DEVELOPMENT OF A PHARMACEUTICAL CARE MODEL WITHIN PAEDIATRIC ONCOLOGY

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

SEPHORAH FALZON

Department of Pharmacy

University of Malta

2018

Author’s declaration

Dedicated to all the young warriors

&

doctors and nurses caring for them at Rainbow Ward.

Acknowledgements

I would like to thank my supervisor Professor Lilian M Azzopardi and co-supervisor Dr Louise Grech for their invaluable guidance and support throughout the Doctorate in Pharmacy course. My sincere gratitude goes to Dr Victor Calvagna, Dr Nathalie Galea, Dr Hermione Andrejevic, Dr Mairi Vella, Mrs Angele Cuschieri and all the other doctors and nurses at Rainbow ward. It was an honour for me to have had the opportunity to work with them. My experience at Rainbow ward was one which I will cherish forever.

I am grateful to the panel of experts who kindly accepted to offer their time to help me with the validation of the tools developed as part of the research. I would also like to thank Professor Liberato Camilleri for helping me with the statistics.

A note of gratitude goes to my friends for their continuous support and encouragement. Finally, I would like to thank my parents, Adrian, Nathanael, Anna, Rebecca, Miguel, my aunt Josephine and my grandmother Carmena for their love, patience and support throughout my studies.

Abstract

A high intensity ward such as a paediatric-adolescent cancer ward (PAW) is a setting that requires a pharmacist to participate in direct patient care. The aim of this research was to develop, implement and evaluate a Pharmaceutical Care Model at the PAW at Sir Anthony Mamo Oncology Centre. During Phase I of the research, the PAW was attended to observe the care practice delivered to the patients at the ward. A Gap-Finding Tool based on clinical pharmacy practice standards put forward by the American College of Clinical Pharmacy, the European Association of Hospital Pharmacy and the Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Clinical Pharmacy was developed to compare local care practice to international care practices and enable the identification of gaps. Subsequently, a Pharmaceutical Care Model was developed, focusing on covering the gaps identified. The gaps identified and implemented included participation in interdisciplinary care through attendance to ward rounds and meetings, participation in the provision of medicines information to healthcare professionals and parents and coordination of patient access to treatment. Services which were optimised included the discharge process by developing a Discharge Medication Guide for parents, the documentation process by developing a Pharmacy Patient Profile and the current medication management process by reviewing prescriptions and treatment charts, ensuring that they are clear and valid and that the prescribed drugs are appropriate. Two questionnaires, one for parents and one for healthcare professionals were developed to assess their satisfaction and perceived benefits of having a clinical pharmacist as part of the interdisciplinary team. A total of 545 pharmaceutical care issues (PCIs) were identified during 325 pharmaceutical care sessions provided over 8 months. The identified PCIs were classified according to an innovative classification system based on

categorisations developed by the Pharmaceutical Care Network Europe Foundation and the Pharmaceutical Society of Australia. The most common PCI categories were counselling (N=147), drug selection (N=129), dose selection (N=105) and monitoring (N=84). For every PCI identified, a pharmaceutical intervention was proposed by the pharmacist and 95% of these pharmaceutical interventions were accepted and implemented. The results of the questionnaires provided evidence that as service users, parents, clinicians and nurses experienced high satisfaction with the pharmaceutical services offered by the pharmacist. This research reflects the relevant contribution of the pharmacist at ward level within the interdisciplinary healthcare team through the implementation of a novel Pharmaceutical Care Model which optimizes patient care. The model adds to the continuous improvement of the standard of care provided to patients attending the paediatric oncology unit at Sir Anthony Mamo Oncology Centre.

Keywords: clinical pharmacy, paediatric oncology, pharmaceutical care, pharmaceutical care issues

Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

ACCP: American College of Clinical Pharmacy

ADR: Adverse drug reaction

DDA: Dangerous drug*

EAHP: European Association of Hospital Pharmacists

HCP: Healthcare professional

PAW: Paediatric-Adolescent Cancer Ward

PCIs: Pharmaceutical Care Issues

PCNE: Pharmaceutical Care Network Europe

PCP: Pneumocystis Carinii Pneumonia

SAMOC: Sir Anthony Mamo Oncology Centre

SHPA: The Society of Hospital Pharmacists of Australia

UREC: University of Malta Research Ethics Committee

***** According to the legal framework in Malta

Note: Parents or legal guardians: For the purpose of this research, the term parents also refers to legal guardians as required.

