted in the pump. This rate should be checked with that printed on the prescription / syringe label and also manually using the relevant information from the "Neonatal Standard Concentration Infusion Table" as follows:

Drug Name	Weight band	REGULAR Concentration (RC)	Default RATE (ml/hr) for default start dose (RC)	Default START DOSE	HIGH concentration (HC) for patients with limited available fluid volume	Default RATE (ml/hr) for default start dose (HC)
FentaNYL	All	5 micrograms/ml	0.2 x Wt (kg)	1microgram/kg/hr	10 micrograms/ml	0.1 x Wt (kg)

NB: The usual dose range is 0.5 - 2 micrograms/kg/hr.

Actual rate (ml/hr) can be calculated using the following formula:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{Prescribed\ Dose\ (Actual\ Dose) x\ Default\ Rate\ (ml\ per\ hour)}{Default\ Start\ Dose}$$

Note: Default rate is calculated by multiplying the default rate constant in the table above by the baby's weight- see sample calculation below:

FentaNYL is prescribed for a 3 kg baby at a dose of 1 micrograms/kg/hr using a concentration of 10 micrograms/ml:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{(1 microgram/kg/hour)\ x\ (0.1\ x\ 3\ kg)}{(1\ microgram/kg/hour)} = 0.3\ ml/hr$$

STORAGE AND SPECIAL PRECAUTIONS FOR HANDLING

- Ampoules should be kept in the outer carton to protect from light and stored below 30°C[6].
- Once opened, use immediately. Solution is stable for 24 hours after dilution.

MONITORING

- Blood pressure, pulse and respiratory rate (rationale: ↓BP, ↑ or ↓pulse, palpitations and respiratory depression) [7]
- Urine output (rationale: urinary retention) [4]
- Bowel sounds and abdominal distention [1]

ADVERSE EFFECTS [4]

The most common side-effects include vomiting (particularly in initial stages), constipation, dry mouth and biliary spasm; larger doses produce muscle rigidity, hypotension and respiratory depression; neonates, particularly if preterm, may be more susceptible. Other common side-effects of opioid analgesics include bradycardia, tachycardia, palpitation, urinary retention, oedema and postural hypotension.

REFERENCES

1. UpToDate, *Fentanyl: Pediatric Drug Information*. 2015, Wolters Kluwer.
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5. Roche Products (Ireland) Ltd, *Summary of Product Characteristics- Hypnovel 10mg/5ml Solution for Injection*. 2015: www.medicines.ie Accessed 29th January 2016.
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Neonatal and Paediatric Pharmacists Group
Neonatal Medication Monograph

Insulin (Actrapid®)
For management of HYPERGLYCAEMIA

Human, fast-acting blood glucose lowering agent [1]

MEDICATION SAFETY ISSUES

- **An analysis of fatal medication errors in hospitalised patients indicated that 33% of these fatalities involved insulin [2].**
- The Institute for Safe Medication Practices (ISMP) classifies Insulin as one of the top 5 'high-alert' medications, causing significant patient harm if used in error [3, 4].
- The Irish Medication Safety Network (IMSN) reports that Insulin related errors are a significant clinical problem in Ireland [4].
- Prescribe insulin in "units"; avoid abbreviations such as "U" or "IU"
- Insulin should be drawn up and measured in Insulin syringes marked in units; standard 1ml or 2ml syringes should not be used.

USES [5-7]

This monograph only addresses the use of Insulin for the treatment of persistent neonatal hyperglycaemia (3 consecutive levels > 12 mmol/l and glycosuria) despite reductions in glucose infusion rate (should not be less than 5 mg/kg/minute).
IMPORTANT: Rule out sepsis and intercurrent illness which may contribute to hyperglycaemia.

PRESENTATION [1]
Insulin is available as Actrapid®.
Each vial contains: 10ml of soluble insulin. Each 1 ml provides 100 units.

DOSAGE [6]

Review the glucose infusion rate (GIR) prior to starting insulin treatment. A GIR < 5 mg/kg/minute is not recommended.

The usual starting dose is 0.05 units/kg/hour.

Insulin is usually administered by continuous intravenous infusion at a rate between 0.02–0.125 units/kg/hour, adjusted according to blood-glucose concentration [6].

A dose range should be specified indicating the minimum and maximum doses (in units/kg/hour).

Titrate Insulin to maintain blood glucose concentration between 8-10 mmol/l [8].

Renal Impairment[6]

Insulin requirements may decrease in patients with renal impairment. The compensatory response to hypoglycaemia is impaired in renal impairment.

RECONSTITUTION

The **recommended concentration for insulin infusion** is **0.1 units/ml.** A higher concentration of 0.2 units/ml can be prepared for neonates with limited available fluid volume.

Alaris GH Pumps deliver a minimum flow rate of 0.1 ml/hr. The 0.2 units/ml concentration might result in a flow rate which is too low (< 0.1 ml/hr) for the pump to deliver. If the flow rate is below 0.1ml/hour, the 0.1 units/ml concentration should be selected.

The concentration should be prescribed in the drug kardex.

PREPARATION OF Insulin REGULAR CONCENTRATION (0.1 unit/ml)

Dilute 5 units (0.05 ml Actrapid®) to a final volume of 50 ml 10% Dextrose

A rate of **0.5 ml/kg/hour provides a dose of 0.05 units/kg/hour**

PREPARATION OF Insulin HIGH CONCENTRATION (0.2 unit/ml) - neonates with limited available fluid volume

Dilute 10 units (0.1 ml Actrapid) to a final volume of 50 ml 10% Dextrose

A rate of **0.25 ml/kg/hour provides a dose of 0.05 units/kg/hour**

ADMINISTRATION

- Insulin is administered by continuous intravenous infusion. Refer to the "Alaris® GH Pump Protocol" for instructions on how administer Insulin using the infusion pump.
- Always check for incompatibilities when administering medications terminally to lines containing other infusions.
- Ensure that every syringe is appropriately labelled.

