HOW A CLOSED LOOP INFUSION THERAPY SYSTEM COULD AFFECT WORK PRACTICES IN A PAEDIATRIC HOSPITAL.

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HOW A CLOSED LOOP INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN A PAEDIATRIC HOSPITAL.

What are the changes to work practices through the proposed implementation of a closed loop infusion therapy system into an existing working paediatric hospital?

Scott Barkley

A dissertation submitted to the University of Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics

2018

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, Trinity College Dublin.

Signed: ⎯⎯⎯⎯⎯⎯⎯⎯⎯⎯⎯

Scott Barkley 16th July 2018

Permission to lend and/or copy

I agree that the School of Computer Science and Statistics, Trinity College Dublin, may lend or copy this dissertation upon request.

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Scott Barkley 17th July 2018

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Abstract

Medication error in hospitals is a significant problem worldwide. These errors inflict the most damage on the most vulnerable cohorts of patients, critically ill paediatric patients in an intensive care unit are in a high risk category. Hospitals and device manufacturers are developing closed loop medication systems in an attempt to reduce this problem. The combination of medical devices and ICT into complex distributed Medical IT Systems is another facet of the solution. The intent behind these innovations is to better manage patient data and to configure devices into networked systems that as a whole provide more functionality and safety than the individual devices can do when they are used in standalone mode. A Complete Closed Loop Infusion Medication System (CCLIMS) is a good example of this combined technology that is being utilised in the battle against medication errors. Systems of this type are much needed in the stressful environment of a paediatric intensive care unit (PICU).

Advances in infusion pump technology and the associated prescribing, labelling and electronic charting systems can (if implemented correctly) help to prevent medication errors. One noticeable gap in the information reviewed relates to identification of those work practices and information flow changes that an organisation should consider in order to successfully implement a system as complex as a CCLIMS. An implementation strategy should take account of all the affected departments and different disciplines that combine together to provide a medication service to the PICU. Another consideration is that the installation of a CCLIMS will need to completely integrate with the existing systems which are functioning already and in clinical use within the PICU.

From the work completed, the results that arose from this study and the knowledge gained on the detailed workings of a CCLIMS, it would be safe to say that many factors associated with stakeholder uptake and acceptance of a CCLIMS are addressed. The integration of a complex, multifaceted system such as a CCLIMS into a busy, stressful working environment would typically come up against significant resistance. It was noted that many barriers were broken down by simply utilising the correct approach to educating the stakeholder and introducing this technology in a correct and controlled manner.

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Abbreviations

Abbreviations	Description
ACU	Aseptic Compounding Unit
ADE	Adverse Drug Event
APG	Auto-Programming
BCMA	Barcode Medication Administration
CDSS	Clinical Decision Support System
CE	Clinical Engineering
CLS	Closed Loop Systems
CCLMIS	Complete Closed Loop Medication Infusion System
CPOE	Computerised Physician Order Entry
CHG	Children's Hospital Group
CIVAS	Central Intravenous Additive Service
DERS	Drug Error Reduction Software
EEPROM	Electronically Erasable Programmable Read-Only Memory
EHR	Electronic Health Record
eMAR	Electronic Medication Administration Record
EMR	Electronic Medical Record
EPR	Electronic Patient Record
EMRAM	Electronic Medical Record Adoption Model
HDO	Health-Care Delivery Organisations
HIMSS	The Healthcare Information and Management Systems Society
HISI	Health Informatics Society of Ireland
HIT	Hospital Information Technology

HSE	Health Service Executive
ICCA	IntelliSpace Critical Care and anaesthesia
ICU	Intensive Care Unit
ISMP	The Institute for Safe Medication Practices
ICT	Information Communication Technology
IT	Information Technology
IV infusion	Intravenous infusion
MUP	Medication Use Process
NCH	New Children's Hospital
POC	Point of Care (testing)
PICU	Paediatric Intensive Care Unit
SaMD	software as a medical device
SIPs	Smart Infusion Pumps
UML	Unified modelling language
VTBI	Volume to be infused (VTBI)

Glossary

Term	Description of Terms
Base Practice	ISO 15504 defines Base Practice as "*an activity that, when consistently performed, contributes to achieving a specific process.*
Barcode Medication Administration BCMA	BCMA is a Bar-code system that uses barcodes to prevent medication errors in healthcare settings and to improve the quality and safety of medication administration.
Clinical workflow	Clinical workflow, is a directed series of steps comprising of a clinical process that are performed by people or equipment/computers, consume, transform, and produce information where patient outcomes count as information.
Complete Closed Loop Infusion Medication System CCLIMS	A complete closed loop infusion medication system (CCLIMS) brings together technical medical equipment previously used in isolation and includes Infusion Pumps, Drug Libraries, Drug Storage, Logistics and monitoring systems and Electronic Health Care Records (EHR). Such systems support the use of engineering controls and decision support software which adds a layer of safety (Miller et al., 2017, Ohashi et al., 2014).
Computerised patient order entry CPOE	A system in which prescriber places the order electronically. 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.
Central Intravenous Additive Service CIVAS	CIVAS is a hospital based centralised aseptic compounding unit which makes up intravenous drugs. This standardization and centralization of the preparations and reconstitutions by the hospital pharmacy make it possible to reduce risks and errors in medication preparation.
Drug Error Reduction Software DERS	Allows infusion pumps to warn operators of incorrect medication orders, calculation errors, or miss-programming that would result in significant under- or over delivery of a drug
Health Level-7 or HL7	Refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers.
RS232	Recommended Standard 232 is a standard introduced in 1960 for serial communication transmission of data.

Chapter 1 Introduction

1.1 Introduction

The difficulties faced by a hospital when implementing a complex closed loop medication system is that a closed loop medication system is putting the minute to minute welfare of very sick patients directly in the hand of a complex multi-faceted machine. If this machine system has not be adapted correctly to its environment it can cause serious harm to patients which can ultimately result in death (Broselow and Schuman, 2008). The question that must be asked; who has the know-how to get the job done?

While researching the literature on implementing a closed loop medication system it was very clear that no one person has the knowledge to complete this process, it would require the combined skills of many diverse stakeholders, not just an IT expert and a biomedical engineer, but an extensive multidisciplinary team.

The following quote is from a paper written on the implication of a complete closed loop infusion medication system (CCLIMS). and it very relevant to this piece of research

"There's not a biomed engineer on the planet that alone with their skills can get this done, and no matter how much the IT folks think they know, there's not an information technology professional alone who can do this." (Pettus and Vanderveen, 2013).

1.2 Background

Hospitals are increasingly combining medical devices and ICT into complex Medical IT Systems. The intent is to manage patient data better and to configure devices into systems that as a whole provide more functionality and safety than the individual equipment can do when used as standalone devices. Even through the individual medical devices are certified it doesn't mean that when they are combined together that they are automatically certified. The pervious statement leads towards the realisation 'software is a medical device' and 'software as a medical device' (SaMD) the function of the combined software possibly changes the intended purpose of the 'newly combined system' ideally this should be re-certified but as this requirement is presently

voluntary, it doesn't regularly happen. *"Examples of SaMD changes; include, but are not limited to defect fixes, aesthetic, performance or usability enhancements and security patches (IMDRF, 2017)."*

Medication error in hospitals is a significant problem worldwide. Hospitals are developing closed loop medication systems in an attempt to reduce this problem. A complete closed loop infusion medication system (CCLIMS) brings together technical medical equipment previously used in isolation and includes Infusion Pumps, Drug Libraries, Drug Storage, Logistics and monitoring systems and Electronic Health Care Records (EHR). Such systems support the use of engineering controls and decision support software which adds a layer of safety (Miller et al., 2017, Ohashi et al., 2014).

The current development of the New Children's Hospital (NCH) on the St James Campus in Dublin's city centre where the design brief to open this 400-bed world class hospital as a Healthcare Information and Management Systems Society (HIMSS Level 7) establishment. (The grading of a hospital in relation to the electronic healthcare record is gauged in the HIMSS scale, level 7 is the highest award possible). To open a large complex 'state of the art' paediatric Hospital at level 7 will require a detailed level of planning that will be a greater challenge than the architectural plans for the buildings themselves. The vast amount of integrated services needed to create this digital environment will only be successful if the right approach to their implementation is followed. The NCH is being designed to 'be born' as a digital hospital (see figure 1-1), to support the 'hub & spoke' delivery approach towards technology will be at the forefront of the venture. This technology will allow seamless efficiency when sharing patient information to ensure patient safety throughout the care model.

Figure 1-1:- 'Born' Digital (eHealth Ireland, 2018)

If the NCH is to be 'born' digital, the HSE need to realise the complexity of this task and resource the project accordingly. Learning from the failed attempts in the integration of systems similar to this in the United States. In a recent journal article, it stated how the US government spent 10 million of the veterans electronic healthcare record (EHR) and destroyed it (Yaraghi, 2018). The development of the NCH as a digital hospital will ensure its success as the governance of such a change is critical and is a true opportunity for the HSE to make an impact with the exciting innovation of a truly paperless/digital new children's hospital for the children of Ireland (eHealth Ireland, 2018).

1.3 Motivation

The researcher is employed as a clinical engineer in a large Dublin Paediatric hospital since 2000 (OLCHC). The advances in Infusion pump technology, especially toward accuracy and safety, has spiralled over the last two decades. A complete closed loop infusion medication system (CCLIMS) is the end of this journey for medication errors. If correctly implemented with true interoperability between the different systems involved the goal of safe, error-free infusion pump administrated medication is here.

These commercially available Closed Loop Systems (CLS) will utilise Auto-Programming (APG), Smart infusion Pumps (SIPs), Drug Error Reduction Software (DERS), Computerised Physician Order Entry (CPOE), Barcode Medication Administration (BCMA) with an Electronic Healthcare Record (EHR) which throughout all the different departments which will make the process possible. This study will look at both the system's technology and infrastructure requirements (within the existing PICU environment in OLCHC), how the introduction and merging of SIP infusions and medical charting system functions, simplify or complicate the working practices of the staff who make up and administer prescribed drug infusions to patients. It is expected that the results from completing this piece of research will help guide the HDO in the correct direction when looking for 'buy-in' from the many stakeholders who's working practices it effects. The medical devices companies are currently forming partnerships to help sell there complementary devices and product to the HDO. This connected technology

partnerships lead to the question 'who is responsible for the certification of the combined products'? Is it the HDO or the equipment manufactures? The standards are lagging behind the speed of the development of these systems it could take 10 years for the standards authority to catch-up (IMDRF, 2017).

1.4 Study Domain

OLCHC is a national 243 bed paediatric children's hospital solely for the care of children in Ireland since 1956. OLCHC employs nearly 1200 staff and has two paediatric intensive care units (PICU 1 & PICU 2). PICU 1 is a 17-bed state of the art modular build facility on the 1st floor and while PICU 2 is an 8-bed unit with 6 open bed bays and 2 isolation room which resides within the original 1956 hospital footprint. PICU 1 has been re-developed and updated many times for the needs of the patients over the last couple of decades but carries an ageing ICT infrastructure which can limit technological advancements when trying to improve the communication and interoperability of any new system such as the one considered in this work.

Presently, both PICUs in OLCHC use the Phillips IntelliSpace Critical Care and anaesthesia (ICCA) electronic patient record (EPR) system which includes an e-prescribing module. In OLCHC, within the PICUs, smart infusion pump technology (SIPs) are already in use with advanced and internally developed Drug Error Reduction Software (DERS) (i.e. Paediatric/Neonatal drug library). This comprehensive drug library is already shared with Temple Street's Children's Hospital and is to be rolled out to the 19 maternity hospitals as part of a national initiative. Standardising practices across sites is laying crucial preparatory work before the opening of the NCH. (Howlett, 2018).

1.5 Research Question

After discovering where to address the focus of this research within the hospital and coupled with the motivation of reducing medication errors to children by using the

combination of available technologies which combined together make a CCLIMS, the research question is;

What are the changes to work practices through the proposed implementation of a closed loop infusion therapy system into an existing working paediatric hospital?

1.6 Study Aims and Objectives

The **aim** of this study is to *ascertain what are the changes needed to work practices in order to effectively integrate a complete closed loop medication system into an existing paediatric intensive care*.

The information gathered will be invaluable when the integration of a complete closed loop infusion medication system (CCLIMS) is to be installed into a existing hospital or quite possibly the construction NCH when it is delivered for the children of Ireland in 2022.

1.7 Outline of the Research

This research set out to identify what are the changes to working practices when a CCLIMS is introduced into a functioning well-advanced highly technical environment such as a working paediatric ICU. This research should clearly highlight the barriers, limitations and advantages to the acquirement and implementation of a CCLIMS. Medication safety is first and foremost, one target for this research is to highlight how a well-integrated system will benefit the sick children of Ireland delivering safer drug infusions within the PICU in either OLCHC or the NCH. The researcher wants to establish the shortcomings if the socio-technical part of the integration process of a multi departmental system is not approached correctly, or the changes to working practices aren't thought-out entirely. If these shortcomings are not addressed in a rigorous manner this complicated CCLIMS which is proposed for the NCH won't be able to be implemented fully, this will unfortunately leave the most vulnerable of patients, children at risk from medication error.

A literature review was conducted which highlighted the difficulties faced by other hospitals around the globe and the solutions that they adopted. Hospitals in the United

States have been developing closed loop systems for many years and they are ahead in this field of technology to-date. Functioning systems in the United States include modules for billing the patient or an insurance company at the end of the hospital stay (automatic billing of the infused medications used etc.), (interestingly the hospitals that have developed these systems are mostly privately-run institutions). The literature is narrow regarding implementing a CCLIMS into a children's hospital ICU (the most noteworthy referenced papers have a strong linkage to medical device manufacturers who has sponsored the publication, the conflict of interest is disclosed and the content is proven to be sound (in relation to what is known about the subject of CCLIMS). To date it is believed a CCLIMS has not been implemented in Ireland or the UK. The difficultly with a children's hospital is the weight range of the patients (ie from 500g to 100kg) using standard concentrations of drugs throughout the needed weight bands becomes a complex task (Irwin et al., 2008).

After interviewing the experts from all the departments which need to be involved when implementing a CCLIMS, comparisons of work and information flows and practices were developed on activity UML diagrams. These proposed, and now discussed system changes to the CCLIMS work practices (and information flows) as outputs of this work will be used to guide the organisation in culminating suggestions to be considered before a CCLIMS is tendered for and implemented into our national children's hospital. Figure 2 shows a flow diagram of the process undergone to complete this dissertation.

Overview of the Research Process

Question
What changes to work practices through the proposed implementation of a closed loop infusion therapy system into an existing working paediatric hospital?

Literature Review

Ethics Application HDO

Ethics Approval HDO — Rejected

Approved

Ethics Application SCSS TCD

Rejected

Ethics Approval TCD SCSS

Approved

Interview Nursing CNS PICU

Interview Informatics Pharmacist

Interview PICU Pharmacist

Interview ICT System Administrator

Interview ICT Project Manager

Interview Clinical Engineer

Interview Clinician PICU intensivist

Interview Transcriptions

Interview Data/Work Flow Analysis

Development of UML Diagrams for Current Work and Information Flow Verses 'Proposed' Closed loop Work Flow

Findings

Comparisons

Conclusion and Future Recommendations

Figure 1-2:- Overview of the Research Process

1.8 Overview of the Dissertation

This chapter has presented the motivation for the research, the study domain, the research question, objectives and an outline of the research.

Chapter 2: - Provides the literature review. It first addresses infusion devices and the recent technological advancements with smart infusion pumps (SIP) and software based safety systems associated with them, re: - Drug Error Reduction Software (DERS). Secondly the literature review explores the use of these smart infusion pumps (SIP) combined with Electronic Health/Medical Records systems (EHR, EMR) to form a combined interoperable system to aid medical staff and allied healthcare professionals.

Chapter 3: - Presents the design of the research study and outlines the methodologies used and the rational for choosing the qualitative method of purposeful specialist sampling based on the expert's knowledge from each specialty field/department and any ethical considerations.

Chapter 4: - Presents the detailed findings of the study, identifying and quantifying the differences and changes to the work and information flow which this new technology introduces and what effects these have on the working practices of the doctors, nurses, pharmacists, ICT and Clinical Engineering Professionals in the proposed system studied.

Chapter 5: - Discusses the findings of the comparisons in the different working practices. How these findings address the research question, the significance of the findings, and the impact of the changes in work practices from one discipline and how it effects the other departments work and information flow. This chapter also addresses the limitations of the study.

Chapter 6: - Concludes the dissertation, makes recommendations for paediatric hospitals planning to implement a complete closed loop medication system and identifies possible future research work in this area.

Chapter 2 Literature Review - State-of-the-art

2.1 Introduction

Before proceeding to describe the research study in full detail, it is necessary to describe the state of the art in this field. Medication safety is a widely discussed topic in medicine and many studies prove that a carefully designed support system to address difficulties in medication compounding add extra value to the essential safety net. The most vulnerable patients to a medication error are the patients in a paediatric intensive care unit. In the landmark study *'to err is human'* this book states frank truth about errors in the health system and how medicine is not as safe as it should be (Linda T. Kohn, 2000). 'Death by decimal' is a article calling for a more aggressive approach to stopping another preventable death of a paediatric patient from occurring (Broselow and Schuman, 2008). This chapter provides the literature review. It first addresses the current, published scientific evidence of the development of infusion devices including the recent technological advancements of these devices into smart infusion pumps (SIPs) and the software based safety systems associated with them, re: - Drug Error Reduction Software (DERS). Secondly the literature review explores the use of these smart infusion pumps (SIPs) combined with Electronic Health/Medical Records systems (EHR, EMR) to form a combined interoperable system to aid, guide and offer assistance to the medical staff and the allied healthcare professionals involved in the delivery of IV infusions. The review will also explore the socio-technical aspect of a complicated hospital wide implementation of a CCLIMS system (or similar equivalent).

2.2 Background

Many hospitals who aspire to implement a closed loop medication system view it as the introduction of a technical system and either don't understand the need for a corresponding change in the socio systems that support drug delivery or underestimate the level of investment needed in the socio side of the socio-technical system.

The medical system suppliers make it sound so straightforward to implement their systems into hospitals. If these systems are carelessly designed, integrated or poorly

resourced they will impact on working practices which can decrease the benefits to patients (Burgin et al., 2014). In reality, there are many failed projects in the domain of health Informatics; this can be due to the complex interdisciplinary tasks needing to be performed. Multidisciplinary teams need to assess various different integrations across many departments in hospitals (Samaranayake et al., 2014).

For example, a complete closed loop paediatric medication system will involve at least five different departments having to work toward a common goal. The professions involved will be from Pharmacy, Medical, Nursing, Clinical Engineering and Information Technology (ICT). These disciplines will have to input into the closed loop medication system (and change their working practices) to ensure it can be integrated into a Hospitals existing infrastructure. The Medical vendors also have a challenging role to action as they need to progress all integrations and ensure the interoperability with the other vendor's systems (i.e. EMR/EHR) until the customer / Health-Care Delivery Organisations (HDO) is satisfied. A phased team approach with a broad training regime will be needed to get a CCLIMS operational (Sims and Schneider, 2012).

2.3 Search Strategy

An extensive, systematic search was conducted using subject matter from several scientific databases, namely TCD Library Stellar Search, Scopus, Pubmed, Science Direct, Google Scholar (these are shown in the table below). When the first phase of searching, a suitable article was found (and a full text version wasn't available); either from a subscription requirement or a restricted journal article, the researcher found that a second input into the TCD stellar search would locate a full text PDF version within the TCD library (including TCD's external library alliances sourcing the required article/paper/journal access with an approximate 85% success rate) so the article could be fully accessed and read for appropriateness for inclusion or exclusion.

Table 2-1:- Electronic Database Information Search Details

Electronic Database Information Search Details	
Databases	TCD Library Stellar Search, Scopus, Pubmed, Science Direct, Google Scholar, Wiley Online Library.
Type	Academic Papers, Journals, Websites, Government Reports,
Keywords 'Terms' Searched	Infusion Pump, Syringe Driver, Smart Infusion Pump, Drug Error Reduction Software, Drug Library, Electronic Health Record, Auto-Programming, Automation, Closed Loop Medication Systems, Medication Errors/prevention & Control Dispensing Cabinets.
Criteria	English Language, Years 2002 to 2018 for CCLIMS, SIP, DERS, BCMA, etc. All years for Infusion pump history timeline

2.4 Infusion Pumps from the beginning

There are mostly two types of infusion pumps used in medicine. Large-volume (Volumetric) infusion pumps and small-volume syringe pumps. Volumetric pumps either use a peristaltic pump head or piston driven drive head which delivers nutrient solutions large enough to feed a patient. These peristaltic/piston type pumps generally use a disposable dedicated giving set which comprises typically of either a silicone section (for the peristaltic type device) or a piston cassette type (which usually comprises of a piston

receiving vessel with a stretched silicone membrane inside it. Small-volume syringe pumps infuse more accurately by using a computer controlled stepper motor attached to a lead screw which in turn activates the plunger on a disposable syringe. Syringe pumps and are generally used for medicines such as opiates and inotropes (Lee, 2015).

Infusion pumps are found in every ward in every hospital today; this was not always the case, the first commercial syringe driver was developed in 1951 and had only a fixed rate of 1ml/hr using a glass syringe (see figure 2-1 below).
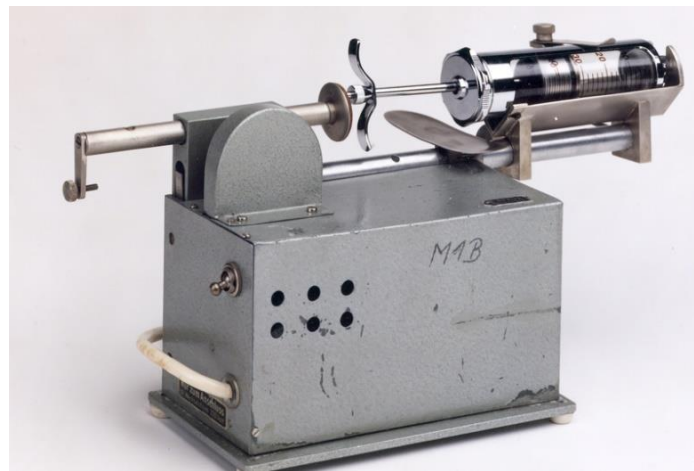
Figure 2-1:- A 1951 Mechanical Syringe pump (B. Braun, 2018b)

Infusion pumps first emerged in UK and Ireland between the 1970's and 1980's these were elementary limited mechanical devices with basic functions and no safety features and flawed user control designs. Interestingly before 1970 in the UK medications (because of their high risk) were only allowed to be administered by an anaesthetist or medical doctor. In 1976 the Breckenridge report recommended for the first time that a nurse can be trained up with a new skill to give a drug with an IV fluids infusion (Lee, 2015).