CHAPTER 1
INTRODUCTION

1.1 Paediatric cancer

In the paediatric population, cancer is rare with an overall worldwide incidence rate varying between 50 and 200 per million children per year[1,2] (Steliarova-Foucher et al, 2017). This represents less than 1% of all cancers diagnosed each year.[3] Despite being rare, it is the second most common cause of mortality in children in developed countries[4] (Kaatsch, 2010).

Over the past 20 to 30 years, survival rates for paediatric cancer have improved significantly[3] (MacDonald, 2010). For Malta, the 5- year survival rate for all paediatric cancers combined diagnosed between 2000 and 2007 was 83%. This value was amongst the highest compared to other European countries. Specifically, for acute lymphoblastic leukaemia, Malta had a 5- year survival rate which was higher than 90%. This was higher than the European mean (Gatta et al, 2014). The decline in mortality for most paediatric cancers reflects improvements in treatments namely surgery, radiation, chemotherapy and supportive care as well as high levels of multicentre collaborations and participation in clinical trials (Calvagna, 2003; Hudson et al, 2015; Siegel et al, 2018). For Malta, the longstanding collaboration with the British National Health Service, whereby patients requiring further specialized treatment which is not available locally are referred to

[1] Stewart BW, Wild CP, editors. World Cancer Report 2014. Lyon: International Agency for Research on Cancer; 2014.
[2] International Agency for Research on Cancer. Latest data show a global increase of 13% in childhood cancer incidence over two decades [Internet]; 2017 [cited 2018 May 30]. Available from: https://www.iarc.fr/en/media-centre/pr/2017/pdfs/pr251_E.pdf.
[3] American Cancer Society. Key Statistics for Childhood Cancers [Internet]; 2016 [cited 2018 May 30]. Available from: https://www.cancer.org/cancer/cancer-in-children/key-statistics.html.
[4] International Agency for Research on Cancer. International Childhood Cancer Day: Much remains to be done to fight childhood cancer [Internet]; 2016 [cited 2018 May 30]. Available from: http://www.acco.org/wp-content/uploads/2016/02/pr241_E.pdf.

oncology centres in the United Kingdom has been crucial and is one of the reasons why Malta has such good outcomes and cure rates (Gatta et al, 2014).

The types of cancers that develop in children and adolescents differ from those that develop in adults[5] (Calvagna, 2003; MacDonald, 2010; Murphy et al, 2013). They tend to occur in different parts of the body to adult cancers and respond differently to treatment.[6] Cure rates are much higher than for most adult cancers.[6] The largest diagnostic groups in childhood are leukaemias, the most common being acute lymphoblastic leukaemia, tumours of the brain and central nervous system and lymphomas (Schmidt, 1998; MacDonald, 2010). The spectrum of the disease differs between children and adolescents. When compared to the younger age groups, in adolescents, leukaemias are less common but carcinomas and germ-cell tumours predominate (Kaatsch, 2010).

The International Classification of Childhood Cancer classifies the types of cancers seen in children into twelve major groups. These are leukaemias, myeloproliferative and myelodysplastic diseases; lymphomas and reticuloendothelial neoplasms; central nervous system and miscellaneous intracranial and intraspinal neoplasms; neuroblastoma and other peripheral nerve cell tumours; retinoblastoma; renal tumours; hepatic tumours; malignant bone tumours; soft tissue and other extraosseous sarcomas; germ-cell tumours, trophoblastic tumours and neoplasms of gonads; other malignant epithelial neoplasms and malignant melanomas and other unspecified neoplasms (Steliarova-Foucher et al, 2005).

[5] American Cancer Society. What Are the Differences Between Cancers in Adults and Children? [Internet]; 2016 [cited 2018 May 30]. Available from: https://www.cancer.org/content/cancer/en/cancer/cancer-in-children/differences-adults-children/.

[6] Children's Cancer and Leukaemia Group. Childhood cancer [Internet]; 2018 [cited 2018 May 30]. Available from: http://www.cclg.org.uk/Childhood-cancer.

