PHARMACEUTICAL SERVICE DEVELOPMENT

IN ANAESTHESIA

submitted in partial fulfilment

of the requirements of the Degree of

Doctorate in Pharmacy

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Author’s declaration

Dedicated to all those battling for their life

at the Intensive Therapy Unit

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Abstract

Intensive Therapy Units (ITUs) are amongst the most resource challenging and demanding areas of hospitals mainly because such settings care for the critically ill hospitalised patients. The delivery of direct, proactive, patient-centered care by pharmacists has been correlated with actual and perceived patient outcome improvement. The aim of this research was to develop and establish a pharmaceutical service within the ITU at Mater Dei Hospital (MDH) specifically tailored to the needs of this area. Prior to commencement of the research, approval by the University Research Ethics Committee was sought. Phase I of the study focused on the development of the pharmaceutical service. During this phase, the pharmacist-researcher attended ward rounds and observed the current care practice delivered. This current practice was compared to international standards of practice for clinical pharmacy services issued specifically for an ITU setting. Phase II of the study targeted the implementation of the pharmaceutical service where the patient medical record was used for patient profile compilation. Pharmaceutical care issues identified were discussed with the interdisciplinary team and the outcomes recorded. Forty patient ward rounds each lasting approximately 3 hours were attended between December 2020 and January 2021. Over the 2 month interval a total of 165 patients were admitted to the ITU and 133 pharmaceutical care issues (PCIs) were identified by the pharmacist-researcher. Classification of identified PCIs revealed that the most common PCI category encountered was drug selection (N=59), followed by dose selection (N=26), drug administration (N=18) and dispensing (N=13). A pharmaceutical intervention was proposed by the pharmacist-researcher for every identified PCI and a 95% acceptance and implementation rate was observed. The results of this research highlight the benefits of the pharmacist as part of the interdisciplinary team tendering care to patients admitted at the ITU for intensive care. The implementation of the developed

service at the ITU further builds on the continuous and relentless effort in improving care standards provided to patients admitted to MDH and lays the groundwork for future implementation of structured improved pharmaceutical services supporting anaesthesia within operating theatres.

Keywords: critical care medicine, clinical pharmacy, pharmaceutical interventions, interdisciplinary team

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List of Abbreviations

ACCP: American Association of Clinical Pharmacy

ADR: Adverse Drug Reaction

ASHP: American Society of Health-System Pharmacists

EAHP: European Association of Hospital Pharmacists

ISMP: Institute for Safe Medication Practices

ITU: Intensive Therapy Unit

MDH: Mater Dei Hospital

PCI: Pharmaceutical Care Issue

SHPA: Society of Hospital Pharmacists of Australia

CHAPTER 1

INTRODUCTION

1.1 Intensive Therapy Units

The intensive therapy unit (ITU) is a hospital area specially committed to the care of patients necessitating life-support and those at exceedingly high risk for organ failure and consequently death (Ervin et al, 2018). ITUs are closely linked with operating theatres, very often even logistically. These areas are amongst the most resource challenging and demanding areas of hospitals as they care for the critically ill hospitalised patients (Ervin et al, 2018). The mortality rate within ITUs is higher than in other areas within the hospital (Luisetto & Mashori, 2017).

Patients hospitalised within ITUs are prescribed twice as many medications in comparison with patients hospitalised within other areas of the hospital. This increases the likelihood of possible drug interactions as well as medication errors (Richter et al, 2016). The ITU patient has organ function which is compromised (such as liver, renal, circulatory or respiratory failure) and often requires circulatory or artificial respiratory support with other possible additional interventions such as hemofiltration, influencing to various degrees the pharmacokinetics and pharmacodynamics of the prescribed medication (Knibbe & Tjoeng, 2008). This contributes towards the vulnerability of this group of patients in regards to the occurence of drug-related problems (DRPs) with patients in critical care reportedly being at twice the risk of experiencing medication errors in comparison to patients based in other wards (Bourne et al, 2017).

1.2 Medication errors in the ITU

Moyen et al (2008) report a medication error range between 1.2 to 947 errors per 1000 patient days at the ITU with a median of 106 errors per 1,000 patient days at the ITU. Similarly, a median of 105.9 per 1000 patient days in terms of frequency of errors in the intensive care setting attributable to drugs was observed in most studies as described in an article by Martins et al, in 2018. The majority of DRPs are predictable and preventable. Optimising pharmacotherapy can contribute towards reducing their frequency.

1.3 Critical care medicine and the role of the pharmacist

Critical care medicine constitutes one of the major components of modern healthcare systems (Martin-Delgado & Calleja-Hernandez, 2018). The role of the pharmacist in the delivery of healthcare, has over the past decades, continued to evolve beyond the traditional dispensing responsibility towards directly related activities as active members of multidisciplinary teams (Saokaew et al, 2009; Wang et al, 2015; Bosma et al, 2018). A crucial part in managing a critically ill patient is medication management (Hisham et al, 2016).

The delivery of direct, proactive, patient-centered care by pharmacists has been correlated with both actual and perceived patient outcome improvement (Chant, 2012; Preslaski et al, 2013; Mailman & Semchuk, 2018; Cvikl and Sinkovič, 2020).

Pharmacy services within the context of critical care have been demonstrated to decrease adverse event and medication costs; improve morbidity, mortality and costs related to infectious disease; aid in bettering clinical and economic outcomes in terms of thromboembolitic and infarction related events; promote proper use of stress ulcer prophylaxis and also enhancement of compliance with ITU protocols (Benedict & Hess, 2015; Stollings et al, 2018). The most frequent activities of pharmacists in the ITU encompass drug information provision, DRPs detection and interactions identification, with these activities representing a proportion of between 3 to over 90% of the overall interventions performed by the pharmacists (Sereno et al, 2018).

The American College of Clinical Pharmacy and the Society of Critical Care Medicine produced a report delineating the fundamental, desirable and optimum activities of pharmacists within intensive care with the scope of clearly defining the scope and purpose of intensive care pharmacists (Rudis & Brandl, 2000). According to this joint position paper, the fundamental activities of an intensive care pharmacist include: evaluation of all drug therapy; nutritional care; identifying and preventing DRPs and medication errors; provide advice on pharmacokinetic monitoring of drugs; provide drug information and other information such as intravenous compatibitily of drugs to be administered; and implement and maintain departmental policies and procedures specifically related to the safe and effective use of medication within the ITU (Rudis & Brandl, 2000).

1.4 Rationale of the research

The concept behind this research started off pre-COVID-19 pandemic, through a mutual shared identification of an unmet need put forward on multiple times by the anaesthetists and the nursing staff within the Intensive Therapy Unit. The possibility of a pharmacist's contribution to optimise the service being provided by the anaesthetists and to assist in addressing pharmaceutical challenges within the Intensive Therapy Unit at Mater Dei Hospital formed the stem of this research. The rationale of the study is to incorporate the skills, expertise and knowledge of a pharmacist within an interdisciplinary team caring for patients within a critical setting such as the Intensive Therapy Unit. The rationale was discussed with the Lead Anaesthetist at the ITU, the Chairperson of the Anaesthesia Department and the head nurse of the ITU.

1.5 Aim

The aim of the research is to develop and establish a pharmaceutical service within the Intensive Therapy Unit (ITU) at Mater Dei Hospital (MDH) which is specifically tailored to the needs of this area.

The objectives of this research are to:

i. study the expectations of the staff within the ITU with respect to the the role of the pharmacist as part of the ITU interdisciplinary team;

ii. carry out a gap analysis in relation to the current practice at ITU with respect to international standards of practice supporting ITU settings;

iii. implement a pharmaceutical service addressing the needs of the ITU at MDH.

CHAPTER 2

METHODOLOGY

2.1 Setting of the research

The research study started off a few days prior to the COVID-19 pandemic. The study is carried out at Mater Dei Hospital (MDH), which is the only acute public general hospital in Malta with a bed capacity of approximately 1000 in-patient beds. The Intensive Therapy Unit (ITU) having a total capacity of 20 beds caters for medical and surgical critically ill patients necessitating intensive care. It is divided into an 8-bedded area, a separate 7-bedded area and 5 negatively pressurised isolation rooms. Patients admitted to this unit are aged 3 years and over. The Department of Anaesthesia is responsible for providing care to patients within this unit. Children younger than three years of age and neonates requiring intensive care are treated in a separate unit, at the Neonatal and Paediatric Intensive Care Unit (NPICU) where the service of a ward based pharmacist is already established. Patients at the NPICU are tended care by the Department of Paediatrics.

During the year 2020 in response to the COVID-19 pandemic, MDH expanded its general bed capacity. The intensive therapy area was increased from one area to a total of four areas spread across the hospital with a total bed capacity of 46 beds. The three newly set up intensive therapy areas at MDH specifically cater for COVID-19 critically ill adults who are still in the active infectious phase of the disease. Once patients within the newly set up additional ITUs recover from the active phase of COVID-19 infection confirmed by having two negative COVID-19 polymerase chain reaction (PCR) tests, they are transferred to the main ITU.

This research, which was undertaken amid the COVID-19 pandemic, focused on patients aged eighteen years and older admitted for intensive care at the main ITU (20 bedded

unit). The pharmaceutical service was also based on the needs of the healthcare professionals (anaesthetists and nurses) providing their services to patients within the main ITU area.

2.2 Research design

The methodology of this study is split into two phases. The first phase of the study is an exploratory one focusing on the tools required to develop an ITU based pharmaceutical service. The second phase of the study focuses on the implementation of the pharmaceutical service developed in phase one (Figure 2.1). Approval by the University Research Ethics Committee (UREC) was sought and granted prior to the initiation of the research study (Appendix 1).

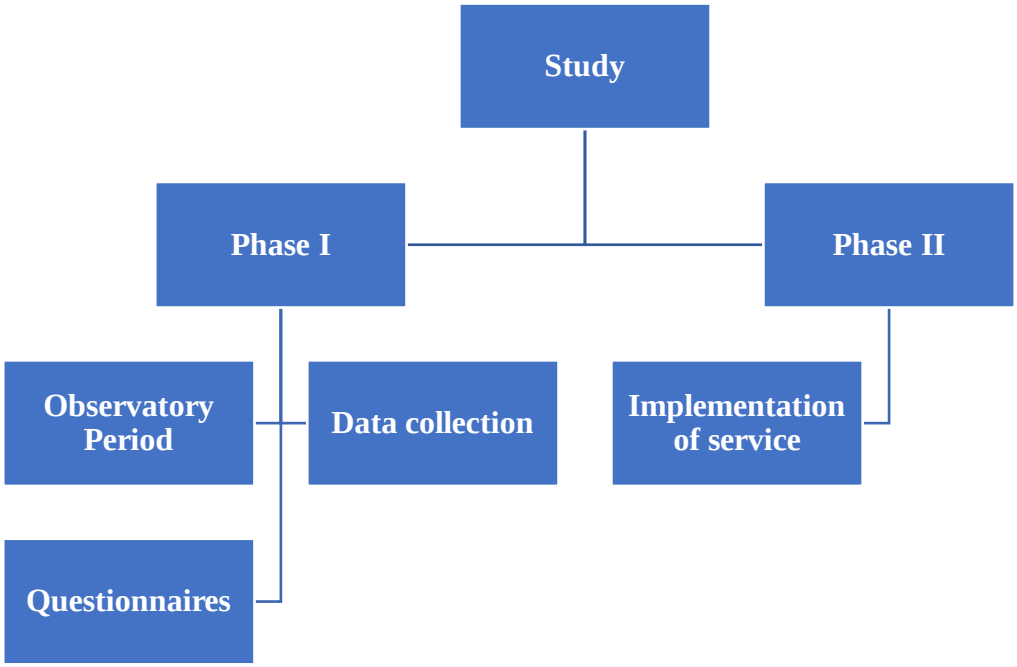

Figure 2.1: Overview of study design

The research is divided into two phases. Phase I consists of an observatory period, data collection using the ITU Gap Finding Tool and the distribution of two questionnaires – "Pre-Service Questionnaire for Anaesthetists" and "Pre-Service Questionnaire for ITU Nurses". This phase aims at identifying a structural framework for the development of the clinical pharmaceutical service and identifying the expectations of the physicians and nurses within ITU on the role of the pharmacist and the expected outcomes of a pharmaceutical service for the ITU. Phase II of the research focuses on the implementation of the clinical pharmaceutical service developed in Phase I.

2.3 Phase I – Development of the Pharmaceutical Service

This phase was carried out between July and November 2020. A pre-service analysis was the focus of this phase. Three tools, namely i) a Gap Finding Tool, ii) a Pre-Service Questionnaire for Physicians, iii) a Pre-Service Questionnaire for Nurses were identified, adapted and validated in order to be used to capture the data required during this phase. The choice and adaptation of these tools is described in detail in the following sections. The current care practice delivered nationally to critically ill patients admitted to the ITU was observed over a period of eight weeks between September and November 2020 during which the tools were adopted within the ITU.

2.3.1 The Gap Finding Tool

The Gap Finding Tool is a data capturing tool developed by Falzon (2018) as part of her Doctorate in Pharmacy research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The scope of the Gap Finding Tool is threefold namely to:

1. determine and document the various roles of the pharmacist at ward level;
2. determine at base if any pharmacy services were being offered already and by who as well as the pharmacy services that were lacking; and to
3. compare the current delivered practice at a paediatric oncology ward to that set in international guidelines.

The tool developed by Falzon (2018) is based on the Standards of Practice for Clinical Pharmacy Services recommended by the SHPA Committee of Specialty Practice in Clinical Pharmacy (2013), the ACCP (2014) and the EAHP (2014) and focuses specifically on a paediatric oncology setting. This tool was chosen because its structure makes it easy to use in a fast-paced ward.

The Gap Finding Tool developed by Falzon was adapted to capture the roles of a pharmacist within a critical care setting such as the ITU according to international standards of practice. The adaptation was based on the international recommendations put forward by the Guidelines on Surgery and Anaesthesiology Pharmaceutical Services published by the American Society of Health-System Pharmacists (ASHP, 1999) and the Standards of Practice for Intensive Care Pharmacy Practice published by the Society of Hospital Pharmacists of Australia (SHPA, 2008). The format of the original tool consisting of a tabular format highlighting nine different sections each having their own header corresponding to a pharmaceutical service expected to be provided at the ward was maintained. Underneath each header is a set of related statements. The researcher applying the Gap Finding Tool is required to indicate whether the service related to each statement is being provided or not. The newly developed ITU Gap Finding Tool was tested for content validity by an expert panel consisting of two Consultant Anaesthetists, two Drug Information Pharmacists, two Quality Assurance Pharmacists, two Nursing Officers and the author of the original tool. The experts were handed a copy of the proposed ITU Gap Finding Tool and given a set of validation questions by which they could express their opinion as regards to the relevance and applicability of the tool (Appendix 2). The same set of questions used in the validation exercise of the original tool was used. The panel was specifically asked what changes, if any, they would implement within the tool. The amendments put forward by the expert panel were taken into consideration and the ITU Gap Finding Tool was finalised (Appendix 2).