In today's world infusion pumps use micro-supercomputers with 40 years of technological developments behind them, (examples of these pumps from two different manufacturers are shown in figure 2-2). This technology aids and governs their use but most importantly adds a layer of safety and helps protect patients from medication

errors (which unfortunately still is a common occurrence with these complicated medical devices) (Ohashi et al., 2014).

Figure 2-2:- Today's infusion pump designs (BD, 2018, B. Braun, 2018a)

2.5 Smart Infusion Pumps with Drug Error Reduction Software (DERS)

'Smart' infusion pumps SIP's (with DERS) were the first wave of defence against the standard 'dumb' infusion pump which could be programmed to infuse drugs/fluids at any setting allowed within the range of that device. These 'dumb' pumps gave no alerts to the user if a high rate was inputted in error or a litre of fluid was set to be infused instead of 100ml (to a child for example). A safety net was needed, hence the birth of the smart infusion pump. A standard pump (without software to assistance the user) could accept an infusion rate from 0.1ml/hr to over 999ml/hr. Mistakes in interpreting the infusion rate for the volume to be infused (VTBI) could cause a fatal administration dose (Proctor, 2014). For over 30 years errors with infusion pumps and pump programming still remain to be a critical issue in infusion therapy. The ECRI Institute' in 2017 had infusion pumps in the number one place on the Health Devices Groups list of the 'Top 10 Health Technology Hazards' (ECRI, 2018).

Computer chip technology advancements made it possible for pump manufacturers to make customisable (by the users) drug safety management software by employing electronically erasable programmable read-only memory (EEPROM). This hardware coupled with the required software allowed the clinicians and pharmacists to develop a hospital wide drug library with specific hard and soft limits (Vanderveen, 2018). Now

armed with standard concentration infusions within specific areas of the hospital for each drug and patients weight bands this was a significant development especially for Paediatric and Neonatal ICU patients. The implementation of SIP's significantly improved IV medication safety (Howlett, 2018). Since the 14 years that SIP's have been in development, their introduction has promoted standardisation and has significantly reduced programming medication errors. Programming an IV infusion pump is one small piece in the complicated process of delivering error free infusion therapy. In a study, 20 months after the introduction of SIP's pumps by Pang et al., a repeat audit was supported for 27 days. The results were a reduction of errors from 18% before the installation of the SIP's to a reduction of errors by 47% from 18% to 9.4% afterwards. What is more significant is where the drug library (DERS) was used the error rate dropped by 79% from 18% to 3.6%, See Figure 2-3 (not all drugs are in the library, and in some cases the clinicians choose to go outside the drug library and use the manual function)(Pang et al., 2011)
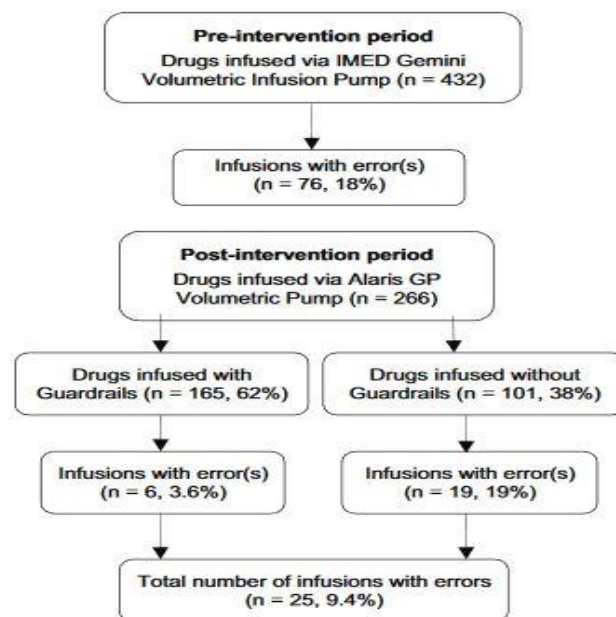
Figure 2-3:- Distribution of errors during the pre- and post- intervention periods (Pang et al., 2011).

Although the results from the introduction and use of SIPs are proved to reduce medication errors, they is still room for improvements as the study by Trbovich et al. shows, that even with the introduction of soft drug dosage limits harm could still get through to the smallest of patients, children. Trbovich et al. proved that hard limits work

but unfortunately, the soft limit warnings were mostly dismissed as nuisance alarms. Armed with this knowledge the call for more safety focused mechanisms like bar-coded medications linking the patient's weight and size from an electronic patient record (EPR) to an electronic medication order (CPOE) thus ensuring accurate safety limits for the weight of the patient are in place (Trbovich et al., 2010).

2.6 Electronic Health Record / Electronic Medical Record (EHR / EMR)

Is an electronic/digital assembly of a person's personal medical information. An EHR consists of a complete medical history for that individual, comprising of medication information, treatment records and diagnoses. The advantages to capturing information digitally and having a complete picture of an individual's health status (which is easily accessible by clinicians), and is sharable from one institution to another all from different sources. This interoperability allows for much easier diagnoses and by getting actuate patient history means better services and outcomes for the patients receiving treatment (Stacy, 2013).

Safran et al. (2010) developed a system that allowed the EMR to monitor the SIP's considering previous dosage levels and patient demographics (weight, age, gender). This study continued for 22.5 months in a 24 bed ICU, monitoring 23 high-risk infusions, this system averaged 1.4 alerts a day which 14% were found to have prevented harm. This advanced integration between an EMR in 2010 showed the benefits of what errors can be addressed with the elimination of manually programming SIP's (Safran et al., 2010, Pettus and Vanderveen, 2013).

2.7 Computerised Physician Order Entry (CPOE)

CPOE is usually an extension to a clinical information system or EMR. These electronic order systems allow the medical practitioner to enter instructions (like prescribing medicines, ordering an x-ray or getting a lab result) for the treatment of patients under their care. CPOE systems reduce transcription errors and increase efficiency by reducing the time to write and distribute orders (Linda T. Kohn, 2000). HDO's implement CPOE to help prevent adverse drug errors and this increased access to patient data improves

clinical standard adherence (Baysari et al., 2018). It has been shown by published studies that CPOE systems have reduced adverse drug events up to 81% (Koppel et al., 2005). Similarly, research carried out in a paediatric hospital's wards and ICU over 6 months, returned results of a 44% reduction in preventable medication errors and 63% in potential medication errors in a comparison study before and after the implementation of a CPOE system (Holdsworth et al., 2008). Another study which highlighted the benefits of a CPOE system across 3 HDO's (systemwide reduction of medication errors by 75%), recommended that the optimisation of workflow needs to be engaged by the multidisciplinary team before the implementation of a CPOE system to ensure inter-professional collaboration (Chung et al., 2018). HDO's looking to implement a CPOE are recommended to implement as many verified clinical decision support systems (CDSS) that are available in order to catch medication errors before they reach the patient. This report suggests that if a clinician is subject to an alert, that when the alert is resolved the user interface places the operator back into a workflow that they had been interrupted from (before the Alert occurred). By following this method, this process can protect the user from Alert fatigue (Kuperman et al., 2007). Alert fatigue can govern how well a new system is accepted into existing workflows, if clinicians regularly have to ignore and override alerts, the alerts become invaluable (Page et al., 2017).

2.8 Barcode Medication Labelling (BCMA)

In healthcare, Barcode Medication Labelling was developed to help prevent medication errors, improve quality, safety and create electronic records of the medication administration process. In the United States, BCMA's became mandated by the federal government on all prescription medications (Cescon and Ethchells, 2008). In a dissertation undertaken by Holecek (2011) on medication errors, before, during and after the implementation of a BCMA in a hospital setting, The administration errors decreased steadily in all times periods throughout the study (Holecek, 2011, Trbovich et al., 2010).

In 2006 a time-motion study conducted by Poon et al. (2006) on the changes of workflow for nurses (in a 739-bed hospital) who recently implemented a BCMA system. The study showed that if a HIT system was correctly implemented, and the staff were adequately

trained, (BCMA systems require a change to workflow, and this could lead to a reduced amount of time the nurse was at a patient's bedside). The introduction of a BCMA would influence the nurse's workflow but not add to the time needed to make up (or in this case print) a drug label. This study consisted of 232 observation sessions over 10 months each lasting 2 hours. The results showed that before the introduction of the BCMA's 26.5% of the nurses time was spent on medication administration, and after it actually reduced to 24.5% (Poon et al., 2006). A similar study by Samaranayake et al. (2014) came up with a similar conclusion as Poon et al. (2006), with the nursing staff involved stating that the introduction of a BCMA helped them with the accuracy of medication administration (Samaranayake et al., 2014, Poon et al., 2006).

BCMA has been proven to reduced medication error in some cases by large percentages (Patterson et al., 2002). In research carried out by Morriss et al. (2009), a 47% reduction in the risk of adverse drug events were prevented in a 92,398 dose administrated study (Morriss et al., 2009). Similarly, Helmons et al. (2009) found BCMA reduced medication errors by 58% in the medical-surgical ward but oddly not in the ICU, (this was believed to be down to time delays in getting medications to patients in ICU) (Helmons et al., 2009).

2.9 Overview of Complete Closed Loop Infusion Management Systems

Complete Closed Loop infusion Management Systems bring together all the individual devices with their advancements in hardware and software design becoming one 'truly intelligent' system. SIP, DERS, BCMA, CPOE and most importantly the EHR/EMR. As mentioned in the introduction, the intent is to manage patient data better and to configure devices into systems that as a whole provide more functionality and safety, then the individual equipment can do when used as standalone devices (PSQH, 2016).

2.9.1 Work/Process Flow & Auto-programming

In a CCLIMS the Physician enters a prescription using CPOE, the Pharmacy (or ICU nursing) staff access the EHR, make up the patient's prescription. The EHR system will then print a barcoded label (BCMA) with all the necessary information on it (for an example of a medication bar-code printer see figure 2-4). The bar-code printer shown in

figure 2-4 has a scanner built into it where a quick check of the labels content is needed for checking purposes.

Figure 2-4:- Barcode Label Printer in Pharmacy (Melsungen1, 2017)

In the next step, the nurse receives the medication from the pharmacy, or make it up, so the next steps are to scan the patient, pump and themselves (the caregiver) (Pettus and Vanderveen, 2013). Now, this is the intelligent part; only if there is a valid prescription in the EMR from the CPOE program, the system will auto-programme the SIP with the correct data, i.e. the drug name, volume and concentration, infusion rate and VTBI. The caregiver must then confirm this 'automatically populated information' before the infusion can start (the caregiver is ultimately responsible for the medication administration by law, not the system). What should be noted is that the DERS within the SIP will continue to work independently from the auto-programming technology (and all the usual safety features on SIP's are still active as they are standalone even when the network might be unavailable). Remember, communication and pump setup information sharing is not possible if the patient/pump association has not been verified (Proctor, 2014).

Figure 2-5, shows graphically a good flow to the order entry and infusion data integration (Pettus and Vanderveen, 2013, Arney, 2018). The flow in the diagram starts with CPOE order (shown as a red line), next following the diagram clockwise around to the pharmacy compounding and labelling (BCMA). The flow line now changes to blue and continues to the patient's bedside. The medication gets scanned along with the patient the infusion pump and the nurse to close the administration loop. Auto documentation happens last with full integration with the electronic patient record.
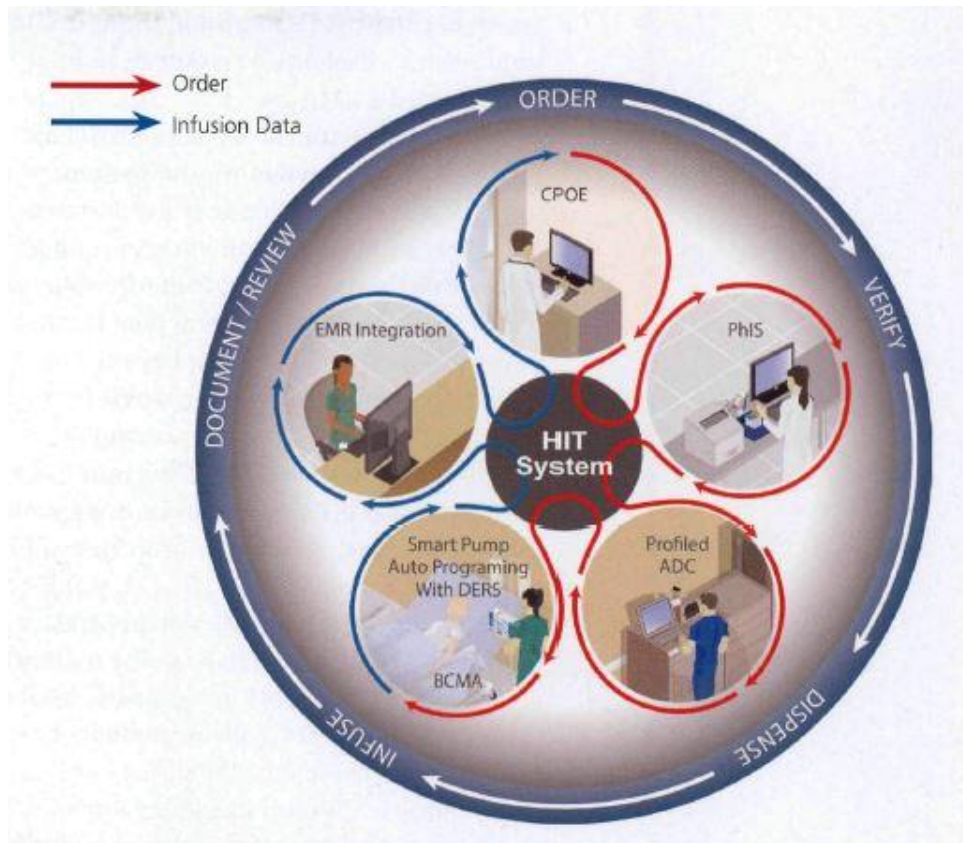
Figure 2-5:- Integrated closed loop medication safety system (A system of Systems) (Pettus and Vanderveen, 2013)

2.9.2 Auto-Documentation

Auto-documentation delivers considerable rewards in productivity gains for nurses when charting multiple IV infusions on critical ICU patients. Prior to auto-documentation, this task was very time consuming for the nurse's taking away clinical nursing time from their patients to do extensive paperwork. Pettus et al. (2017) discussed the substantial amount of time needed to manually chart IV infusions (see figure 2-6 for an example of systems components needed), this charting can distract the nurse and may introduce serious errors. It was discovered that the seamless electronic transfer of the SIP's data to the EMR gives the nurse back much needed time for direct patient care. The caregiver's role has changed (from the previous practice of medication administration calculations) and is now to review and confirm all the infusion data going from the SIP's to the EMR is correct and complete (Pettus et al., 2017). This automated action is welcomed by the nursing staff and was included in a technology 'wish list' for intelligent infusion systems (Proctor, 2014).

A PhD study by J. Melius (2012) looked at the relationship between mathematics anxiety and nurses working environment; her study subject ranged from nurses not liking mathematics to medication administration stress (when the nurses were exhausted at the end of a 12-hour shift). The number of hours a nurse worked was in a direct relationship with the mathematics anxiety score (Melius, 2012). The author colourfully stated that the nurses would benefit from technology to work out complex medications formulas. A CCLIMS would remove this burden on nurses and improve medication safety.
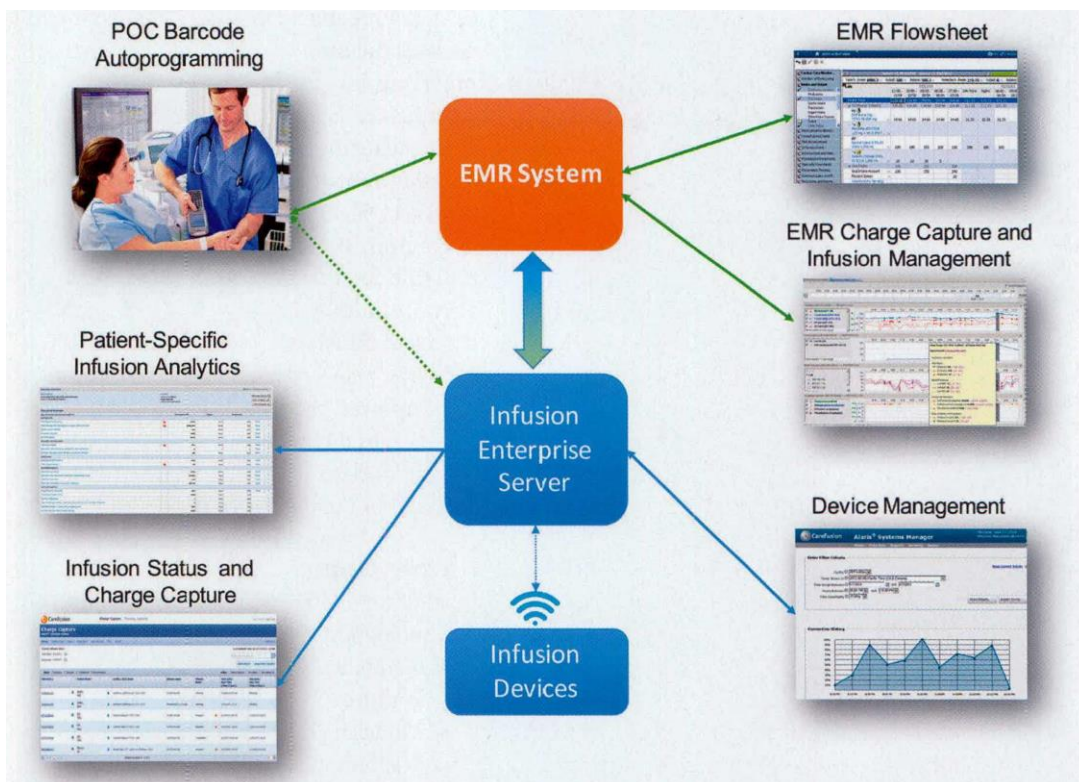
Figure 2-6:- Graphical overview of system components (Pettus et al., 2017)

In this dissertation, some of the steps involved will be simplified to allow for a more transparent overview on how a complete CCLIMS sits within a HDO. The advanced pharmacy systems element will primarily be the most 'just excepted' example of simplification to a process and workflow (to deeply evaluate it is outside the scope of this study). The Researcher will discuss the pharmacy element of this research further in the coming chapters. The main reason for the pharmacy to be treated differently is

the way the pharmacy services in Europe and the work practices differ to the pharmacy services in the United States (more about these differences later).

2.10 Will a CCLIMS Help Prevent Medication Errors?

Over the last 10 years, CCLIMS development certainly takes the biggest step towards this challenge and has been proven to be successful within private hospitals in the United States. The complexity of a CCLIMS installation has to date always relied on an external equipment vendor and presents too complex for individual hospitals to manage only with internal departments expertise (Pettus and Vanderveen, 2013). Fig 10 shows where the individual systems stop and smart pumps take over, auto programming fills this GAP but only if the interoperability between the systems is 100%. Without auto programming administration errors can still easily reach the patient as show in the red part of the diagram below.

Figure 1. CPOE, BCMA and IV Infusion Errors
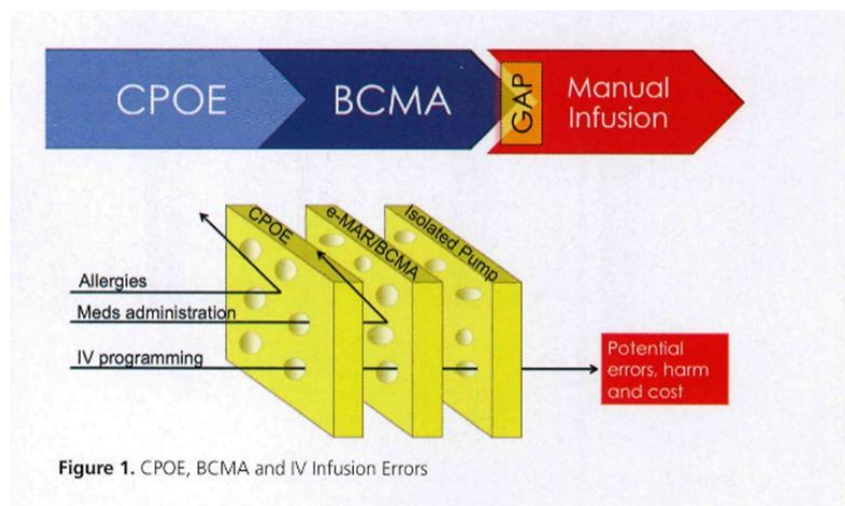
Figure 2-7:- The GAP Auto programming fills (Pettus and Vanderveen, 2013)

The benefits of a CCLIMS appears to be a clear and concise message to the HDO's that if all the hurdles with interoperability can be overcome then some real strides will be made in eradicating prescribed medications differing from the administered amount by closing the loop in infusion and medication safety (Pettus et al., 2017). The challenges don't stop with the technology's integration. The many users of a CCLIMS need to adapt from their current work practices to the demands of the new system. In many cases the

technical advancements (once the advances are adapted to) will actually relieve the users (nurses) stress in drug admixture and administration (Brady, 2010). A study on paediatric nurses' knowledge of pharmacology resulted in an outcome of 61.5% showed insufficient knowledge when administering infusions to paediatric patients. Evidence-based results also state that 9.2% of the reported incorrect doses monitored has serious significances for the children involved (Lan et al., 2014). These studies and many more, place the evidence front and centre to why medication safety through implementing a CCLIMS in our paediatric hospital should be a priory in the battle against adverse drug events (Chung et al., 2018, Pham et al., 2016, Pettus and Vanderveen, 2013, Prusch et al., 2011, Russell et al., 2010, Hennings et al., 2010) .

2.11 Improved work flow for SIP & Drug Library updating using CCLIMS

Biomedical engineering departments have a difficult job in maintaining hundreds and in some hospitals thousands of infusion devices. Not only do these infusion devices need maintenance and calibrations carried out there has been the added task of rolling out the latest version of the hospital pharmacies drug library (PSQH, 2016). When these pumps were single smart pumps without being networked, this task involved locating and upgrading every pump singly or in small batches, this procedure takes up valuable manpower hours and is often fault ridden due to devices not being located correctly. The advantages of having all the pumps networked for interoperability gives the biomedical engineer a powerful new engineering software tool. Drug library updates and real-time pump location history (not to mention the usefulness of real time battery status for replacement purposes etc). Drug library changes need to be carefully coordinated with the pharmacy and CPOE systems to ensure correct connections between standard drug concentrations and weight banding are preserved. Incidences of mismatched prescriptions will be high if the drug library does not mirror the ordering system (AAMI, 2014). Each pump should be able to be traceable on a Biomedical/Clinical Engineering dashboard (similar to a pharmacy dashboard) and each SIP that is infusing in the hospital will be able to be monitored from this infusion portal regardless of the SIP's location (Pettus et al., 2017, Pettus and Vanderveen, 2013). These system tools will change the current pump maintenance practices but will increase efficiencies it the process.