For the purpose of this research, the patients' diagnoses are classified into haematological cancers; solid cancers and other conditions which are not cancer but are treated with chemotherapy or require a bone marrow transplant. If one had to classify patients' diagnoses by specific cancer types or according to the International Classification of Childhood Cancer, there would have been diagnoses for which there was only a single patient. The focus of this research was not on the diagnoses but the emphasis lied within the development of a pharmaceutical care model which ensures safety, quality and efficacy of the pharmacotherapy used.

1.1.1 Etiology of paediatric cancer

In contrast to most cancers in adults, the etiology of most cancers in children and adolescents is unknown (Murphy et al, 2013; O'Neill et al, 2015). Possible risk factors have been studied and for each type of cancer, the risk factors can be of known, suggestive, limited or no conclusive evidence (Ries et al, 1999).

Factors linked to childhood and adolescent cancers include demographics, namely age, gender (more common in males than in females) and ethnicity; ionizing and non-ionizing radiation exposure; chemical carcinogens exposure (prior chemotherapy, pesticides, parental smoking, parental alcohol and illicit drug use); advanced parental age; inadequate maternal diet during pregnancy; structural birth defects; low and high birth weight; genetic factors; infections caused by certain viruses; immunodeficiency and medical conditions (Schmidt, 1998; Ries et al, 1999; O'Neill et al, 2015; Belson et al, 2007; Spector et al, 2015).

1.1.2 Epidemiology of paediatric cancer in Malta

According to the National Statistics Office, a total of 201 new cases of cancer in children aged 0-14 years were registered between 1993 and 2007. Out of this total, 119 were males and 82 were females. The average number of cases per year was about 14. Over the same time period, the most common type of cancer occurring in children up to the age of 14 was leukaemia (32.3%). Lymphomas and tumours occurring within the central nervous system (brain and spine) amounted to 12% and 18% of all malignancies respectively in this age group. Other tumours which occurred to a lesser extent were sympathetic nervous system tumours (neuroblastoma and ganglioneuroblastoma), retinoblastoma, renal tumours, malignant bone tumours, soft tissue tumours, germ-cell tumours and carcinomas. The carcinomas were the least common (2%).[7]

Statistics for new cases of cancer in children aged 0-14 years registered between 1989 and 2004 were issued by the Malta National Cancer Registry in November 2005. In addition to children aged 0-14 years, this report also included statistics for adolescents aged 15- 19 years old. It was noted that leukaemias, lymphomas, central nervous system tumours, sympathetic nervous system tumours, retinoblastoma, renal tumours, malignant bone tumours and soft tissue sarcomas appeared predominantly in the 0-14 year age group whereas carcinomas such as thyroid carcinomas and malignant melanomas and gonadal neoplasms appeared predominantly in the 15-19 year age group.[8] This pattern is in agreement with that discussed by Kaatsch in 2010.

[7] Children 2010 [Internet]. Valletta: National Statistics Office; 2010 [cited 2018 May 30]. Available from: https://nso.gov.mt/en/publicatons/Publications_by_Unit/Documents/C1_Living_Conditions_and_Culture_Statistics/Children_2010.pdf.

[8] Malta National Cancer Registry- Department of Health Information. Childhood Cancers [Internet]; 2005 [cited 2018 May 30]. Available from: https://health.gov.mt/en/dhir/Documents/childhood_cancers.pdf.

1.2 Complexity of pharmacotherapy in cancer patients

The pharmacotherapy of cancer is very complex. This is because it integrates multiple medications, most of which are high alert medications. These include chemotherapy, supportive care medications and medications for the management of co-morbidities (Liekweg et al, 2004). The complex pharmacotherapy carries a high risk of potentially serious patient safety issues including serious medication errors (Erdlenbruch et al, 2002). The consequences of such issues can not only be irreversible and interfere with the patient's health outcomes and reduce the patient's quality of life but can sometimes result in death (Liekweg et al, 2004; Viktil et al, 2008). A potentially serious patient safety issue in cancer patients is the wrong administration of chemotherapy drugs. Depending on the type of cancer and the protocol employed for its management, chemotherapy drugs can be administered by different routes of administration (e.g. intravenous, intrathecal and intramuscular) in various doses (e.g. standard versus high) over various periods of time (e.g. bolus versus continuous intravenous infusion) (Ramadaniati et al, 2016). Some chemotherapy agents can be safely given by one route but not by another (Ramadaniati et al, 2016). The more complex the drug regimen, the higher is the risk of side effects, drug interactions and medication misadventures (Liekweg et al, 2004; Cehajic et al, 2015).