Priming [7, 8]

- Prime the plastic tubing with insulin and leave to rest for at least 20 minutes before treatment; insulin non-specifically binds to the tubing, resulting in decreased availability to the patient.
- Then flush 2 ml of the insulin solution through the infusion line. This step should be done BEFORE inserting the syringe into the syringe driver.
- Finally, insert the syringe into the syringe driver and reconnect to the patient.

SAMPLE CALCULATION

The correct infusion rate will be provided by the infusion pump given that the correct drug and concentration are selected and that the correct weight and dose are inserted in the pump. This rate should be checked with that printed on the prescription / syringe label and also manually using the relevant information from the "Neonatal Standard Concentration Infusion Table" as follows:

Drug Name	Weight band	Regular Concentration (RC)	Default RATE (ml/hr) for default start dose (RC)	Default START DOSE	High concentration (HC) for patients with limited available fluid volume	Default RATE (ml/hr) for default start dose (HC)
Insulin	All	0.1 units/ml	0.5 x Wt (kg)	0.05 unit/kg/hr	0.2 units/ml	0.25 x Wt (kg)

N.B: The usual dose range is 0.02 - 0.125 units/kg/hr.

Actual rate (ml/hr) can be calculated using the following formula:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{Prescribed\ Dose\ (Actual\ Dose)\ x\ Default\ Rate\ (ml\ per\ hour)}{Default\ Start\ Dose}$$

Note: Default rate is calculated by multiplying the default rate constant in the table above by the baby's weight- see sample calculation below:

Insulin is prescribed for a 0.8 kg baby at a dose of 0.07 unit/kg/hr using a concentration of 0.2 units/ml:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{(0.07\ unit/kg/hour)\ x\ (0.25\ x\ 0.8\ kg)}{(0.05\ unit/kg/hour)} = 0.28\ ml/hr$$

STORAGE AND SPECIAL PRECAUTIONS FOR HANDLING

- Before opening: Store in a refrigerator (2°C – 8°C); do not freeze. [1].
- During use: Store below 25°C. Do not refrigerate or freeze. The undiluted product can be stored for a maximum of 6 weeks [1].
- Keep the vial in the outer carton in order to protect from light [1]
- Do not use if the solution is viscous or cloudy; only use if clear and colourless [1].
- A fresh syringe should be prepared every 24 hours [5].
- Each vial should be reserved for ONE baby O NLY. Label the vials appropriately with patient's name, hospital number and date of opening.

MONITORING

- Blood sugar levels should be monitored within one hour of the start of the infusion and after any change in the rate of glucose or insulin infusion. Monitor hourly until stable, and then less frequently [7].
- Serum potassium levels should be monitored as clinically indicated [3].
- Re-assess GIR daily.

SIDE EFFECTS [6]

Hypoglycaemia and hypokalaemia are the main side effects. Insulin should always be run in a 10% dextrose solution to help prevent hypoglyacemia. Other side effects include transient oedema and local reactions.

REFERENCES

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5. NHS Injectable Medicines Guide, *Child and Neonate Intravenous Medicines - Insulin (soluble), human*. 2014.
6. *BNF for Children*. 2015, Pharmaceutical Press: London.
7. UpToDate, *Neonatal Hyperglycaemia: Pediatric Drug Information*. 2015, Wolters Kluwer.
8. Alsweiler, J.M., Harding, J. E., and Bloomfield, F. H.,, *Tight glycemic control with insulin in hyperglycemic preterm babies: a randomized controlled trial.* Pediatrics, 2012. **129**(4): p. 639-47.

Neonatal and Paediatric Pharmacists Group (NPPG)
Neonatal Medication Monograph

Midazolam (Hypnovel®)

Benzodiazepine sedative and anticonvulsant.

MEDICATION SAFETY ISSUES [1-3]

- Look-alike, sound-alike drug names. Confusion has been reported with diazepam and lorazepam.
- High-alert medication that has an increased risk of significant harm if used in error.
- Rapid intravenous injection (less than 2 minutes) may cause seizure-like myoclonus in preterm neonates; has been associated with severe hypotension in neonates, particularly when the patient has also received fentanyl.
- Abrupt discontinuation following prolonged use may lead to withdrawal symptoms; taper dose gradually when discontinuing.

USES [2, 3]

- Sedation in mechanically ventilated babies in intensive care
- Sedation, intermittent dosing or procedural (intubation)
- Management of refractory seizures

PRESENTATION
Hypnovel® 10 mg/5 ml solution for injection [4].

DOSAGE [2-4]

Indication	Dose
Sedation in intensive care	< 32 weeks corrected gestational age: 0.5 micrograms/kg/minute by continuous intravenous infusion; adjust according to response (max. treatment duration 4 days) [2, 3]. > 32 weeks corrected gestational age: 1 microgram/kg/minute by continuous intravenous infusion; adjust according to response (max. treatment duration 4 days) [2]. (Usual dose range is 0.5 -3 micrograms/kg/minute) [1].
Sedation, intermittent dosing or procedural (intubation)*	50-100 micrograms/kg/dose by intravenous injection over 5 minutes [3].
Management of refractory seizures	Loading dose: 150-200 micrograms/kg over 5 minutes, followed by a continuous infusion of 1 microgram/kg/minute. Increase by 1 microgram/kg/minute every 15 minutes until seizure controlled (maximum: 5 microgram/kg/minute) [2]. (Usual dose range is 0.5-7 micrograms/kg/minute [3]; doses greater than 5 micrograms/kg/minute require consultant approval).