2.11.1 Faults and a Complex System who's problem is it?

The traditional repair route in any HDO would be to send the individual item/pump etc. to the Clinical Engineering (CE) department for repair. Now considering the fact that with interoperability all these medical devices are now connected and with the technologies involved hospital staff will need to be aware that if a pump doesn't work or if the drug library won't upload is it the SIP or the network? Who can determine what is wrong IT or CE? When the process needs all the systems to work together to achieve the goal (i.e. EMR's, SIP's, CPOE, BCMA & IT Networks) the problem becomes far more challenging and complex to identify. A very high level of the interdisciplinary interdepartmental understanding will be required to find a solution and rectify the issues and stop it happening again (Pettus et al., 2017). The working practices within and between the ICT department and CE department will change dramatically as the informatics roles increase in the hospital. The introduction of these complex systems will have a dramatic effect on the socio-technical dynamics within the hospital and the HDO will need to give considerable thought on employing an informatics trained medical device engineer can understand the complete system and has the skills to deal with issues and maintain these complex systems. The current literature on this subject is sparse and any reports found indicates that the equipment vendors are currently supporting and controlling the systems as a whole. These are mainly in private hospitals within the United States. The certification status of these devices when combined is still unclear while the standards authority tries to catch up (IMDRF, 2017).

2.12 Summary

The introduction of a CCLIMS at any level within a HDO will lead to a change of clinical working practices and can shift certain responsibilities from one discipline to another (e.g. drug admixture could move from the ICU nurses' role into the Pharmacy department). It is imperative to appraise these working practices before implementing any computerised clinical system so that the HDO can make an informed decision on deployment before any adverse event or risks of error can affect patient safety.

2. 13 Conclusion

The literature review confirms the advancements in medication infusion systems in reducing medication error and increasing patient safety. Regardless of the cost of interoperability every HDO should exhaust every means to deliver this safety driven technology for the wellbeing of their patients. The changes to working practices in the literature reviewed signals a comparable work load for most of the staff involved in medication administration, e.g. BCMA label printing and affixture are offset by the removal of other tasks (like handwriting out drug labels etc.). After staff get familiar with the operation of the system the clinicians' will benefit from the increased information available to care for their patients when and where the need arises.

The next chapter describes the methods used for the research methodology used to provide the discoveries and findings to answer the research question.

Chapter 3 Research Methodology

3.1 Introduction

The literature review in the previous chapter established that with the advances in infusion pump technology and the associated prescribing, labelling and electronic charting systems can (if implemented correctly) help to prevent medication errors. One noticeable gap in the information reviewed is, what work practice's and information flow changes does a HDO have to consider in order to successfully implement a system as complex as a CCLIMS across all the affected departments and different disciplines that combine together to provide a medication service to the PICU. Another consideration (as mentioned in chapter 1) is that the installation of a CCLIMS will need to completely integrate with the existing systems which are functioning already and in clinical use within the HDO.

3.1.1 Review of the Research Question

Remembering the motivation of reducing medication errors associated with the intensive care of children using the combination of available technologies which combined together form a CCLIMS, the research question is: -

What are the changes to work practices through the proposed implementation of a closed loop infusion therapy system into an existing working paediatric hospital?

3.2 Reminder of the Study aims and objectives.

The aims of this research are to: -

1) Determine the conditions under which a completely closed loop infusion therapy system can be safely integrated into a working paediatric hospital.

2) Investigate and document what are the changes to work practices for the following stakeholder's: -

- Pharmacy professionals
- Nursing professionals
- Clinicians
- Clinical Engineers
- ICT professionals

It is anticipated that the improved overall understanding of a CCLIMS will help to guide and prepare the healthcare institution towards the correct approach for purchasing and implementing a CCLIMS. It is also expected that the sociotechnical element of the installation of a CCLIMS can be partly prepared for from the outcomes of this research study which should help the many different professionals who will be required to operate and maintain it.

3.3 Study design.

This study will use mainly qualitative and applied research methodologies. The information gathered from semi-structured individual interviews with selected staff on the existing procedural work practices (when delivering a medication with an infusion pump to a patient) in their departments. The information gathered will then be compared against the new perceived work practices which are associated with the proposed system (these new work and information flows shall be described by the researcher, with the utilisation of a digital media source coupled with an in-depth discussion of the technical detail of the perceived use of the proposed closed loop system). It is proposed that this approach will add to the knowledge and awareness towards the changes involved in implementing such an intricate system across many departments and disciplines.

3.4 Participant Recruitment and Rationale for selection: -

Participants are work colleagues from OLCHC and are known to the researcher. They will be purposefully selected for their expert knowledge in each of their specialities, this recruitment procedure will be purely on a voluntary basis.

It is proposed to interview five to seven individuals in Pharmacy, Medical, Nursing, Clinical Engineering and ICT backgrounds. These purposefully selected experts (in their professions) coupled with their experience and their in-depth knowledge of the current working practices (within a paediatric hospital's ICU) will guide the researcher with the knowledge to critique the required work practices of the proposed CCLIMS. These five to seven individuals represent the total number needed for the research to be carried out. The rationale behind only interviewing one or two professionals from each department is backed up by the researcher's outlining knowledge of the procedure's and systems used to deliver medications with infusion pumps to patients within a PICU. The Researcher coupled with the knowledge of knowing the selected interviewees and their skills and comparing this information with the knowledge gained from a wider range of subjects (who don't have as deep a knowledge of the systems in use) will only dilute the accuracy of the findings.

The researcher is a working colleague with no influence over the selected participants with regards to participation in this study. Their participation will be completely on a voluntary basis. Each participant will be invited to take part in writing by the researcher (after an informal conversation to ascertain if it is something they would be willing and interested to take part in).

3.5 Study methodology

3.5.1 Semi structured interviews: -

The researcher proposes to carry out semi structured interviews with selected staff (using purposeful sampling) from: - (See Table 3-1 Below),(Rogers, 2018, Tuckett, 2004).

Table 3-1 Purposefully Selected Participants

Department	Title	Role
Clinical Care	Clinician /ICU Intensivist	Cares for critically ill patients mostly in the ICU and Theatre environments.
Pharmacy	Informatics Pharmacist	To ensure medication guidelines are supported within the HDO while utilising technology
Nursing	Clinical Nurse Specialist (CNS)	Trainer on smart pump technology and application
Clinical Engineering	Clinical Engineering Technician	Medical Device management and support
ICT	System administrator	Clinical Data Gatekeeper for PICU's EPR system.

The structure for all the interviews will be similar (the direction and content will differ greatly with the variation of participants and their disciplines) and should produce a good overview of the methods under review: -

3.5.2 Step 1 (Interview explaining existing practices)

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

3.5.3 Step 2 (Digital media presentation of a CCLIMS)

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html.   This video shows how a CCLIMS can ensure the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the information systems and the physical product including the patient which gives a good awareness of the new work practices to be introduced when a system like this is to be implemented.

3.5.4 Step 3 (Critiquing of the proposed new work flow)

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again, this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

The Comparisons in the work and information flow practices will be deliberated the main differences written out and where applicable highlighted using unified modelling language (UML) activity diagrams. The varying roles between the different disciplines will be prevalent, but this will help develop a broad base of knowledge with interesting interoperability comparisons.

3.6 Ethical Considerations

Before any participant recruitment could take place in the HDO the researcher had to apply for ethics approval from both the HDO (OLCHC) and Trinity College Dublin through the School of Computer Science and Statistics (SCSS) Ethics committee. The application to the HDO was a long process delayed further by the rescheduling of meeting dates etc.

- The full HDO (OLCHC) application is in Appendix B.
- The HDO (OLCHC) Approval Letter was received on the 28th of February and is in Appendix A.

Once the HDO had approved the ethics application for this research an application to Trinity College Dublin could be submitted. The application to the Ethics committee of the SCSS was made online through the Trinity Ethics WebApp (see Appendix C).

- The SCSS Ethics Trinity application (Appendix C) was approved on the 27th April
- This application involved submitting a Research Project Proposal (Appendix D)
- An Information Sheet for Prospective Participants (Appendix E)
- An Informed Consent Form (Appendix F)

3.6.1 Potential conflict of interest

As the researcher is a work colleague and known to all the purposed participants there is a potential conflict of interest in relation to this research study. However, it is the researcher's intention to adhere to good practice and follow the ethical code for research at all times during this study.

3.6.2 Participant debriefing arrangements: -

The Researcher will inform the participants of the purpose of this research. If participants request further information it will be arranged to send them the completed copy of the final dissertation in a PDF format.

3.6.3 Data Protection

As per the Data Protection acts 1988 & 2003 all data collected will be anonymized, this will be done by ensuring no participant is named or identified from their unique role in the HDO or by any information disclosed, (See 3.6.4 & 3.6.5 below). No disclosures of participants identities or any personal information will be provided, participants will be referred to by their professional title No consent is required from the data controller.

All research documents for this dissertation are stored (or will be stored) on the researcher's personal laptop computer. This personal laptop computer is password protected and is encrypted with the safehouse explorer 448-bit encryption software program.

3.6.4 Data collected

Data will only be retained for as long as necessary by Trinity College though the researcher after which it will be destroyed using Safehouse Explorer's shredding file facility. When digital shredding takes place, spurious data is interlaced throughout the file volumes and then deleted to leave no legible trace.

3.6.5 Confidentiality of collected data: -

No personal information will be collected or recorded and all data will be totally confidential and anonymous.

3.7 Conclusion: -

This chapter described the research methodology and rationale for the selection of participants needed to answer the research question. The ethical approval processes of the HDO and the college was explained in detail and the outcomes stated, (the full ethical application is included in Appendix A for the HDO, and in Appendix C for Trinity College Dublin, including screen grabs from the online application approval process).

The following chapter will present the findings of the investigations undertaken when preparing to answer the research question.

Chapter 4 Results

4.1 Introduction: -

This chapter explores and develops the knowledge and pathways investigated during the selective interview process as outlined by the methodology in chapter 3. Each interviewee's knowledge and experience was used to build up an accurate description of the existing work practices of the various different healthcare professionals (see table 3-1 In chapter 3) who play a role in delivering medications using smart infusion pumps to PICU patients within OLCHC.

4.2 Clinical Engineer Interview: - (Full interview transcription see Appendix J)

4.2.1 Summary of the main points in step 1 (Clinical Engineer Interview)- Existing Practices: -

Clinical engineering (CE) is responsible for the complete management and lifecycle of medical devices within the HDO. Infusion pumps historically put a strain on CE resources as they are frequently moved for use and cleaning procedures and unfortunately see more than their fair share of rough handling lending to frequent repairs outside the manufacturer's maintenance schedule. Due to the critical requirement for accuracy and reliability with infusion pumps, HDO nursing staff are very cautious when using these devices, and if a problem is only suspected, then the pump is returned to the CE workshop for inspection, repair and safety checks.

4.2.1.1 Smart Infusion Pumps (SIP's) are significantly more complicated than a standard infusion pump and more time consuming to maintain and service. SIP's drug libraries (DERS) need updating whenever there is a modification needed to the medication data in the drug library; this includes parameters and default settings, hard and soft limits and drug concentrations (in any of the five weight bands) within OLCHC. The DERS update requires the CE department to individually physically find and update every SIP in the HDO with a laptop and cable using a bespoke vendor service program. The updating process is a time consuming costly and labour-intensive procedure especially when OLCHC has approximately 350 high and low volume SIP's which all will need

upgrading together. Having two different DERS software versions in one HDO is potentially dangerous for the patient as the users need training and familiarity with the software to ensure that user errors do not occur.

- It is worth noting here that Pharmacists are responsible for all the data in the drug library, they decide and set all the hard and soft limits, drug concentrations and patient weigh bands (these figures are decided on as part of a multidisciplinary team with the clinicians).
- The role of Clinical Engineering in this process is to update this information on the medical device.

4.2.1.2 The Networking of the SIP's: - The CE department is also responsible for physical networking between the SIP and the HDO's EPR. In OLCHC an intermediate data capture module (Capsule Terminal Server by Qualcomm, this module is a serial to network bridge which has drivers to interface with most medical equipment and then output in health level 7 (HL7) standards see figure 4-1) is needed at every PICU bed space to interface the SIP data with the EPR. In OLCHC the EPR provider is the '*IntelliSpace Critical Care and anaesthesia suite' (ICCA)* by Philips. The need for the intermediate data capture module is a requirement of the ICCA system. The SIPs utilise a serial output (RS232) interface connected to the data capture module (See figure 4-2). The CE department is responsible for the technology and maintain these wired interface connections. They are also the first point of call when a communication error between the SIP and the EPR is reported.

Figure 4-1 Data Capture server in situate & **Fig 4-1.2** SIP rack with an RS232 connection situated in PICU, OLCHC

The UML diagram below shows the manual steps needed to update the drug library on a single smart infusion pump currently in OLCHC. (Figure 4-2). This process will need to be repeated for every pump in the HDO.
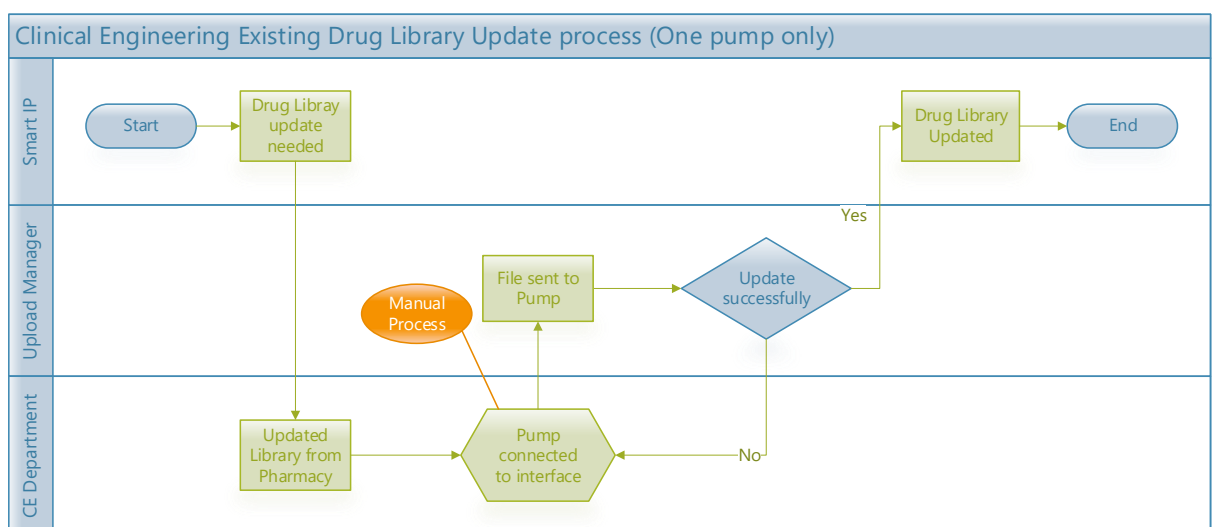
Figure 4-2 UML Diagram; Manual steps needed to update a single pump.

4.2.2 Summary of the main points in Step 2 (Clinical Engineer Interview)- The Digital media presentation of a CCLIMS: -

- The researcher and interviewee viewed the presentation video (http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html)(B.Braun, 2018).

- The SIP vendor's maintenance software program was explored on the world wide web (OnlineSuite™, this is bespoke software from pump vendor (B.Braun))(Melsungen2, 2017). OnlineSuite™ allows the CE department to remotely monitor all networked (wired and wireless) SIP's in the HDO. This useful software is key to assisting the CE department to monitor and update the SIP's drug library software without having to locate and handle each SIP on a hospital-wide basis.

- More online research was carried out, and the remote upgrading and device management functionally is a feature that most of the current suppliers of auto programmable SIP's offer to their clients (or have in development)(BD, 2018, Smiths, 2018).

4.2.3 Summary of the main points in Step 3 (Clinical Engineer Interview)- Critiquing of the proposed new workflow): -

After viewing the video, the five rights of medication delivery utilising a CCLIMS was discussed at length, and the complex integrations needed between this technology and the information systems (i.e. EPR, CPOE) took place.

The SIP Device interface options available were also discussed utilising the researcher's knowledge of a CCLIMS and the interviewee's expertise of the existing system integrations.

One critical discovery is that when a data capture module is used through an RS232 connection data can only flow unidirectionally from the SIP. The RS232 setup does not allow the SIP to receive medication data from the EPR (See Table 4.1).

Table 4-1 SIP Out & In-bound available connections

Outbound SIP Data to the EPR System	In-bound EPR Data to SIP
Ethernet (1Gbit/s)	Ethernet (1Gbit/s)
Wireless LAN (Supporting 802.11b/g/n)	Wireless LAN (Supporting 802.11b/g/n)
RS 232 Serial Connection (9600-115kbaud)	N/A

Another localised realisation is that the data capture module only requires one network port to function, this means up to 4 or 8 medical devices can be combined only while utilising one network point. If these SIPs need a dedicated wired connection at every PICU bed space to function reliably. Presently every network connection (at every bed icu bed space) is utilised within the PICU 1 in OLCHC. The ganged approach of using a network hub is already in use and importantly this approach is not recommended by the device manufacturers. If a connectivity issue occurs this approach to a worsening problem becomes a hard to resolve issue with the equipment vendor as the ganged approach is not recommend. The limited number of network points could be a limitation for the HDO to consider before purchasing a CCLIMS system. The installation of adding more network points to a PICU would require a full unit decant to another area of the hospital which is a complicated procedure to undertake and very disruptive to the consistency of care to the patients.

The UML diagram in Figure 4-3 shows the SIP's Drug library update pathways when a CCLIMS is in use in a HDO. This system utilises a dedicated pump server with the ICT infrastructure to manage all the SIP's and SIP docking stations.

Clinical Engineering Drug Library Update process Networked Pumps
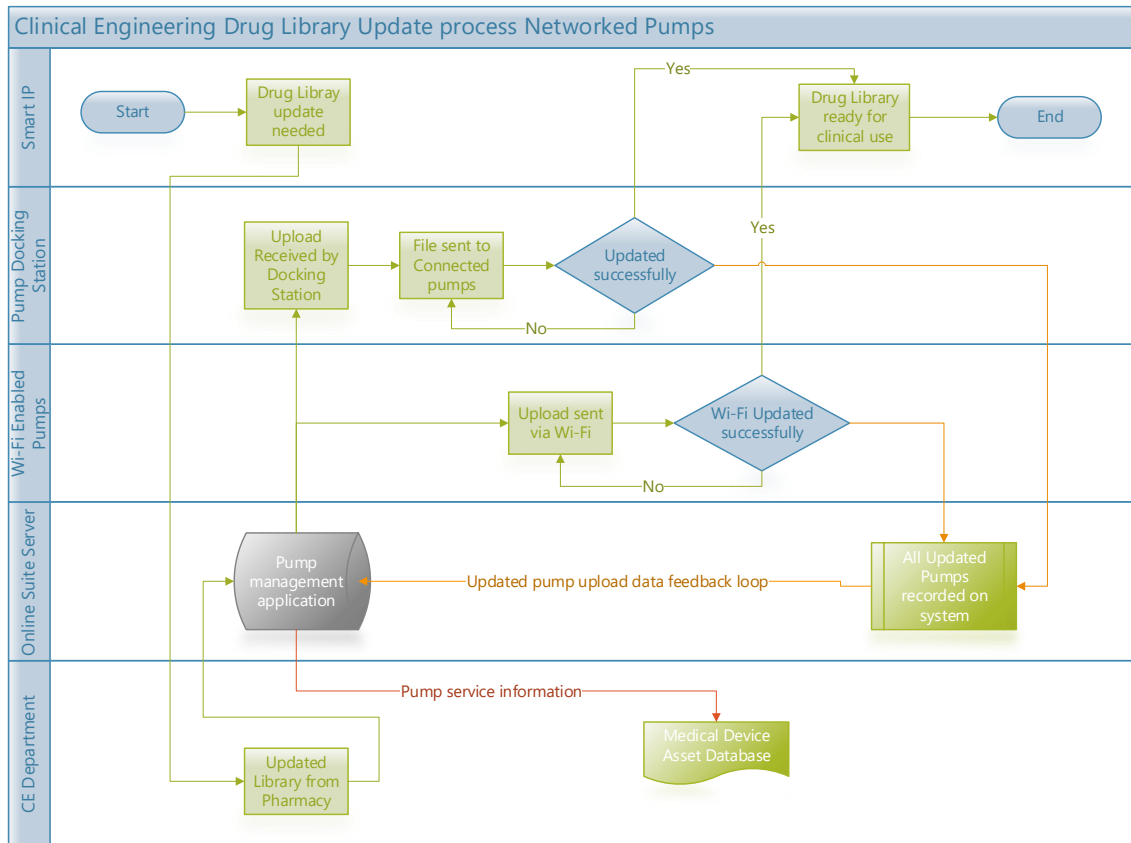
Figure 4-3 UML Diagram; Drug Library update all networked SIP

4.3 Clinician Interview Step 1: - (Full interview transcription see Appendix K)

4.3.1 Summary of the main points in Step 1 (Clinician Interview)-Existing Practices: -

The Clinicians' workflow was the most straightforward of all the disciplines involved in this study. The Clinician in OLCHC is currently provided with the use of a CPOE prescribing system which integrates with the EPR (ICCA) in both PICUs. The clinicians use order sets to prescribe multiple infusions (editing the order set's drugs to suit each patient's needs). The order sets consist of groups of drugs listed in standard concentrations in five weight bands. If only one or two infusions are required for a patient, the clinician will prescribe these directly not utilising the order sets (but the CPOE system still uses the drug library and limits to assist them). They currently prescribe in a range with no set starting dose. The drug library data in the CPOE system and the SIP's drug library should be identical (this can easily not be the case), these libraries are not linked as both drug libraries require manual human input to update.

- Interoperability (or lack of it) between the two active drug libraries will be discussed further during the Pharmacists and System administrators interview summary's.
- The SIP library updates were discussed in the Clinical Engineers interview summary.