1.2.1 The case of paediatrics suffering from cancer

Paediatric cancer patients have special pharmaceutical care needs (Tuffaha and Abdelhadi, 2012). Drug therapy / disease management of cancer in this patient cohort is challenging for multiple reasons. As in the case of adults, cancer management integrates multiple medications. However, children have unique characteristics when compared to

adults. The wide variation in size from infancy through adolescence and the associated developing physiological processes affect the drugs' pharmacokinetics (absorption, distribution, metabolism and excretion) and pharmacodynamics (Ramadaniati et al, 2016). In the child suffering from cancer, this will lead to varying levels of exposures and clearance of chemotherapy and other medications, hence, in difficulty to predict efficacy and toxicity. It also leads to the need for frequent individual dosing calculations (Ramadaniati et al, 2016). To meet the need of small doses, in these patients, dosage formulations are often cut, crushed and dissolved by the parents or extemporaneously compounded (Walsh et al, 2009; Ramadaniati et al, 2016). The process from selection and prescribing to monitoring chemotherapy and related medications is very complex. These challenges make paediatric cancer patients a high-risk patient population (Delpeuch et al, 2015; Ramadaniati et al, 2016).

Clinical pharmacists possess specialized knowledge and skills about medications and their role in cancer, making them essential interdisciplinary cancer team members (Defoe et al, 2018). In collaboration with other healthcare professionals (HCPs), they are in an ideal position to provide high- quality evidence- based pharmaceutical care to the young patient suffering from cancer, including initial and subsequent therapeutic management, supportive care and survivorship (Tuffaha and Abdelhadi, 2012; Holle and Michaud, 2014; Leveque et al, 2014; Ma, 2014; Delpeuch et al, 2015; Farias et al, 2016; Holle et al, 2016). Clinical pharmacists play a pivotal role in maximizing the benefits of the complex pharmacotherapy involved and minimizing its toxicities, ensuring that the drugs are utilized to their fullest therapeutic potential (Kaboli et al, 2006; Valgus et al, 2011; Mancini, 2012; Bhatt-Mehta et al, 2012; Lin et al, 2015).

1.3 Pharmaceutical care model in paediatric oncology

When a pharmaceutical care model is in place, clinical pharmacists work in collaboration with the patient and the patient's other HCPs to design, implement and monitor a pharmacotherapeutic plan which is tailor-made to each individual patient's requirements and optimizes patient's therapeutic outcomes (Hepler and Strand, 1990).

Problems identified by the clinical pharmacist during the provision of pharmaceutical care are referred to as pharmaceutical care issues (PCIs) (Krska et al, 2000; Krska et al, 2002). PCIs cover a wider spectrum of care issues when compared to drug-related problems (DRPs). DRPs are defined as events or circumstances involving drug therapy that actually or potentially interfere with desired health outcomes (van Mil, 2005; Hepler, 2010). PCIs include potential and actual DRPs as well as patients' need for information, support and other pharmaceutical services (Krska et al, 2002). There are various classification systems for categorising PCIs. Some examples of PCIs as categorsied by the PCNE classification for drug related problems version 8 (2017) and the DOCUMENT system include drug interaction, inappropriate dosage form, contraindication, dose too high, dose too low, drug use without indication, too many drugs prescribed for an indication and side effect[9] (Williams et al, 2012).

Development of an optimum pharmacotherapeutic plan involves the clinical pharmacist making an assessment of the paediatric patient's drug related needs, identifying PCIs, proposing ways to solve and prevent the identified PCIs and making follow-ups and

[9] Pharmaceutical Care Network Europe (PCNE) Foundation: PCNE Classification for drug related problems. V8.0. 2017. Available from: http://www.pcne.org/upload/files/215_PCNE_classification_V8-01.pdf.

medication monitoring to evaluate outcomes (Tulip and Campbell, 2001). Subsequently, this ensures the safe and optimum use of medications, improving or maintaining the paediatric patient's health-related quality of life (ASHP Statement on Pharmaceutical Care, 1993; Cipolle et al, 2004; Liekweg et al, 2004; Beavers, 2007; Viktil et al, 2008; ACCP, 2014).