** should be used in conjunction with appropriate analgesia before procedures if required.*

A dose range should be specified indicating the minimum and maximum doses (in microgram/kg/minute).

Renal Impairment [2]
Use with caution in chronic renal failure—increased cerebral sensitivity

RECONSTITUTION

Intravenous Injection

- Add 2.5 ml (5 mg) of midazolam to 22.5 ml of Dextrose 5% or Sodium Chloride 0.9%. This will yield a concentration of (5 mg in 25 ml), equivalent to **200 micrograms/ ml**.
- Calculate the volume you need to administer based on the prescribed dose.
- Withdraw the required volume.
- Dilute further if necessary to facilitate administration by intravenous injection over 5 minutes.

Continuous Infusion

Dilute Midazolam to one of the concentrations recommended in Table 1. Select the appropriate weight band. Then choose between regular or high concentration depending on the neonate's available fluid volume.

Table 1: Regular and high strength concentrations for Midazolam according to the patient's weight

Weight (kg)	Midazolam REGULAR CONCENTRATION	Midazolam HIGH CONCENTRATION (for patients with limited available fluid volume)
≤ 2.5	200 micrograms / ml	500 micrograms/ml
> 2.5	500 micrograms / ml	1000 micrograms/ ml

*The above standard concentrations are appropriate for the majority of neonatal infusions. A **minority** of neonatal infusions need to be prepared at different concentrations based on the unique needs of the neonate.*

Alaris GH Pumps deliver a minimum flow rate of 0.1 ml/hr. The higher concentrations may result in a flow rate which is too low (< 0.1 ml/hr) for the pump to deliver. If the flow rate is below 0.1ml/hour, a lower concentration should be selected to get a flow rate that the pump can deliver.

Dilution recommendations are provided in Table 2 below.

Table 2: Dilution recommendations for Midazolam concentration solutions

Concentration	Amount to add to the infusion fluid*	Volume to withdraw from the 10 mg/5 ml Midazolam ampoule	Volume of Infusion Fluid* (final volume in syringe is 50 ml)
200 micrograms/ ml	10 mg	5 ml	45 ml
500 micrograms/ml	25 mg	12.5 ml	37.5 ml
1000 micrograms/ml	50 mg	25 ml	25 ml

* Infusion fluid refers to Dextrose 5% or Sodium Chloride 0.9%, as prescribed

ADMINISTRATION

- Midazolam is administered by continuous intravenous infusion. Refer to the "Alaris® GH Pump Protocol" for instructions on how administer Midazolam using the infusion pump.
- Always check for incompatibilities when administering medications terminally to lines containing other infusions.
- Ensure that every syringe is appropriately labelled.

SAMPLE CALCULATION

Example 1: Intravenous Injection

A loading dose of 150 micrograms/kg of Midazolam is prescribed for a 1 kg baby.

- Dose: 150 micrograms x 1 kg = 150 micrograms.
- Prepare a solution of midazolam 200 micrograms/ml as described above.
- Calculate the volume required to administer 150 micrograms using the 200 micrograms per ml solution: (150 micrograms x 1 ml / 200 micrograms) = 0.75 ml.
- Dilute further as necessary to facilitate administration by intravenous injection over 5 minutes.

Example 2: Continuous Infusion

The correct infusion rate will be provided by the infusion pump given that the correct drug **and concentration** are selected and that the correct weight and dose are inserted in the pump. This rate should be checked with that printed on the prescription / syringe label and also manually using the relevant information from the "Neonatal Standard Concentration Infusion Table" as follows:

Drug Name	Weight band	REGULAR Concentration (RC)	Default RATE (ml/hr) for default start dose (RC)	Default START DOSE	HIGH concentration (HC) for patients with limited available fluid volume	Default RATE (ml/hr) for default start dose (HC)
Midazolam	≤ 2.5 kg	200 micrograms/ml	0.3 x Wt (kg)	1microgram/kg/min	500 micrograms/ml	0.12 x Wt (kg)
	> 2.5 kg	500 micrograms/ml	0.12 x Wt (kg)		1000 micrograms/ml	0.06 x Wt (kg)

NB: The usual dose range is:

- *0.5 -3 micrograms/kg/minute for sedation in intensive care*
- *0 - 7 micrograms/kg/minute for seizures*

Actual rate (ml/hr) can be calculated using the following formula:

$$\textit{Actual rate for the dose prescribed (ml per hour)} = \frac{\textit{Prescribed Dose (Actual Dose)} \times \textit{Default Rate (ml per hour)}}{\textit{Default Start Dose}}$$

Note: Default rate is calculated by multiplying the default rate constant in the table above by the baby's weight- see sample calculation below:

Midazolam is prescribed for a 0.89 kg baby at a dose of 0.5 micrograms/kg/minute using a concentration of 200 micrograms/ml:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{(0.5\ microgram/kg/minute)\ x\ (0.3\ x\ 0.89\ kg)}{(1\ microgram/kg/minute)} = 0.13\ ml/hr$$

STORAGE [4]
Keep the ampoules in the outer carton in order to protect from light. Discard any unused solution.

MONITORING [1, 4]
Respiratory rate, oxygen saturation, cardiac function.

ADVERSE EFFECTS[2]
Most common adverse effects include gastro-intestinal disturbances, dry mouth, hiccups, jaundice hypotension, cardiac arrest, heart rate changes, anaphylaxis, thrombosis, laryngospasm, bronchospasm, respiratory depression and respiratory arrest, seizure-like activity, myoclonic jerks (preterm infants), urinary retention.