4.3.2 Summary of the main points in Step 2 (Clinician Interview)- The Digital media presentation of a CCLIMS: -

The researcher and interviewee viewed the presentation video (http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html)(B.Braun, 2018)

The Clinician was also very interested in the diagram in the video presentation of ensuring the five rights of medication safety (see figure 4-4) (Melsungen1, 2017). This diagram was of the workflow from the clinician ordering (item 1 CPOE), to drug preparation (item 2), which included the barcode labelling and onwards to the medication administration stage, including identifying the patient to the prescription through the complete process (barcode scanning item 3). The ease and efficiency of the system to match the order to the patient and the prescription (item 4) all the way to the auto-programming the infusion pump (item 5) is a significant step towards ensuring the medication safety for the patients in reducing the chances of an adverse drug event/medication error. Item 6 in the diagram is auto documentation which is currently active within the OLCHC PICU environment. The system administrator interview summary will go into the feature in depth.
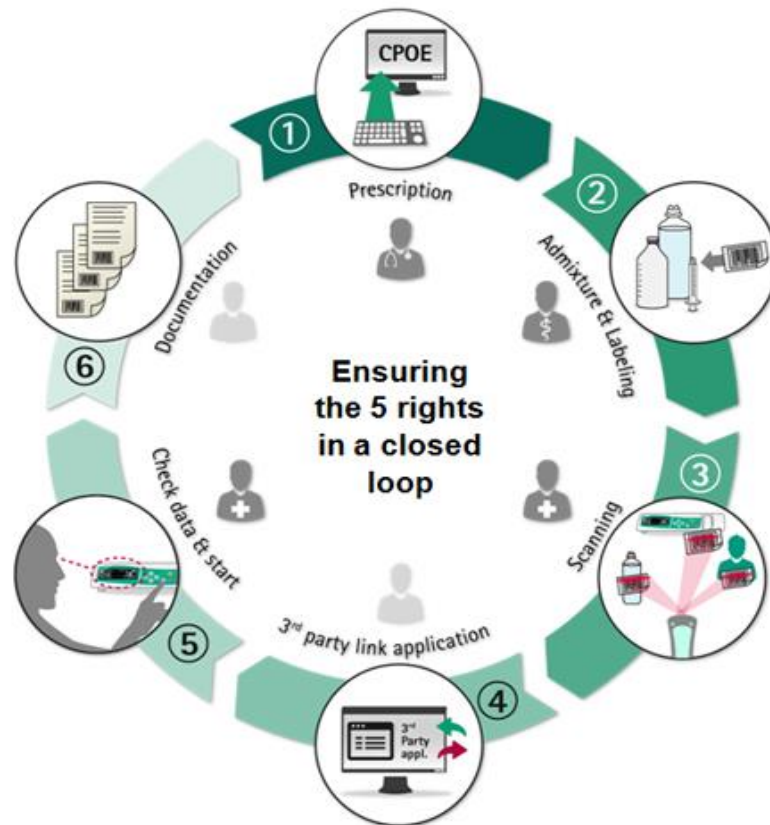
Figure 4-4 Ensuring the 5 rights (Melsungen1, 2017)

4.3.3 Summary of the main points in Step 3 (Clinician Interview)-

After viewing the video, the five rights of medication delivery utilising a CCLIMS were discussed at length. The clinical advantages of having a completely closed loop medication system encouraged the clinician to examine the complicated integrations needed between this technology and the information systems further.

It was at this point that the distinctness of the pharmacy component associated with this model of the closed-loop system came to the researcher's attention. The pharmacy model used in this system is typical of a Central Intravenous Additive Service (CIVAS) service. A hospital-based CIVAS service minimises the risks and errors by the reconstitution and preparation of intravenous infusions, this is achieved by removing this task away from the nursing role by centralising it in an aseptic environment in a department run by pharmacy department (Allwood, 1994, Armour et al., 1996, Hecq, 2011, Nemec et al., 2012).

The UML diagram in Figure 4-5 shows the Clinicians work flow remains practically unchanged. The small consideration the clinicians need to do to comply with the requirements of a CCLIMS is to prescribe a starting dose with the prescribed range they would normally prescribe. If they omit this phase the SIP will not have enough information to start without the nurse intervening.
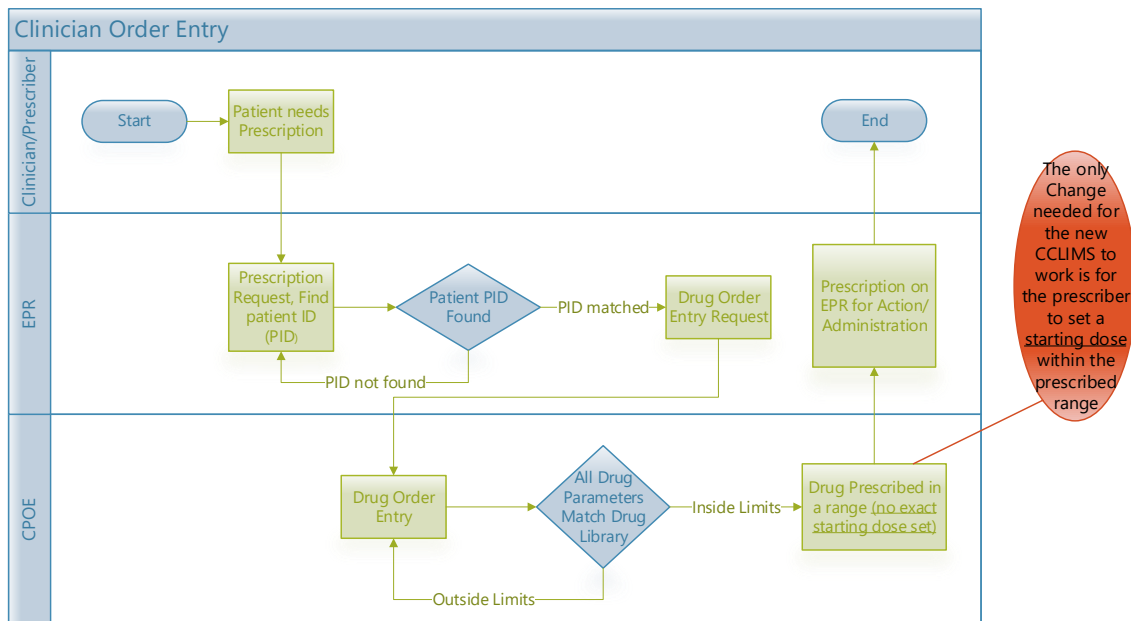
Figure 4-5 UML Diagram; Clinician's work flow in prescribing an IV medication

4.4 Pharmacist Interview Step 1: - (Full interview transcription see Appendix L)

4.4.1 Summary of the main points in step 1 (Pharmacist)- Existing Practices: -

The PICU Pharmacist has an overseeing role with regards to medications prescribed and given to patients. The Pharmacist undertakes ward rounds where the complete medication cycle is thoroughly checked, i.e. that the prescription matches the medications given and the drug concentrations are correct and correctly labelled not to mention that the SIP is programmed correctly to make the prescribed dose.

Pharmacy supply all the data needed to correctly handle all medications and intravenous infusions (IV's) are no different. Pharmacy educates both the clinicians and nurses on the interactions and incompatibility of the prescribed medicines with each another. They also supply multiple information sheets including sample calculations in various forms. A drug IV monograph is one example of the information pharmacy supply to a nurse to ensure that a drug is made up correctly (for example every drug has an IV monograph assigned to it, which explains how to make up the drug and what volume of fluid is needed to be mixed with it).

The standard concentration table is another example of the data needed in handling IV medications. The usability of the drug library in the SIP is intrinsically linked with using a standard concentration drug format. This drug error reduction software (DERS) is specifically tailored to a patient's weight band to help ensure medication safety across the varying sizes of patients (i.e. in a PICU it means neonates from 500 grams are protected as well as teenagers weighing upwards to 100 kilograms).

The UML Diagram below (Figure 4.6) shows the existing pathways available to the pharmacist for upgrading the Drug Library on both the SIP's and in the CPOE module of the EPR (ICCA) available. It is the pharmacist's role to maintenance the information in both of the drug libraries.

Ideally the informatics pharmacist would like to control how and when both of these systems are upgraded, but due to this system not linking together it tends to be a slow and drawn out process to upgrade all the SIP in the HDO.

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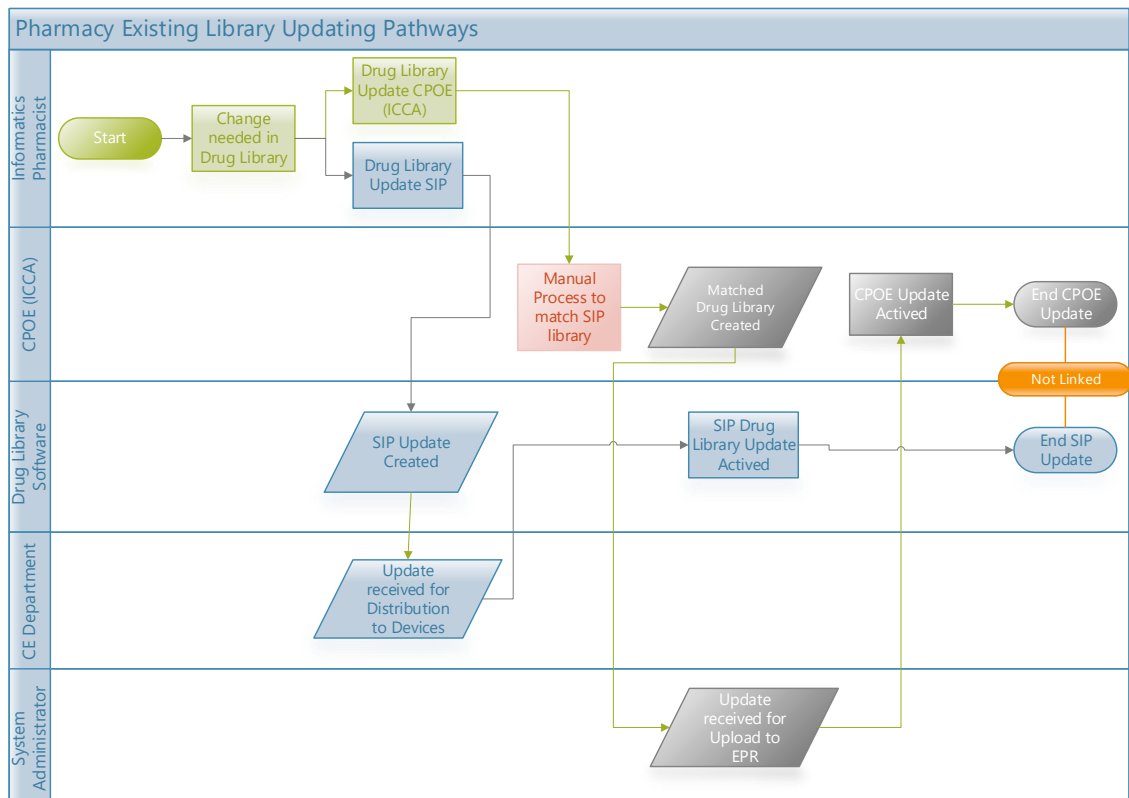
Figure 4-6 UML Diagram; Pharmacy's Existing Drug Library Updating Pathways

4.4.2 Summary of the main points in Step 2 (Pharmacist)- The Digital media presentation of a CCLIMS: -

The researcher and interviewee viewed the presentation video (http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html)(B.Braun, 2018)

After studying the presentation, the Pharmacist immediately pointed out that the CCLIMS in the video is based in a hospital that had a CIVAS medication service (run by the pharmacy department). The Pharmacist also stated that in the ideal world this is where all IV drug admixture should be done. (The new paediatric Hospital (NCH) planned for the Dublin area is expected to incorporate such a facility when it is built in 2022)(eHealth Ireland, 2018).

4.4.3 Summary of the main points in Step 3 (Pharmacist)-

The Pharmacist thought the interoperability of the CCLIMS would help with the prevention of medication error. The availability of a CIVAS service to the PICU was discussed (also see Clinicians interview (section 4.3.3) which explains a CIVAS service). The Pharmacist made it clear that a CIVAS service is for the whole hospital, not just a PICU and it was estimated to the researcher that a for a hospital the size of OLCHC that a staff requirement of 45 to 55 pharmacy technicians would be required to work there.

Presently OLCHC has a compounding unit for chemotherapy drugs, the aseptic compounding unit (ACU) with supplies the oncology ward and staffs 10 technicians).

The functionality of the EPR to mirror the drug library on the SIP's was a welcomed feature as the process of updating both SIP library and the EPR (ICCA) is a separate and manual process (which is the responsibility of the informatics pharmacist).

The pharmacist welcomes the use of bar-code labelling as it has a proven track record in reducing medication administration errors, (as discussed in chapter 2.8) (Holecek, 2011, Patterson et al., 2002, Samaranayake et al., 2014, Tsai et al., 2010, Cescon and Ethchells, 2008). It is felt that even if a CIVAS service was implemented, a bar-code printer would be a welcome addition in the PICU for the nursing staff to print directly from the EPR and close the loop in matching the syringe contents to the prescription and the pump before administration starts.

The UML Diagram below (Figure 4.7) shows the CCLIMS pathways available to the pharmacist for upgrading both of the Drug Library's. The Pump Server can upgrade all pump and docking stations with one script and similarly one simple activation and the EPR (ICCA) receives the update.
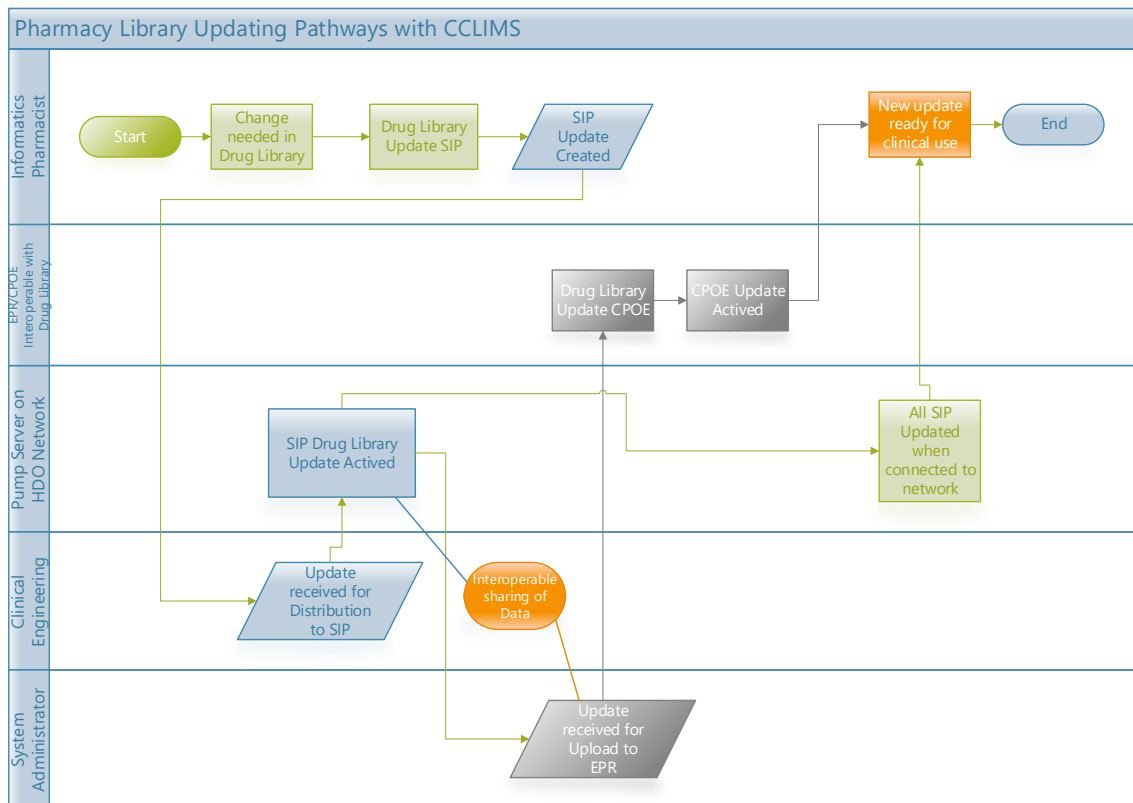
Figure 4-7 UML Diagram; Library Updating Pathway with CCLIMS

4.5 Clinical Nurse Specialist Interview Step 1: - (Full interview transcription see Appendix M)

4.5.1 Summary of the main points in step 1 (Clinical Nurse Specialist)- Existing Practices: -

Currently, in OLCHC PICU's, the drug is prescribed on the EPR (ICCA) in PICU for documentation. After the clinician has prescribed the drug, two nurses check the order against the medication policy and check it against the standard concentration infusion table and this makes sure that the limits are appropriate. When the prescription is checked by the nurses and the equipment needed to make up the drug is available a label is prepared so that there is full accountability for what is in the syringe that's going to be used to deliver the medication.

The next step is to draw up the amount of drug and diluent that is needed and mix the two of them together in a syringe (inverting the syringe a few times to make sure it has mixed well), put a giving set on it and prime the line.

Next, the syringe is loaded into a pump; the pump is then programmed by selecting the area that the patient is in, the weight band that the patient falls into and the drug that is prescribed. When selecting the drug, the nurse is offered different concentrations to choose from. There is a prompt from the pump to input a volume to be infused (VTBI) at this point the infusion time may have to be amended depending if its continuous or non-continuous infusion.

Doses can be changed once they are still within the drug library limits and within the prescribed limits. When the information is entered into the pump the infusion can be started; the next item is to connect the infusion to the patient, and the drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug, it will continue to run for the amount of time that has been programmed. If the syringe is almost empty or if there is an occlusion at any point a warning will be displayed. Otherwise, a continuous infusion will remain running going until the VTBI has expired.

A requirement when opening a drug order on the EPR (ICCA) is there are now four signature boxes. Person 1 & 2 sign for preparation which includes checking the order, checking the standard concentration and physically making up the drug (i.e. putting the drug in the syringe) This procedure from start to finish should be carried out by the same two nurses at the same time (not one doing and one checking they must do it together). The signing of these extra two boxes is a new step for the nurses but has been introduced for medication safety reasons; the second nurse checking can be a different nurse than the 1st check. The second stage of this process is the pump check. The two nurses that programme the pump must sign to confirm that they have both checked that the pump program matches the drug order (i.e. sign the second two boxes), but before they sign they also must do a manual calculation of the rate the pump is to run at.

The two signatures for the pump check is a new step introduced within the last two to three months. The second pump checker is relying on the fact that the drug label (which was signed by the first two nurses that prepared the drug) is correct.

Please note the 20 manual steps including 5 calculations when programming the smart pump in Figure 4-8 below.
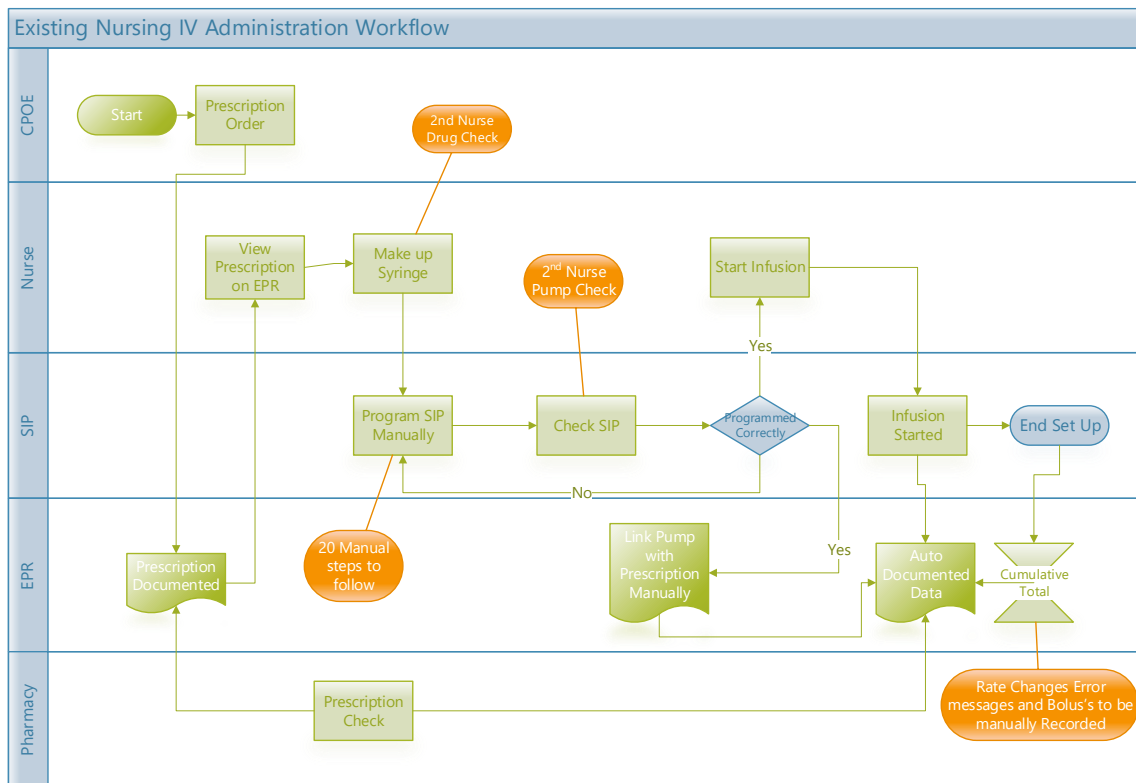
Figure 4-8 UML Diagram; Existing Nursing IV Administration Workflow

4.5.2 Summary of the main points in Step 2 (Clinical Nurse Specialist)- The Digital media presentation of a CCLIMS: -

The researcher and interviewee viewed the presentation video (http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html)(B.Braun, 2018)

After viewing media presentation of the nurse operating the CCLIMS, the CNS interviewed was responsive to the fact that the nurses would trust a system like this and

that it would remove some challenging work so the nurses could concentrate more on caring for their sick patients.

4.5.3 Summary of the main points in Step 3 (Clinical Nurse Specialist)-

The clinical nurse specialist believed the CCLIMS would work well because the system is always checking itself. It was pointed out that the nurses using the system would trust that the bar-coded infusions which were pre-prepared would be in line with their order (for the scanned patient). The valid point was made that there were no second checks in the video and that the practice of not double checking the IV infusions with two nurses before administering the IV would not be accepted so the full nursing checks would still have to be carried out.

The CNS believed that this system would not be too difficult to adapt to for the nurses because already in the PICU some drugs are delivered to the unit pre-prepared, such as Total parenteral nutrition (TPN) and Lipids. Even though they are infusions bags (and not syringes) they still go through the existing SIP's and the nursing staff are used to checking them. The chemotherapy drugs made up the ACU in OLCHC come pre-prepared (although with no bar-code labelling). The installation of a BCMA printer in the ACU would be needed for the CCLIMS to work for chemotherapy IV medications in OLCHC

One limitation to be noted would be when a drug is needed in an emergency situation. Nursing staff would be unable to wait for pharmacy to receive the order, prepare the drug and delivered it to ICU. Nurses would need to act immediately and prepare this type of infusion themselves for the clinical need of their patients, so they would need full access to the system and all necessary equipment so that they can prepare urgently needed drugs themselves.

The CNS expects that the emergency drugs that are needed to always be available in the PICU will not work as part of a CIVAS service. If these emergency drugs were made available via a dispensing cabinet in the PICU, there would be significant waste because just for one patient, it would need at least five emergency drugs, that is five syringes for the five weight bands, so that is 25 syringes, include a second emergency patient, and

that's over 50 syringes. Having emergency drugs made up amounts to much waste (and creates unnecessary work for pharmacy) as emergency inotrope drugs only last 24 hours when made up.