In paediatric oncology, the therapeutic outcomes are to cure a patient's disease if possible, to eliminate or reduce patient's symptoms, to arrest or slow disease progression and to prevent disease or its symptoms namely mortality, adverse effects, severe organ toxicity and drug resistance (Liekweg et al, 2004). In oncology, some adverse effects are dose limiting and could even necessitate drug interruption. This implies that therapeutic success strongly relates to the extent of therapy-associated toxicity. An optimal pharmacotherapeutic plan should be developed to limit these side effects, thus achieving optimal treatment outcomes (Liekweg et al, 2004).

1.3.1 Medication management

In an article focusing on the role of the pharmacists in optimising the use of anticancer drugs in the clinical setting, Ma (2014) made reference to several critical steps that constitute safe and complete medication management. The steps are drug selection, prescribing, dosing, procurement, reconstitution, dispensing and storage, administration, monitoring and evaluation and education. In paediatric oncology, pharmacists have a significant role in every step. It may not be possible for a single pharmacist to provide services related to all the steps. However, it would be ideal to have a clinical pharmacist at ward level who ensures that the complex and regularly updated drug regimens are safe and optimal. The pharmacist on the ward will act as a coordinator to ensure that all the

critical steps are in place for the patient to receive treatment in an efficient manner within a pharmaceutical care model**.**

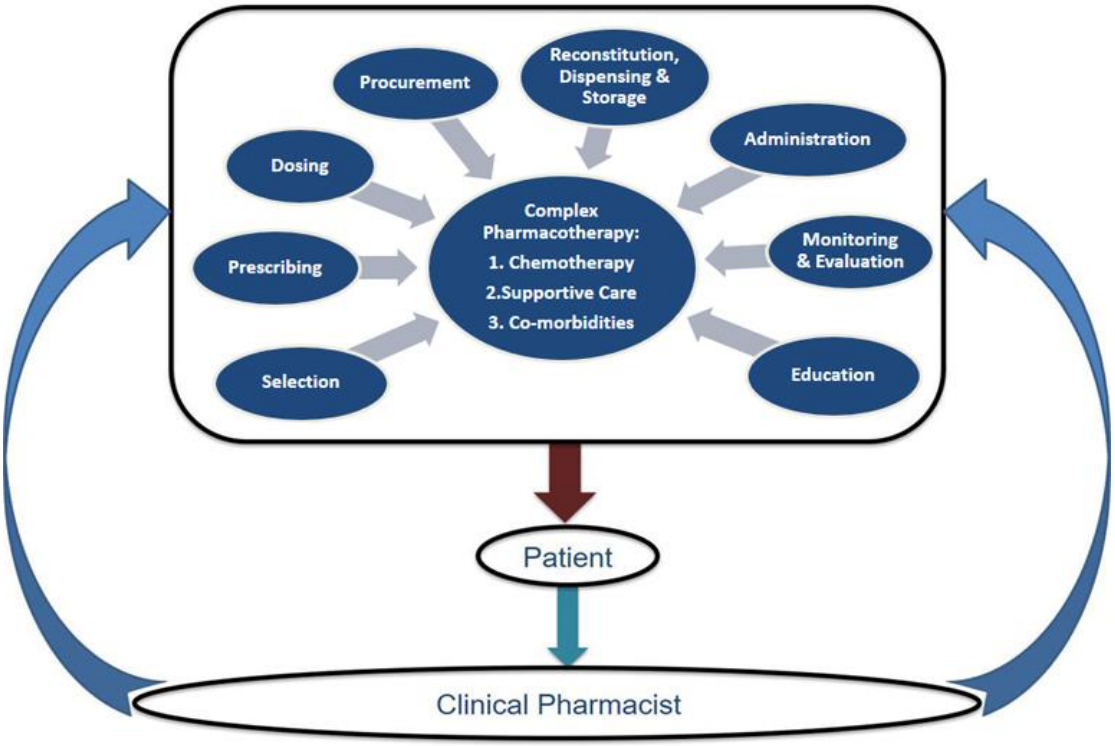


Figure 1.1: The medication management process and the pharmacist as co-ordinator

The diagram is adapted from Ma (2014). The clinical pharmacist is co-ordinating the 8 steps identified by Ma (2014) as critical within the pharmaceutical care model. Taking it a step further, the pharmacist is ensuring that the complex pharmacotherapy involving chemotherapy, supportive care and management of co-morbidities present within paediatric oncology are being taken into consideration at each step of the process such as drug selection, prescribing, dosing, procurement, reconstitution, dispensing and storage, administration, patient education and monitoring or follow-up.