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Neonatal and Paediatric Pharmacists Group
Neonatal Medication Monograph

Morphine sulphate

Opioid analgesic

MEDICATION SAFETY ISSUES

- Morphine has been repeatedly associated with fatal medication errors in a NICU setting [1, 2].
- Ten-fold dosing errors with intravenous opioids have frequently occurred in a NICU setting [3].
- The Institute for Safe Medication Practices (ISMP) classifies morphine as a high alert medication [4].
- Response to morphine varies between babies, possibly due to pharmacogenomic variation.
- Naloxone (opioid antagonist) injection and resuscitative equipment should be immediately available, particularly if morphine is prescribed in unventilated babies [4].
- Rapid IV administration is associated with a higher incidence of respiratory depression and arrest requiring mechanical ventilation and with chest wall rigidity [4].
- Abrupt discontinuation following prolonged use may also lead to withdrawal symptoms; taper dose gradually when discontinuing [5].

USES

Management of moderate to severe pain or sedation in ventilated neonates. Seek consultant advice if morphine is required in non-ventilated neonates.

PRESENTATION

Morphine sulphate 10mg/ml in a 1 ml ampoule.

DOSAGE [6]

Table 1: Intravenous doses of Morphine sulphate in neonates

Administration method	Neonatal Dose
Continuous intravenous infusion	Initially 50 micrograms/kg by intravenous injection over at least 5 minutes* **then** 5–20 micrograms/kg/hour adjusted according to response (usual starting dose is 10 micrograms/kg/hour)
Intermittent intravenous injection over 5 minutes	50 micrograms/kg every 6 hours, adjusted according to response

**A further loading dose may be required under consultant supervision.* (Onset of action of IV morphine is 5 minutes; time to peak concentration is 10-60 minutes)[7]

A dose range should be specified indicating the minimum and maximum doses (in microgram/kg/hour).

Renal Impairment[6]

Avoid use or reduce dose.

RECONSTITUTION

Loading dose

- Add 0.5 ml (5 mg) of morphine sulphate to 25 ml of Sodium Chloride 0.9%, Dextrose 5% or Dextrose 10%. This will yield a concentration of 200 micrograms/ml.
- Calculate the volume you need to administer based on the prescribed dose.
- Withdraw the required volume.
- Administer by intravenous injection over 5 minutes.

Continuous Infusion

Dilute morphine sulphate to one of the following concentrations recommended in Table 2. Select the appropriate weight band. Then choose between regular or high concentration depending on the neonate's available fluid volume.

Table 2: Regular and High strength concentrations for Morphine depending on the patient's weight

Weight (kg)	MORPHINE REGULAR CONCENTRATION	MORPHINE HIGH CONCENTRATION (for patients with limited available fluid volume)
≤ 2.5	50 micrograms/ml	100 micrograms/ml
> 2.5	100 micrograms/ml	200 micrograms/ml

Alaris GH Pumps deliver a minimum flow rate of 0.1 ml/hr. The higher concentrations may result in a flow rate which is too low (< 0.1 ml/hr) for the pump to deliver. If the flow rate is below 0.1ml/hour, a lower concentration should be selected to get a flow rate that the pump can deliver. If none of the above concentrations are suitable, a 25 micrograms/ml concentration can be used.

Dilution recommendations are provided in Table 3 below.

Table 3: Dilution recommendations for Morphine concentration solutions

Concentration	Amount to add to the infusion fluid*	Volume to withdraw from the 10 mg/ ml morphine ampoule	Volume of Infusion Fluid* (final volume in syringe is 50 ml)
25 micrograms/ml	1.25 mg	0.13 ml	49.87 ml
50 micrograms/ ml	2.5 mg	0.25 ml	49.75 ml
100 micrograms/ml	5 mg	0.5 ml	49.5 ml
200 micrograms/ml	10 mg	1 ml	49 ml

* Infusion fluid refers to Sodium Chloride 0.9%, Dextrose 5% or Dextrose 10% as prescribed

ADMINISTRATION

- Morphine sulphate is administered by continuous intravenous infusion. Refer to the "Alaris® GH Pump Protocol" for instructions on how administer Morphine sulphate using the infusion pump.
- Always check for incompatibilities when administering medications terminally to lines containing other infusions.
- Ensure that every syringe is appropriately labelled.

SAMPLE CALCULATION

Example 1: Intravenous Injection over 5 minutes

A stat dose of Morphine is prescribed for a 3-day old, 3 kg baby, born at 37-weeks gestation, as a slow intravenous injection, for short term pain relief.

Dose: 50 micrograms/kg = 150 micrograms.

Prepare morphine sulphate 200 micrograms/ml as described above.

Calculate the volume required to administer 150 micrograms using the 200 micrograms per ml solution: (150 micrograms x 1 ml / 200 micrograms) = 0.75 ml.

Administer by intravenous injection over 5 minutes.

Example 2: Loading dose followed by Continuous Intravenous infusion

The correct infusion rate will be provided by the infusion pump given that the correct drug and **concentration** are selected and that the correct weight and dose are inserted in the pump. This rate should be checked with that printed on the prescription / syringe label and also manually using the relevant information from the "Neonatal Standard Concentration Infusion Table" as follows:

Neonatal Standard Concentration Infusion Table

Drug Name	Weight band	Regular Concentration (RC)	Default RATE (ml/hr) for default start dose (RC)	Default START DOSE	High concentration (HC) for patients with limited available fluid volume	Default RATE (ml/hr) for default start dose (HC)
Morphine	≤ 2.5 kg	* 25 micrograms/ml	0.4 x Wt (kg)	10 micrograms/kg/hr		
		50 micrograms/ml	0.2 x Wt (kg)		100 micrograms/ml	0.1 x Wt (kg)
	> 2.5 kg	100 micrograms/ml	0.1 x Wt (kg)		200 micrograms/ml	0.05 x Wt (kg)

* Low concentration for use where flow rates below 0.1ml/hr occur with other concentrations- refer to monograph.