During the eight week observatory period (October to November 2020), the pharmacist-researcher placed a tick next to each statement indicating whether the particular service

was being provided or not and if yes, the 'Comment' field next to each tick was used to annotate who was providing the said service.

2.3.2 The Pre-Service Questionnaire for Physicians

The "Pre-Service Questionnaire for Physicians" is a tool developed by Portelli (2018) as part of her Doctorate in Pharmacy research entitled 'Establishment of Pharmaceutical Services within the Emergency Department'. The tool which consists of thirty-one questions is designed to capture the expected roles of the pharmacist at the Emergency Department as perceived by emergency physicians. This tool was chosen because it was developed for an equally fast-paced ward and based on the typical ward set-up found in Mater Dei Hospital.

The "Pre-Service Questionnaire for Physicians" was adapted in order to capture the expected roles of the pharmacist at the ITU as perceived by anaesthetists based at the ITU. The newly developed "Pre-Service Questionnaire for Anaesthetists" consisted of twenty-five questions and took approximately 10 minutes to complete (Appendix 3). Questions one to three were closed ended questions and covered the anaesthetists' demographics. Questions four to eleven covered the anaesthetists' working experience and training abroad and consisted of three open ended questions and five closed ended questions. Questions twelve to fifteen dealt with the logistics of the proposed pharmaceutical services and consisted of two closed ended questions, a Likert scale (5 item) question and an order ranking question. Questions sixteen to twenty-three were based on a Likert scale (5 item) and covered the impact that proposed roles undertaken by a pharmacist at the ITU can have. Question twenty-four was a closed ended question related to the pharmacist and medication reconciliation while question twenty-five was

an open ended question intended to provide respondents with the ability to put forward any other comments or opinions about the service of a pharmacist.

The validation of the “Pre-Service Questionnaire for Anaesthetists" was carried out by an expert panel consisting of two Drug Information Pharmacists, two Quality Assurance Pharmacists and the author of the original tool. The two Drug Information Pharmacists and the two Quality Assurance Pharmacists were the same experts who validated the ITU Gap Finding Tool. The experts were each handed a copy of the questionnaire and a set of questions which would help them express their views on the relevance and applicability of the tool. The experts were also given the faculty of putting forward any changes they would deem fit to the tool (Appendix 3). The alterations to the tool suggested by the expert panel were applied and the “Pre-Service Questionnaire for Anaesthetists” finalised. Following discussions with the Chairperson for the Department of Anaesthesia, it was decided that in view of the COVID-19 pandemic, the “Pre-Service Questionnaire for Anaesthetists” is disseminated to anaesthetists electronically. The information letter, consent form and validated questionnaire were uploaded to Google Forms. The link for participation was sent to the secretary for the Department of Anaesthesia who in turn forwarded it to all the anaesthetists based at the ITU.

In order to compare the mean rating scores provided to statements within the “Pre-Service Questionnaire for Anaesthetists”, the Friedman test was used. The mean rating scores ranged from 1 to 5 where 1 corresponds to not essential and 5 corresponds to essential. The larger the mean rating score, the higher the impact.

2.3.3 The Pre-Service Questionnaire for Nurses

The "Pre-Service Questionnaire for Nurses" which is another tool developed by Portelli (2018) as part of the study entitled 'Establishment of Pharmaceutical Services within the Emergency Department' was developed to capture the expected roles of the pharmacist at the Emergency Department as perceived by emergency nurses. This tool was chosen because it was developed for an equally fast-paced ward and based on the typical ward set-up found in Mater Dei Hospital.

The tool which consists of thirty-three questions was adapted to capture the expected roles of the pharmacist at the ITU as perceived by critical care nurses based at the ITU. The "Pre-Service Questionnaire for ITU Nurses" consisted of twenty-five questions and took approximately ten minutes to complete (Appendix 4). Questions one to eight cover the critical nurses' demographics and consisted of six closed ended questions and two open ended questions. Questions nine to fourteen cover the level of education of the nurses and consisted of two open ended questions and four closed ended questions. Questions fifteen to twenty-three deal with the treatment room and consisted of one open ended question and eight Likert scale (5 item) questions. Questions twenty-four to twenty-seven consisted of three open ended questions and a Likert scale (5 item) question. Questions twenty-four and twenty-five aim at identifying medication related problems encountered by nurses and how they generally solve them. Question twenty-six aims at determining the nurses' opinion with regards to the need for an in-house pharmacist at the ITU while question twenty-seven provided the respondents with the option of providing further comments or suggestions.

The validation of the tool was carried out by the same expert panel that evaluated the "Pre-Service Questionnaire for Anaesthetists". The experts were each handed a copy of the questionnaire and a set of questions which would help them express their views on the relevance and applicability of the tool. The experts were given the opportunity of putting forward any changes they would deem fit to the tool. The recommendations put forward by the expert panel were taken into consideration and the Pre-Service Questionnaire for ITU Nurses (Appendix 4) was finalised. On discussion with the head nurse at ITU, the "Pre-Service Questionnaire for ITU Nurses" was disseminated to 40 nurses as a hard copy. Multiple copies of the information letter, consent form (Appendix 5) and the questionnaire were printed and left with the two Nursing Officers as the signed intermediaries. A copy of each was handed by the intermediaries to nurses who agreed to participate. In order to maintain anonymity participating nurses were asked to leave the completed questionnaire in a box specifically set up inside the intermediaries' office.

The mean rating scores provided to statements within the "Pre-Service Questionnaire for ITU Nurses" were compared using the Friedman test. The mean rating scores ranged from 1 to 5 where 1 corresponds to poor and 5 corresponds to excellent.

The mean rating score provided to a statement found in both the "Pre-Service Questionnaire for Anaesthetists" and the "Pre-Service Questionnaire for ITU Nurses" was compared using the Mann Whitney test.

2.4 Phase II – Implementation of the Pharmaceutical Service

This phase was carried out between December 2020 and January 2021. Patients eighteen years or older or their legal guardian or next of kin, were handed an information letter in English or Maltese by the intermediaries. The information letter (Appendix 6) contained details about the study. All the patients approached by the intermediaries, opted to participate in the study and consented. Since this study was carried out during the COVID-19 pandemic, obtaining consent from the legal guardian or next of kin proved to be quite challenging in that visits at hospital were no longer allowed. Consent was therefore in these instances obtained by the intermediaries on the phone in the same way that consent for intubation was being obtained.

During this phase, the ITU was attended daily. The focus of the pharmacist-researcher during these visits was to provide the service as identified through the phase I ITU Gap Finding Tool and responses obtained from the healthcare professionals' questionnaires.

Activities carried out by the pharmacist-researcher during this phase included:

- Attendance and participation in patient ward rounds held daily at the ITU. Patient ward rounds are led by a consultant anaesthetist together with an interdisciplinary team consisting of a resident specialist, a higher specialist trainee, a basic specialist trainee, the nurse attached to the patient, the Nursing Officer and a physiotherapist. Due to the COVID-19 pandemic, a resident specialist from the emergency department and a resident specialist from the cardiology department were included in the interdisciplinary team at the time of the study. This was done for training in the provision of intensive care in case the pandemic situation in the country escalated.

Consultant anaesthetists were assigned to the ITU on rotation from Monday to Thursday and from Friday to Sunday.

- Daily reviewing of patients' treatment charts, vitals charts and files. Treatment chart reviewing focused on confirming that the drug prescribed was suitable for the indication and that the dose and dosing frequency was correct based on the patients' characteristics and parameters reflected in the vitals chart. Prescribed treatment was also screened for possible existing contraindications and interactions.

- Personalised patient profile compilation and pharmaceutical care issue (PCI) identification. The validated Pharmacy Patient Profile developed by Falzon (2018) was used for patient profile compilation (Appendix 7). PCIs identified were discussed with the clinicians and nurses. Solutions to the PCIs identified were proposed and the outcome of such propositions was recorded. Classification of PCIs identified was carried out using the PCI classification system developed by Falzon (2018) (Appendix 8).

- Other pharmacy related activities identified during Phase I of the study such as the re-organisation of the clean utility.

CHAPTER 3

RESULTS

The research results are divided into two sections mirroring the methodology outlined in Chapter 2. The results from Phase I describing the adaptation of the tools used in the research are presented in the first section of this Chapter while the results from Phase II describing the implementation of the service are presented in the second section.

3.1 Findings of Phase I – Development of the Pharmaceutical Service

In this section, the results pertaining to the validation and implementation of the ITU Gap Finding Tool, the Pre-Service Questionnaire for Anaesthetists and the Pre-Service Questionnaire for ITU Nurses will be presented.

3.1.1 The ITU Gap Finding Tool

During the validation process, all 9 members of the expert panel consisting of two Consultant Anaesthetists, two Drug Information Pharmacists, two Quality Assurance Pharmacists, two Nursing Officers and the author of the original tool gave positive feedback with respect to the relevance of the sections of the ITU Gap Finding Tool (Appendix 2) in assessing what pharmacy services are offered at the Intensive Therapy Unit and what pharmacy services are lacking. All the expert panel also gave positive feedback with respect to how much the statements categorised within a section were related to the heading of the same section. A total of 14 suggestions were put forward and taken into consideration in the final version of the ITU Gap Finding Tool. The suggestions put forward by the expert panel are summarised in Table 3.1.

Table 3.1: Suggested amendments to the adapted Gap Finding Tool by the expert panel

Suggestion	Suggested by	Modification
Remove statement under the section 'Accurate History' referring to obtaining information about the use of adherence aids	All experts	Statement removed
Remove statement under the section 'Accurate History' referring to obtaining information about the storage of current medications at home	Anaesthetists	Statement removed
Remove statement under the section 'Accurate History' referring to assessing the patient's/ legal guardian's/ next of kin's understanding of the patient's illness and determining if there is a need for further education about their illness	Anaesthetists	Statement removed
Remove statement under the section 'Current Medication Management' referring to the provision on extemporaneous oral formulations	Anaesthetists	Statement removed
Remove statement under the section 'Adverse Drug Reaction (ADR) Management' referring to the involvement in the management of sedation and analgesia	Anaesthetists and Drug Info Pharmacists	Statement removed
Remove statement under the section 'Information for Ongoing Care' referring to discussing the medicines that need to be supplied or sourced on discharge or transfer with the patient/ parent	Anaesthetists	Statement removed
Remove statement under the section 'Information for Ongoing Care' referring to the removal of ceased medicines for destruction with the patient's/ parent's permission	Anaesthetists	Statement removed
Remove the statement under the section 'Information for Ongoing Care' referring to providing the patients/ parents with the medicines that they/ their child requires	Anaesthetists	Statement removed
Removing the statement under the section 'Information for Ongoing Care' referring to the provision of a written list of the discharge medications as well as direction of how they should be taken, why they are used, start and stop date as well as a hospital contact name and telephone number	Anaesthetists	Statement removed
Removing the statement under the section 'Information for Ongoing Care' referring to encouraging patients/ parents to contact their hospital pharmacist at any time, even after discharge as they may require further information despite comprehensive counselling	Anaesthetists	Statement removed
Removing the statement under the section 'Information for Ongoing Care' referring to educating patients/ parents on how they/ their child should take any new medication prescribed, how to identify side effects and what to do if they occur after being discharged	Anaesthetists	Statement removed
Change the wording of a statement under the section 'Information for Ongoing Care' from 'Annotating which medicines need to be supplied on discharge on the patient profile' to 'Annotating which medicines need to be supplied on transfer on the patient profile'	All experts	Statement changed
Remove the word 'discharge' from the statement under the section 'Information for Ongoing Care' reading 'details of medicines prescribed on discharge or transfer, a contact name within the hospital and a telephone number'	All experts	Word removed

The expert panel put forward fourteen suggestions which were taken up and implemented. 12 out of the 14 suggestions were related to removal of a statement because the statement was deemed as not fitting the case of the ITU scenario.

The results of the completed ITU Gap Finding Tool used during Phase I of the study are presented below. Most of the processes listed in the ITU Gap Finding Tool were covered by anaesthetists, nurses or both.

The principal gaps identified at the ITU were:

- Interdisciplinary care lacked the input of a pharmacist
- Data with regards to recently stopped or changed medication was not obtained during history taking
- Medications were not always being prescribed by the active ingredient, abbreviations were being used and the units of medications were not always properly annotated on the treatment chart
- No guidelines were being followed at times especially when starting treatment and treatment prescribed depended on the consultant anaesthetist working on the day
- Availability and accessibility to the prescribed medication was not being checked and no liaison was being done with the dispensary – this was leading to avoidable delays in treatment
- Drug interactions were not always being cross-checked
- Drugs that needed to be transferred with the patient once the patient was deemed fit to be transferred to another ward (medical/surgical) were not being annotated – this again led to avoidable delays in treatment once the patient got transferred
- On the spot medicines information needed at the bedside was lacking – information only provided by contacting the Pharmacy Medicines Information section.

3.1.2 The Pre-Service Questionnaire for Anaesthetists

During the validation process, all 5 members of the expert panel consisting of two Drug Information Pharmacists, two Quality Assurance Pharmacists and the author of the original tool gave positive feedback with respect to the relevance of the questions of the "Pre-Service Questionnaire for Anaesthetists" (Appendix 3) in assessing the current level of satisfaction in relation to the pharmacy services currently offered at the Intensive Therapy Unit and the perception of the roles of a future ward based pharmacist assigned to the area. A total of 5 suggestions were put forward and taken into consideration in the final version of the "Pre-Service Questionnaire for Anaesthetists". The suggestions put forward by the expert panel are summarised in Table 3.2.

Table 3.2: Suggested amendments to the "Pre-Service Questionnaire for Anaesthetists" by the expert panel

Suggestion	Modification
Add 'Other' as one of the gender options.	Option added
Reword heading 'Abroad training/ working experience'	Heading reworded to 'Training abroad/ working experience'
Reword question 12	Question 12 reworded from 'Are the services of MDH Pharmacy enough for the ITU?' to 'Are the current services provided by MDH Pharmacy sufficient for the needs of ITU?'
Reword question 14	Question 14 reworded from 'What would be the ideal hours for a pharmacist to be present at shop floor? Assign your order of preference for the proposed times*' to 'What would be the ideal working hours for a pharmacist to be present at shop floor? Assign your order of preference for the proposed times*'
Reword statement 16	Statement 16 reworded from 'Direct patient rounds and attendance i.e. review of patients at bed side*' to 'Attendance and participation in patient rounds i.e. review of patients at bed side*'

The expert panel put forward five suggestions which were taken up and implemented.