1.3.1.1 Drug selection

Drug selection refers to the appropriate choice of medications for a specific indication (Pedersen et al, 2016; Maxwell, 2016). The clinical pharmacist aids in the selection of medications used for the management of paediatric cancer including chemotherapy,

supportive care medications and medications for the management of co-morbidities, taking into consideration several factors such as latest evidence regarding the drugs' efficacy as well as comparative efficacy and safety of therapeutic alternatives and organ dysfunction. The clinical pharmacist has the important role of obtaining and documenting a complete medication history on admission (SHPA Committee of Specialty Practice in Clinical Pharmacy, 2013, ACCP, 2014, EAHP, 2014). This helps to elucidate the patient's tolerance of current and previous medications. These are major factors that must be considered during drug selection (Ma, 2014).

1.3.1.2 Prescribing

Drug prescribing in paediatric oncology patients is prone to error as it incorporates the risks inherent to paediatrics and those in oncology (Davis, 2011; Ramadaniati et al, 2016; Hamel et al, 2017). "A prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or increase in the risk of harm when compared with generally accepted practice" (Dean et al, 2000).

The clinical pharmacist plays a major role in detecting and reducing paediatric prescribing errors by reviewing patients' files, prescriptions and treatment charts and checking for any possible PCIs including prescribing errors. Prescribing errors may arise due to drug interactions, inappropriate dosage forms, contraindications, duplications, ineffective drugs, drugs for which there is no indication, improper doses, improper dosage regimens, improper durations of treatment, drugs for which the patient has a documented clinically significant allergy, adverse drug reactions, illegible writing, abbreviated drug names and wrong units. This background justifies the importance of the presence of a clinical

pharmacist at ward level as a contribution to improving the quality and safety of care provided to children (Kaushal, 2001; Davis, 2011; Eisenhut et al, 2011; Fernandez-Llamazares et al, 2013; Ma, 2014; Alenezi et al, 2016; Fosbrook, 2016).

1.3.1.3 Dosing

In paediatrics, dosing errors are one of the most frequent prescribing errors (Kaushal, 2001; Guy et al, 2003; Wong et al, 2004; Fernandez-Llamazares et al, 2012; Porter et al, 201). In children, varying patient age which affects organ maturity, varying body size, possibly varying organ function and occurrence of toxicity over the course of therapy impact on chemotherapy dosing and overall complex chemotherapy treatment regimens (Alenezi et al, 2016). The latter also impact on the dosing of other medications which may be necessary such as anti- infective agents and supportive care medications. Also, in paediatrics, most drugs are used in an off- label manner, implying less clear dosing guidance (Ramadaniati et al, 2016).

These features make this patient cohort at high risk of dosing errors which may have potentially serious consequences, either via enhanced toxicity or via impaired disease control (Ma, 2004; Davis, 2011; Watts and Parsons, 2013). The clinical pharmacist plays a key role in supporting the complexity of prescribing as well as checking that drug doses are appropriate (Ma, 2004; SHPA Committee of Specialty Practice in Clinical Pharmacy, 2013, ACCP, 2014, EAHP, 2014). It is well documented in literature that the clinical pharmacist's intervention has a major impact in detecting and reducing dosing errors in paediatric patients (Wong and Gray, 1999; Dean et al, 2000; Prot-Labarthe et al, 2008; Davis, 2011; Tuffaha and Abdelhadi, 2012; Fernandez Llamazares et al, 2012; Bauters et al, 2014; Ma, 2014; Ramadaniati et al, 2016).

1.3.1.4 Procurement

Making a drug available for a patient is a necessary step. The clinical pharmacist at ward level has the role of trying to procure chemotherapy and other drugs which are not readily available on the hospital formulary (Ma, 2014).

1.3.1.5 Reconstitution, dispensing and storage

Proper storage of chemotherapy agents is crucial to ensure that they maintain their full dose activity. In the case of agents that are intended to be given via the parenteral route, proper storage is important both before as well as after reconstitution. The pharmacist plays a key role in ensuring proper storage of chemotherapy agents, until the drug reaches the patient. Pharmacists are also responsible for the preparation and dispensing of chemotherapy agents. In relation to the dispensing step, pharmacists make sure that the final drug product is properly labelled and contains all ancillary notification (Ma, 2014).