N.B: The usual dose range is 5-20 micrograms/kg/hr

Actual rate (ml/hr) can be calculated using the following formula:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{Prescribed\ Dose\ (Actual\ Dose) x\ Default\ Rate\ (ml\ per\ hour)}{Default\ Start\ Dose}$$

Note: Default rate is calculated by multiplying the default rate constant in the table above by the baby's weight- see sample calculation below:

Morphine is prescribed for a 1.2 kg baby at a dose of 15 micrograms/kg/hr using a concentration of 50 micrograms/ml:

$$Actual\ rate\ for\ the\ dose\ prescribed\ (ml\ per\ hour) = \frac{(1.5\ microgram/kg/hr)\ x\ (0.2\ x\ 1.2\ kg)}{(10\ microgram/kg/minute)} = 0.36\ ml/hr$$

STORAGE AND SPECIAL PRECAUTIONS FOR HANDLING

- Ampoules should be kept in the outer carton to protect from light and stored below 25°C.
- Once opened, use immediately. Solution is stable for 24 hours after dilution.

MONITORING

- Monitor patients for adequacy of analgesia/sedation and signs and symptoms that would indicate toxicity such as decreased respiratory rate, oxygen saturation, and alertness [4].
- Blood pressure and heart rate should also be monitored.
- Monitor for respiratory depression especially during initiation and titration [5].

SIDE EFFECTS

The most common side-effects include vomiting (particularly in initial stages), constipation, dry mouth and biliary spasm; larger doses produce muscle rigidity, hypotension and respiratory depression; neonates, particularly if preterm, may be more susceptible. Other common side-effects of opioid analgesics include bradycardia, tachycardia, palpitation, oedema and postural hypotension [6].

REFERENCES

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Appendix D. REFERENCE GUIDE FOR SIMULATION PROCEDURE

REFERENCE GUIDE FOR THE SIMULATION PROCEDURE

RETRIEVING INFORMATION:

Each participant will get information of five infusion orders from Page1. This information is same as you will see in the order sheet in MN-CMS.

- Patients details with special note if any (Fluid restriction in this case)
- Pending infusion order details.
- Clicking on the green text in last column will take you to the view as you will see in Nurses View in MN-CMS.