The “Pre-Service Questionnaire for Anaesthetists” was disseminated to twenty anaesthetist. Twelve anaesthetists out of twenty anaesthetists completed the “Pre-Service Questionnaire for Anaesthetists”. Out of the twelve participants, four were consultants, three were resident specialists and five were higher specialist trainees. Nine participants had trained or worked in a hospital abroad namely in the United Kingdom (n=5), Belgium (n=1), Ireland (n=1), Italy (n=1), Serbia (n=1) and Ukraine (n=1). One participant had working experience in two hospitals abroad (Ireland and Italy). The majority of the respondents (n=10) felt that the current services provided by MDH Pharmacy were not sufficient for the needs of the ITU. Eleven out of the twelve respondents felt that the service of an in-house pharmacist should be provided between 8am and 4pm, with the service being department-based rather team-based (n=10).

3.1.2.1 Perceived impact that proposed roles undertaken by a pharmacist can have at the ITU

Table 3.3 summarises the mean rating scores given by anaesthetists to the impact that proposed roles undertaken by a pharmacist can have at the ITU. The highest mean rating score was provided to ‘Involvement in guidelines and policies’ and ‘Involvement in inadvertent medicinal incident flagging, investigation and monitoring’ (4.75), indicating highest impact. These are followed by ‘Review of essential drug classes’ pharmacology’ (4.58), ‘Attendance and participation in patient rounds’ and ‘Medication stock selection, procurement and control’ (4.50), ‘Offer medicine information services on the spot’ (4.42) and ‘Conduct internal departmental audits’ and ‘Involvement in emergency preparedness strategies and planning’ (4.17).

Table 3.3: Mean rating scores for perceived impact of pharmacist roles at the ITU

Proposed pharmacist role	Mean	Std. Dev	Minimum	Maximum
Attendance and participation in patient rounds	4.5000	0.905	2	5
Offer medicine information services on the spot	4.42	0.900	2	5
Involvement in guidelines and policies	4.75	0.622	3	5
Review of essential drug classes' pharmacology	4.58	0.793	3	5
Medication stock selection, procurement and control	4.50	0.674	3	5
Involvement in inadvertent medicinal incident flagging, investigation and monitoring	4.75	0.452	4	5
Conduct internal departmental audits	4.17	0.835	3	5
Involvement in emergency preparedness strategies and planning	4.17	1.115	2	5

$X^2(7) = 11.667, p = 0.112$

The mean rating scores for all the statements were very high. They ranged from 4 to 5 with 5 being the maximum, implying that on average, the anaesthetists felt that the impact of the proposed pharmacist role at the ITU was important or essential.

3.1.3 The Pre-Service Questionnaire for ITU Nurses

During the validation process, all 5 members of the expert panel consisting of two Drug Information Pharmacists, two Quality Assurance Pharmacists and the author of the original tool gave positive feedback with respect to the relevance of the questions of the "Pre-Service Questionnaire for Nurses" (Appendix 4). A total of 4 suggestions were put forward and taken into consideration in the final version of the "Pre-Service Questionnaire for ITU Nurses". The suggestions put forward by the expert panel are summarised in Table 3.4.

Table 3.4: Suggested amendments to the "Pre-Service Questionnaire for ITU Nurses" by the expert panel

Suggestion	Modification
Reword the third option of question 2	Third option of question 2 reworded from 'Prefer not to say' to 'Other'
Reword question 9	Question 9 reworded from 'Initial nursing course' to 'Current qualifications'
Reword question 14	Question 14 reworded from 'Did you do any other courses following your initial nursing course?*' to 'Did you participate in any other courses following your initial nursing course?*
Reword question 26	Question 26 reworded from 'Would you see the presence of a pharmacist helpful in the ITU?*' to 'In your opinion, is there a need for an in-house pharmacist/s at the ITU of MDH?*'

The expert panel put forward four suggestions which were taken up and implemented.

The number of nurses within the ITU who completed the questionnaire was eighteen out of forty. The eighteen participants had been practising as nurses for a mean of 15 years (± 7 years) and had been practising within the ITU for a mean of 11 years (± 8 years). Only two out of the eighteen respondents had working experience outside of Malta. Issues with dilution and administration instructions were reported by twelve out of eighteen participants.

3.1.3.1 Aspects with respect to the clean utility at the ITU

Table 3.5 summarises the mean rating scores given by nurses to aspects with respect to the clean utility at the ITU. The highest mean rating score was provided to 'Layout of medication storage and shelving' (4.06), indicating that the respondents feel that the way medication is stored within the utility is very good. The lowest mean rating score was provided to 'Directions for dilutions and reconstitution of IV treatment' (2.72), indicating that the respondents feel that directions for dilutions and reconstitution of IV treatment within the clean utility is fair.

Table 3.5: Mean rating scores for aspects related to the clean utility at the ITU

Clean utility aspect	Mean	Std. Dev	Minimum	Maximum
Overall layout of the room	3.94	0.802	3	5
Layout of medication storage and shelving	4.06	0.938	2	5
Labelling of medication shelves/trays	3.67	1.138	1	5
Availability of medications in the treatment room	3.94	0.802	2	5
Directions for dilutions and reconstitution of IV treatment	2.72	1.364	1	5
Adequate space for drug dilution and reconstitution	2.89	1.367	1	5
Disposal of expired/broken medications	3.33	1.188	1	5
Correct handling of multi-dose vials	3.39	1.195	1	5

$X^2(7) = 34.808, p = 0.000$

The mean rating scores for the different aspects related to the clean utility at the ITU ranged from 3 to 4. The mean rating scores differed greatly. This is confirmed by a p-value of 0.000 and thus the rejection of the null hypothesis stating that the mean scores assigned by nurses to the various aspects relating to the clean utility at the ITU is comparable.

3.1.4 The need for an in-house pharmacist/s at the ITU

The twenty-sixth question of the Pre-Service Questionnaire for ITU Nurses aimed at gathering the opinion of nurses with respect to the need for an in-house pharmacist/s at the ITU. Nurses were asked to express their opinion by means of a 5-Likert scale (1 to 5). A score of five meant that the nurses felt that an in-house pharmacist at the ITU was essential while a score of one meant that the nurses felt that they could do without an in-house pharmacist at the ITU. The same identical question was posed to anaesthetists in the thirteenth question of the Pre-Service Questionnaire for Anaesthetists. The mean rating score provided by nurses and anaesthetists respectively was compared (Table 3.6).

Table 3.6: Mean rating score for the need of an in-house pharmacist/s at the ITU

Profession	Mean	Std. Dev	Minimum	Maximum	P-value
Nurses	4.44	0.616	3	5	0.518
Anaesthetists	4.58	0.669	3	5	

The mean rating scores ranged between 4 and 5 with 5 being the maximum. The p-value for the mean rating score provided by the nurses and anaesthetists exceeded the 0.05 level of significance. This implies that the mean rating score was comparable between the nurses and anaesthetists. The score provided by the nurses was slightly lower when compared to the score provided by the anaesthetists for the same question.

3.2 Phase II – Implementation of the Pharmaceutical Service

The developed pharmaceutical service was implemented between December 2020 and January 2021. This section describes the study findings pertaining to the clinical implementation of the pharmaceutical service.

3.2.1 Patient characteristics

The total number of patients that were admitted to the ITU between December 2020 and January 2021 is 165. From these 165 patients, 116 (70%) were males (mean age: 65 years ± 13 years) and 49 were females (mean age: 63 years ± 17 years). The duration of stay at the ITU for these patients ranged between 1 day and 58 days (mean duration of stay: 7 days). The most common reasons for admission to the ITU included post-op observation (n=37), post COVID-19 infection complications (n=23), bleeding (n=12), post CPR (n=11), sepsis (n=10), COVID-19 infection (n=10), respiratory failure (n=8), confusion (n=8), AKI (n=7), pneumonia (n=6), pulmonary oedema (n=5), MVA (n=4), hypotension (n=4) and FFH (n=3). Other reasons for admission to the ITU included pancreatitis (n=2), chest pain (n=2), CHF (n=2), COPD (n=1), fits (n=1), GBS (n=1), hyponatraemia (n=1), poisoning (n=1), overdose (n=1), status epilepticus (n=1), syncope (n=1), tetanus (n=1), throat cancer (n=1) and trauma (n=1).

Out of the 23 patients admitted to the ITU for post COVID-19 infection complications during the study period, unfortunately, 3 patients passed away. The 23 patients admitted with post COVID-19 infection complications consisted of 21 males (mean age: 67) and only 2 females (aged 61 and 72 years respectively). The length of stay at the ITU for these patients ranged from 6 days to 58 days (mean duration of stay: 23 days).

3.2.2 Pharmaceutical Care Interventions

A total of 40 patient ward rounds were attended. Each patient round lasted approximately 3 hours. During these 40 patient ward rounds, a total of 133 PCIs were identified. No PCIs were identified among the patients admitted for post-op observation. An average of 1 PCI per patient admitted to the ITU for reasons other than post-op observation was identified. The majority of the PCIs were categorised in the drug selection [44.4% (n=59)], the dose selection [19.5% (n=26)], the drug administration [13.5% (n=18)] and the dispensing [9.8% (n=13)] categories (Figure 3.1).

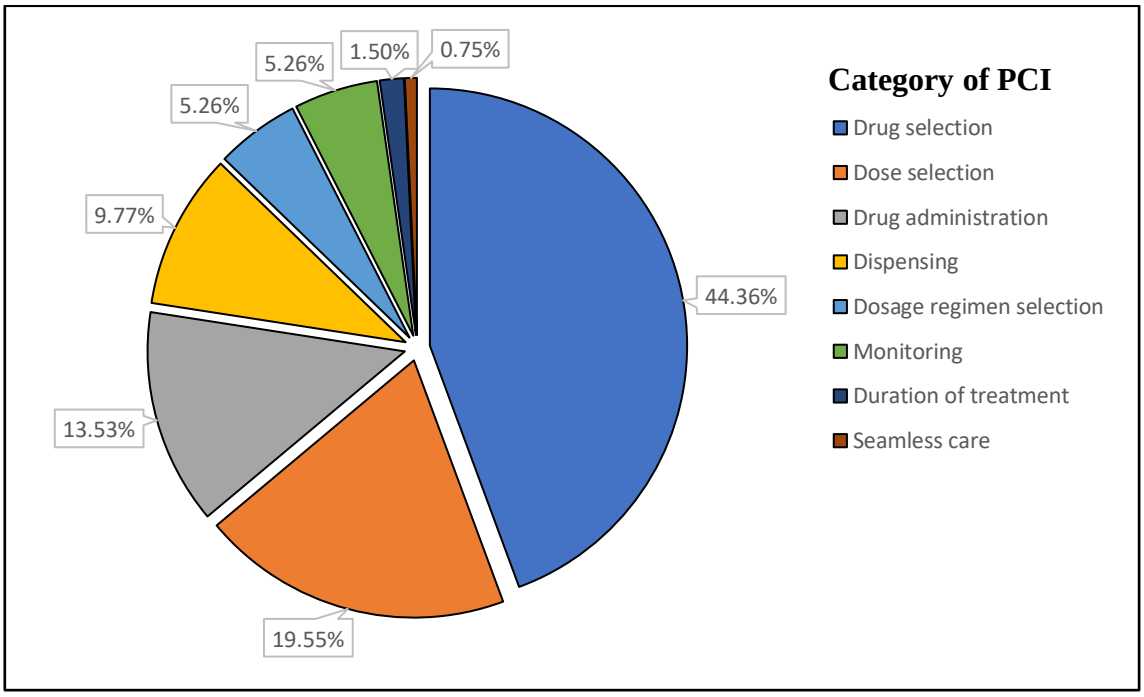

Figure 3.1: Classification of identified PCIs into categories

PCIs were most commonly classified into the following categories: drug selection, dose selection, drug administration and dispensing. Other categories included dosage regimen selection (5.26%), monitoring (5.26%), duration of treatment (1.5%) and seamless care (0.75%). Examples of PCIs identified included the selection of an antifungal depending on the incidence of altered liver function tests they cause (common vs uncommon) and selecting the dose of baclofen appropriate in treating tetanus induced spasms.

3.2.2.1 Drug selection

The most common PCI encountered within this category was 'Need for an additional drug to properly manage a condition (undertreated condition)' (n=23). This was followed by 'No indication for drug or indication no longer apparent' (n=16), 'Other drug selection problems' (n=8), 'No drug treatment despite existing indication requiring management or prevention i.e. untreated actual or potential indication' (n=5), 'Contraindication' (n=4), 'Non-adherence to protocol or guidelines' (n=2) and 'Incorrect strength' (n=1). The most common pharmaceutical intervention was to add an additional drug as needed (Table 3.7).

Table 3.7: Drug selection: Identified PCIs and interventions proposed

PCI (N=59)	Example of PCI	Pharmaceutical intervention proposed
Need for an additional drug to properly manage a condition (n=23)	Persistent agitation despite maximum dose of prescribed treatment	Add drug as needed
No indication for drug or indication no longer apparent (n=16)	Patient received 5 days of Pabrinex® IV. No need for further IV supplementation	Stop unnecessary drug
Other drug selection problems (n=8)	Selecting an antifungal less hepatotoxic than fluconazole since patient already exhibited altered LFTs	Itraconazole proposed instead of fluconazole
No drug treatment despite existing indication (n=5)	Patient had a red eye and purulent discharge from the eye	Add drug as needed
Contraindication (n=4)	Atenolol and patient suffering from sick sinus syndrome	Stop drug and prescribe alternative
Non-adherence to protocol or guidelines (n=2)	First-line treatment for patient's infection is co-amoxiclav IV and Tazocin® IV started	Adhere to protocol
Incorrect strength (n=1)	Lactulose prescribed in mg instead of mL	Prescribe the correct strength

3.2.2.2 Dose selection

The most common PCI encountered within this category was 'Dose too low for patient's age, weight and indication and/or severity' (n=15). This was followed by 'Other dose selection problem' (n=10) and 'Dose too high for patient's age, weight and indication and/or severity' (n=1) (Table 3.8). Most of the proposed pharmaceutical interventions involved increasing the dose of a drug.

Table 3.8: Dose selection: Identified PCIs and interventions proposed

PCI (N=26)	Example of PCI	Pharmaceutical intervention proposed
Dose too low for patient's age, weight and indication and/or severity (n=15)	Dose of caspofungin (35 mg) too low for patient's renal function (creatinine clearance 120 mL/min)	Increase dose
Other dose selection problem (n=10)	Tailoring the dose to a particular indication e.g. dose of neostigmine for obstruction	Suggest the prescribing of 2 mg
Dose too high for patient's age, weight and indication and/or severity (n=1)	Patient taking too long to respond once infusion of propofol is stopped	Decrease dose

3.2.2.3 Drug administration

The most common PCI encountered within drug administration was 'Other drug administration problem' (n=16). This was followed by 'Inappropriate route' (n=1) and 'Inappropriate timing of administration and/or dosing intervals' (n=1) (Table 3.9).

Table 3.9: Drug administration: Identified PCIs and interventions proposed

PCI (N=18)	Example of PCI	Pharmaceutical intervention proposed
Other drug administration problem (n=16)	Patient was fluid restricted and prescribed teicoplanin 400 mg	Instructed to reconstitute using a minimum of 3 mL for each 400 mg
Inappropriate route (n=1)	Guidelines suggest starting treatment orally if the patient is conscious rather than IV	Change route
Inappropriate timing of administration and/or dosing intervals (n=1)	Patient on haemodialysis. Meropenem administration scheduled 1 hour before the session. Meropenem should be administered 1 hour after session completion as it is dialysable.	Discuss with anaesthetist. Time of administration changed on treatment chart.