A better option would be having the barcode system available to the nursing staff in the PICU and the drugs and all the equipment required available to use in an emergency situation. This point of care bar-coding option should be available to nursing staff even if a centralised pharmacy service is available. For standard prescribed IV infusions the nurses would not need the bar-code printer as they would receive the medications made up from the pharmacy they would still have to be able to access emergency drugs so they could make up their infusions when urgently required keeping the SIP programming in the closed loop proposed.

It should be noted that writing multiple labels sometimes can take 15 minutes so with a bar-code printer this could speed up the process, even though it would be adding the process of accessing the printer and printing the labels.

Please note; the 5 bar-code scanning steps below which replace the 20 manual steps when programming the smart pump for clinical use in Figure 4-9 below. What this UML diagram does show is the complexity of the different steps. Although there are more processes displayed in fig 4-9 than 4-8 the steps are mostly confirmation key presses which take only a few seconds to step through (with no associated calculations) the only calculations the nurse has to do are the manual rate and dose safety checks.
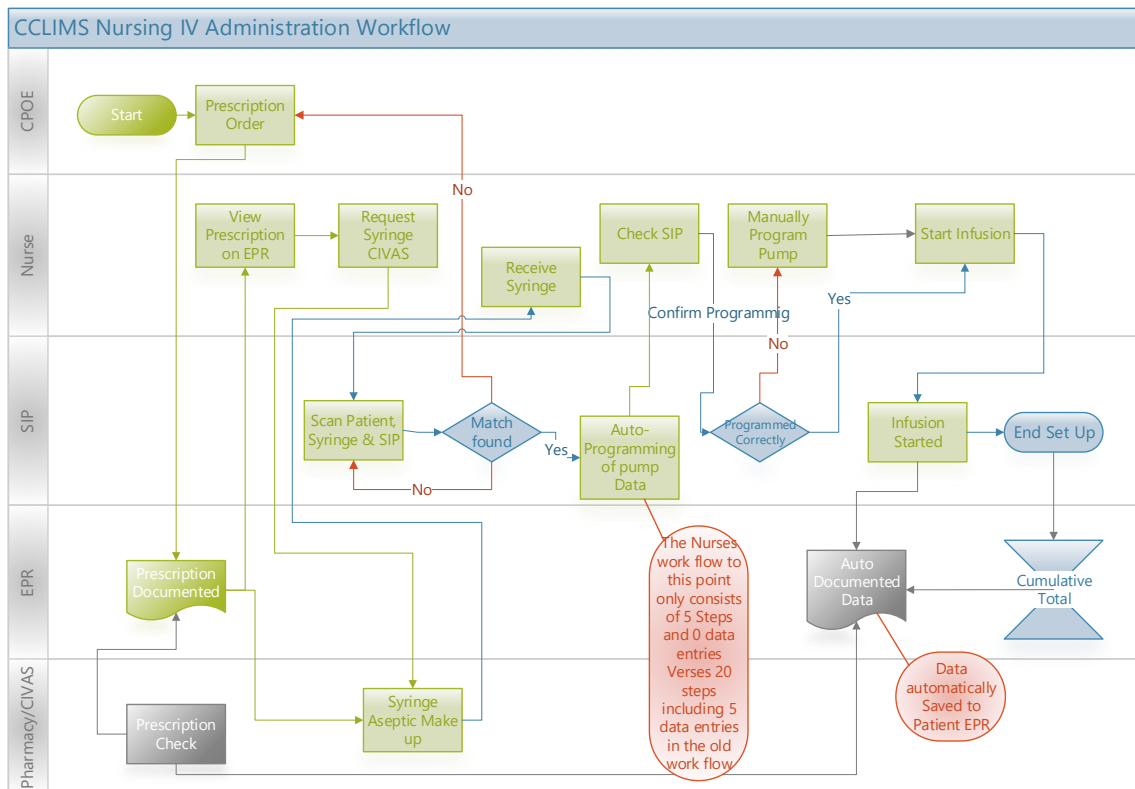
Figure 4-9 UML Diagram; CCLIMS Nursing IV administration Workflow

4.6 System Administrator Interview Step 1: - (Full interview transcription see Appendix I)

4.6.1 Summary of the main points in step 1 (System Administrator)- Existing Practices: -

The systems administrator role is very narrow in the service loop of drug administration and prescription matching; an interface was developed to read data coming for the SIP's into the EPR (ICCA). The interface involved a significant number of manual connections that had to be made between the systems. This large volume of work involving matching prescriptions to SIP's is an entirely manual process carried out by the systems administrator under the guidance of the informatics pharmacist.

The system is limited as not all infusions can be matched with a prescription in the ICCA system as blood products (for example), legally need the piece of paper to be signed and

kept with the product, this means it cannot be prescribed or transferred over to the electronic prescribing system on the EPR. For the nurse administrating a blood product, it means that the system will have a pump active on the EPR but will not be able to be assigned to a prescription. Manual free form prescriptions can also never be matched to a pump on the (ICCA) EPR, but the pump will be visible on the system, this can cause problems in the matching of other pumps to prescriptions on the EPR at the bedside. What happens is the wrong pump can be matched to the wrong prescription. When this happens, the volumes infused and the totals for the wrong drug at the wrong rate get matched with the wrong drug cause many headaches to rectify. If this is not realised early enough, the patient will be at risk of an adverse drug event (ADE) if the pump is adjusted to suit the prescription (i.e. the incorrect prescription)

When training the nurses on the EPR that is currently in use in the PICU, it is thought to the nurses that the human's input and the human decision overrides the technology. It is considered that the human has the last say an can override the values in the system if errors in volumes delivered from SIP's are detected (this is a rare occurrence but can happen 1% of the time), this system fault will be explained further in step 3 below.

The UML diagram Figure 4-10 below shows the breaks in connectivity as red manual steps. What it doesn't portray is the 6000+ drug matching cross checks that the Informatics Pharmiasist need to double check. In this UML diagram one of the 'other' manual processes is the SIP upgrade that can that 3 people over 3 days to complete.
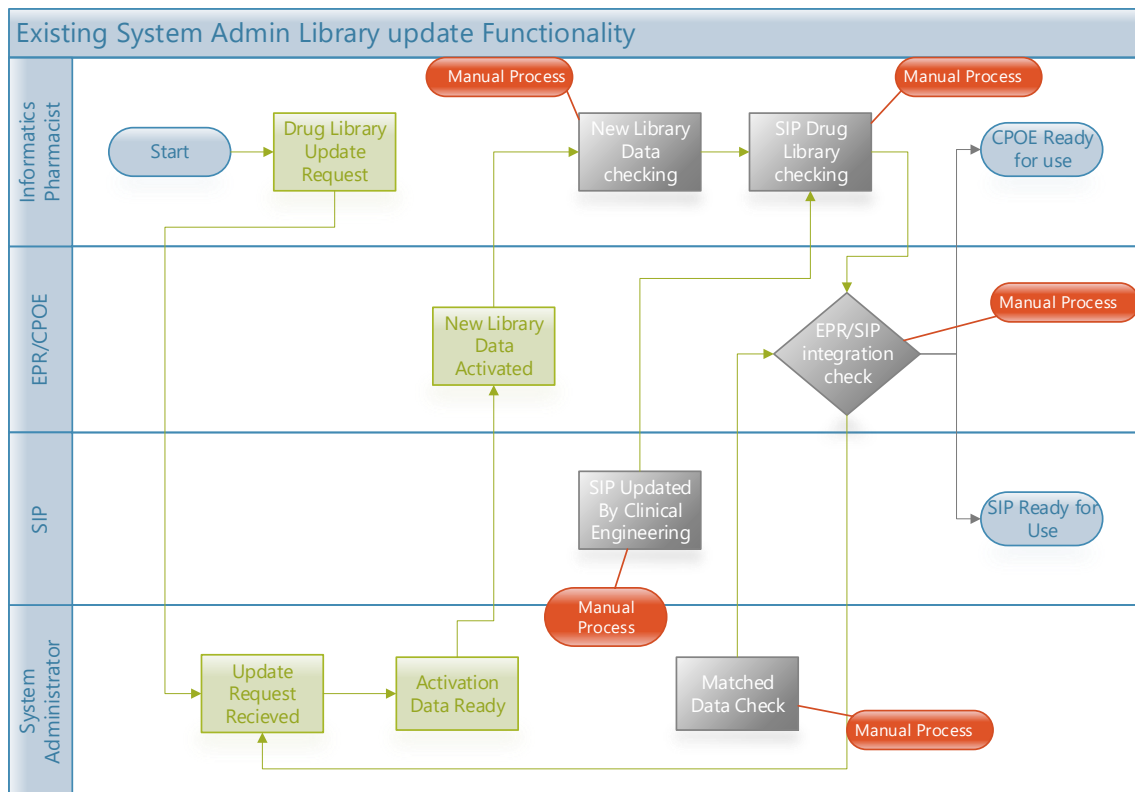
Figure 4-10 UML Diagram; Existing System Administration Library Update Functionality

4.6.2 Summary of the main points in Step 2 (System Administrator)- The Digital media presentation of a CCLIMS: -

The researcher and interviewee viewed the presentation video (http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html)(B.Braun, 2018)

After viewing the media presentation, the systems administrator commented that the CCLIMS was at a '*very high level*'. The implementation of a CCLIMS certainly has the potential to reduce medication and administration errors and help the issues discussed in step 1 previous discussed

4.6.3 Summary of the main points in Step 3 (System Administrator)-

The feedback from the discussion after viewing the media presentation was very positive towards a CCLIMS; there were points made about various difficulties regarding the current use of the (ICCA) EPR and the SIP's data matching. If this CCLIMS was implemented, it is considered by the systems administrator 'as an enormous improvement' over the existing system in the PICU in OLCHC. The current system relies

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on the nurses to make a manual connection in the software to connect an infusion pump to a prescription. What can happen is two pumps can be assigned to one prescription cause the total volume of the drug-infused to be wildly incorrect. This pump mismatch will be eliminated with the use of a CCLIMS.

The systems administrator is often asked to check the data from certain drugs because either the rounding difference are too significant or the total volume infused has been lost by the EPR. This issue is rare, but it still can happen with about 1% of all the infusions given in the PICU. In the previous example of a system error, it is usual for the ICCA system to display 'questionable data' or 'questionable assignment' from the SIP. The lack of detail in this error message is unhelpful to the systems administrator in finding the source of this data transfer issue; again it is felt the use of a CCLIMS would finally resolve this and stop it from occurring.In Figure 4-11 This UML diagram shows off a fully integrated SIP drug Library upgrade linked to the EPR so both versions can go line on the same day.
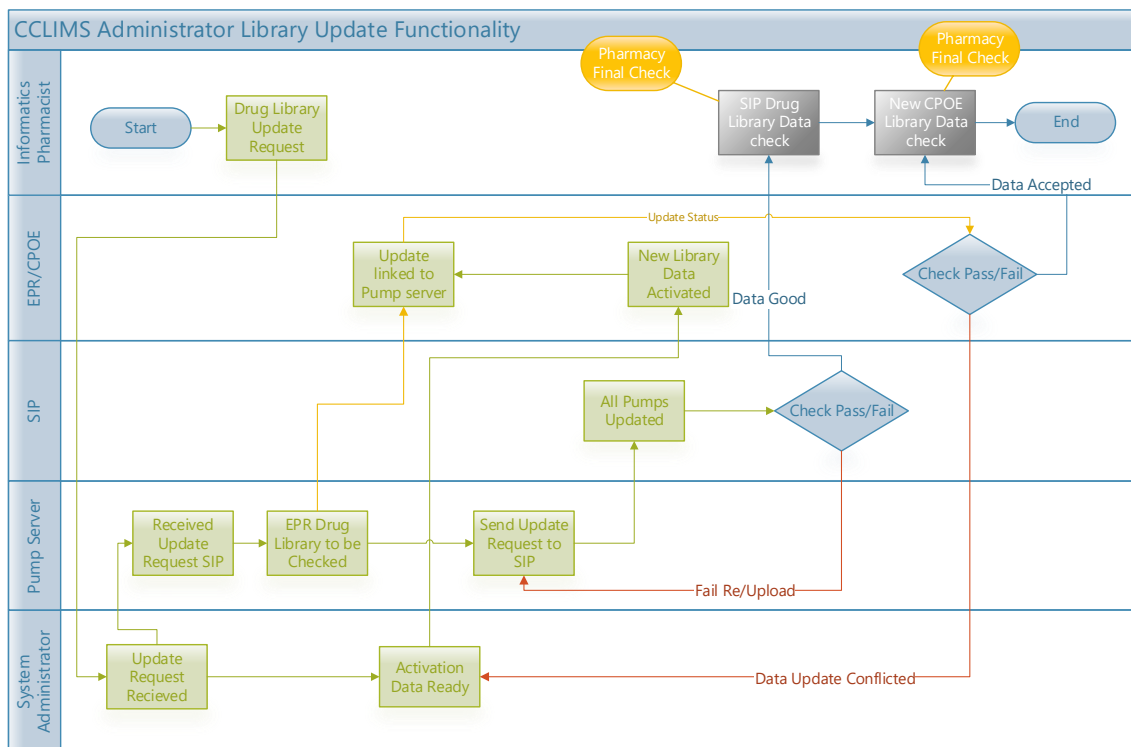
Figure 4-11 UML Diagram; CCLIMS System Administrators Library Update Functionality

Chapter 5 Evaluation

5.1 Introduction: -

In this chapter we look at providing an answer to the Research Question, the research carried out in this study has provided a thorough insight into what changes can be expected within the different departments when delivering an IV infusion to a patient through a CCLIMS.

5.2 Discoveries after interviews and UML development

5.2.1 Clinical Engineering: -

Clinical engineering is responsible for the upkeep and maintenance of the SIP inventory in the HDO. This inventory consists of over 350 smart infusion pumps (SIPs). These SIPs have a requirement of needing to be networked with the HDO's IT infrastructure; this allows the SIP to send the live infusion data (when the SIP is in clinical use) to the electronic patient record (EPR). The SIP has a drug error reduction software (DERS) Drug Library stored on the pumps electronically erasable programmable read-only memory (EEPROM).

The present procedure for updating this EEPROM memory (i.e. the drug library) for the whole collection of pumps can take many days as all the pumps have to be manually handled and connected to a laptop to be updated. A significant advancement with the proposed CCLIMS is the installation of a dedicated smart pump server on the HDO's network. The functionally of this server with its bespoke software makes for a very welcoming tool when it comes to managing a SIP drug Library and software update. One upload for 350 devices is the height of efficiency considering this currently takes several technicians many days to complete; this is one feature of the proposed system; many more are available with this interoperable connected network of infusion devices. The CCLIMS also has the capability of operating using wi-fi, this is useful in keeping a consistent patient record when patients are moving from PICU to theatre. The added benefit is all pumps, and their maintenance check and battery status can be monitored remotely to ensure that no pump is un-serviced or relying on a faulty battery. The alarm

logging service available on these devices is available remotely through the dedicated pump server and is useful in detecting what went wrong in miss matched infusions that the Systems Administrator discussed in chapter 4.

In summary, CCLIMS would dramatically reduce the workload of the Clinical Engineering by simplifying the working practices regarding SIP technology.

5.2.2 Clinician's, CPOE on the EPR: -

Computerised prescriber order entry (CPOE) is a feature currently in use in the PICU in OLCHC. The work practices of the Clinicians change the least out of all the professions with the introduction of a CCLIMS. They similarly need to prescribe a starting dose within the range that they usually prescribe. The CCLIMS, mimicking the function of the current CPOE module, works out the rate (speed of infusion) that the SIP needs to run at to supply the correct dose to the patient. This task (which historically has been prone to error) is a long-standing feature of a smart pump but one that prevents errors reaching patients (Russell et al., 2010, Pang et al., 2011, Wright et al., 2009).

Even though the Clinician's workflow is the least disrupted and presented by the UML diagram in Figure 4-2 chapter 4, the benefits to them are only bettered by the benefit to the patients themselves. Clinicians are as legally responsible for the care of their patients regardless of who (or what) causes the harm), i.e. they will be the person called to court if an adverse drug event occurs.

5.2.3 Pharmacist

The pharmacist's role in the process can be informed by asking What is the ultimate goal of the pharmacist role every day? One answer could be -

To ensure that all medications are correctly compounded, administered and documented so no harm can come from medicines. This might be a simplistic view of a

pharmacist's role but realistically why not make a complicated process into manageable steps which are easily achievable for busy staff to carry out?

The Pharmacy department has risen in statue within the HDO's worldwide they are now designed to be 'front and centre' in any modern hospital (ehealthIreland, 2012). Why is this? Well, the message is clear that medication errors need to become a history item that is only researched.

The development of the proposed CCLIMS was so highly placed by the pharmacists that at a recent multidisciplinary meeting (that the researcher attended, for knowledge on the subject of CCLIMS) no one made the point a CIVAS service requiring significant allocation of resources, would be needed to implement a CCLIMS as it was presented at that meeting. The pharmacists intuitively know that a CIVAS service is the only proven way to address the vast majority of compounding errors with medications (Allwood, 1994, Armour et al., 1996, Nemec et al., 2012, Hecq, 2011). The fact that most of the bar-coding (BCMA) happens during the compounding phase of a CIVAS service was omitted from the discussion.

During the interviewing process for this study that it was made clear to the researcher that the omission of not discussing a CIVAS service was purely an oversight, as the pharmacists believe a CIVAS service will be delivered as part of the design of the NCH. The fact that the other medical device and system suppliers (including the HDO's patient identification system) rely on the correct bar-code labelling of medication which is needed to interface the patient's data with the medication correctly and the computerised order entry systems that as a whole form a CCLIMS.

The Informatics Pharmacist will benefit significantly from the new work practices which would be introduced by the introduction of the CCLIMS within CE department. The primary example of this improved workflow is the substantial obstacle of updating the SIP's drug libraries which with the introduction of a CCLIMS is simplified into to running a script on the dedicated pump server.

Lastly, the Informatics Pharmacist own manual matching and copying of the SIP's drug library to match the standalone drug library on the EPR (ICCA) system will become

automated with the interoperability of the proposed CCLIMS. This change of work practice is quite significant as there are approximately 6000 drug combinations in the current version of the Paediatric and Neonatal Library.

5.2.4 Clinical Nurse Specialist

It is evident from the volume of knowledge received during the interview with the nursing representative that the nurse's role in delivering an IV infusion to a patient (in the PICU) was a difficult and extremely complex task. Discovering that nurses compound 80% to 90% of all the IV infusions administered within the PICU. This role is complicated and confusing in any environment (regardless that a paediatric ICU is a busy, high-stress environment with multiple alarms going off continuously from hemodynamic monitors to ventilators). The nurse's role currently involves numerous staged tasks mostly needing a second nurse to check that the procedure is being correctly adhered to (due to the complexity of the task).

The introduction of a CCLIMS to relieve the substantial burden of safe medication compounding and administration will be welcome by most nurses in the PICU environment. The proposed introduction of auto-programming to the nurse's role (as displayed in the UML activity diagram Figure 4-9) will reduce the manual programming of a drug into a SIP utilising the drug library from 20 steps (including 5 calculation steps) down to a maximum of 5 steps (mostly barcode scanning) with zero calculations needed. The workflow UML diagram for the proposed CCLIMS looks more complicated for the nurse administrating the medication, but the actual ease of the steps is not portrayed in the activity diagram. This was discussed during the interview with the clinical nurse specialist (CNS) and the acceptance of allowing the technology work with the nurse in calculating the infusion rate is a welcomed feature of the CCLIMS which allows the nursing staff to use the time saved to safely and accurately check the infusion rate manually, which is one of the requirements of the nursing role in the PICU.

BCMA was discussed at length during the CNS interview, it was agreed that in the PICU (if a CIVAS service is available or not in the HDO), that the installation of bar-code

printers and the necessary interoperability software interfaces (which allows the printing of BCMA syringe drug labels from the CPOE/EPR system). This would be acceptable to the nursing staff for the emergency drugs that are needed within the PICU environment. These emergency drugs are always needed in a PICU for many different reasons. The most obvious is children's reserves are small and a sick child can become unwell exceptionally quickly and the clinician's and nurses need access to drugs with minimal delays. The CNS also felt that if enough BCMA equipment was available to the staff in the PICU's that it would be more efficient and a lot safer than having to handwrite drug infusion labels (Untalan et al., 2013, Poon et al., 2006, Morriss et al., 2009, Cescon and Ethchells, 2008, Franklin et al., 2007, Agrawal, 2009).

To extend the use of BCMA equipment within the PICU further, it was suggested that a CCLIMS could be implemented into a PICU without the CIVAS service being available. This pathway of the proposed BCMA labelling system being available to the PICU staff suggests that a CCLIMS could be introduced into nurses existing workflow so the benefits of the auto-programming features can be utilised.

5.2.5 System Administrator

It is evident from the interview with the system administrator that a real high level of understanding between where all the data connections of complex electronic reporting and recording system are made. The systems administrator explained how only eight parameters are being excepted from the smart pumps into the ICCA (EPR) system. This limitation of the ICCA system is the reason for two separate drug libraries' having to be maintained by the informatics pharmacist and the system administrator. The systems are not linked but work off the same information; this can be explained by an example.

If an IV infusion is running, both the SIP and the EPR have been programmed with the prescription, so both systems know what the dose should be. Now say the SIP is infusing at 1ml/hr. (the dose is also displayed on the pump as micrograms per kilogram per minute (mg/kg/min), as worked out from the standard concentration table). Every hour on the hour the EPR system does not take the dose from the SIP it makes its own calculation working on the prescription information programmed into the EPR and rate the pump is running at (i.e. 1ml/hr). What it does do is take the cumulative volume from

the pump every hour and displays that amount on the patient chart. Although this system has been in clinical use since 2014 problems and miss matching can occur (as discussed in chapter 4 section 4.6.1). The introduction of a CCLIMS will address this issue and many more associated with similar scenarios due to manual the linking process of matching a pump to a particular prescription.

The system administrator is in favour of a CCLIMS due to the advantages in consistently gathering critical patient information, this coupled with the interoperable drug libraries will minimise the need for human intervention in the electronic patient records.

5.3 Summary of findings

The table 5-1 below straightforwardly displays the main advantages to the different stakeholders working practices that were discovered during the research process in chapter 4, of this study.