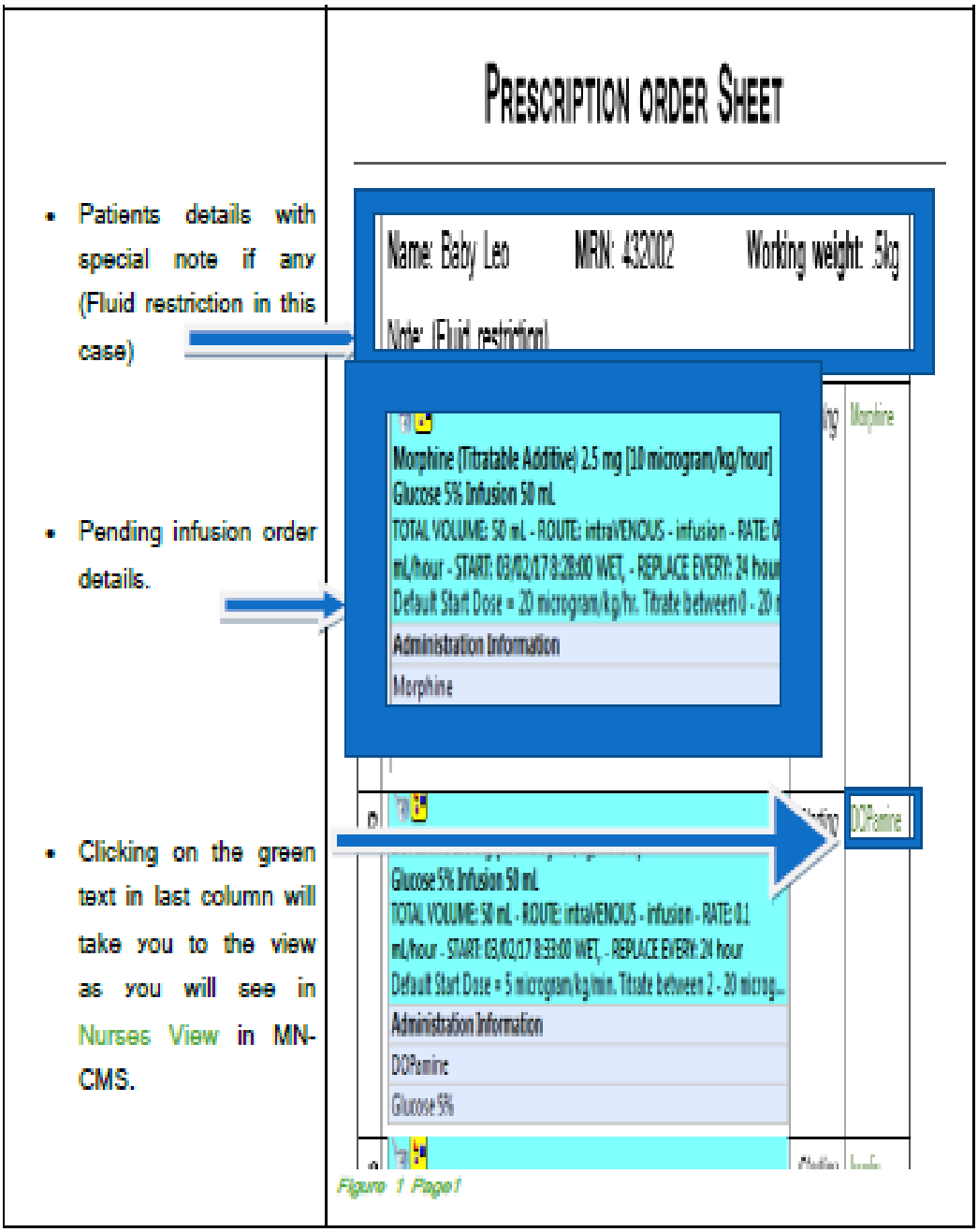

Figure 1 Page1

After retrieving the information, the participant should check the information against the linked medication protocol.

- This view will give information about drug and diluent to be added.
- To see medication protocol click here

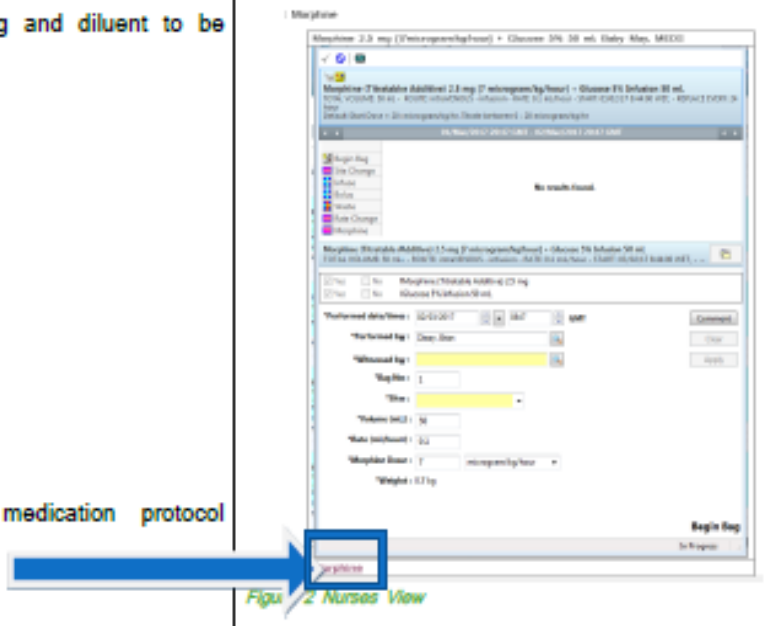

Figure 2 Nurses View

- Anytime to go back to prescription order sheet click the link provided at the bottom of each page

LABELLING:

After cross checking against protocol, the participant will prepare the labels of the orders and stick on to the provided sheet.

PROGRAMMING THE PUMP:

After preparing the label, the participant will program the pump using drug library. If the drug prescribed is not in the drug library, the participant will use the option ml/hour in the pump to enter the dose.

Drug library	
Select ml/hr for programming the dose if the prescribed drug is not listed in the drug library.	

Post-Simulation Feedback Survey

Tick (√) as Appropriate

1 **Which age group you belong?**
- ☐ 20 – 30
- ☐ 31- 40
- ☐ 41-50
- ☐ Over 50

2 **Experience as a NICU nurse**
- ☐ 0-5 years
- ☐ 6-15 years
- ☐ 16-25 years
- ☐ >25 years

3 **How often do you use drug library in the infusion pump?**
- ☐ Never
- ☐ 1-2 times per month
- ☐ once a week
- ☐ Most days

		Strongly Disagree (5)	Disagree (4)	Neither agree/ disagree (3)	Agree (2)	Strongly Agree (1)
4.	Overall the administration process in this system is easy to implement in a real scenario.					
5.	Overall the administration process in this system is safe to implement.					
6.	Transcribing the prescription order was safe in the system.					
7.	Transcribing the prescription order was easy in the system					
8.	Labelling the infusion was safe in this process					
9.	Labelling the infusion was easy in this process					

		Strongly Disagree (5)	Disagree (4)	Neither agree / disagree (3)	Agree (2)	Strongly Agree (1)
10	Programming the infusion pump was safe in this process					
11	Programming the infusion pump was easy in this process					

12. Any Comments on the simulation session:

13. Any suggestions to improve the medication process used for administration of high-risk infusions during simulation

Appendix F.PARTICIPANTS INFORMATION LEAFLET

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

THE ROTUNDA HOSPITAL
DUBLIN

Ospidéal an Rotunda
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www.rotunda.ie

Participant Information Leaflet

Title: A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System.

Principal Investigator: Anu Garg, CNM1, NICU

You are being invited to take part in the study mentioned above which is being carried out as part of a MSc. in Health Informatics, SCSS, Trinity College Dublin. However, before you decide whether or not to participate, it is important that you fully understand what the research is about and what you will be asked to do. It is important that you read the following information to make an informed decision and if you have any questions about any aspects of the study that are not clear to you, do not hesitate to ask me. Please make sure that you are satisfied before you decide to take part or not. Thank you for your time and consideration of this invitation.

Purpose of the Research Study

The Maternal & Newborn Clinical Management System (MN-CMS) is an electronic patient record system that will go live in 2017 in the Rotunda Hospital. For this research study, the researcher wants to identify any patient safety concerns at the administration stage of high-risk infusions within the

NICU using the upcoming MN-CMS in a simulated environment. This study will help the organisation plan measures in advance to improve medication safety before the MN-CMS. To do this, the researcher will evaluate the clinical workflow during the administration of high-risk infusions in a simulated clinical environment.