3.2.2.4 Dispensing

There were 13 PCIs related to dispensing. These PCIs arose from two categories, namely 'Other dispensing problem' (n=11) and 'Prescribed drug not available in the required form' (n=2) (Table 3.10).

Table 3.10: Dispensing: Identified PCIs and interventions proposed

PCI (N=13)	Example of PCI	Pharmaceutical intervention proposed
Other dispensing problem (n=11)	Gabapentin prescribed for pain related to GBS. Gabapentin is protocol regulated and GBS does not feature as indication in the regulating protocol	Fill in forms for approval as exceptional treatment
Prescribed drug not available in the required form (n=2)	Atropine required orally but available in hospital only as injection.	If it is not a problem to administer dose using available form, use available form as is

3.2.2.5 Monitoring

PCIs encountered from this category were 'Monitoring need' related to the need to undertake necessary laboratory and non-laboratory monitoring (N=7). When patients were prescribed haloperidol in addition to quetiapine, the pharmacist-researcher updated the need for monitoring to include continuous ECG monitoring in view of an increased risk of QTc interval prolongation and ventricular arrhythmias.

3.2.2.6 Dosage regimen selection

There were 7 PCIs related to dosage regimen selection. These PCIs arose from two categories, namely 'Dosage regimen too frequent' (n=5) and 'Dosage regimen not frequent enough' (n=2) (Table 3.11).

Table 3.11: Dosage regimen selection: Identified PCIs and interventions proposed

PCI (N=7)	Example of PCI	Pharmaceutical intervention proposed
Dosage regimen too frequent (n=5)	COVID-19 positive patient with D-dimer value below 1500 and not overweight. Enoxaparin sodium 40 mg prescribed twice daily when it should be given once daily	Decrease dosage regimen frequency
Dosage regimen not frequent enough (n=2)	COVID-19 positive patient with D-dimer value over 2000. Enoxaparin sodium 40 mg prescribed once daily when it should be given twice daily	Increase dosage regimen frequency

3.2.2.7 Duration of treatment

There were 2 PCIs related to duration of treatment each one arising from a different subcategory. These subcategories were 'Duration of treatment too short' and 'Other duration of treatment' (Table 3.12).

Table 3.12: Duration of treatment: Identified PCIs and interventions proposed

PCI (N=2)	Example of PCI	Pharmaceutical intervention proposed
Duration of treatment too short (n=1)	Patient was intubated for 28 days and at ITU recovering from COVID-19 infection. *Stenotrophomonas maltophilia* infection contracted resulting in bacteraemia only responsive to trimethoprim. The patient was prescribed 15 mg/kg/day divided in 3 doses. Treatment was going to be stopped 7 days after initiation when the treatment for this bacteraemia should have a duration of 14 days.	Increase the duration of treatment of the drug
Other duration of treatment (n=1)	Patient was on intubation for 14 days and therefore eligible for tracheostomy – thus reducing further sources of infection	Discussed with anaesthetist and patient scheduled for tracheostomy on the day

3.2.2.8 Seamless care

The PCI encountered for this category was an 'Other seamless care problem'. The patient was receiving treatment with tigecycline and was about to be transferred to another ward. Tigecycline treatment at MDH is made available from Pharmacy against a patient's ID number and the amount covering the duration of treatment is dispensed all at once. Therefore, the tigecycline that was dispensed for this patient needed to be transferred with him to the new ward. A note was made by the pharmacist-researcher with this regard in order to avoid unnecessary delays in the administration of treatment arising from the stock not being transferred to the new ward.

3.2.3 Outcome of the proposed interventions

Out of the total of 133 proposed pharmaceutical interventions, 126 (95%) were accepted and implemented by the anaesthetists or nurses. The remaining 5% were discussed with the anaesthetists and although accepted as valid interventions, not implemented.

3.2.4 Other pharmacy related activities – Clean utility re-organisation

A decentralised medication storage process based on a non-automated dispensing medicinal system is in place at ITU. The clean utility is a temperature controlled room designated for the storage of all medication ordered for use within the ITU. Two support staff are responsible for everyday stock monitoring and rotation within this clean utility. The support staff alert the Nursing Officer when stocks level is low and need replenishment.

The clean utility was re-organised such that drugs were segregated according to the formulation. Categories were namely parenteral, oral tablets, oral solutions, inhalers,

nebulised solutions, powders, suppositories and others. Anti-infective parenteral agents as well as parenteral medication classified as high-alert medication by the Institute for Safe Medication Practices (ISMP) were further segregated on shelves separate from the rest of the parenteral medications[1]. Medicinal products within the clean utility were labelled according to their active ingredient (with the exception of biologic agents) following Tall-Man-Lettering as recommended by the ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters[2].

3.2.4.1 Preparation of medicinal boxes for the emergency set up of an ITU

In response to the COVID-19 pandemic, the pharmacist-researcher discussed the possibility of setting up boxes to be used in the emergency set up of further ITUs at MDH. Discussions were held with the lead anaesthetist and the Nursing Officers. The medicinal products as well as quantities were agreed upon and conferred to Pharmacy. Three emergency boxes were prepared at Pharmacy for this purpose. The contents of each box are present in Table 3.13. Each emergency box amounted to a cost of €1417.19.

[1] Institute for Safe Medication Practices. http://www.ismp.org/Tools/highalertmedications.pdf
[2] Institute for Safe Medication Practices. https://www.ismp.org/Tools/tallmanletters.pdf

Table 3.13: Contents of emergency boxes

Medicinal product	Quantity
Noradrenaline 1:1000 injection	50
Adrenaline 1:10000 injection	50
Propofol 10 mg/mL injection x 20mL	100
Tazobactam e' Piperacillin 4.5g injection	50
Rocuronium bromide 50 mg/5 mL injection	30
Atracurium 25mg injection	50
Complete nutritional preparation x 200 mL	12
Complete nutritional preparation x 500 mL	15
Esomeprazole 40 mg injection	10
Enoxaparin® sodium 4000 IU injection	10
Furosemide 20 mg/2 mL injection	50
Atropine minijet	5
Adrenaline minijet	10
Paracetamol 10 mg/mL x 100 mL injection	30
0.9% normal saline x 100 mL	50
0.9% normal saline x 50 mL	50
0.9% normal saline x 500 mL	20
Compound lactated ringer solution x 1000 mL	30

CHAPTER 4

DISCUSSION

The discussion and conclusion are presented in the final chapter of this dissertation. This chapter showcases what has been undertaken and what has been achieved out of the work invested despite the limitations put forward by the challenging times related to Covid-19 pandemic. It also proposes improvement to research and attempts at discussing a way forward resulting from this research.

The research started off by acknowledging that an increased prevalence of critical care illnesses resulting from an ageing population and breakthroughs in higher risk medical therapies has led to a growing demand for critical care (Courtright and Kerlin, 2014). The rationale behind this study was that in this scenario, the addition of a pharmacist with the proper medication management skills, to the current interdisciplinary team managing the processes within the ITU would elevate the level of service provided and ameliorate the outcomes of patients admitted for intensive care.

An English quote states that “you are only as good as your tools”. Comparably, the tools used to capture data and knowledge about processes in place, are what makes the basis for the successful development and implementation of a service. Based on this concept, this study commenced with the search for and identification of tools which would provide the greatest insight to the current practices in place at the ITU and to the particular needs of the setting. The Gap Finding Tool, the Pre-Service Questionnaire for Physicians and the Pre-Service Questionnaire for Nurses were identified as the most suitable tools for this study. The quality of the tools chosen is as important as the tools themselves when it comes to quality of the resultant work. Following this rationale, the tools identified were adapted to portray the needs of an intensive care setting and re-validated by a panel of experts. The ITU Gap Finding Tool enabled the pharmacist-researcher to draw a

comparison between the standards of care practice which should be provided in intensive care suggested in international guidelines with the current practice delivered nationally at the ITU. The Pre-Service Questionnaire for Anaesthetists and the Pre-Service Questionnaire for ITU Nurses enabled the pharmacist-researcher to capture the expectations of the main members of the interdisciplinary team providing current care at the ITU such that these expectations may be addressed and incorporated within the developed service.

4.1 Gaps identified at the ITU

The ITU Gap Finding Tool highlighted several gaps in the current service provision. One of the most evident gaps identified was the lack of pharmacist input and pharmacy related knowledge skills in the interdisciplinary care provided. Proper service provision demands the active physical presence of the pharmacist at the ITU. In fact, a study carried out across twenty-one different ITUs in the United Kingdom (UK) demonstrated that up to 60% of contributions made by pharmacists are done during the daily interdisciplinary ward round (Schulman et al, 2015). The responses given by the healthcare professionals to the Pre-Service Questionnaire for Anaesthetists and the Pre-Service Questionnaire for ITU Nurses further confirm that this was expected of the pharmacist.

The lack of medicines information available at bedside was another gap which was identified and confirmed as an expected role of the pharmacist through the disseminated questionnaires. The frustration of anaesthetists and nurses faced with a drug related query which they could not manage to address themselves was observed during Phase I. This was further accentuated by the fact that the increase in number of COVID-19 infections in the country at the time was starting to have its toll on the number of new admissions at

the ITU and hence the time that could be dedicated to each patient during the patient ward rounds was becoming less and less. During Phase II, all medication information related queries arising during the patient ward round were directed to the pharmacist-researcher. The response to the query by the pharmacist-researcher was used to guide changes or amendments needed to the patient's pharmaceutical care plan. Examples of medicines information queries included information about the half life of drugs such as quetiapine and haloperidol, information with regards to what is considered second and third line treatment of hypertension, information about the sodium content of the complete nutritional preparations available and information on tailoring down the dose of methadone. The fact that the pharmacist was present and provided this information on the spot allowed for more time to be invested in other aspects of care the patients needed.

Another gap identified was the fact that the availability of the drug and the allowed prescribing criteria for the chosen drug were not being checked at the point of prescribing. This was leading to situations where the drug prescribed would successively be ordered by the Nursing Officer from the Pharmacy and the request bouncing back because either the drug prescribed is not available on the hospital formulary or the drug prescribed is protocol regulated with a set of prescribing rights which were not met. The Nursing Officer would then need to contact the prescribing anaesthetist with this information and wait for another drug to be prescribed or the necessary paperwork to be filled in before being able to administer the treatment to the patient leading to unnecessary delays. During Phase II of the study, the pharmacist-researcher was checking the availability of the drug prescribed against the hospital formulary list and liaising immediately with the Pharmacy as to which paperwork would be required directly at the point of prescribing and informing the anaesthetist immediately such that an alternative drug would be

immediately chosen in the case of unavailability or the proper paperwork filled in thus reducing delays in treatment administration. It is well documented in literature that pharmacists are in the best position at providing such information (Papadopoulos et al, 2002; Mica and Green, 2012; Tahniyath, 2017; Bronkhorst et al, 2020). Additionally, any significant changes in the prescribing trends observed, were being communicated in real time by the pharmacist-researcher to the Pharmacy personnel responsible of stock ordering to avoid hospital out of stock situations due to increased unexpected consumptions. A case in point would be with co-trimoxazole injections. During a particular week in Phase II of the study, there was an outbreak of *Stenotrophomonas maltophilia* giving rise to complicated chest infections among patients recovering from COVID-19 infection. These four patients had been administered a multitude of anti-infective agents during the active phase of their COVID-19 infection and therefore when the sensitivities were returned, it was observed that the only agent to which the infective organism was susceptible was co-trimoxazole. Co-trimoxazole is not a drug which is frequently prescribed owing to the availability of other drugs with a much lesser negative renal affecting profile therefore stocks procured by the Pharmacy are usually limited. The dose of co-trimoxazole prescribed was based on the trimethoprim component with an expected duration of 14 days and once calculated, it amounted to approximately eleven ampoules needed daily per patient. This was bound to lead to the hospital running out of the medication in a short period of time unless the information was relayed in a timely manner and further stocks were ordered.

The ITU Gap Finding tool also highlighted the need for improvement in the medication management process. This was particularly evident with regards to prescribing following guidelines and protocols. During the observatory phase, the pharmacist-researcher

observed that the drugs prescribed to treat a patient varied depending on the consultant anaesthetist on duty on the day. Consultant anaesthetists were rostered for work at the ITU from Monday to Thursday and from Friday to Sunday. Most often, it was observed that the consultant anaesthetist rostered from Monday to Thursday would start the patient on one treatment but then the consultant anaesthetist scheduled at the ITU between Friday and Sunday, would change the treatment come Friday on the first day rostered. During Phase II of the study, the pharmacist-researcher guided the consultant anaesthetist on duty towards prescribing based on guidelines resulting in a more standardised prescribing and therefore less therapy changes with changes in the rostered consultant anaesthetist. Literature frequently mentions that the inclusion of a pharmacist in the interdisciplinary team leads to an increase in adherence to guidelines and standardisation of therapy prescribed (Marshall, Finn and Theodore, 2008; Hunfeld et al, 2010; Jurado and Steelman, 2013; Borthwick, 2019; Kessemeier et al, 2019).

4.2 Interventions carried out by the pharmacist

The drug selection category was the most common PCI category identified during the study period, with ‘Need for an additional drug to properly manage a condition’ (n=23) being the most common PCI. The result is comparable to several published studies where the highest number of interventions also pertained to this subcategory (Hunfeld et al, 2010; Klopotowska et al, 2010; Bosma et al, 2018; Mahmoodpoor et al, 2018). The subcategory ‘No indication for drug or indication no longer apparent’ (n=16) was the second most common subcategory identified from this category. An example of no indication for drug or indication no longer apparent included failure to stop Pabrinex® injections prescribed for the prevention of Wernicke's encephalopathy in patients admitted to the ITU suffering from alcohol dependence following 5 days of treatment.

The position statement by the Derbyshire Joint Area Prescribing Committee (JAPC) recommends the use of high dose intravenous vitamin supplementation in this type of patient for a duration of 3 to 5 days and switching to oral thiamine 50 mg four times daily and folic acid 5 mg once daily with the total duration of treatment lasting 28 days[3]. Another case example is that of a patient who was not absorbing the feed for which he was receiving erythromycin. A recommendation was made by the pharmacist-researcher to stop the therapy on the 4th day because the recommended duration of therapy for this indication is 3 days and the nurse assigned to the patient confirmed that the patient was now absorbing his feed.