Table 5-1 Summary of the findings

Department	Stakeholder	Main Advantages over existing working practices
Clinical Care	Clinician /ICU Intensivist	Adding an extra layer to the challenge of eliminating medication errors, Accurate and detailed reporting.
Pharmacy	Informatics Pharmacist	Easy uploading of a shared drug library + availability of accurate real-time information allowing the pharmacist to react in real time rather than retrospectively. Possible starter to implement a CIVAS service
Nursing	Clinical Nurse Specialist (CNS)	Multiple advantages from simplified SIP auto programming (reduction of 20 step to 5 steps). BCMA interoperability for simplification of syringe preparation. Detailed automatic electronic charting, efficiency benefit so more face time can be spent with patients

Clinical Engineering	Clinical Engineering Technician	Much improved workflow for SIP management, One script upload for drug library updates, real-time device status (battery & service logs), remote infusion history access.
ICT	System administrator	Shared drug library upload linked to SIP library, Full SIP parameters easily interfaced into EPR for prescription, charting and drug matching. Full SIP infusion alarm history available and chartable.

5.4 Strengths and Limitations of the study

The Strengths and Limitations of the study will be discussed separately about the outcomes with regards to the changes to the working practices of the different departments.

5.4.1 The Strengths of the study

The Pharmacy department (OLCHC) in conjunction with the PICU Clinicians have developed an extensive SIP drug library over the last four years (Howlett, 2018). On reflection of this study, this SIP library contains the building blocks to a successful CCLIMS integration. This Library has been shared at a national level with the other two children's hospitals, the Neonatal Transport service and the Paediatric Transport service. Planning has taken place to have a paediatric SIP available for use with children in the adult accident and emergency departments across Ireland.

The researcher as a member of the Clinical Engineering department in OLCHC has had exposure and expertise to infusion technology for 18 years. A close technical relationship has developed over the years with pump manufacturers due to technical requests for updates to software and certain pump features. Because of this history, it is a regular occurrence to be asked for a technical option on new software or programming features. This technical expertise sharing allowed the researcher to get a

thorough understanding of what a CCLIMS could technically deliver to the stakeholders in the HDO. This knowledge was disseminated to the stakeholders during the interview discussions which coupled with the stakeholder's areas of expertise allowed for a broad overview of the proposed integration of s CCLIMS with the PICU of the HDO. So, the consultation during the study was bi-directional with benefits going in both directions.

Lastly, the current implementation of the existing EPR with the CPOE module with the infusion pump charting data integration in 2014 gave the Systems Administrator valuable knowledge into how challenging a medication ordering and SIP drug library integration could be. The System Administrator's in-house knowledge on how the existing system is working enabled valuable insights towards the next step in the challenge of erasing medication errors in a PICU with the help of technology.

5.4.2 Limitations of the study

It was to complex a system to investigate and get a broad opinion on what changes were required to the current systems and what working practices were going to be affected. Every stakeholder's workload appeared to be lightened due to the assistance of the technology in the CCLIMS. The exception to this was the pharmacy department as the proposed system utilised the use of a CIVAS service (as previously stated in chapter 4) this service is widely used in the USA). The undertaking of an HDO to provide a CIVAS service is outside the scope of this study. (As mentioned previously, it was estimated to the researcher that for a hospital the size of OLCHC a CIVAS service would involve over 40-50 pharmacy technicians and would require a purpose built clean room (HEPA filtered environment) for drug compounding. Another difficulty would be the fact that there is legislation in Ireland that states if a drug is made in advance of a prescription order it is deemed as a manufacturing process. This would open up the HDO to have to comply with multiple standards to gain compliance for such a service.

It would be good to note at this point that PICU stakeholders working practices were only studied in one of the three amalgamating hospitals that are to form the NCH in 2022. Although the practices should not differ significantly, it is still a limitation on the results found.

5.5 Future work

An interesting study would be to mock up a CCLIMS (workstation within the PICU unit including all needed equipment found at a PICU bed-space), this complete test area could be used as a training facility before a CCLIMS was implemented. This area would be ideal to run a time study into changes in the nurse's role when using a CCLIMS for patient care.

Another area of advancement on this study would be to look at the drugs outside the CPOE system, these electronic non-prescribable products, i.e. blood products have a legal requirement for the prescribed 'piece of paper' to stay with the product, or it cannot be used inpatients care.

Lastly this leads to the fact that all the safety features and benefit from the use of a CCLIMS, all the safety benefits can just be overridden in the pump user options and this needs to be explored further to increase patient safety and prevent children from receiving medication errors.

An area that was missed during this study is that the pharmacy system for the PICU is not integrated with the EPR system. There is no interoperability between the pharmacy system and CPOE module. This means that the medication stock control for the pharmacist in the PICU comes down to the pharmacist physically looking on shelves to manage the stock control element of their duties. Although this point sits with the EPR functionally, it was worth mentioning because one system is being employed to use medications and the other is used to replace them, after all it is a working practice of the PICU pharmacist.

5.6 Dissemination

The finding of this study will be disseminated through a number of channels. See table 5-2 Below. Firstly, a copy of this study will be stored securely on-line in a Microsoft OneDrive folder and the link will be given to any participants who requested a copy when it was finished. The researcher was approached by the Biomedical and Clinical Engineering Association of Ireland (BEAI) to submit a paper on the finding of this dissertation for the spectrum journal. The BEAI have also requested a presentation on

the topic at their annual science meeting in September. The Health Informatics Society of Ireland (HISI), have put out a call for papers and posters for their 23rd Annual Conference, which is due to take place on the 6th and 7th of November 2018 at Croke Park Conference Centre, it is the researcher's intention to submit either a poster or paper on the results from this study, the submission deadline is the 30th of September. The researcher will also report the finding of this study to the equipping team in the NCH so all aspects can be considered before the specifications for the supply of medical devices is tendered.

Table 5-2 Dissemination of Results

Audience	Organisation	Action
Participants	OLCHC	Download of this dissertation to be made available or emailed on request.
Biomedical/Clinical Engineers	BEAI	To Present at the annual science meeting.
Biomedical/Clinical Engineers	BEAI	To Submit an article for the 'Spectrum' Journal
Healthcare Professionals	HISI	Submit either a poster or paper on the results from this study
Equipping Team	NCH	To educate and share the study information before the specifications are decided for infusion therapy for the NCH

5.6 Reflection

What was new about this study is the fact that auto-programming has not been considered to be implemented in a HDO that doesn't run a CIVAS service. The fact that Irish nurses and pharmacy working practices differ primarily from the services available in the United States. The fact remains that a complicated system like this requires buy-in from all the stakeholders to be successfully implemented. If the correct channels are not followed the application of this complex socio-technical system (and the education of the stakeholders to the benefits of such a system) within a children's hospital will most likely struggle to be adopted due to a lack of understanding of the benefits (including medication prescribing, compounding and administration safety) of a CCLIMS.

5.7 Conclusion: -

The Chapter discussed the finding of the interviews and the discussions of the changes to working practices if the HDO purchased a CCLIMS. The evaluation of the clinical workflows through the use of UML activity diagrams which gave an excellent visual representation of the existing work practices against the proposed new work practices if this closed loop medication system was to be implemented. The reasoning behind implementing an elaborate system to help the delivery of medication is always driven first and foremost by patient safety. In the case of a PICU, the patient population is always innocent children.

This Chapter also explored a workaround to a problem encountered with implementing a CCLIMS with the pharmacy services that are currently delivered in paediatric hospitals in Ireland. In reporting this, it should be noted that the Irish government is supporting the introduction of a CIVAS drug preparation service in the NCH which is scheduled to open in 2022.

Following the discussions of the findings, the strengths and limitations were discussed with the knowledge was what learned carrying out the literature review and completing the study methodology. Possible future work and the dissemination of results concluded this chapter. The Next Chapter will briefly conclude this research study.

Chapter 6 Conclusion

From the work completed, the results that arose from this study and the knowledge gained on the detailed workings of a CCLIMS, it would be safe to say that many factors to the stakeholder's uptake and acceptance of a CCLIMS are addressed. The integrating of a complex, multifaceted system such as a CCLIMS into a busy, stressful working environment would typically come up against significant resistance. It was surprising to witness how many barriers were broken down by the correct approach to educating the stakeholder and introducing this technology in a correct controlled manner. The semi-structured interview process paved the way to introducing this complicated technology slowly while gaining trust. It was unusual that the stakeholders excepted this CCLIMS without any negativity straight from the start. Maybe this is not so unusual as it is everyone's goal within the healthcare community to improve the care to patients. If this study assists in the process of the acceptance of implementing complicated technology in a socio-technical environment (by proving to the stakeholders that it will improve their working practices) and as a result improve patient care, this a worthwhile process to have completed. When one tries to eliminate medication errors from our hospital systems, doing this effectively will safeguard the children under medical care in our institutions.

A fitting example of implementing such a system should be in the building of the National Children's Hospital (NCH) as this facility is being designed to be a flagship of technology and the platform to launch the national electronic health record (EHR) (ehealthIreland, 2012). Surely with a national EHR on the horizon, the interoperability of the medical devices within this iconic building being built should be a number one priority to be interfaced correctly. There couldn't be a better way to ensure adverse drug reactions do not cause harm to the most vulnerable group of patients, children.

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Appendices

Appendix A: Ethics, OLCHC Approval Letter

Not for prescription purposes

ETHICS (MEDICAL RESEARCH) COMMITTEE OFFICE
Tel: + 353 (01) 409 6307/6243

Mr Scott Barkley
Senior Clinical Technician
Clinical Engineering Department
Our Lady's Children's Hospital
Crumlin
Dublin 12

28th February 2018

REC Reference: GEN/631/18

An investigation into how implementing a closed loop paediatric infusion therapy system effects work practices in an existing working paediatric hospital
Principal Investigators: Mr. Scott Barkley

Dear Mr Barkley
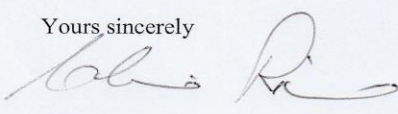
The Ethics (Medical Research) Committee at this hospital, at a meeting that took place on 27th February 2018, reviewed and approved the above Study.

The Committee requested that:

- Data be retained by you in this hospital and not in TCD, as stated in the Application Form;

- The statement *"I understand that if I or anyone in my family has a history of epilepsy that I am proceeding at my own risk"* be deleted from the Consent Form.

The Committee wish you every success with your Study.

Yours sincerely

Claire Rice
Secretary
Ethics (Medical Research) Committee

STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, <u>which are not</u> Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: _ AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.
_____

Application Version No: _Version 2.1_____

Application Date: _30/01/2018_____

For Official Use Only – Date Stamp of Receipt by REC:

This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.

➢ SECTION A GENERAL INFORMATION

A1 Title of the Research Study:

AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.

A2 (a) Is this a multi-site study?   No

If you chose 'yes' please delete questions A2 (e) and (f), If you chose 'no' please delete Questions A2 (b) (c) and (d)

A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.

Title: Mr.   **Name:** Scott Barkley
Qualifications: Post Grad Diploma studying for MSc.
Position: Senior Clinical Engineering Technician
Dept: Clinical Engineering
Organisation: Our Lady's Children's Hospital Crumlin
Address: Crumlin, Dublin 12.
Tel**:** 087 6504183   E-mail**:** scott.barkley@olchc.ie / barkleys@tcd.ie

A2 (f) For single-site studies, please name the only site where this study will take place.

Our Lady's Children's Hospital Crumlin

A3. Details of Co-investigators:

Name of site (if applicable)**:** Not-applicable
Title: Dr. / Ms. / Mr. / Prof.   **Name:** Answer
Qualifications**:** Answer
Position**:** Answer
Dept : Answer
Organisation**:** Answer
Address: Answer
Tel**:** Answer   E-mail**:** Answer
Role in Research e.g. statistical / data / laboratory analysis: Answer

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Name: Scott Barkley
Position**:** Senior Clinical Engineering Technician
Organisation**:** Our Lady's Children's Hospital Crumlin
Address for Correspondence: Clinical Engineering, Our Lady's Children's Hospital Crumlin, Dublin 12.
Tel (work)**:** 01 4096171 Tel (mob.)**:** 0876504183 E-mail**:** scott.barkley@olchc.ie / barkleys@tcd.ie

A5 (a) Is this study being undertaken as part of an academic qualification? Yes

A5 (b) If yes**, please complete the following:**
Student Name(s): Scott Barkley
Academic Course: MSc Health Informatics
Academic Institution: Trinity College Dublin

A5 (c) Academic Supervisor(s):

Title: Dr.   **Name:** Damon Berry
Qualifications: PhD MSc. BSc. DipEE.
Position: Lecturer
Dept: School of Electrical & Electronic Engineering
Organisation: Dublin Institute of Technology
Address: Kevin St, Dublin 2
Tel**:** 087 6699932   E-mail**:** damon.berry@dit.ie

> **SECTION B   STUDY DESCRIPTORS**

SECTION B IS MANDATORY

B1.   What is the anticipated start date of this study?

| Mid-March / April 2018 |

B2.   What is the anticipated duration of this study?

| 2 Months |

B3.   Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

Background

Medication error in hospitals is a significant problem worldwide. Hospitals are increasingly combining medical devices and ICT into complex Medical IT Systems. The intent is to improve the management of patient data and to integrate devices

into systems that as a whole provide more functionality and safety than the individual equipment can do when used as standalone devices.

Hospitals are developing closed loop medication systems in an attempt to reduce the problem of medication error. A closed loop medication system brings together technical medical equipment previously used in isolation and includes Infusion Pumps, Drug Libraries, Drug Storage, Logistics and monitoring systems and Electronic Health Care Records (EHR). Such systems support the use of engineering controls and decision support software which adds a layer of safety (Miller et al., 2017, Ohashi et al., 2014).

These closed loop medication systems are marketed by medical technology companies and many hospitals aspire to procuring and implementing them to improve patient safety. However, a closed loop medication system is in fact a socio-technical system and if system engineering tools are used it becomes clear that to implement such a system, several groups of professionals in the hospital need to integrate and change their work practice with the introduction of the new technology (Baxter and Sommerville, 2011).

The medical system suppliers tend to give the impression that it is a simple matter to implement their systems in hospital environments. Although the individual devices are well engineered, if the integrated system is carelessly designed and/or poorly resourced they'll impact on working practices which can decrease the benefits to patients (Burgin et al., 2014).
In reality, there have been many failed projects in the domain of health Informatics, this can be due to the complex interdisciplinary tasks needing to be performed. Multidisciplinary teams therefore need to assess various different integrations across many departments in hospitals.
For example, a complete closed loop paediatric medication system will involve at least five different departments who are working to a common goal. The professionals involved will be from Pharmacy, Medical, Nursing, Clinical Engineering and Information Technology (ICT). The perspectives of these disciplines will have to inputted into the closed loop medication system (and change their working practices) to ensure it can be integrated into a Hospitals existing infrastructure. The Medical vendors also have a difficult role to action as they need to progress all integrations until the customer / hospital is satisfied. A phased team approach with a large training regime will be needed to get the system operational.

Focus of this work

The purpose of this project is to conduct research to determine what are the changes to work practices, (in all the effected disciplines i.e. Pharmacy, Nursing, Clinicians, Clinical Engineering and Information Communication Technology (ICT), if a complete closed loop infusion therapy system was to be implemented within an existing working paediatric hospital.
An understanding of the processes will be formed by the discussion and investigation though interviews with specialists in each of the different disciplines. The proposed integration of this (extremely complex and technical) closed loop infusion therapy system will require a multidisciplinary approach for its possible integration into the healthcare practices across many disciplines.

B4. Provide brief information on the study background.

References:-

BAXTER, G. & SOMMERVILLE, I. 2011. Socio-technical systems: From design methods to systems engineering. *Interacting with Computers,* 23**,** 4-17.

BURGIN, A., O'ROURKE, R. & TULLY, M. P. 2014. Original Research: Learning to work with electronic patient records and prescription charts: experiences and perceptions of hospital pharmacists. *Research in Social and Administrative Pharmacy,* 10**,** 741-755.

MILLER, K. E., ARNOLD, R., CAPAN, M., CAMPBELL, M., ZERN, S. C., DRESSLER, R., DURU, O. O., EBBERT, G., JACKSON, E., JR., LEARISH, J., STRAUSS, D., WU, P. & BENNETT, D. A. 2017. Improving Infusion Pump Safety Through Usability Testing. *Journal Of Nursing Care Quality,* 32**,** 141-149.

OHASHI, K., DALLEUR, O., DYKES, P. C. & BATES, D. W. 2014. Benefits and risks of using smart pumps to reduce medication error rates: a systematic review. *Drug Safety,* 37**,** 1011-1020.

B5. List the study aims and objectives.

The aims of this research are:

1) Determine the conditions under which a completely closed loop infusion therapy system should be safely integrated into a working paediatric hospital.

2) Investigate and document are the changes to work practices for the following stakeholder's?
 - Pharmacy professionals
 - Nursing professionals
 - Clinicians
 - Clinical Engineers
 - ICT professionals

It is anticipated that the improved understanding of a closed loop medication infusion therapy system will help guide and prepare the healthcare institution in the correct approach to purchasing and implementing of such a system.

B6. List the study endpoints / measurable outcomes (if applicable).

Not applicable

B7. Provide information on the study design.

This study will use mainly qualitative and applied research methodologies. The information gathered from semi-structured individual interviews with selected staff on the existing procedural work practices in their departments. This will then be

compared against the new perceived work practices of the proposed closed loop system, thus giving greater depth and awareness into the changes involved in implementing such a complex system across many disciplines.

B8.   Provide information on the study methodology.

The researcher proposes to carry out semi structured interviews with selected staff (using purposeful sampling) from: -

Pharmacy (Chief Pharmacist Informatics (ICU element of study)
Pharmacy (Senior Pharmacist Wards)
Nursing (Assistant director of nursing (ADN))
Clinicians (Consultant Anaesthetist/Intensivist)
Clinical Engineering (Principle Clinical Engineering Technician)
ICT (Project Manager)

The structure for all the interviews will be similar (but the direction and content will vary greatly with all the varying participants disciplines): -

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html. This video shows the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the technology and the product which gives a good awareness of the new work practices to be introduced into a system like this.

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

The Comparisons in the work flow practices will be highlighted using unified modelling language (UML) activity diagrams. The varying roles between the different disciplines will be wide making a broad base of knowledge with interesting interoperability comparisons.

B9.   Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

Not appropriate

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Answer see below

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

It is proposed to interview individuals in Pharmacy, Medical, Nursing, Clinical Engineering and with experience and an in-depth knowledge of current working practices within a paediatric hospital and with the insight to critique the required work practices of the proposed new closed loop system. These individuals represent the total number needed for the research to be carried out.

B11. How many research participants are to be recruited in total?

Five to Seven participants depending on their specialised knowledge,

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).

Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:
Answer	Answer	Answer	Answer	Answer
Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:
Answer	Answer	Answer	Answer	Answer

B12 (b) Please provide details on the method of randomisation (where applicable).

Not Applicable

B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.

Site:	Number of Research Participants at this site:
OLCHC	5-7

> **SECTION C   STUDY PARTICIPANTS**

SECTION C IS MANDATORY

> **C1   PARTICIPANTS – SELECTION AND RECRUITMENT**

C1.1 How will the participants in the study be selected?

Participants are work colleagues and are known to the researcher and will be purposefully selected for their knowledge purely on a voluntary basis.

C1.2 How will the participants in the study be recruited?

The participants will be invited to take part on a voluntary basis in writing by the researcher.

C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)

Not applicable- as the participants were purposefully selected for their knowledge in their various areas of expertise.

C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

Not necessary

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project? Not to my knowledge

> **C2   PARTICIPANTS – INFORMED CONSENT**

C2.1 (a) Will informed consent be obtained? Yes

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

Not applicable

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

Prior to any interviews a study informed consent form will be given by the researcher to the participants.

INFORMED CONSENT FORM

LEAD RESEARCHERS: Scott Barkley

BACKGROUND OF RESEARCH: The purpose of this project is to conduct research to determine what are the changes to work practices (in all the effected disciplines i.e. Pharmacy, Nursing, Clinicians, Clinical Engineering and Information Communication Technology (ICT)), if a complete closed loop infusion therapy system was to be implemented into an existing working paediatric hospital.

PROCEDURES OF THIS STUDY:

Participants are asked to do the following:-

The researcher proposes to carry out semi structured interview:-

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (This information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html.
This video shows the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the technology and the product which gives a good awareness of the new work practices to be introduced into a system like this.

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again, this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

PUBLICATION: This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications and it is possible that the results of the work will be presented in a public forum such as the HISI and BEAI conferences or similar events.

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:
• 	I am 18 years or older and am competent to provide consent.
• 	I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
• 	I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
• 	I understand that if I make illicit activities known, these will be reported to appropriate authorities.
• 	I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).
• 	I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.
• 	I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
• 	I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
• 	I understand that my participation is fully anonymous and that no personal details about me will be recorded.
• 	I have received a copy of this agreement.
PARTICIPANT'S NAME:

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.

RESEARCHERS CONTACT DETAILS: Scott Barkley (barkleys@tcd.ie Mobile: -087 6504183)

INVESTIGATOR'S SIGNATURE:

Date:

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes

C2.2 (b) If no, please justify.

Answer

C2.3 (a) Will there be a time interval between giving information and seeking consent? No

C2.3 (b) If yes, please elaborate.

Not applicable

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.

It is proposed to present the study information sheet and consent form at the beginning of the semi structured interview process. These interviews will take 30-50 minutes depending on discipline and will need to be arranged in advance with the selected voluntary participants.

> **C3   ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY**

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes

If answer is Yes, please delete remaining questions in Section C3

➢ C4   PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

If answer is <u>No</u>, please delete remaining questions in Section C4

➢ C5   PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. <u>It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.</u>

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients No

- **Unconscious patients** No
- **Current psychiatric in-patients** No
- **Patients in an emergency medical setting** No

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships No

- **Students** No
- **Employees / staff members** Yes
- **Persons in residential care** No
- **Persons highly dependent on medical care** No

(e) Intellectually impaired persons No

(f) Persons with a life-limiting condition No
(Please refer to guidance manual for definition)

(g) Persons with an acquired brain injury No

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

> The researcher is a working colleague with no influence over the selected participants with regards to participation. Their participation will be on a voluntary basis.

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

> Not applicable

> ➢ **SECTION D   RESEARCH PROCEDURES**

<div align="center">SECTION D IS MANDATORY</div>

D1 (a) **What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?**

> Participate in a semi structured interview, Read transcription of interview and verify it is a true and accurate account of what was spoken.

D1 (b) What other activities (if any) are taking place for the <u>purposes of this research study</u> e.g. chart review, sample analysis etc?

> The creating of UML activity diagrams to show and document the current working practices and the proposed closed loop working practices.

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

> None

D3. What is the potential benefit that may occur as a result of this study?

> To provide advanced knowledge and insight before a paediatric hospital purchases a state of the art closed loop infusion system with little knowledge of how it will integrate and effect the working practices of the many professionals who will be required to operate it.

D4 (a) Will the study involve the withholding of treatment?
Not applicable

D4 (b) Will there be any harms that could result from withholding treatment? Not applicable

D4 (c) If yes, please elaborate.

> Not applicable

D5 (a) How will the health of participants be monitored <u>during</u> the study, and who will be responsible for this?