Why as a Participant/Respondent have I been asked to take part in this study?

You are being invited to participate in the study as you are working in the NICU as a nurse and you will be a real user of MN-CMS. There will be approximately 25-30 participants. However, taking part in this research study is entirely up to you and if you do decide to take part you will be provided with an information leaflet to take with you. Additionally, you will be required to sign a consent form. However, if you do not wish to participate and if you change your mind at any time (before publication), you can withdraw from the Research Study without giving a reason.

During the Study

You will be informed about the venue and time of simulation session a day before the session to check your availability. There will be only one simulation session per participant. One simulation session will take approximately 30 minutes including training session. On the day of a simulation session, you will receive a standardised quick reference guide which will give an overview of the drug chart and how prescriptions are presented in the system. During the simulation, you will transcribe five prescription orders, then prepare the infusion label for each prescription and lastly, you will program the infusion pump using the drug library. Post simulation session, you will be asked to complete a short survey to obtain feedback about the simulation session and the medication process itself.

Potential Harms/Risks

There is no potential harm in this research study at a psychological level or physiological level. The researchers' contact details are on the consent form if you want to make any further enquiry.

Potential Benefits/Lack of Benefit

The individual staff members may benefit from improved workflows developed as a consequence of the study. Patients will benefit if system risks can be removed before MN CMS 'go live'.

Confidentiality

The electronic data collected during the study will be stored on a secure network password encrypted personal computer in NICU. Paper-based data will be stored in a safe locker in NICU. No identifiable data will be collected during the study.

At the End of the Study

At the completion of the study, the observations made by the researcher during the simulation session will be analysed using the appropriate statistical method. The data collected in the form of the survey will be retained after completion of the study for indefinite period.

Contact Details

Researcher: Anu Garg
Contact no: 0862341785
Email: agarg@rotunda.ie

Appendix G.CONSENT FORM

CONSENT FORM

Research title: A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System (MN-CMS)

Researcher: Anu Garg **Tel**: 0862341785 **E-mail:** aqarg@rotunda.ie

DECLARATION by participant: Please tick (✓) and provide your initials		
1.	I have read the information leaflet for this research study and I understand the contents.	Yes [ ] No [ ] initials [ ]
2.	I have had the opportunity to ask questions and all my questions have been answered to my satisfaction.	Yes [ ] No [ ] initials [ ]
3.	I fully understand that my participation is completely voluntary and that I am free to withdraw from the study at any time (prior to anonymization /publication) without giving a reason.	Yes [ ] No [ ] initials [ ]
4.	I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.	Yes [ ] No [ ] initials [
5.	I understand that information from this research will be published but that I will not be identified as a participant in this research in any publication.	Yes [ ] No [ ] initials [ ]
6.	I understand that I will not be identified as a participant in this study (unless a legal requirement).	Yes [ ] No [ ] initials [ ]
7.	I consent to my study data being retained after this study has been completed.	Yes [ ] No [ ] initials [ ]
8.	I understand that the researchers undertaking this research will hold in confidence and securely all collected data and other relevant information.	Yes [ ] No [ ] initials [ ]
9.	I freely and voluntarily consent to participating in this research study.	Yes [ ] No [ ] initials [ ]
10.	I understand that if I make illicit activities known, these will be reported to appropriate authorities	Yes [ ] No [ ] initials [ ]

11. I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk. **Yes [ ] No [ ] initials [ ]**

12. I am 18 years or older and am competent to provide consent. **Yes [ ] No [ ] initials [ ]**

PARTICIPANT'S NAME .....

Contact Address.....

.....

Phone number: ..... **Email:** .....

Participant's signature: ..... **Date:** .....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Name of person taking consent: ..... Signature: .....Date: .....

Researcher: ..... Signature: ..... Date: .....

Appendix H. RESEARCH PROPOSAL

RESEARCH ETHICAL PROPOSAL

TITLE:

A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System

PURPOSE:

To prospectively evaluate the clinical workflow and patient safety related to administration of high-risk infusions in a NICU using a clinical simulation technique in MN-CMS.

This study is carried out for the fulfilment of an MSc. in Health Informatics, SCSS, Trinity College Dublin.

STUDY METHODOLOGY:

In the proposed study, we will evaluate the clinical workflow and patient safety related to high-risk infusions at the administration stage in a simulated clinical environment. Initially, the investigator will generate 150 prescription orders of high-risk infusions of test patients using MN-CMS. The Nurses' view of prescription orders in MN-CMS screenshots will be saved as a Portable Document File (PDF). The orders will consist of five different high-risk infusions e.g. morphine, insulin, fentanyl, dopamine and dobutamine that are frequently used in NICU settings. We do not want ourselves to be constrained to these drugs; we may use nonstandard concentration samples also as there may be a greater risk of a pump programming error.

There will be 20-30 simulation sessions, and each session will be approximately 30 minutes including a training session. An information leaflet about the study will be given to volunteer participants and consent will be obtained before the simulation session.

All participants will receive a standardised quick reference guide which will provide an overview of the drug chart and how prescriptions are presented in the system. A step by step guide will be given to the participant to use in a simulation session. Each participant will get five prescription orders in PDF which will be displayed on the computer screen. The participant will transcribe the prescription orders from the computer screen, prepare the infusion label and then program the infusion pump using the drug library. Each participant will complete a short survey to provide feedback about the simulation session and the administration process of high-risk infusions in MN-CMS.

Data Collection: The researcher will observe the whole process and collect the data on the set form.

Inclusion criteria: Participants should be currently working as nurses in the NICU, Rotunda Hospital, as they will be real end users of the MN-CMS.