The dose selection category was the second most common PCI category identified during the study period, with 'Dose too low for patient's age, weight and indication and/or severity' (n=15) being the most common PCI. A case example of dose too low for patient's age, weight and indication and/or severity is the case of a 32-year old male admitted to the ITU following a fall from height of 4 storeys. The patient presented with multiple fractures including a fracture to the skull. Despite the considerable fall and amount of fractures, the patient was recovering following emergency surgery. The nurses reported, however, that the patient was so agitated that he almost extubated himself. He was already on the maximum daily dose of clonidine, haloperidol and lorazepam and the quetiapine added by the anaesthetist on call during the night had little effect. The pharmacist-researcher drew the attention of the consultant anaesthetist on duty that the dose of quetiapine prescribed during the night (25 mg twice daily) was too low as the

[3] http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_9/Vitamin_supplementation_in_alcohol_misuse.pdf

recommended starting dose for patient developing ITU associated delirium and/or agitation was 50 mg twice daily.

The drug administration category was the third most common PCI category encountered during this study, with 'Other drug administration problem' (n=16) being the most common subcategory of PCIs. The majority of the PCIs were related to problems with dilutions, a problem reported by 12 out of the 18 nurses who responded to the Pre-Service Questionnaire for ITU Nurses. Similarly, it is reported in the study by Fideles et al (2015) that 14.4% of the pharmacist interventions encountered concerned dilutions. It was noted that as the country's COVID-19 case load worsened resulting in the hospital having to open new areas dedicated to the provision of intensive care, nurses usually assigned to non-critical areas suddenly found themselves working in one and PCIs related to dilutions increased. The presence of the pharmacist-researcher was providential in lessening the burden and preventing further possible medication errors in view of the situation. A case example of other drug administration problem involved the dilution of co-trimoxazole. The patient was prescribed 10 vials of co-trimoxazole intravenously divided into three doses daily. The nurse asked the anaesthetist on how to dilute the doses, who in turn referred her to the pharmacist-researcher. Since the patient was not fluid restricted, the pharmacist-researcher recommended that the 3 ampoules prescribed in the morning and at noon should be diluted with 500 mL of 0.9% normal saline and that the 2 ampoules prescribed in the evening are diluted with 250 mL of 0.9% normal saline. The pharmacist-researcher recommended that the patient is monitored for possible fluid overload and agreed with the consultant anaesthetist that should fluid overload occur, a stat dose of furosemide 20 mg is administered.

The fourth most common PCI category encountered in this study was the dispensing category, with the 'Other dispensing problem' subcategory being the most common PCI identified. A case example of other dispensing problem is the case of an elderly patient who required treatment with clarithromycin. The consultant anaesthetist wanted to prescribe clarithromycin suspension because the patient suffered from dysphagia. The pharmacist-researcher advised the anaesthetist that although available within the hospital, only consultant paediatricians had prescribing rights for the clarithromycin suspension and that he should either prescribe an alternative or fill in the necessary paperwork for exceptional treatment. The consultant anaesthetist opted for the exceptional treatment route because of the sensitivity results and the pharmacist-researcher helped filling in and liaising with the Pharmacy dispensary to speed up the process and avoid delays in the start of therapy.

The monitoring category, the dosage regimen category, the duration of treatment category and the seamless care category were the other categories of PCIs encountered by the pharmacist-researcher during this study.

The study recorded a 95% (n=126) acceptance and implementation rate for the pharmaceutical interventions identified by the pharmacist-researcher. This compares well with the reported acceptance and implementation rates of similar studies published in literature (Leape et al, 1999; Chant et al, 2015; Rudall et al, 2017; Sereno et al, 2018; Hasan et al, 2019; Rubio et al, 2019).

4.3 Recommendations

A number of recommendations were identified during this research for both further service development and further research development.

4.3.1 Service development

The expansion of ward based pharmacy services is part of the vision of the Maltese Ministry for Health. This research has demonstrated the positive value and effect of direct pharmacist participation at ward level and thus supports the need to implement the pharmaceutical service developed at the ITU on a permanent basis. The development of standardised hospital guidelines within the context of critical care, such as the weaning off of opiates and the vaccinations required in the post emergency splenectomy scenario would also improve the standardisation and level of care provided to patients. Furthermore, the implementation of the pharmaceutical service developed within the ITU lays the groundwork for future implementation of structured improved pharmaceutical services supporting anaesthesia within operating theatres.

4.3.2 Research development

Further research which could be carried out would include assessing the clinical significance and importance of the identified PCIs. An array of tools has been developed with the aim of assessing pharmacists' interventions significance (Vo et al, 2016). One of these assessment tools is the tested tool developed by Overhage and Lukes (1999). The 'Instrument for characterizing pharmacists' clinical activities' tool enables the simultaneous assessment of the severity of medication errors and the value of

interventions carried out by the pharmacist making it greatly appropriate in assessing the significance of the interventions identified by this study.

Other further research could aim at analysing the cost effectiveness of the developed and implemented pharmaceutical service possibly comparing the average length of stay of patients prior to the implementation of the developed service with the average length of stay of patients post implementation.

4.4 Limitations

The limitations of this study are related to the COVID-19 pandemic and to the limited time period available to carry out the study. Due to the COVID-19 pandemic, all patients requiring critical care due to cardiac related events/surgery were no longer being transferred to the main intensive therapy unit and managed at the cardiac intensive care unit. Elective cardiac surgeries were also postponed. This was a move that the hospital management made such that the main ITU where this study was set, could accommodate patients who were no longer infective but still needed intensive care post COVID-19 infection for complications related to the disease.

4.5 Conclusion

The results of this research highlight the benefits of the pharmacist as part of the interdisciplinary team tendering care to patients admitted for intensive care. This research has provided a quantitative scientific based platform proving that the implementation of the developed service at the ITU further builds on the continuous and relentless effort in improving care standards provided to patients admitted to Mater Dei Hospital. The study

findings were taken up by the lead anaesthetists within the Intensive Therapy Unit at Mater Dei Hospital to support their request for the continuous pharmacy service within the ITU to the Mater Dei Hospital administration. This request was acceded to. At the time of the writing up of this research, a plan to expand the service to include another 3 pharmacists to assist in running the continuation of the pharmaceutical care service at ITU on a permanent basis was drafted while the service is being continued.

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Appendix 1

UREC Approval Letter

L-Università ta' Malta

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Ref No: FRECMDS_1920_222

15 December 2020

Ms Deborah Louise Rayner
67, Il-Girna,
Triq Louis Schickluna,
Fgura. FGR2072

Dear Ms Rayner,

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Pharmaceutical Service Development in Anaesthesia

The Faculty Research Ethics Committee granted ethical approval for the above mentioned application reviewed on 15 October 2020, following receipt of amendments requested, on 4 December 2020.

Yours sincerely,

Professor Pierre Mallia
Chairman
Faculty Research Ethics Committee

Appendix 2

ITU Gap Finding Tool

ITU Gap Finding Tool validation questionnaire

Dear Colleague,

*Thank you for accepting to participate in the re-validation of the **Gap Finding Tool** which has been adapted as part of the research entitled 'Pharmaceutical Service Development in Anaesthesia'.*

The questions below will enable you to voice your opinion on the Gap Finding Tool which shall be filled in by the Pharmacist-Researcher during Phase I of the research.

The aim of this tool is to assess and document what Pharmacy services are offered at the Intensive Therapy Unit and what Pharmacy services are currently lacking.

Please answer the below questions:

1. From a scale of 0 to 4, how **relevant** do you think the sections of the Gap Finding Tool (n=9) are to assess what Pharmacy services are offered at the Intensive Therapy Unit and what Pharmacy services are lacking? Kindly indicate any changes that you consider necessary in the comments section.

SECTION 1: ACCURATE HISTORY				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 2: CURRENT MEDICATION MANAGEMENT				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 3: CLINICAL REVIEW				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 4: THERAPEUTIC DRUG MONITORING				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 5: PROVIDING MEDICINES INFORMATION				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 6: ADR MANAGEMENT				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 7: PARTICIPATING IN INTERDISCIPLINARY CARE				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 8: INFORMATION FOR ONGOING CARE				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 9: DOCUMENTATION				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

2. From a scale of 0 to 4, how much do you think that the **statements** of each section (n=9) of the Gap Finding Tool **relate** to the **heading** of the section? Kindly indicate any changes that you consider necessary in the comments section.

SECTION 1: ACCURATE HISTORY				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 2: CURRENT MEDICATION MANAGEMENT				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 3: CLINICAL REVIEW				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				
SECTION 4: THERAPEUTIC DRUG MONITORING				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				
SECTION 5: PROVIDING MEDICINES INFORMATION				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 6: ADR MANAGEMENT				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 7: PARTICIPATING IN INTERDISCIPLINARY CARE				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 8: INFORMATION FOR ONGOING CARE				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 9: DOCUMENTATION				
Not Relevant	**Slightly Relevant**	**Moderately Relevant**	**Relevant**	**Very Relevant**
0	1	2	3	4
Comments _____ _____ _____				

3. Are there any sections or statements which you would like to add?

_____

_____

_____

_____

4. Did the Gap Finding Tool give a positive impression?

Yes ☐ No ☐

Further comments and recommendations which you wish to suggest regarding the Gap Finding Tool.

_____

_____

Thank you for your time and assistance.

Deborah Louise Rayner

Doctorate of Pharmacy Student

ITU Gap Finding Tool

1. Accurate History	Tick	Comments
Obtaining and documenting a complete **Drug History** including prescription and non-prescription medications and their dose, regimens and administration routes to determine the list of current medications		
Obtaining and documenting a complete **Past Medical History**		
Confirming and documenting **ADR's/sensitivities**		
Reconciliation of medication therapy – comparing the medication history with the prescribed medications and following-up discrepancies		
Asking about recently **stopped/changed medications** and the reasons for the changes		
Assessing legal guardian's/ patient's understanding and attitude to their guardianee's/ their **current drug therapy**		
Assessing the need to refer to medical staff		

2. Current Medication Management	Tick	Comments
A. Reviewing all prescriptions and treatment charts to ensure clarity and validity		
Ensuring prescriber's intention is clear to enable the safe supply and administration of medicines		
Ensuring that prescriptions and treatment charts are comprehensive and unambiguous		
Ensuring all drugs are prescribed by their active ingredient unless the drug is a biosimilar in which case it would need to be prescribed by tradename		
Ensuring that drug names are not abbreviated		
Ensuring that the date and time at which medicine administration is to commence and cease are written		

Ensuring that the time the dose should be given is endorsed in the relevant section of the chart		
Checking that patient identifiers are documented		
Ensuring that the order is signed and the prescriber can be identified		
B. Reviewing prescriptions and treatment charts to ensure appropriateness of all drugs		
Confirming that there is a clear **indication** for each drug		
Confirming that the medicine is prescribed for an **approved** or recognised indication. If not, ensuring that the necessary forms are filled		
Ensuring protocols and guidelines (local where appropriate) are considered during prescribing		
Considering the **latest evidence** regarding the medicine's efficacy, comparative efficacy and safety of therapeutic alternatives and likelihood of side effects compared to therapeutic alternatives		
Ensuring that the **method of administration** selected is the most appropriate: route, regimen, dosage form, administration times (e.g. with respect to food/feeds, convenience, scheduled procedures/investigations, TDM requirements) and duration of administration		
Ensuring that the infusion solution and concentration are appropriate for parenteral drugs		
Checking that **drugs and doses** are appropriate with respect to: (1) patient specific considerations e.g. disease state, age, body weight, body surface area, laboratory results e.g. renal function, liver function, patients' previous experience with drug (2) therapeutic goals of each drug and (3) licensed dose		
Checking **dose conversions** with changes to route or formulation		
Checking that the drug has been achieving **goals of therapy**		
Checking for **duplication**		

Checking for **contraindications**		
Checking for **drug interactions** and assessing their clinical significance. Drug interactions include: drug-drug, drug-patient, drug-disease, drug-nutrient interactions and drug-laboratory tests interactions		
Ensuring that the **units** of the drug prescribed are clearly indicated		
Liaising with the compounding service to coordinate the timely supply of items requiring specialised reconstitution and preparation		
Ensuring drugs are available at the ward and where necessary are ordered, e.g. current medicine, named patient medicine, prophylactic treatment		
Checking the medication administration record to ensure that all doses ordered have been administered		
Annotating treatment charts as necessary		
Ensuring that the order is cancelled in all sections of the medication administration record when medicine therapy is intended to cease		
Checking availability and access to medications, i.e. government restrictions, marketing approval, hospital formulary limitations, methods of obtaining further supply outside the facility		
Considering cost of the medicine to the patient and hospital and considering therapeutic alternatives		

3. Clinical Review	Tick	Comments
Reviewing and monitoring patient-specific clinical information including patient's signs and symptoms (from discussions with the patient or through review of clinical progress notes), parameters (e.g. pulse rate, temperature, blood pressure, blood glucose level and patient weight), biochemical tests (e.g. serum electrolytes, creatinine, liver function tests, haematology results and microbiology results) and other tests (e.g. radiological investigations, pain scores, bowel charts, peak flow/spirometry) **to evaluate the response to the drugs and adjust therapy accordingly**		
Identifying **actual and potential medicines-related problems** and evaluating collaboratively with other members of the healthcare team the need for intervention and prioritising these per their risk and urgency		

4. Therapeutic Drug Monitoring (TDM)	Tick	Comments
When necessary, the pharmacist should give exact instructions **when** and **how** TDM is to be carried out		
Informing the prescriber of the **results** of TDM in a timely manner, including recommended **action a**nd future **monitoring requirements**		

5. Medicines Information	Tick	Comments
Providing medicines information to **healthcare professionals** to provide patient-centred care and optimise quality use of medicines		

6. Adverse Drug Reaction (ADR) Management	Tick	Comments
A. Detection and prevention of an ADR		
Identifying and monitoring susceptible patients: patients on multiple drugs, paediatric patients, patients treated with drugs known to have a high incidence of and serious adverse effects including narrow therapeutic index drugs, previously experienced ADRs, hepatic and renal impairment, multiple disease processes		
B. Suspected ADR		
Assessing the details of the ADR in the context of patient-specific and medications-related factors		
C. Management of an ADR		
Considering the likelihood of the suspected medicine(s) having caused the reaction and the clinical significance when assessing whether to continue treatment with the suspected medicine(s).		
Recommending treatment options for the ADR and, if appropriate, recommending alternative treatments		

7. Participating in Interdisciplinary Care	Tick	Comments
Being physically present to **participate in ward rounds, clinics and meetings** attended by other healthcare professionals where the overall care of the patient is discussed and planned		
Preparing accurate and comprehensive **patient profiles** for assistance when preparing for a ward round		
Contributing information about the patient's medicines and medicines management		
Making suggestions for **selecting** and **monitoring** medicines		

Be fully informed about **current patient-specific issues**		
Prioritising **patients requiring further review or education** by the pharmacist		
Participating in **transition of care**		
Developing and implementing pharmacological treatment policies and procedures related to the safe and effective use of medications in the critical care setting		

8. Information for Ongoing Care	**Tick**	**Comments**
A. Managing the patient's medicines and communicating with them/ their legal guardians on transition		
Annotating which medicines need to be supplied on transfer on the patient profile		
B. Liaising with other Healthcare Professionals on transition		
Obtaining consent and then communicating all medicines-related information in a timely manner to patient's GP, community pharmacist, residential care provider or other healthcare professional; • details of medicines prescribed on transfer, a contact name within the hospital and a telephone number • verified list of all the patient's medicines beginning at the episode of care, changes made during the episode of care, and a detailed rationale of these changes • monitoring requirements for ongoing management of the patient's medicines		

• information regarding the patient's need for periodic medicines review and follow up including post-acute care follow-up and outpatient or non-admitted medication review • reported adverse drug events and adverse drug reactions during the episode of care		

9. Documentation	Tick	Comments
Documenting the medication related assessment and plan of care to optimise patient outcomes directly in the patient file The following components are essential to be included; **A. Patient medication record** Past medical history, drug history, ADR/sensitivities, current medications noting start and stop date (if applicable) **B. Active medication problem** Date of onset, problems identified, comments, date resolved **C. Pharmaceutical care issues** Date when pharmaceutical care issue arose, care issue, date when action is taken, action taken, date of outcome, outcome **D. Medication Therapy Plan** Implemented collaboratively by the healthcare team including drug, dose, route, frequency, and relevant monitoring parameters (including therapeutic drug monitoring; medication, reference range, result, date and time of last dose administered, date and time of last sample taken, comments) and follow-up		

Adapted from:

American Society of Health-System Pharmacists. ASHP guidelines on surgery and anaesthesiology pharmaceutical services. American Society of Health-System Pharmacists. American Journal of Health-System Pharmacy. 1999; 56(9):887-895.