Not applicable

D5 (b) How will the health of participants be monitored <u>after</u> the study, and who will be responsible for this?

Not applicable

D6 (a) Will the interventions provided <u>during the</u> study be available if needed after the termination of the study? Non-applicable

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Not applicable

D7. Please comment on how individual results will be managed.

Answer

D8. Please comment on how aggregated study results will be made available.

This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications.

D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)? Non-applicable

D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)? Non-applicable

> **SECTION E   DATA PROTECTION**

SECTION E IS MANDATORY

> **E1   DATA PROCESSING - CONSENT**

E1.1 (a) Will <u>consent</u> be sought for the processing of data? Yes

E1.1 (b) If no, please elaborate.

Answer

> **E2   DATA PROCESSING - GENERAL**

E2.1 Who will have <u>access</u> to the data which is collected?

Only the researcher and the project supervisor for verification purposes.

E2.2 What <u>media</u> of data will be collected?

Digital audio recordings (from interviews)

E2.3 (a) Would you <u>class</u> the data collected in this study as **anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?**

Anonymised (no names will be used)

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

Answer

E2.4 Where will data which is collected be stored?

The data will be store in an encrypted password protected vaulted file on the researcher's laptop

E2.5   Please comment on security measures which have been put in place to ensure the security of collected data.

An encryption program is in use (safehouse explorer) on the researcher's laptop. This software will also encrypt, password protect and vault files including digital voice recordings etc. It also has the ability to password protect and encrypt USB keys and external hard drives if these need to be used during this dissertation.

E2.6 (a) Will data collected be at any stage leaving the site(s) of origin?
Yes

E2.6 (b) If yes, please elaborate.

Data may be transported to Trinity's college library on the researcher's encrypted password protected laptop for analysis .

E2.7   Where will data analysis take place and who will perform data analysis (if known)?

Data Analysis will take place on the researcher's encrypted laptop in Our Lady's Children's Hospital, Crumlin and/or the Trinity College library by the Researcher

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Data will only be retained for as long as necessary by Trinity College after which it will be destroyed using Safehouse Explorer's shredding file facility. (In shredding spurious data is interlaced throughout the file volumes and the deleted to leave no legible trace).

E2.8 (b) Please elaborate.

All data files (audio recordings) will be destroyed after transcription has taken place.

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

As above (files will be destroyed using Safehouse shredding software)

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Data will only be retained in Our Lady's Children's Hospital, Crumlin for as long as necessary by the Researcher, after which it will be destroyed.

E2.9   Please comment on the confidentiality of collected data.

No personal information will be collected or recorded and all data will be totally confidential and anonymous.

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? Yes

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Yes

E2.11 (a) Will any of the study data collected consist of photographs/ video recordings? No

E2.11 (b) If yes, please elaborate.

Non-applicable

> ## E3   ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? No

If answer is No, please delete remaining questions in Section E3

> ## SECTION F   HUMAN BIOLOGICAL MATERIAL

> ## F1   BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? No

If the answer is No, please delete Section F

SECTION G   RADIATION

G1   RADIATION – GENERAL

G1.1 (a) Does this study/trial involve exposure to radiation? No

If answer is No, please delete remaining questions in Section G

SECTION H   MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a <u>medical device</u>? No

If answer is No, please delete remaining questions in Section H.

SECTION I   MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

I.1   NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a <u>medicinal product</u>? No

If the answer is No, please delete remaining questions in subsection I1

I.2   COSMETICS

I2.1 (a) Does this study involve a <u>cosmetic</u>? No

If the answer is No, please delete remaining questions in subsection I2

I.3   FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve <u>food or food supplements?</u> No

> **SECTION J   INDEMNITY AND INSURANCE**

SECTION J IS MANDATORY

J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.

> The researcher (Scott Barkley) is a staff member of the Clinical Engineering department of OLCHC. The interviews are with staff participants and will take place in OLCHC. It is not envisioned that insurance/indemnity is required.

J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.

> The researcher (Scott Barkley) is a staff member of the Clinical Engineering department of OLCHC. The interviewees are also staff members of OLCHC. It is not thought that insurance/indemnity is required.

J3.1   Please give the name and address of the organisation / or individual legally responsible for this research study?

> Our Lady's Children's Hospital, Crumlin.
> (This study is part of a taught master's dissertation which is a requirement for an MSc on Health Informatics in Trinity College Dublin.)

J3.2   Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company No
A medical device company No
A university   No
A registered charity Yes
Other No   **If yes, please specify:** Answer

J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?

> Not-applicable

> **SECTION K   COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS**

SECTION K IS MANDATORY

> **K1   COST AND RESOURCE IMPLICATIONS**

K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)

No costs involved

➢ K2 FUNDING

K2.1 (a) Is funding in place to conduct this study?
Funding not required

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.
Not-applicable

K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.

Source of funding (industry, grant or other):
N/A
Name of Funder:
N/A
Amount of Funding:
N/A
Duration of Funding
N/A

K2.1(d) Please provide additional details in relation to management of funds.

Not-applicable

K2.1(e) Is the study funded by a 'for profit' organisation? No

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? No

K2.2 (b) If yes, please elaborate.

Not-applicable

➢ K3 PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? No

K3.1 (b) If yes, please provide details of payments (including amount).

Not-applicable

> **K4   PAYMENTS TO PARTICIPANTS**

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? No

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

Not applicable

> **SECTION L   ADDITIONAL ETHICAL ISSUES**

L1 (a)   Does this project raise any additional ethical issues? No

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

Appendix C: TCD Research Ethics WebApp (Approved)

TCD Research Ethics WebApp

My account   Log out

Home

Navigation

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- Create REC Application
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- Help

Home › AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL

AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL

| Status | View | Assign Supervisor |

Current Status	Submission date	Last Status Update	Academic Supervisor / Lead Researcher	Application Number
Approved	Wednesday, March 28, 2018 - 03:59	Friday, April 27, 2018 - 10:50	dberry	20180310

No workflow transitions are possible at this time.

Final Comments from the Research Ethics Committee

This application is complete and can proceed.

Status:
Approved

Timeline of state changes for this application

Status:
Approved

Timeline of state changes for this application

Friday, April 27, 2018 - 10:50
State change:
from *Commented by Reviewers; Pending REC Meeting*
to ***Approved***

Thursday, April 26, 2018 - 13:59
State change:
from *Assigned to Reviewers; Pending Comments*
to ***Commented by Reviewers; Pending REC Meeting***

Thursday, April 5, 2018 - 10:25
State change:
from *Submitted to REC; Awaiting Reviewer Assignment*
to ***Assigned to Reviewers; Pending Comments***

Wednesday, April 4, 2018 - 22:19
State change:
from *Submitted to Supervisor; Pending Review*
to ***Submitted to REC; Awaiting Reviewer Assignment***

Tuesday, April 3, 2018 - 10:38
State change:
from *Ready for Submission to Supervisor for Review*
to ***Submitted to Supervisor; Pending Review***

Wednesday, March 28, 2018 - 04:03
State change:
from *Draft*
to ***Ready for Submission to Supervisor for Review***

Wednesday, March 28, 2018 - 03:59
State change:
from *(creation)*
to ***Draft***

Ethical Approval

Research Project Proposal

- **Project Title: -**

AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.

Project Purpose: -

The purpose of this project is to conduct research to determine what are the changes to work practices (in all the effected disciplines i.e. Pharmacy, Nursing, Clinicians, Clinical Engineering and Information Communication Technology (ICT)), if a complete closed loop infusion therapy system was to be implemented into an existing working paediatric hospital.

Medication error in hospitals is a significant problem worldwide. Hospitals are increasingly combining medical devices and ICT into complex Medical IT Systems. The intent is to improve the management of patient data and to integrate devices into systems that as a whole provide more functionality and safety than the individual equipment can do when used as standalone devices.

Hospitals are developing closed loop medication systems in an attempt to reduce the problem of medication error. A closed loop medication system brings together technical medical equipment previously used in isolation and includes Infusion Pumps, Drug Libraries, Drug Storage, Logistics and monitoring systems and Electronic Health Care Records (EHR). Such systems support the use of engineering controls and decision support software which adds a layer of safety.

These closed loop medication systems are marketed by medical technology companies and many hospitals aspire to procuring and implementing them to improve patient safety. However, a closed loop medication system is in fact a socio-technical system and if system engineering tools are used it becomes clear that to implement such a

system, several groups of professionals in the hospital need to integrate and change their work practice with the introduction of the new technology.

The medical system suppliers tend to give the impression that it is a simple matter to implement their systems in hospital environments.

For example, a complete closed loop paediatric medication system will involve at least five different departments who are working to a common goal. The professionals involved will be from Pharmacy, Medical, Nursing, Clinical Engineering and Information Technology (ICT). The perspectives of these disciplines will have to inputted into the closed loop medication system (and change their working practices) to ensure it can be integrated into a Hospitals existing infrastructure. The Medical vendors also have a difficult role to action as they need to progress all integrations until the customer / hospital is satisfied. A phased team approach with a large training regime will be needed to get the system operational.

Methods

The researcher proposes to carry out semi structured interviews: -

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (This information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html. This video shows the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the technology and the product which gives a good awareness of the new work practices to be introduced into a system like this.

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again, this information will be recorded on a digital data device and later

transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Participant Recruitment

Participants are work colleagues from Our Lady's Children's Hospital Crumlin and are known to the researcher. They will be purposefully selected for their expert knowledge in each of their specialities purely on a voluntary basis.

It is proposed to interview five to seven individuals in Pharmacy, Medical, Nursing, Clinical Engineering and ICT. It's with these experts in their professions and with experience and an in-depth knowledge of current working practices within a paediatric hospital and with the insight to critique the required work practices of the proposed new closed loop system. These individuals represent the total number needed for the research to be carried out.

The researcher is a working colleague with no influence over the selected participants with regards to participation. Their participation will be completely on a voluntary basis.

Ethical Considerations

As the researcher is a work colleague and known to all the purposed participants there is a potential conflict of interest in relation to this research study. However, it is the researcher intention to adhere to good practice and follow the ethical code for research at all times during this study.

Debriefing Arrangements

I will inform the participants of the purpose of this research. If participants request further information I will arrange to send them the completed copy of the final dissertation in a PDF format.

Data Protection

As per the Data Protection acts 1988 & 2003 all data collected will be anonymized. No disclosures of participants identities or personal information will be provided. No consent is required from the data controller.

All research documents for this dissertation is stored (or will be stored) on the researcher's personal laptop computer. This personal laptop computer is password protected and is encrypted with the safehouse explorer 448-bit encryption software program.

TRINITY COLLEGE DUBLIN

INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS

Project Title: -
AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.
Name of Lead Researcher: Scott Barkley
Name of Supervisor: Dr. Damon Berry
Lead Researcher's email: barkleys@tcd.ie
Lead Researcher's Contact Mobile No.: 087 6504183
Couse Name and Code: MSc Health Informatics (PTCS-HINF-1P)
Estimated start date of interviews/research: April 2018

BACKGROUND OF RESEARCH: -
  The purpose of this project is to conduct research to determine what are the changes to work practices (in all the effected disciplines i.e. Pharmacy, Nursing, Clinicians, Clinical Engineering and Information Communication Technology (ICT)), if a complete closed loop infusion therapy system was to be implemented into an existing working paediatric hospital.

PROCEDURES OF THIS STUDY:
Participants are asked to do the following: -
The researcher proposes to carry out semi structured interviews: -

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (This information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation, http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html. This video shows the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the technology and the product which gives a good awareness of the new work practices to be introduced into a system like this.

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again, this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

The Clinical Engineering and ICT participants will be asked to analyse the technology advancements and information pathways at this point. The researcher will be concentrating on the differences between the existing ICT/Clinical Engineering systems/network structures and the working practice changes to allow a closed loop medication system to be implemented into the current hospital systems.

PUBLICATION: -

This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications and it is possible that the results of the work will be presented in a public forum such as the HISI and BEAI conferences or similar events.

These interviews will take 30-50 minutes depending on discipline and will need to be arranged in advance with the purposefully selected voluntary participants.

Additional information: -
- Your participation in this research study is voluntary
- The researcher is a working colleague but has no influence over you with regards to participation in this research.
- The data will be anonymized, and preservation of your and 3rd party anonymity in all publication, analysis and presentations resulting from this study
- I do not anticipate any risks to you during this study. The benefits of participating in this study will provide advanced knowledge and insight before a paediatric hospital purchases a state of the art closed loop infusion system with little knowledge of how it will integrate and effect the working practices of the many professionals who will be required to operate it.
- When complete, a copy of this dissertation can be supplied to you upon request. If you require further information on this study feel free to ask.
- In the unlikely event that an illicit activity is reported to me during this these interviews, I will be obliged to report it to the appropriate authorities.
- I will act in accordance with the information provided, (so if I say I will not do something, then I will not do it).
- In my dissertation I may use direction quotations (when they are contextually appropriate) but you will remain anonymous.
- No audio or video recordings will be made available to anyone other than the researcher and supervisor, nor will any such recordings be replayed in any public forum or presentation of the research.

Appendix F: Informed Consent Form

TRINITY COLLEGE DUBLIN
INFORMED CONSENT FORM

AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.

LEAD RESEARCHERS: Scott Barkley

BACKGROUND OF RESEARCH: The purpose of this project is to conduct research to determine what are the changes to work practices (in all the effected disciplines i.e. Pharmacy, Nursing, Clinicians, Clinical Engineering and Information Communication Technology (ICT)), if a complete closed loop infusion therapy system was to be implemented into an existing working paediatric hospital.

PROCEDURES OF THIS STUDY:

Participants are asked to do the following: -

The researcher proposes to carry out semi structured interview: -

Firstly, the participant will be asked to describe and step though their current procedures in detail with regards to delivering an infusion to a patient. (This information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

Secondly, the researcher will display a tutorial/informative short video (less than 5 minutes long) on a closed loop infusion therapy system in operation http://www.space.bbraun.com/cps/rde/xchg/hc-space-en-int/hs.xsl/7743.html. This video shows the 5 rights of medication delivery stepping through all the phases quickly and safely. This commercially available video simplifies the complex integrations between the user, the technology and the product which gives a good awareness of the new work practices to be introduced into a system like this.

Thirdly, the participant will be asked to discuss the new therapy delivery techniques and critique the finer details with the researcher who has studied the new system in depth. Again, this information will be recorded on a digital data device and later transcribed and returned to the participant for an accuracy check and amendment (if deemed necessary).

PUBLICATION: This research will be used in the researcher's dissertation that will be submitted to Trinity College Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics. The research may also be published in scientific publications and it is possible that the results of the work will be presented in a public forum such as the HISI and BEAI conferences or similar events.

Individual results may be aggregated anonymously and research reported on aggregate results.

DECLARATION:

•   I am 18 years or older and am competent to provide consent.

•   I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.

•   I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.

•   I understand that if I make illicit activities known, these will be reported to appropriate authorities.

•   I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).

•   I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.

•   I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

•   I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.

•   I understand that my participation is fully anonymous and that no personal details about me will be recorded.

•   I have received a copy of this agreement.

PARTICIPANT'S NAME:

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.

RESEARCHERS CONTACT DETAILS: Scott Barkley (barkleys@tcd.ie Mobile: - 087 6504183)

INVESTIGATOR'S SIGNATURE:

Date: -

Appendix G: Declaration sign off

Title: - AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL.

1   I confirm that I have read and understood the information sheet for this study. I have had the opportunity to consider the information, and have asked and received answers to any questions asked.

2   I understand that my participation is voluntary and I/we am free to withdraw at any time, without giving a reason, and without sanction.

3   I understand that the research team will hold all information and data collected securely and in confidence, and that individual participants will not be identified.

4   I give the researcher permission to hold relevant personal data.

I consent to taking part in this study: -

Appendix H: SCSS Research Ethics Application (signed)

School of Computer Science & Statistics   **Research Ethics Application**

Part A

Project Title: AN INVESTIGATION INTO HOW IMPLEMENTING A CLOSED LOOP PAEDIATRIC INFUSION THERAPY SYSTEM AFFECTS WORK PRACTICES IN AN EXISTING WORKING PAEDIATRIC HOSPITAL...

Name of Lead Researcher (student in case of project work): ....Scott Barkley...

Name of Supervisor:..........Dr Damon Berry...

TCD E-mail: barkleys@tcd.ie........................ Contact Tel No.: ...087 6504183...

Course Name and Code (if applicable): ......MSc Health Informatics...

Estimated start date of survey/research: ......02/04/2018...

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Signed: .... Date: ...78/3/2018.........................
Lead Researcher/student in case of project work

Part B

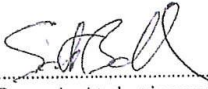| Please answer the following questions.		Yes/No
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		Yes
Will your project deliberately involve misleading participants in any way?		No
Does this study contain commercially sensitive material?		No
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		No
Does your study involve any of the following?	Children (under 18 years of age)	No
	People with intellectual or communication difficulties	No
	Patients	No

School of Computer Science and Statistics
Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.
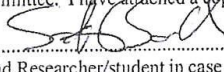
Signed: ....

Lead Researcher/student in case of project work

Date: ....28/3/2018.........................

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external or other TCD Ethics Committee approval has been received, please complete below.

External/TCD ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: ....

Lead Researcher/student in case of project work

Date:....28/3/2018......................

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on the submission checklist is accounted for) and are in a form that is suitable for review by the SCSS Research Ethics Committee

Signed: ....

Supervisor

Date:....28/3/2018..........................

Completed application forms together with supporting documentation should be submitted electronically to the online ethics system - https://webhost.tchpc.tcd.ie/research_ethics/ When your application has been reviewed and approved by the Ethics committee, hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room 104, Lloyd Building, Trinity College, Dublin 2.

Ethics Application Guidelines – 2016

CHECKLIST

Please ensure that you have submitted the following documents with your application:

1.	• SCSS Ethical **Application Form**	
2.	• **Participant's Information Sheet** must include the following: a) Declarations from Part A of the application form; b) Details provided to participants about how they were selected to participate; c) Declaration of all conflicts of interest.	
3.	• **Participant's Consent Form** must include the following: a) Declarations from Part A of the application form; **b)** Researchers contact details provided for counter-signature (your participant will keep one copy of the signed consent form and return a copy to you).	
4.	• **Research Project Proposal** must include the following: a) You must inform the Ethics Committee **who** your intended participants are i.e. are they your work colleagues, class mates etc. b) How will you recruit the participants i.e. **how** do you intend asking people to take part in your research? For example, will you stand on Pearse Street asking passers-by? c) If your participants are under the age of 18, you must seek both parental/guardian AND child consent.	
5.	• Intended **questionnaire**/survey/interview protocol/screen shots/representative materials (as appropriate)	
6.	• **URL** to intended on-line survey (as appropriate)	

Notes on Conflict of Interest

1. If your intended participants are work colleagues, you must declare a potential conflict of
   interest: you are taking advantage of your existing relationships in order to make
   progress in your research. It is best to acknowledge this in your invitation to participants.
2. If your research is also intended to direct commercial or other exploitation, this must be
   declared. For example, *"Please be advised that this research is being conducted by an
   employee of the company that supplies the product or service which form an object of
   study within the research."*

Notes for questionnaires and interviews

1. If your questionnaire is **paper based**, you must have the following **opt-out** clause on the top
   of
   each page of the questionnaire: *"Each question is optional. Feel free to omit a response
   to any question; however the researcher would be grateful if all questions are responded
   to."*
2. If you questionnaire is **on-line**, the first page of your questionnaire must repeat the content
   of the information sheet. This must be followed by the consent form. If the participant
   does not agree to the consent, they must automatically be exited from the questionnaire.
3. Each question must be **optional**.
4. The participant must have the option to '**not submit, exit without submitting**' at the
   final submission point on your questionnaire.
5. If you have open-ended questions on your questionnaire you must warn the participant
   against naming **third parties**: *"Please do not name third parties in any open text field of
   the questionnaire. Any such replies will be anonymised."*
6. You must inform your participants regarding **illicit activity**: *"In the extremely unlikely
   event that illicit activity is reported I will be obliged to report it to appropriate authorities."*

Appendix I: Interview System Administrator Transcript

Transcript of Interview with PICU Systems Administrator: -

Researcher: Thank for agreeing to this interview, Can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Systems Admin: So at the moment the drug as prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is our computer system which we use in PICU for documentation, when the doctor has prescribed the drug we check the order against the medication policy and against the standard concentration infusion table that we have and make sure that the limits match. After we are happy with the drug we prepare our equipment that is needed to make up the drug after that we write a label so that there is full accountability for what is in the syringe that's going to be delivering the drug.

After we prepared all of our equipment and we have checked everything we know how much we need so we draw up the amount of drug we need and we draw up the amount of diluent that we need and mix the two of them, give it a 'good shake' put a giving set on it, prime the line from there you load the syringe into your pump then you program your pump by selecting your area that you are in, the weight of band that you are in, the drug that you want, within the drug you are offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not) Sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous, doses can be changed once they are still within the drug library limits and within the prescription and when you are happy with all your information you have entered into the pump you press start on the infusion you connect the infusion to the patient an then that's your drug delivery.

If is a drug that is a dose over time it will alarm either when the syringe is coming towards the end or when the time has elapsed or if it is a continuous drug it will continue to go for the amount of time you have programmed it to run, if the syringe is coming to an end you will get a warning or if there is an occulusion at any point you will get warning otherwise continuous will remain running going until your VTBI has expired.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Systems Admin: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient.

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Systems Admin: When you prepare the drug, you have to sign that you have prepared the drug.

Researcher: Where do you sign that?

Systems Admin: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 for preparation which includes checking your order, checking your they have to do it together).

Researcher: So, the same 2 people should do these steps from start to finish?

Systems Admin: Yes, but when the drug is made up it can sit in a tray (for a period of time), the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the pump check you're making sure your pump programming matches the ICCA order, (so it can be a different 2nd person who checks that).

Researcher: And the second two check boxes on the ICCA system?

Systems Admin: That is where the second two boxes come into play, so the two people that take on the pump part, they both check what's been inputted into the pump is the same to what's on the order

Researcher: …. and there's two boxes for them to sign?

Systems Admin: …Yes that's correct (the second two boxes), before they sign these they also have to do a manual calculation of the rate so within those checks when programming a pump, you do a manual calculation of the rate, they are the two people who sign the second two boxes, so it's two correct, because one of the people checking it will be the same as the person who prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Systems Admin: the route is only stated on the medication order, not on the syringe.

(video demonstration of a complete closed loop medication system with auto-programming was displayed)

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Systems Admin: I think nurses in ICU would appreciate is this system it would work because the system is always checking itself so I think the nurses would trust that the infusion that's comes up would be inline with their order (for the scanned patient). I think to adapt to this system would not be that difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, like TPN and Lipids even though they are infusions bags they still go through

One limitation would be when a drug is needed in an emergency I don't think nursing staff will be comfortable waiting for pharmacy to receive the order, prepare the drug and delivered it to ICU. Nurses would need to act immediately and prepare this type of infusion themselves for the clinical need of their patient, so there would need full access to the system and all necessary equipment so that they can prepare urgently needed drugs themselves.