Exclusion criteria: Nurses not working in Rotunda Hospital NICU are excluded from the study.

Outcomes: The results of the study will expose any potential patient safety concerns (if any) at the administration phase of high-risk infusions in MN-CMS which may help the organisation to plan safety measures before the MN-CMS 'go live' in the Rotunda Hospital.

Sample Size: The sample size was chosen as a pragmatic approach given the staffing constraints and current workload in the NICU. Due to time limitation and staff shortage issues, only 125-150 prescription orders will be processed in 30 simulation sessions. There will be one participant for each simulation session. There will be approximately 25-30 participants.

Recruitment: An invitation will be displayed on the notice board in NICU, and potential participants will be approached by the researcher in person as well.

Data Analysis: Descriptive analysis will be performed with the help of Prof Mary Sharp, Assistant Professor in School of Computer Science and Statistics, Trinity College Dublin. This descriptive study will give an initial estimate of the error rate per 100 orders. This study is not an experimental study and rates will not be compared between different groups.

Data Protection: The data will be collected on the papers and electronically on the computers using data collection tools. All paper-based data will be transcribed into an electronic database designed for this study. The data will be anonymised, and no identifiable data will be collected during the study. The data will be stored on a secure network password encrypted personal computer in NICU. All the data will be stored on the secure hospital network in a NICU folder that will be accessed through password protected computer. The data collected on the paper will be kept in a researchers' safe locker in NICU, Rotunda Hospital. As no patient or health professional identifiable information will be collected, the data will be stored indefinitely.

Cost and resource implications: Each simulation session will be approximate of 30 minutes, and there will be 25-30 sessions. Legally there is need of two participants for each session to double check high-risk infusions. However, the researcher is aware of critical staff shortages. Thus the researcher decided to use one participant for each simulation session. The session will be conducted near to the NICU. The simulation session would be cancelled in the event the unit gets busy. In no circumstances will the working of the NICU and patient safety be compromised due to the study.

Ethical Consideration: If the researcher determines that there is a risk to patient safety as a consequence of the findings of the study or due to the performance of one of the study participants, this finding will be reported to the Neonatal Medication Safety Committee to ensure that patient care is not adversely affected.

Appendix I. Ethical Approval from The Rotunda Hospital

THE ROTUNDA HOSPITAL DUBLIN

Ospidéal an Rotunda
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www.rotunda.ie

30th January, 2017

Ms. Anu Garg
Clinical Nurse Manager 1, NICU
Rotunda Hospital

Our ref: **REC-2016-027** *(please quote this reference on all correspondence)*
Re: **A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System**

Dear Anu,

Many thanks for the amended documentation received in relation to the above research. I am pleased to advise that the requirements set out by the Committee in respect of your study have now been met. This being the case, ethical approval for the research is granted and it may now commence.

You are requested to submit a progress report to the Committee in twelve months, and annually thereafter as applicable. We would also like to know when and where you publish or present your results. Please be aware of your responsibilities with respect to the Hospital's good research practice policies and guidelines, copies of which are available on the Q-Pulse system.

Kind regards.

Yours sincerely,

Dr. Maeve Eogan,
Acting Chairman,
Research Ethics Committee

CARING FOR GENERATIONS
SINCE 1745

Appendix J.Ethical Approval from Trinity College Dublin

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

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A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System (MN-CMS)

Status | View | Assign Supervisor

Submitted by gargan on Mon, 01/30/2017 - 09:30

Project overview

Name of Applicant:
Anu Garg
Academic Supervisor / Lead Researcher:
Prof Mary Sharp
Research Project Type:
Element of Taught Postgraduate Course
Project Duration:
Saturday, February 25, 2017 to Thursday, June 22, 2017

Funder

Funder:
N/A

File Attachment

REC Application Form:

Filename	Date Uploaded	Size
Ethics Anu Signed[1689].pdf	2017-02-06 15:35:15	9.46 MB

Admin fields

Academic Supervisor / Lead Researcher (username):
msharp
Application Number:
20170112
Status:
Approved

Appendix K.RECRUITMENT FLYER

Participants needed for the research project

A simulation study to prospectively evaluate the clinical workflow for administering high-risk infusions in a Neonatal Intensive Care Unit (NICU) in Maternal & Newborn Clinical Management System

Principal Investigator:
Anu Garg
CNM 1
NICU

Contact Information:

For more information about the study or to participate in the study, please contact:

Anu Garg
Email: agarg@rotunda.ie
Phone no: 0862341785

Start date: 14th March 2017

Date: 7th March 2017

What is the purpose of the study?

This study is done as a part of MSc. Health Informatics, Trinity College, Dublin

Purpose of the study is to prospectively evaluate the clinical workflow and patient safety related to administration of high-risk infusions in a NICU using a clinical simulation technique in MN-CMS.

Who can participate?

All registered nurses currently working in NICU, Rotunda Hospital.

What does the study involve?

A simulation session (approximate 30 min duration) in which participant has to transcribe, label and program in the pump five infusion orders. Participants will be asked to fill a short post simulation survey.

What else you should also know?

All information will be kept confidential.

Venue and timing of session will be arranged as per your convenience. However, you will be informed in case of cancelation due to unavoidable circumstances

What are the benefits of participating?

The individual staff members may benefit from improved workflows developed as a consequence of the study. Patients will benefit by reducing system risks before MN CMS 'go live'.

Appendix L.DATA COLLECTION AT THE LABELLING PHASE

Prescription order no:		
NO	Rough work area	Label
A		
B		
C		
D		
E		

Appendix M. Pump logging data collection sheet

Pump logging data collection

Order no	Drug	Strength	Dose	Rate/Weight	Clear set up	Start time	Finish time