Falzon S. Development of a Pharmaceutical Care Model within Paediatric Oncology [dissertation]. Msida (Malta): University of Malta; 2018.

SHPA Committee of Specialty Practice in Critical Care. SHPA standards of practice for critical care pharmacy practice. Journal of Pharmacy Practice and Research. 2008; 38(1):58-60.

Appendix 3

Pre-Service Questionnaire for Anaesthetists

Dear Colleague,

*Thank you for agreeing to form part of the expert panel for the validation of the **Pre-Service Questionnaire for Anaesthetists** which will be distributed as part of the research entitled 'Pharmaceutical Service Development in Anaesthesia'. The following are questions enabling you to voice your opinion about the questionnaire, which shall be filled in by anaesthetists working at the Intensive Therapy Unit before the pharmaceutical service has been developed.*

The aim of this questionnaire is to assess anaesthetists' demographics and past working experience within an interdisciplinary context as well as their perspectives and ideas in terms of the logistics for the proposed pharmaceutical services and roles of the clinical pharmacist within an intensive care setting.

Please answer the following questions:

1. From a scale of 0 to 4, how much do you think the **wording** of the questionnaire is easy to understand?

Not easy	Slightly easy	Moderately easy	Easy	Very easy
0	1	2	3	4

2. From a scale of 0 to 4, how much do you think that the content of the questionnaire is **relevant** to fulfil its aims?

Not relevant	Slightly relevant	Moderately relevant	Relevant	Very relevant
0	1	2	3	4

3. Kindly indicate any questions which you would add or omit.

_____

_____

_____

_____

4. Is there anything that you would change to the format of the questionnaire?

   Yes □ No □

   If yes, kindly specify.

_____

_____

5. From a scale of 0 to 4, how adequate do you think that the **length** of the questionnaire is?

Not adequate	Slightly adequate	Moderately adequate	Adequate	Very adequate
0	1	2	3	4

6. From a scale of 0 to 4, how **accurate** do you think that the questionnaire is?

Not accurate	Slightly accurate	Moderately accurate	Accurate	Very accurate
0	1	2	3	4

7. From a scale of 0 to 4, how much do you think that the questionnaire is **user-friendly**?

Not user-friendly	Slightly user-friendly	Moderately user-friendly	User-friendly	Very user-friendly
0	1	2	3	4

8. Did the questionnaire create a positive impression?

   Yes □ No □

   Further comments and recommendations which you wish to suggest regarding the Pre-Service Questionnaire for Anaesthetists.

   _____

   _____

Thank you for your time and help.

Deborah Louise Rayner

Doctorate of Pharmacy student

Pre-Service Questionnaire for Anaesthetists

ITU Anaesthetists Demographics

*Required

1. **Position** *
   Tick only one box

   □ Consultant
   □ Resident Specialist
   □ Higher Specialist Trainee
   □ Basic Specialist Trainee
   □ Foundation Year 2

2. **Gender** *
   Tick only one box

   □ Female
   □ Male
   □ Other

3. **Have you trained or worked in hospitals abroad?** *
   Tick only one box

   □ Yes
   □ No *Skip to question 7*

Training abroad/ working experience

4. **Specify the country/countries** *

   _____

5. **Name of Hospital/s**

   _____

6. **For how long?** *
   Tick only one box
   □ 0-1 years
   □ 1-3 years
   □ 3-5 years
   □ >5 years

Past Working Experience in Interdisciplinary Team Approach

7. **Do you have any experience in working with pharmacists as part of an interdisciplinary team?** *
   Tick only one box

   □ Yes *Proceed to question 8*
   □ No *Skip to question 12*

8. **Was this team-based approach in Critical Care medicine or in other medical specialities?**
   Kindly specify

   _____
   _____

9. **Did you experience this approach in Malta or abroad?**
   Tick only one box

   □ Malta
   □ Abroad
   □ Both in Malta and abroad

10. **Was the pharmacist team-based (working as part of a particular medical team and not the whole department) or departmental-based?**
    Tick only one box

    □ Team-based
    □ Departmental-based

11. **How many pharmacists were part of this interdisciplinary team?**
    Tick only one box

    □ 1
    □ 2
    □ 3
    □ 4
    □ >4

Logistics of Proposed Pharmaceutical Services

Your perspectives and ideas of how and what should be the pharmaceutical services provided

12. Are the current services provided by MDH Pharmacy sufficient for the needs of the ITU?

Tick only one box

□ Yes
□ No

13. In your opinion, is there a need for an in-house pharmacist/s at the ITU of MDH? *

Tick only one box

	1	2	3	4	5	
Can do without	□	□	□	□	□	Essential

14. What would be the ideal working hours for a pharmacist to be present at shop floor? Assign your order of preference for the proposed times *

Tick only one box per row

	(Least preferred) 1	2	3	4 (Most preferred)
08:00 – 16:00	□	□	□	□
16:00 – 00:00	□	□	□	□
00:00 – 08:00	□	□	□	□
24 hours	□	□	□	□

15. Should the service be team-based or departmental-based? *

Tick only one box

□ Team-based
□ Department-based

Roles

Rate the impact that proposed roles undertaken by a pharmacist can have at the ITU

16. Attendance and participation in patient rounds i.e. review of patients at bed side *

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

17. Offer medicine information services on the spot

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

18. Involvement in guidelines and policies

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

19. Review of essential drug classes' pharmacology *

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

20. Medication stock selection, procurement and control *

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

21. Involvement in inadvertent medicinal incident flagging, investigation and monitoring

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

22. Conduct internal departmental audits

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

23. Involvement in emergency preparedness strategies and planning

Tick only one box

	1	2	3	4	5	
Not essential	☐	☐	☐	☐	☐	Essential

Medication Reconciliation

24. Do you feel medication reconciliation could be improved if a pharmacist is on board? *

Tick only one box

- ☐ Yes
- ☐ No
- ☐ Not sure

Any other suggestions or comments for this service?

Kindly share your comments and opinions about this service

25. _____
_____
_____
_____

Thank you for your time and assistance.

Deborah Louise Rayner

Doctorate of Pharmacy Student

Adapted from:

Portelli G. Establishment of Pharmaceutical Services within the Emergency Department [dissertation]. Msida (Malta): University of Malta; 2018.

Appendix 4

Pre-Service Questionnaire for ITU Nurses

Dear Colleague,

*Thank you for agreeing to form part of the expert panel for the validation of the **Pre-Service Questionnaire for ITU Nurses** which will be distributed as part of the research entitled 'Pharmaceutical Service Development in Anaesthesia'. The following are questions enabling you to voice your opinion about the questionnaire, which shall be filled in by nurses working at the Intensive Therapy Unit before the pharmaceutical service has been developed.*

The aim of this questionnaire is to assess nurses' demographics and past working experience within an interdisciplinary context as well as their perspectives and ideas in terms of the logistics for the proposed pharmaceutical services and roles of the clinical pharmacist within an intensive care setting.

Please answer the following questions:

1. From a scale of 0 to 4, how much do you think the **wording** of the questionnaire is easy to understand?

Not easy	Slightly easy	Moderately easy	Easy	Very easy
0	1	2	3	4

2. From a scale of 0 to 4, how much do you think that the content of the questionnaire is **relevant** to fulfil its aims?

Not relevant	Slightly relevant	Moderately relevant	Relevant	Very relevant
0	1	2	3	4

3. Kindly indicate any questions which you would add or omit.

   _____

   _____

   _____

   _____

4. Is there anything that you would change to the format of the questionnaire?

   Yes □ No □

   If yes, kindly specify.

   _____

   _____

5. From a scale of 0 to 4, how adequate do you think that the **length** of the questionnaire is?

Not adequate	Slightly adequate	Moderately adequate	Adequate	Very adequate
0	1	2	3	4

6. From a scale of 0 to 4, how **accurate** do you think that the questionnaire is?

Not accurate	Slightly accurate	Moderately accurate	Accurate	Very accurate
0	1	2	3	4

7. From a scale of 0 to 4, how much do you think that the questionnaire is **user-friendly**?

Not user-friendly	Slightly user-friendly	Moderately user-friendly	User-friendly	Very user-friendly
0	1	2	3	4

8. Did the questionnaire create a positive impression?

   Yes □ No □

   Further comments and recommendations which you wish to suggest regarding the Pre-Service Questionnaire for ITU Nurses.

   _____

   _____

Thank you for your time and help.

Deborah Louise Rayner

Doctorate of Pharmacy Student

Pre-Service Questionnaire for ITU Nurses

ITU Nurses Demographics

*Required

1. **Age** *
   Tick only one box

   □ 20-30
   □ 30-40
   □ 40-50
   □ >50

2. **Gender** *
   Tick only one box

   □ Female
   □ Male
   □ Other

3. **For how long have you been working as a nurse? Specify the years** *

   _____

4. **For how long have you worked at the ITU? Specify the years** *

   _____

5. **Was the ITU the first department you have worked in?** *
   Tick only one box

   □ Yes
   □ No

6. **Do you or have you worked in other departments in MDH?** *
   Tick only one box

   □ Yes
   □ No

7. Have you worked in other hospitals/ healthcare entities apart from MDH?
Tick only one box

□ Yes
□ No

8. If you have answered 'Yes' to the above question, have you worked in Malta or abroad?
Tick only one box

□ Malta
□ Abroad
□ Both in Malta and abroad

Education

9. Current qualification
Tick only one box

□ Degree
□ Diploma
□ Other: _____

10. Other qualifications (please specify)

_____

11. **During your nursing course, were you given lectures about pharmacology?**
Tick only one box

□ Yes *Proceed to question 12*
□ No *Proceed to question 13*
□ I do not know

12. Do you feel the knowledge was sufficient for your line of work in the ITU?
Tick only one box

□ Yes
□ No

13. Have you ever been given training after your nursing course? In your opinion, are they necessary? Explain your views.

_____
_____
_____
_____

14. Did you participate in any other courses following your initial nursing course? *
Tick any boxes that apply

□ Yes
□ No
□ Other: _____

Treatment Room

Ask yourself whether any of the below mentioned aspects are correct or otherwise, with respect to the treatment room

15. Overall layout of the room *
Tick only one box

	1	2	3	4	5	
Poor	□	□	□	□	□	Excellent

16. Layout of medication storage and shelving *
Tick only one box

	1	2	3	4	5	
Poor	□	□	□	□	□	Excellent

17. Labelling of medication shelves/trays *
Tick only one box

	1	2	3	4	5	
Poor	□	□	□	□	□	Excellent

18. Availability of medications in the treatment room
Tick only one box

	1	2	3	4	5	
Poor	□	□	□	□	□	Excellent

19. Directions for dilutions and reconstitution of IV treatment *

Tick only one box

	1	2	3	4	5	
Poor	☐	☐	☐	☐	☐	Excellent

20. Adequate space for drug dilution and reconstitution *

Tick only one box

	1	2	3	4	5	
Poor	☐	☐	☐	☐	☐	Excellent

21. Disposal of expired/broken medications *

Tick only one box

	1	2	3	4	5	
Poor	☐	☐	☐	☐	☐	Excellent

22. Correct handling of multi-dose vials *

Tick only one box

	1	2	3	4	5	
Poor	☐	☐	☐	☐	☐	Excellent

23. Are there any other issues not mentioned above or any other suggestions for improvement you would like to add? *

_____

_____

_____

Overall

What are your thoughts about the following?

24. Within your practice, what are the main issues encountered when preparing and/or administering medication/s? *

_____

_____

_____

25. When you encounter problems with medication/s, who do you refer to? *

_____
_____
_____

26. In your opinion, is there a need for an in-house pharmacist/s at the ITU of MDH? *
Tick only one box

	1	2	3	4	5	
Can do without	☐	☐	☐	☐	☐	Essential

27. Any other comments/suggestions?

_____
_____
_____

Thank you for your time and assistance.

Deborah Louise Rayner

Doctorate of Pharmacy Student

Adapted from:

Portelli G. Establishment of Pharmaceutical Services within the Emergency Department [dissertation]. Msida (Malta): University of Malta; 2018.

Appendix 5

Information letter and consent form for healthcare professionals

Information Letter for Health Care Professionals

Dear Colleague,

I am a Senior Pharmacist working at MDH Pharmacy and a second-year student reading for a Doctorate in Pharmacy (PharmD). For the fulfilment of the requirements for the Doctorate Degree, I am working on a research entitled "Pharmaceutical Service Development in Anaesthesia". The research is being carried out under the supervision of Dr. Louise Grech and Professor Anthony Serracino Inglott.

The aim of this research is to develop and establish a pharmaceutical service within the Intensive Therapy Unit at Mater Dei Hospital. Phase I of the study includes capturing the expected role of the pharmacist at ITU and the complimentary pharmaceutical service as required by ITU as deemed by clinicians and nurses. As a clinician or nurse working at the Intensive Therapy Unit, you are requested to complete a questionnaire that will not take more than ten minutes to complete. Information such as whether you have had previous experience of working in a team with a pharmacist and whether you feel that a pharmacist should be present at the ward will be collected.

Even though you are under no obligation to participate, your participation would be greatly appreciated. Should you wish to stop your participation in this study, you may do so at any time and without any need to give a reason. Your identity and all the information disclosed will be kept confidential and will only be to the researcher. The information may be published as part of this study but the information will never be traceable to you.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Thank you in advance for your participation,

Deborah Louise Rayner
B.Sc. Pharm. Sci. (Hons.) (Melit.) M.Pharm. (Melit.) M.Sc. Clin. Pharm. (Robt Gor)

Consent Form for Health Care Professionals

I, the undersigned certify that I am a Maltese citizen and am over eighteen (18) years of age. I have been asked to participate in a research study entitled 'Pharmaceutical Service Development in Anaesthesia'.