Researcher: Do you feel a dispensing cabinet premade, barcoded syringes would work in ICU

Systems Admin: Firstly, you was have to isolate the specific drugs that you wanted to be your emergency drugs. On reflection using standard drug concentrations there would be a lot of waste because just for one patient you would need at least 5 emergency drugs, that is 5 syringes for the 5 weight bands so that is 25 syringes, include a second emergency patient and that's 50 syringes. I feel this would be very wasteful (and a lot of work for pharmacy) as emergency inotrope drugs only last 24 hours when made up.

Researcher: That does sound very wasteful

Systems Admin: I think a better option be having barcode system available to the nursing staff in the ICU and all of the drugs and all of the equipment required, even though the nurses wouldn't use them as standard they would still have to be able to access them so they could make up their own infusions when urgently required.

Researcher: Ok, could you see this working in any other way like the nurses in ICU making up every drug and barcoding the syringes themselves?

Systems Admin: So just follow the practice exactly the way it is but introduce a bar coding system?

Researcher: Yes, would you feel that this could be advantageous?

Systems Admin: Well from a safety point of view it would, it's going to add extra work to the nurse, but it could possibly reduce some nurse time as well and even the processes out. Writing multiple labels sometimes can take 15 minutes so with a bar-code printer this could speed up the process, even though it would be adding the process of accessing the printer and printing the labels

Researcher: Do you see the four signature boxes changing with this process?

Systems Admin: No, because it used to be only two signature boxes and it would be two nurses sign for a full check/prepare/load everything, so the second set of boxes has actually only been introduced in the last few months. That was from a safety point of view but also for nursing registration because when you sign for a drug you are also signing that you administered it.

Researcher: Ok, Great Thank you very much for that insight into nursing using smart pumps.

Researcher: Thank for agreeing to this interview, Can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Systems Admin: So at the moment the drug as prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is our computer system which we use in PICU for documentation, when the doctor has prescribed the drug we check the order against the medication policy and against the standard concentration infusion table that we have and make sure that the limits match. After we are happy with the drug we prepare our equipment that is needed to make up the drug after that we write a label so that there is full accountability for what is in the syringe that's going to be delivering the drug.

After we prepared all of our equipment and we have checked everything we know how much we need so we draw up the amount of drug we need and we draw up the amount of diluent that we need and mix the two of them, give it a 'good shake' put a giving set on it, prime the line from there you load the syringe into your pump then you program your pump by selecting your area that you are in, the weight of band that you are in, the drug that you want, within the drug you are offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not) Sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous, doses can be changed once they are still within the drug library limits and within the prescription and when you are happy with all your information you have entered into the pump you press start on the infusion you connect the infusion to the patient an then that's your drug delivery.

If is a drug that is a dose over time it will alarm either when the syringe is coming towards the end or when the time has elapsed or if it is a continuous drug it will continue to go for the amount of time you have programmed it to run, if the syringe is coming to an end you will get a warning or if there is an occlusion at any point you will get warning otherwise continuous will remain running going until your VTBI has expired. standard concentration infusion table that we have and make sure that the limits match. After we are happy with the drug we prepare our equipment that is needed to make up the drug after that we write a label so that there is full accountability for what is in the syringe that's going to be delivering the drug.

After we prepared all of our equipment and we have checked everything we know how much we need so we draw up the amount of drug we need and we draw up the amount of diluent that we need and mix the two of them, give it a 'good shake' put a giving set on it, prime the line from there you load the syringe into your pump then you program your pump by selecting your area that you are in, the weight of band that you are in, the drug that you want, within the drug you are offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not) Sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous, doses can be changed once they are still within the drug library limits and within the prescription.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Systems Admin: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient.

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Systems Admin: When you prepare the drug, you have to sign that you have prepared the drug.

Researcher: Where do you sign that?

Systems Admin: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 for preparation which includes checking your order, checking your standard concentration and actually making up the drug (i.e. putting the drug in the syringe) from start to finish so it should be the same two people doing the prep (not one doing and one checking they have to do it together).

Researcher: So, the same 2 people should do these steps from start to finish?

Systems Admin: Yes, but when the drug is made up it can sit in a tray (for a period of time), the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the pump check you're making sure your pump programming matches the ICCA order, (so it can be a different 2nd person who checks that).

Researcher: And the second two check boxes on the ICCA system?

Systems Admin: That is where the second two boxes come into play, so the two people that take on the pump part, they both check what's been inputted into the pump is the same to what's on the order

Researcher: .... and there's two boxes for them to sign?

Systems Admin: ...Yes that's correct (the second two boxes), before they sign these they also have to do a manual calculation of the rate so within those checks when programming a pump, you do a manual calculation of the rate, they are the two people who sign the second two boxes, so it's two boxes for drug prep and two boxes for pump check, the two signatures for the pump check is a new procedure within the last two months. You're are trusting that the label that was done in the first stage and the two nurses signatures on that label your trusting that and all the information is correct, because one of the people checking it will be the same as the person who prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Systems Admin: the route is only stated on the medication order, not on the syringe.

(video demonstration of a complete closed loop medication system with auto-programming was displayed)

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Systems Admin: I think nurses in ICU would appreciate is this system it would work because the system is always checking itself so I think the nurses would trust that the infusion that's comes up would be inline with their order (for the scanned patient). I think to adapt to this system would not be that difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, like TPN and Lipids even though they are infusions bags they still go through are existing smart pump system and we are used to checking them, and there are one or two drugs that come from the ACU compounding unit (pre-prepared) as well.

One limitation would be when a drug is needed in an emergency I don't think nursing staff will be comfortable waiting for pharmacy to receive the order, prepare the drug and delivered it to ICU. Nurses would need to act immediately and prepare this type of infusion themselves for the clinical need of their patient, so there would need full access to the system and all necessary equipment so that they can prepare urgently needed drugs themselves.

Researcher: Do you feel a dispensing cabinet premade, barcoded syringes would work in ICU

Systems Admin: Firstly, you was have to isolate the specific drugs that you wanted to be your emergency drugs. On reflection using standard drug concentrations there would be a lot of waste because just for one patient you would need at least 5 emergency drugs, that is 5 syringes for the 5 weight bands so that is 25 syringes, include a second emergency patient and that's 50 syringes. I feel this would be very wasteful (and a lot of work for pharmacy) as emergency inotrope drugs only last 24 hours when made up.

Researcher: That does sound very wasteful

Systems Admin: I think a better option be having barcode system available to the nursing staff in the ICU and all of the drugs and all of the equipment required, even though the nurses wouldn't use

Researcher: Ok, could you see this working in any other way like the nurses in ICU making up every

Systems Admin: So just follow the practice exactly the way it is but introduce a bar coding system?

Researcher: Yes, would you feel that this could be advantageous?

Systems Admin: Well from a safety point of view it would, it's going to add extra work to the nursehough it would be adding the process of accessing the printer and printing the labels

Researcher: Do you see the four signature boxes changing with this process?

Systems Admin: No, because it used to be only two signature boxes and it would be two nurses sign for a full check/prepare/load everything, so the second set of boxes has actually only been

Researcher: Ok, Great Thank you very much for that insight into nursing using smart pumps.

Interview ends

Appendix J: Interview Clinical Engineer Transcript

Transcript of Interview with Clinical Engineer : -

Researcher: Thank for agreeing to this interview, Can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Clinical Engineer: At the moment the drug is prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is the computer system used in PICU for documentation. When the doctor has prescribed the drug two nurses check the order against the medication policy and against the standard concentration infusion table and make sure that the limits are appropriate. Once we are happy with the prescription, we prepare our equipment that is needed to make up the drug and we write a label so that there is full accountability for what is in the syringe that's going to be used to deliver the drug.

The next step is to draw up the amount of drug and diluent that we need and mix the two of them together in a syringe (inverting the syringe a few times to make sure it has mixed well), put a giving set on it and prime the line.

From there we commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running going until your VTBI has expired.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Clinical Engineer: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient.

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Clinical Engineer: When you prepare the drug, you have to sign that you have prepared the drug.

Researcher: Where do you sign that?

Clinical Engineer: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 sign for preparation which includes checking your order, checking your standard concentration and actually making up the drug (i.e. putting the drug in the syringe) from

Researcher: So, the same 2 people should do these steps from start to finish?

Clinical Engineer: Yes, but if there is a delay between preparation and infusion the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the

Researcher: And the second two check boxes on the ICCA system?

Clinical Engineer: The two people that programme the pump sign to confirm that they have both checked that the pump program matches the drug order

Researcher: …. and there's two boxes for them to sign?

Clinical Engineer: …Yes that's correct (the second two boxes), and before they sign they also have to do a manual calculation of the rate. They are the two people who sign the second two boxes (so it's two signatures for drug prep and two signatures for pump check). The two signatures for the pump check is a new step within the last two months. You are trusting that drug label, which is signed by the two nurses preparing the drug, is correct. At least one of the people checking the pump will have prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Clinical Engineer: the route is only stated on the medication order, not on the syringe.

(video demonstration of a complete closed loop medication system with auto-programming was displayed)

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Clinical Engineer: I think nurses in ICU would appreciate this system. It would work because the system is always checking itself. I think nurses would trust that the infusion that is pre-prepared would be in line with their order (for the scanned patient), although full checks would still be carried out. I think to adapt to this system would not be too difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, such as TPN and Lipids. Even though they are infusions bags they still go through our existing smart pump system and we are used to checking them, and there are one or two drugs that come from the ACU compounding unit (pre-

that they can prepare urgently needed drugs themselves.

Researcher: Do you feel a dispensing cabinet premade, barcoded syringes would work in ICU

Clinical Engineer: Firstly, you would have to isolate the specific drugs that you wanted to be your emergency drugs. On reflection using standard drug concentrations there would be a lot of waste because just for one patient you would need at least 5 emergency drugs, that is 5 syringes for the 5 weight bands so that is 25 syringes, include a second emergency patient and that's 50 syringes. I feel this would be very wasteful (and a lot of work for pharmacy) as emergency inotrope drugs only last 24 hours when made up.

Researcher: That does sound very wasteful

Clinical Engineer: I think a better option would be having the barcode system available to the nursing staff in the ICU and all of the drugs and all of the equipment required available. Even though the nurses wouldn't use them as standard they would still have to be able to access them so they could make up their own infusions when urgently required.

Researcher: Ok, could you see this working in any other way like the nurses in ICU making up every drug and barcoding the syringes themselves?

Clinical Engineer: So just follow the practice exactly the way it is but introduce a bar coding system?

Researcher: Yes, would you feel that this could be advantageous?

Clinical Engineer: Well from a safety point of view it would, it's going to add extra work to the nurse, but it could possibly reduce some nur se time as well and even the processes out. Writing multiple labels sometimes can take 15 minutes so with a bar-code printer this could speed up the process, even though it would be adding the process of accessing the printer and printing the labels

Researcher: Do you see the four signature boxes changing with this process?

Clinical Engineer: No, because it used to be only two signature boxes and it would be two nurses sign for a full check/prepare/load everything, so the second set of boxes has actually only been introduced in the last few months. That was from a safety point of view but also for nursing registration because when you sign for a drug you are also signing that you administered it.

Researcher: Ok, Great Thank you very much for that insight into nursing using smart pumps.

Interview ends

Appendix K: Interview Clinician Transcript

Transcript of Interview with PICU Clinician: -

Researcher: Thank for agreeing to this interview, Can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Clinician: At the moment the drug is prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is the computer system used in PICU for documentation. When the doctor has prescribed the drug two nurses check the order against the medication policy and against the standard concentration infusion table and make sure that the limits are appropriate. Once

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Clinician: the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running

(video demonstration of a complete closed loop medication system with auto-programming was displayed)

Researcher: Where do you sign that?

Clinician: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 sign for preparation which includes checking your order, checking your standard concentration and actually making up the drug (i.e. putting the drug in the syringe) from start to finish so it should be the same two people doing the prep (not one doing and one checking they have to do it together).

Researcher: So, the same 2 people should do these steps from start to finish?

Clinician: Yes, but if there is a delay between preparation and infusion the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the pump check you're making sure your pump programming matches the ICCA order, (so it can be a different 2nd person who checks that).

Researcher: the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced. we are happy with the prescription, we prepare our equipment th at is needed to make up the drug and we write a label so that there is full accountability for what is in the syringe that's going to be used to deliver the drug.

The next step is to draw up the amount of drug and diluent that we need and mix the two of them together in a syringe (inverting the syringe a few times to make sure it has mixed well), put a giving set on it and prime the line.

From there we load the syringe into a pump, then we program the pump by selecting the area that you are in, the weight band t hat the patient falls into, the drug that you want. Within the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its co ntinuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapse d. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running going until your VTBI has expired.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Clinician: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient. If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, othe rwise continuous will remain running**Clinician:** The two people that programme the pump sign to confirm that they have both checked that the pump program matches the drug order

Researcher: …. and there's two boxes for them to sign?

Clinician: …Yes that's correct (the second two boxes), and before they sign they also have to do a manual calculation of the rate. They are the two people who sign the second two boxes (so it's two signatures for drug prep and two signatures for pump check). The two signatures for the pump check is a new step within the last two months. You are trusting that drug label, which is signed by the two nurses preparing the drug, is correct. At least one of the people checki ng the pump will have prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Clinician: the route is only stated on the medication order, not on the syringe.

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Clinician: I think nurses in ICU would appreciate this system. It would work because the system is always checking itself. I think nurses would trust that the infusion that is pre-prepared would be in line with their order (for the scanned patient), although full checks would still be carried out. I thin k to adapt to this system would not be too difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, such as TPN and Lipids. Even though they are infusions bags they still go through our existing smart pump system and we are used to checking them, and there are one or two drugs that come from the ACU compounding unit (pre-prepared) as well.

Interview ends

Appendix L: Interview Pharmacist Transcript

Transcript of Interview with PICU Clinician: -

Researcher: Thank for agreeing to this interview, Can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Clinician: At the moment the drug is prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is the computer system used in PICU for documentation. When the doctor has prescribed the drug two nurses check the order against the medication policy and against the standard concentration infusion table and make sure that the limits are appropriate. Once

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Clinician: the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running

(video demonstration of a complete closed loop medication system with auto-programming was displayed)

Researcher: Where do you sign that?

Clinician: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 sign for preparation which includes checking your order, checking your standard concentration and actually making up the drug (i.e. putting the drug in the syringe) from start to finish so it should be the same two people doing the prep (not one doing and one checking they have to do it together).

Researcher: So, the same 2 people should do these steps from start to finish?

Clinician: Yes, but if there is a delay between preparation and infusion the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the pump check you're making sure your pump programming matches the ICCA order, (so it can be a different 2nd person who checks that).

Researcher: the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced. we are happy with the prescription, we prepare our equipment that is needed to make up the drug and we write a label so that there is full accountability for what is in the syringe that's going to be used to deliver the drug.

The next step is to draw up the amount of drug and diluent that we need and mix the two of them together in a syringe (inverting the syringe a few times to make sure it has mixed well), put a giving set on it and prime the line.

From there we load the syringe into a pump, then we program the pump by selecting the area that you are in, the weight band that the patient falls into, the drug that you want. Within the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running going until your VTBI has expired.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Clinician: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient. If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running

Clinician: The two people that programme the pump sign to confirm that they have both checked that the pump program matches the drug order

Researcher: …. and there's two boxes for them to sign?

Clinician: …Yes that's correct (the second two boxes), and before they sign they also have to do a manual calculation of the rate. They are the two people who sign the second two boxes (so it's two signatures for drug prep and two signatures for pump check). The two signatures for the pump check is a new step within the last two months. You are trusting that drug label, which is signed by the two nurses preparing the drug, is correct. At least one of the people checking the pump will have prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Clinician: the route is only stated on the medication order, not on the syringe.

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Clinician: I think nurses in ICU would appreciate this system. It would work because the system is always checking itself. I think nurses would trust that the infusion that is pre-prepared would be in line with their order (for the scanned patient), although full checks would still be carried out. I think to adapt to this system would not be too difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, such as TPN and Lipids. Even though they are infusions bags they still go through our existing smart pump system and we are used to checking them, and there are one or two drugs that come from the ACU compounding unit (pre-prepared) as well.

Interview ends

Appendix M: Interview Nurse Specialist Transcript

Transcript of Interview with PICU Nurse Specialist Smart Infusion Pumps: -

Researcher: Thank for agreeing to this interview, can you please explain to me from the nursing perspective how you program smart pump to administer an infusion to a patient in the PICU in OLCHC.

Nurse Specialist: At the moment the drug is prescribed on ICCA (IntelliSpace Critical Care and anaesthesia) which is the computer system used in PICU for documentation. When the doctor has prescribed the drug two nurses check the order against the medication policy and against the standard concentration infusion table and make sure that the limits are appropriate. Once we are happy with the prescription, we prepare our equipment that is needed to make up the drug and we write a label so that there is full accountability for what is in the syringe that's going to be used to deliver the drug.

The next step is to draw up the amount of drug and diluent that we need and mix the two of them together in a syringe (inverting the syringe a few times to make sure it has mixed well), put a giving set on it and prime the line.

From there we load the syringe into a pump, then we program the pump by selecting the area that you are in, the weight band that the patient falls into, the drug that you want. Within the drug you are often offered different concentrations, so you select the concentration that you want. Sometimes there is a prompt to input a volume to be infused (VTBI) (and sometimes there is not); sometimes you have to amend the time and sometimes you don't depending if its continuous or non-continuous. Doses can be changed once they are still within the drug library limits and within the prescription limits. When we are happy with all of our information entered into the pump we press start on the infusion, connect the infusion to the patient and then drug delivery has commenced.

If the drug is a dose over a specific time, it will alarm either when the syringe is almost empty or when the time has elapsed. If it is a continuous drug it will continue to run for the amount of time you have programmed it to run, if the syringe is almost empty or if there is an occlusion at any point you will get warning, otherwise continuous will remain running going until your VTBI has expired.

Researcher: Perfect, thank you, just one question? do you press start before you connect the patient

Nurse Specialist: Yes before, as we want to ensure that the drug is at the end of the giving set and no air is present before connecting to the patient.

Researcher: Ok, so after the infusion is running do you chart the delivery every hour? [04.10.58]

Nurse Specialist: When you prepare the drug, you have to sign that you have prepared the drug.

Researcher: Where do you sign that?

Nurse Specialist: On the ICCA system. When you open up a drug order on ICCA there are now 4 signature boxes. Person 1 & 2 sign for preparation which includes checking your order, checking your standard concentration and actually making up the drug (i.e. putting the drug in the syringe) from start to finish so it should be the same two people doing the prep (not one doing and one checking they have to do it together).

Researcher: So, the same 2 people should do these steps from start to finish?

Nurse Specialist: Yes, but if there is a delay between preparation and infusion the 2nd checker could also be called away to do something else during this time, so at this stage it is appropriate for a different 2nd checker to assist the 1st person now to do the pump check, so again when doing the pump check you're making sure your pump programming matches the ICCA order, (so it can be a different 2nd person who checks that).

Researcher: And the second two check boxes on the ICCA system?

Nurse Specialist: The two people that programme the pump sign to confirm that they have both checked that the pump program matches the drug order

Researcher: …. and there's two boxes for them to sign?

Nurse Specialist: …Yes that's correct (the second two boxes), and before they sign they also have to do a manual calculation of the rate. They are the two people who sign the second two boxes (so it's two signatures for drug prep and two signatures for pump check). The two signatures for the pump check is a new step within the last two months. You are trusting that drug label, which is signed by the two nurses preparing the drug, is correct. At least one of the people checking the pump will have prepared it.

Researcher: as these are all IV infusions is the route of drug delivery stated anywhere?

Nurse Specialist: the route is only stated on the medication order, not on the syringe.

<u>(video demonstration of a complete closed loop medication system with auto-programming was displayed)</u>

Researcher: Thank you for watching the video demonstration, can you tell me your thoughts on how the introduction of this type of system might change your working practises? Also, if you think this system and its work flow would be accepted within the existing PICU in OLCHC.

Nurse Specialist: I think nurses in ICU would appreciate this system. It would work because the system is always checking itself. I think nurses would trust that the infusion that is pre-prepared would be in line with their order (for the scanned patient), although full checks would still be carried out. I think to adapt to this system would not be too difficult because already in the intensive care unit there are some drugs that are delivered to the unit pre-prepared, such as TPN and Lipids. Even though they are infusions bags they still go through our existing smart pump system and we are used to checking them, and there are one or two drugs that come from the ACU compounding unit (pre-prepared) as well.

One limitation would be when a drug is needed in an emergency - I don't think nursing staff will be comfortable waiting for pharmacy to receive the order, prepare the drug and delivered it to ICU. Nurses would need to act immediately and prepare this type of infusion themselves for the clinical need of their patient, so they would need full access to the system and all necessary equipment so that they can prepare urgently needed drugs themselves.

Researcher: Do you feel a dispensing cabinet premade, barcoded syringes would work in ICU

Nurse Specialist: Firstly, you would have to isolate the specific drugs that you wanted to be your emergency drugs. On reflection using standard drug concentrations there would be a lot of waste because just for one patient you would need at least 5 emergency drugs, that is 5 syringes for the 5 weight bands so that is 25 syringes, include a second emergency patient and that's 50 syringes. I feel this would be very wasteful (and a lot of work for pharmacy) as emergency inotrope drugs only last 24 hours when made up.

Researcher: That does sound very wasteful

Nurse Specialist: I think a better option would be having the barcode system available to the nursing staff in the ICU and all of the drugs and all of the equipment required available. Even though the nurses wouldn't use them as standard they would still have to be able to access them so they could make up their own infusions when urgently required.

Researcher: Ok, could you see this working in any other way like the nurses in ICU making up every drug and barcoding the syringes themselves?

Nurse Specialist: So just follow the practice exactly the way it is but introduce a bar coding system?

Researcher: Yes, would you feel that this could be advantageous?

Nurse Specialist: Well from a safety point of view it would, it's going to add extra work to the nurse, but it could possibly reduce some nurse time as well and even the processes out. Writing multiple labels sometimes can take 15 minutes so with a bar-code printer this could speed up the process, even though it would be adding the process of accessing the printer and printing the labels

Researcher: Do you see the four signature boxes changing with this process?

Nurse Specialist: No, because it used to be only two signature boxes and it would be two nurses sign for a full check/prepare/load everything, so the second set of boxes has actually only been introduced in the last few months. That was from a safety point of view but also for nursing registration because when you sign for a drug you are also signing that you administered it.

Researcher: Ok, Great Thank you very much for that insight into nursing using smart pumps.

Interview ends