The purpose and details of the research have been explained to me by Deborah Louise Rayner and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator (Ms. Deborah Louise Rayner) to make the appropriate observations.

I understand that the results of this research may be used for medical or scientific purposes and that the results achieved from the research in which I am participating may be reported or published: however, I shall not be personally identified in any way, either individually or collectively, without my express written permission.

I am under no obligation to participate in this research and this is being done voluntarily.

I may withdraw from the research at any time, without giving any reason.

I am not receiving any remuneration for participating in this study.

For any further details or queries, I may contact Deborah Louise Rayner on 79496191 or via email at deborah-louise.rayner.07@um.edu.mt

Signature of Participant _____

Name and ID number of Participant _____

Signature of Principal Investigator _____

Name of Principal Investigator and ID number _____

Signature of Supervisor _____

Date _____

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Appendix 6

Information letters and consent forms for patients and legal guardian or next of kin in English and Maltese

Information Letter for Patients

Dear patient,

I am Deborah Louise Rayner, a pharmacist and a student reading for a Doctorate in Pharmacy. For the fulfilment of the requirements for the Doctorate Degree, I am working on a research project entitled “Pharmaceutical Service Development in Anaesthesia”. The research is being carried out under the supervision of Dr. Louise Grech and Prof. Anthony Serracino Inglott in collaboration with the Anaesthesia Department.

The purpose of this research is to develop pharmacy services to cover the Intensive Therapy Unit at Mater Dei Hospital.

This research involves the pharmacist-researcher contributing to the safe and optimum use of the medications used in the management of your illness. This is done in collaboration with the doctors and nurses taking care of you at the Intensive Therapy Unit. Information such as current renal function as well as past medical history will be collected in order to be able to do so.

Your identity will not be revealed in anyway, any information collected will be kept anonymous throughout the research and you may quit the study at any time.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Thank you in advance.

Ittra ta’ informazzjoni għal pazjenti

Għażiż/ għeżiża pazjent/pazjenta,

Jiena Deborah Louise Rayner, spiżjara u studenta tal-kors tad-dottorat tal-farmaċija. Sabiex jiġu sodifatti r-rekwiżiti tal-lawrja ta’ dottorat, jiena qiegħda naħdem fuq riċerka intitolata “Żvilupp ta’ servizz farmaċewtiku fl-anestesija”. Din ir-riċerka qiegħda issir taħt is-superviżjoni tad-Dott. Louise Grech u l-Professur Anthony Serracino Inglott flimkien mad-Dipartiment ta’ l-Anestesija.

L-għan ta’ din ir-riċerka huwa l-iżvilupp ta’ servizzi tal-farmaċija sabiex tiġi koperta s-sala tal-Kura Intensiva ġewwa l-isptar Mater Dei.

Din ir-riċerka tinvolvi lill-ispiżjara riċerkatriċi tikkontribwixxi għall-użu sikur u l-aħjar tal-mediċini li jintużaw fil-ġestjoni tal-kundizzjoni tiegħek. Dan ser isir b’ kollaborazzjoni mat-tobba u l-infermiera li jieħdu ħsiebek ġewwa s-sala tal-Kura Intensiva. Informazzjoni bħal funzjoni attwali tal-kliwi tiegħek, kif ukoll kundizzjonijiet mediċi passati, se tiġi miġbura għal dan il-għan.

L-identita tiegħek mhux ser tiġi rivelata bl-ebda mod, l-informazzjoni li ser tinġabar ser tinżamm anonima matul ir-riċerka u inti tista tieqaf milli tieħu sehem f’ din ir-riċerka meta trid.

Taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li timplimenta u tispeċifika aktar id-dispożizzjonijiet relevanti ta' limsemmi Regolament, għandek d-dritt li tikseb aċċess għal, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċerna lilek titħassar.

Grazzi bil-quddiem.

Information Letter for Legal Guardian/ Next of Kin

Dear legal guardian/ next of kin,

I am Deborah Louise Rayner, a pharmacist and a student reading for a Doctorate in Pharmacy. For the fulfilment of the requirements for the Doctorate Degree, I am working on a research project entitled “Pharmaceutical Service Development in Anaesthesia”. The research is being carried out under the supervision of Dr. Louise Grech and Prof. Anthony Serracino Inglott in collaboration with the Anaesthesia Department.

The purpose of this research is to develop pharmacy services to cover the Intensive Therapy Unit at Mater Dei Hospital.

This research involves the pharmacist-researcher contributing to the safe and optimum use of the medications used in the management of your guardianee/ relative’s condition. This is done in collaboration with the doctors and nurses taking care of your guardianee/ relative at the Intensive Therapy Unit. Information such as current renal function as well as past medical history will be collected in order to be able to do so.

The identity of your guardianee/ relative will not be revealed in anyway, any information collected will be kept anonymous throughout the research and you and your guardianee/ relative may quit the study at any time.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Thank you in advance.

Ittra ta’ informazzjoni għat-tutur legali/ qarib

Għażiż tutur legali/ qarib,

Jiena Deborah Louise Rayner, spiżjara u studenta tal-kors tad-dottorat tal-farmaċija. Sabiex jiġu sodifatti r-rekwiżiti tal-lawrja ta’ dottorat, jiena qiegħda naħdem fuq riċerka intitolata “Żvilupp ta’ servizz farmaċewtiku fl-anestesija”. Din ir-riċerka qiegħda issir taħt is-superviżjoni tad-Dott. Louise Grech u l-Professur Anthony Serracino Inglott flimkien mad-Dipartiment ta’ l-Anestesija.

L-għan ta’ din ir-riċerka huwa l-iżvilupp ta’ servizzi tal-farmaċija sabiex tiġi koperta s-sala tal-Kura Intensiva ġewwa l-isptar Mater Dei.

Din ir-riċerka tinvolvi lill-ispiżjara riċerkatriċi tikkontribwixxi għall-użu sikur u l-aħjar tal-mediċini li jintużaw fil-ġestjoni tal-kundizzjoni tal-persuna li minnha inti responsabbli/ qarib. Dan ser isir b’ kollaborazzjoni mat-tobba u l-infermiera li jieħdu ħsieb lill-persuna li minnha inti responsabbli/ qarib ġewwa s-sala tal-Kura Intensiva. Informazzjoni bħal funzjoni attwali tal-kliwi tal-pazjent, kif ukoll kundizzjonijiet mediċi passati, se tiġi miġbura għal dan il-għan.

L-identita tal-persuna li minnha inti responsabbli/ qarib mhux ser tiġi rivelata bl-ebda mod, l-informazzjoni li ser tinġabar ser tinżamm anonima matul ir-riċerka u inti u l-persuna li minnha inti responsabbli/ qarib tistgħu tieqfu milli tieħdu sehem f’ din ir-riċerka meta trid.

Taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li timplimenta u tispeċifika aktar id-dispożizzjonijiet relevanti ta' limsemmi Regolament, għandek d-dritt li tikseb aċċess għal, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċerna lilek titħassar.

Grazzi bil-quddiem.

Consent Form for Patients

I, the undersigned certify that I am a Maltese citizen and am over eighteen (18) years of age. I have been asked to participate in a research study entitled 'Pharmaceutical Service Development in Anaesthesia'.

The purpose and details of the research have been explained to me by Deborah Louise Rayner and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator (Ms. Deborah Louise Rayner) to make the appropriate observations.

I understand that the results of this research may be used for medical or scientific purposes and that the results achieved from the research in which I am participating may be reported or published: however, I shall not be personally identified in any way, either individually or collectively, without my express written permission.

I am under no obligation to participate in this research and this is being done voluntarily.

I may withdraw from the research at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me.

I am not receiving any remuneration for participating in this study.

For any further details or queries, I may contact Deborah Louise Rayner on 79496191 or via email at deborah-louise.rayner.07@um.edu.mt

Signature of Patient _____

Name of Patient and ID number _____

Signature of Principal Investigator _____

Name of Principal Investigator and ID number _____

Signature of Supervisor _____

Date _____

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Formola tal-kunsens għall-pazjenti

Jiena, is-sottofirmat/a niċċertifika illi jiena ċittadin/a Malti u li għandi 'il fuq minn tmintax(18)-il sena.

L-għan u d-dettalji tar-riċerka ntitolata "Żvilupp ta' servizz farmaċewtiku fl-anestesija" spjegathomli Deborah Louise Rayner li wkoll iċċaratli xi mistoqsijiet li għamilt.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka (Ms. Deborah Louise Rayner) biex tagħmel l-osservazjonijiet illi hemm bżonn.

Jiena nifhem illi r-riżultati tar-riċerka jistgħu jintużaw għal skopijiet xjentifiċi u jista' jiġi ppubblikat rapport bil-miktub: jekk isir hekk b'ebda mod, ma nistgħa nkun identifikat/a, individwalment jew bħala parti minn grupp, mingħajr il-kunsens tiegħi bil-miktub.

Jiena m'għandi l-ebda obbligu li nieħu sehem f'din ir-riċerka u dan qed isir b'mod volontarju.

Jiena nistgħa, meta rrid, ma nkomplix nieħu sehem fir-riċerka, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk, jiena se nibqa nieħu l-kura li ssoltu tingħatali.

Jiena mhux qed nitħallas biex nieħu sehem f'din ir-riċerka.

Jekk ikolli xi diffikulta nista' nikkuntatja lil Deborah Louise Rayner fuq 79496191 jew bl-email fuq deborah-louise.rayner.07@um.edu.mt

Firma tal-pazjent/a _____

Isem tal-pazjent/a u Numru ta' l-ID _____

Firma tal-persuna responsabbli minn din ir-riċerka _____

Isem tal-persuna responsabbli minn din ir-riċerka u Numru ta' l-ID _____

Firma tas-superviżur _____

Data _____

Taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li timplimenta u tispeċifika aktar id-dispożizzjonijiet relevanti ta' l-imsemmi Regolament, għandek d-dritt li tikseb aċċess għal, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċerna lilek titħassar.

Consent Form for Legal Guardian/ Next of Kin

I, the undersigned certify that I am the legal guardian/ next of kin of _____ (ID number: _____) and I have the right to make decisions for my guardianee/ relative that reflect his/ her well-being.

The purpose and details of the research entitled 'Pharmaceutical Service Development in Anaesthesia' have been explained to me by Deborah Louise Rayner and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator (Ms. Deborah Louise Rayner) to make the appropriate observations.

I understand that the results of this research may be used for medical or scientific purposes and that the results achieved from the research in which my guardianee/ relative and I are participating may be reported or published: however, myself and my guardianee/ relative shall not be personally identified in any way, either individually or collectively, without my express written permission.

My guardianee/ relative and I are under no obligation to participate in this research and this is being done voluntarily.

My guardianee/ relative and I may withdraw from the research at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to my guardianee/ relative.

My guardianee/ relative and I are not receiving any remuneration for participating in this study.

For any further details or queries, I may contact Deborah Louise Rayner on 79496191 or via email at deborah-louise.rayner.07@um.edu.mt

Signature of Legal Guardian/ Next of kin _____

Name of Legal Guardian/ Next of kin and ID number _____

Signature of Principal Investigator _____

Name of Principal Investigator and ID number _____

Signature of Supervisor _____

Date _____

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

Formola tal-kunsens għat-tutur legali/ qarib

is-sottofirmat niċċertifika li jiena t-tutur legali/ qarib ta' _____ (Numru ta' l-ID: _____) u li jiena għandi dritt, għan-nom tiegħu/tagħha, illi nieħu deċiżżjonijiet għall-ġid tiegħu/tagħha.

ıu d-dettalji tar-riċerka ntitolata "Żvilupp ta' servizz farmaċewtiku fl-anestesija" spjegathomli Deborah Louise r, li wkoll iċċaratli xi mistoqsijiet li jien għamilt.

i l-kunsens tiegħi lill-persuna responsabbli minn din ir-riċerka (Ms. Deborah Louise Rayner) biex tagħmel ˈvazjonijiet meħtieġa.

nifhem illi r-riżultati tar-riċerka jistgħu jintużaw għal skopijiet xjentifiċi u jista' jiġi ppubblikat rapport bil-
ɔ: jekk isir hekk b'ebda mod, la jiena u lanqas il-persuna minnha jiena responsabbli/ qarib, ma nistgħu identifikati, individwalment jew bħala parti minn grupp, mingħajr il-kunsens tiegħi bil-miktub.

ı l-persuna li minnha jiena responsabbli/ qarib, m' għandna l-ebda obbligu li nieħdu sehem f'din ir-riċerka u ɛd isir b'mod volontarju.

ı l-persuna li minnha jiena responsabbli/ qarib nistgħu, meta rrid, ma nkomplux nieħdu sehem fir-riċerka, u ajr ma' nagħti raġuni. Jekk nagħmel hekk, il-persuna li minnha jiena responsabbli/qarib xorta jibqa'/ tibqa' -kura li ssoltu tingħatalu/a.

ı l-persuna li minnha jiena responsabbli/ qarib mhux qed nitħallsu biex nieħdu sehem f'din ir-riċerka.

kolli xi diffikulta nista' nikkuntatja lil Deborah Louise Rayner fuq 79496191 jew bl-email fuq deborah-rayner.07@um.edu.mt

tat-tutur legali/ qarib _____

at-tutur legali/ qarib u Numru ta' l-ID _____

tal-persuna responsabbli minn din ir-riċerka _____

al-persuna responsabbli minn din ir-riċerka u Numru ta' l-ID _____

tas-superviżur _____

_____

r-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li timplimenta u fika aktar id-dispożizzjonijiet relevanti ta' limsemmi Regolament, għandek d-dritt li tikseb aċċess għal, ɛġi, u fejn applikabbli titlob li d-data li tikkonċerna lilek titħassar.

Appendix 7

Pharmacy Patient Profile

SPTAR MATER DEI

Pharmacy Patient Profile

Patient Details

Profile No _____

Name	Surname	ID number	DOB	Age
Ward	Consultant	Weight (kg)	Height (m)	Body Surface Area (m^2)
Admission Date	Medical Diagnosis	Protocol	Central line Yes ☐ Type _____ No ☐	Enteral Tube Yes ☐ Size _____ No ☐ Type _____

Family History	Past Medical History and Drug History			
	Date	Condition	Medication	Dose and Frequency
ADR/ Sensitivities				

Developed by S. Falzon as part of the dissertation entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology' as partial fulfillment for the Doctorate of Pharmacy, 2017

Patient name: ID number:

Current Medications

Chemotherapy and related medications							
Phase	Course/Cycle	Medication	Days	Dates (dd/mm/yyyy)	Dose	Frequency and Time	Route

Current Medications

Other medications						
Start Date (dd/mm/yyyy)	Medication	Form	Dose	Frequency	Route	Stop Date (dd/mm/yyyy)

Parents or Legal Guardians				Cards	
Name	Surname	Address	Telephone/ Mobile No.	Schedule II card	☐
				Schedule V card	☐
				Drug Control card	☐
				None	☐

Patient name: ID number:

Patient name: ID number:

Pharmaceutical Care Issues

Date	Care Issue	Date	Action	Date	Outcome

Appendix 8

PCI Classification System

Category of PCI	Category Description	PCI	Pharmaceutical intervention	Outcome
1. Drug selection	The PCI relates to the drug selected	1.1 No drug treatment despite existing indication requiring management or prevention i.e. untreated actual or potential indication	1.1 Add drug as needed	- Pharmaceutical intervention accepted and implemented - Pharmaceutical intervention accepted and not implemented - Pharmaceutical intervention not accepted
		1.2 Inappropriate dosage form	1.2 Change dosage form	
		1.3 Incorrect strength	1.3 Prescribe the correct strength	
		1.4 Contraindication	1.4 Stop drug and prescribe an alternative	
		1.5 No indication for drug or indication no longer apparent	1.5 Stop unnecessary drug	
		1.6 Too many drugs prescribed for indication	1.6 Stop unnecessary drugs	
		1.7 Drug interaction	1.7 Depends on severity: If **contraindicated**-avoid combination. If **major**- consider therapy modification. If **moderate**- monitor therapy. If **minor**- no action needed.	
		1.8 Need for an additional drug to properly manage a condition (undertreated condition)	1.8 Add drug as needed	
		1.9 Ineffective drug	1.9 Stop ineffective drug and prescribe an alternative if indication still apparent	
		1.10 Non- adherence to protocol or guidelines	1.10 Adhere to protocol or guidelines	

		1.11 Other drug selection problem	1.11 Pharmaceutical intervention for other drug selection problem	
2. Dose selection	The PCI relates to the drug dose selected	2.1 Dose too low for patient's age, weight and indication and/or severity	2.1 Increase dose	
		2.2 Dose too high for patient's age, weight and indication and/or severity	2.2 Decrease dose	
		2.3 Other dose selection problem	2.3 Pharmaceutical intervention for other dose selection problem	
3. Dosage regimen selection	The PCI relates to the dosage regimen selected	3.1 Dosage regimen too frequent	3.1 Decrease dosage regimen frequency	
		3.2 Dosage regimen not frequent enough	3.2 Increase dosage regimen frequency	
		3.3 Other dosage regimen selection problem	3.3 Pharmaceutical intervention for other dosage regimen selection problem	
4. Duration of treatment	The PCI relates to the duration of treatment selected	4.1 Duration of treatment too short	4.1 Increase duration of treatment	
		4.2 Duration of treatment too long	4.2 Decrease duration of treatment	
		4.3 Other duration of treatment	4.3 Pharmaceutical intervention for other duration of treatment	
5. Unwanted drug effects	The PCI relates to the occurrence of unwanted signs or symptoms that may be attributed to a drug	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) [ADR- an undesired occurrence that results from taking a drug correctly SE- an undesired effect when drug is administered regardless of the dose]	5.1a. Treatment options for the ADR/SE and/or 5.1b. Stop drug and never re- challenge. Consider an alternative or 5.1c. Continue drug but decrease subsequent doses or 5.1d. If ADR/SE less serious than the effects of the disease itself, continue the drug at same dose or 5.1.e Stop drug and try re- challenging with pre- medications	

		5.2 Toxicity (Overdose)	5.2a. Stop drug, evaluate situation and consider treatment options for toxicity	
		5.3 Other problem related to unwanted drug effects	5.3 Pharmaceutical intervention for other problem related to unwanted drug effects	
6. Dispensing	The PCI relates to the dispensing process	6.1 Wrong drug dispensed	6.1 Stop from administering a drug that has been dispensed wrongly. Check that the correct drug has been prescribed and/or ordered and fill in an incident report	
		6.2 Wrong strength dispensed	6.2 Stop from administering a drug that has been dispensed wrongly. Check that the correct strength has been prescribed and/or ordered and fill in an incident report	
		6.3 Wrong formulation dispensed	6.3 Stop from administering a drug that has been dispensed wrongly. Check that the correct formulation has been prescribed and/or ordered and fill in an incident report	
		6.4 Prescribed drug not available in the required strength	6.4 If it's not a problem to administer dose using available strength, use available strength. If not possible, prescribe an alternative	
		6.5 Prescribed drug not available in the required form	6.5a If it's not a problem to administer dose using available form, use available form as is or 6.5b Available dosage form to be altered by patient/ carer just before administration. Off-licence to be filled in by prescribing doctor or	

			6.5c Extemporaneous compounding. Off-licence to be filled in by prescribing doctor or 6.5d Alternative treatment	
		6.6 Prescribed drug not available at all	6.6 Prescribe an alternative	
		6.7 Other dispensing problem	6.7 Pharmaceutical intervention for other dispensing problem	
7. Compliance	The PCI relates to the way the drug is being given to the child by the parent or the legal guardian once discharged from hospital	7.1 Non-compliance	7.1a Verbal drug counselling to parents or legal guardians including provision of written information to resolve compliance issues. Refer to prescriber when necessary and/or 7.1b Suggest an alternative to the clinician	
		7.2 Other compliance problem	7.2 Pharmaceutical intervention for other compliance problem	
8. Drug administration	The PCI relates to the way the drug is administered by a healthcare professional (clinician or nurse)	8.1 Inappropriate timing of administration and/or dosing intervals	8.1 Discuss with prescriber. If ok, administer drug at the right time	
		8.2 Drug under- administered	8.2 Discuss with prescriber. If ok, correct the frequency of drug administration	
		8.3 Drug over- administered	8.3 Discuss with prescriber. If ok, correct the frequency of drug administration	
		8.4 Drug not administered at all	8.4 Discuss with prescriber. If ok, start administering a drug	
		8.5 Wrong drug administered	8.5 Stop the administration of a wrong drug. Discuss with prescriber.	

		8.6 Wrong dilution	8.6a If drug not administered yet, discard diluted product and prepare a fresh supply as per product information. 8.6b If any doses have already been administered, discuss with clinician, monitor the patient and correct dilution for subsequent doses.	
		8.7 Inappropriate infusion rate	8.7 Correct the rate of dose administration of the parenteral drug. Discuss with clinician.	
		8.8 Inappropriate route	8.8 Change route	
		8.9 Other drug administration problem	8.9 Pharmaceutical intervention for other drug administration problem	
9. Monitoring	The PCI relates to the need for monitoring the efficacy or adverse effects of a drug or disease	9.1 Monitoring need	9.1 Undertake necessary laboratory and non- laboratory monitoring	
		9.2 Other monitoring problem	9.2 Pharmaceutical intervention for other monitoring problem	
10. Counselling	The PCI relates to the need for counselling to parents or legal guardians about their child's drug/s or disease state/s. Information can be requested by the parents/ legal guardians or else the pharmacist identifies	10.1 Counselling need to parents or legal guardians	10.1 Provision of drug and disease-related information to parents or legal guardians including written information	
		10.2 Other patient related counselling problem	10.2 Pharmaceutical intervention for other patient related counselling problem	

	the need for the provision of the information.			
11. Seamless Care	The PCI relates to the need to ensure smooth transition of patients from secondary to primary care.	11.1 Counselling need to parents or legal guardians on the procedure to obtain medicine stocks upon discharge	11.1 Verbal/ written counselling to parents or legal guardians on bureaucratic procedures to be entitled and obtain stock	
		11.2 Other seamless care problem	11.2 Pharmaceutical intervention for other seamless care problem	

Definitions

Pharmaceutical Care Issue (PCI): An issue which is related to drug therapy and which is addressed by the pharmacist. The issue can be a drug related problem, a patients' need for information, support or other pharmaceutical service.

Pharmaceutical Intervention (PI): Action or recommendation to be proposed by the pharmacist in order to solve the PCI

Outcome: Status of the action or recommendation; whether it has been accepted or not and whether it was implemented

Appendix 9

Publications

Abstract entitled 'The Role and Value of a Ward Based Pharmacist in the Intensive Care Unit: The Critical Care Physicians' and Nurses' Perceptions' submitted and accepted for poster presentation at the 25th EAHP Annual Congress 2021 held from 23 to 28 March 2021.

4CPS-399 EVALUATING CLINICAL PHARMACY SERVICES ON AN INTENSIVE CARE UNIT: A SATISFACTION SURVEY

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10.1136/ejhpharm-2021-eahpconf.231

Background and importance Clinical pharmacists involved in critical care are well described in the literature. Additionally, a computerised physician order entry (CPOE) system reduces the incidence of medication errors, especially when it allows pharmacy validation. Despite these potential benefits, integrating new members and implementing new tools in an ICU team is a complex process and it can influence overall staff satisfaction.

Aim and objectives To assess the satisfaction of ICU doctors and nurses with the new critical care pharmacist role during the last 2 years and the new CPOE 1 year after implementation.

Material and methods A cross sectional study was carried out in September 2020 in an 18 bed medical/surgical adult ICU in a second level hospital. A 5 point Likert scale based survey (5=highest level of agreement) was electronically distributed to ICU staff. The surveys contained 17 Likert questions in three sections: pharmacist integration on ICU team; pharmacist role; and CPOE. The results were expressed as a percentage of the maximum score (a value ≥4). Demographic data and sections for comments were included. Cronbach's alpha coefficient was performed to assess reliability. Data analysis was conducted using the SPSS statistical software 20.0.

Results 31/72 nurses and 15/18 doctors completed the survey (42% vs 83.3% response rate). Regarding the pharmacist's integration, 100% of doctors versus 22.6% of nurses knew the pharmacist by name and 100% of doctors versus 71% of nurses considered pharmacists accessible professionals. Both considered the pharmacist as an important liaison between the pharmacy and ICU (100% vs 96.8%). Doctors were satisfied with statements such as timely resolution to drug related questions (100% vs 67.7% of nurses), ICU–pharmacy relationship has improved since the pharmacist joined (100% vs 61.3%) and overall satisfaction with the pharmacist (100% vs 64.5%).

Concerning CPOE: pharmaceutical validation makes the CPOE safer (80% vs 41.9%), taking into account the pharmacist's advice (90% vs 96.7%), and CPOE presents more advantages than disadvantages (80% vs 61.3%). Cronbach's alpha statistical analysis indicated that the survey's reliability was high (nurses 0.77, doctors 0.89).

Conclusion and relevance Physicians appreciated the clinical pharmacist's work and its impact on daily clinical practice. Nurses gave lower scores, but nevertheless their role as an intermediary was highly valued. The evaluation of the new CPOE was satisfactory, however it is necessary to focus on nurses´ needs to improve the pharmacist service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-400 THE ROLE AND VALUE OF A WARD BASED PHARMACIST IN THE INTENSIVE CARE UNIT: THE CRITICAL CARE PHYSICIANS' AND NURSES' PERCEPTIONS

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Background and importance Patients hospitalised within the intensive care unit (ICU) are prescribed almost twice as many medications compared with patients hospitalised within other areas of the hospital. This increases the likelihood of possible drug interactions as well as medication errors.[1]

Aim and objectives The aim of this study was to assess the expected role and perceived value of a ward based pharmacist in the ICU, as deemed by critical care physicians and nurses at an acute general teaching hospital prior to the introduction of the service.

Material and methods The pre-service questionnaires developed by Portelli (2018), targeting nurses and physicians, respectively, were adapted to portray the requirements of a critical care setting and validated for content by an expert panel. The validated tools were disseminated among ICU based physicians and nurses. The responses obtained were analysed descriptively and by content analysis.

Results The vast majority of nurses gave a score of 4 or higher on a 5 point Likert scale (with 5=essential) when asked whether they felt there was a need for an inhouse pharmacist in the ICU. Similarly, the majority of physicians gave a score of 4 or higher on the same 5 point Likert scale when posed the same question.

Conclusion and relevance The delivery of direct, proactive, patient centred care by pharmacists has been correlated with both actual and perceived improvement in patient outcomes.[2] [3] Most of the respondents were positive that the presence of a pharmacist in the ICU would improve the outcomes for patient safety and better quality care.

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Conflict of interest No conflict of interest

4CPS-401 TELEPHARMACY PROGRAMME IMPLEMENTATION DURING THE COVID-19 PANDEMIC

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Background and importance The COVID-19 pandemic has created a new scenario for the dispensing of hospital drugs.

THE ROLE AND VALUE OF A WARD BASED PHARMACIST IN THE INTENSIVE CARE UNIT: THE CRITICAL CARE PHYSICIANS' AND NURSES' PERCEPTIONS

Abstract Number: 4CPS-400

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BACKGROUND AND IMPORTANCE

Patients hospitalised within ICUs are prescribed twice as many medications in comparison to patients hospitalised within other areas of the hospital. This increases the likelihood of possible drug therapy problems such as drug interactions as well as medication errors impacting safety and cost.[1]

AIM AND OBJECTIVES

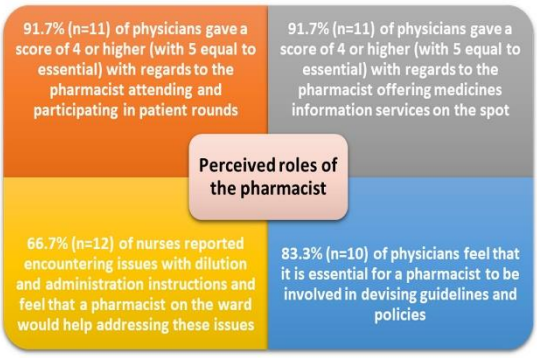
To capture the expected role and perceived value of a ward based pharmacist in the ICU as deemed by the critical care physicians and nurses at an acute general teaching hospital prior to the introduction of the service.

MATERIALS AND METHODS

- The Pre-Service Questionnaires developed by Portelli[2], targeting nurses and physicians respectively, were adapted to gather the requirements of a critical care setting.
- The questionnaires were validated for content by an expert panel consisting of two Medicines Information pharmacists, two Quality Assurance pharmacists and the author of the original tools.
- Questions asked consisted of a mix of open ended, closed ended and 5-point Likert scales.
- The validated tools were disseminated among ICU based physicians and nurses.
- The questionnaire took not more than ten minutes to complete and consisted of 25 questions for physicians and 27 questions for nurses.

RESULTS

- 12 physician responses out of 20 disseminated and 18 nurse responses out of 45 disseminated
- 73% of the respondents were females
- Physicians: 16.7% were consultants, 41.7% were resident specialists and 41.7% were higher specialist trainees
- Nurses: 28% have been working at the ICU for 1 to 5 years, 22% for 6 to 10 years, 22% for 11 to 15 years and 28% for 16 years and over



CONCLUSION AND RELEVANCE

The study highlights the positive response of critical care physicians and nurses towards the presence of a pharmacist at the ICU. This would improve the outcomes for patient safety and better quality care.

The delivery of direct, proactive, patient-centered care by pharmacists has been correlated with both actual and perceived patient outcome improvement.[3,4]

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