1.3.1.6 Administration

In paediatric oncology, administration of drugs remains a nursing mainstay, especially for parenteral drugs, however, nurses often ask for information to the clinical pharmacist on the proper administration of drugs such as the method of reconstitution and dilution, compatibility with multiple infusion lines, scheduling and sequencing, infusion rates, manipulation of concentrations in fluid restriction, viable intravenous access to avoid extravasation and supportive care in case extravasation occurs (Ma, 2014; Lin et al, 2015). Collaboration between the clinical pharmacist, the clinicians and the nurses is central to decrease potential medication errors, thereby increasing the safety and efficacy of the service offered to patients (Fisher et al, 2017).

Together with the nurses, the clinical pharmacist ensures that drugs are available at the ward for when they are due to be administered. For example, the clinical pharmacist makes sure that prophylactic steroid eye drops against conjunctivitis are ordered and available at the ward when a patient is due to take high-dose cytarabine (Ma, 2014).

Administration preparedness also includes prophylaxis in supportive care areas such as preventing nausea and vomiting. In collaboration with clinicians, the clinical pharmacist may establish protocols such as prophylaxis protocols that match levels of regimen emetogenicity in paediatric cancer patients (Ma, 2014).

Administration challenges can also occur with oral dosage forms. The clinical pharmacist has an important role in educating parents and ensuring compliance with medications at home because even tough cancer is a life-threatening disease, proper administration and compliance can still be an issue (Taylor et al, 2006; Ma, 2014).

1.3.1.7 Monitoring and evaluation

Monitoring and evaluation of drug therapy refers to the activities that occur after that the child receives a drug to evaluate response to drug therapy and adjust as required (Pedersen et al, 2016). Monitoring activities include but are not limited to monitoring therapeutic drug levels, monitoring laboratory and non- laboratory parameters (e.g. urea and electrolytes, liver function tests, haematology results and microbiology results and pulse rate, blood pressure, temperature, blood glucose level and patient weight), monitoring side effects, monitoring changes in organ function and clinical status, monitoring for medication errors and monitoring treatment outcomes (Ma 2014; Pedersen et al, 2016). Some examples of monitoring which are specific to paediatric oncology include monitoring the child's ability to tolerate hydration regimens, electrolyte abnormalities,

possible tumour lysis syndrome, occurrence of nausea and vomiting during chemotherapy administration and monitoring of blood parameters to ensure that they are within acceptable limits for the next cycle of chemotherapy (Ma, 2014).

By being physically present on the ward to join medical ward rounds and to perform clinical reviews, that is, reviewing of patient- specific clinical information and proposing interventions to make changes as required, the clinical pharmacist in collaboration with other members of the healthcare team can help to optimize drug therapy administered to children suffering from cancer (SHPA, 2013; Ma, 2014).

1.3.1.8 Education

Parent education is paramount to empower them in their child's care. Information and advice by the clinical pharmacist about chemotherapy and other medications should be provided throughout the treatment experience, especially prior to initiation, when there is a change in therapy, and prior to discharge from hospital (Donald et al, 2017). Drug information that should be provided includes but is not limited to the indication, the scheduling of the drugs as per protocol, side effects to be expected and their management, safe handling and administration, proper storage and details regarding further supply of medicines upon discharge.

Being the expert on drugs, the clinical pharmacist also provides medicines information to HCPs, mostly clinicians and nurses. This ensures the safe and optimum use of the complex pharmacotherapy used in paediatric cancer management (Taylor et al, 2006; Ma, 2014; Avery and Williams, 2015).

1.3.1.9 Other roles of the clinical pharmacist within paediatric oncology

Other important roles of the clinical pharmacist at ward level are attending and actively participating in interdisciplinary meetings; reviewing patient files, treatment charts and prescriptions to prepare accurate and comprehensive pharmacy patient profiles; be fully informed about current patient specific issues and participating in discharge planning (Sessions et al, 2010).

1.4 Rationale of the study

To date, within the paediatric oncology field in Malta, there is no clinical pharmacist working as an integral member of the interdisciplinary healthcare team to aid in the management of cancer in this patient cohort. This research aims at integrating clinical pharmacy knowledge and skills into the system of interdisciplinary care for the benefit of all children and adolescents suffering from cancer.

1.5 Aim and Objectives

The aim of this research was to develop, implement and evaluate a Pharmaceutical Care Model at the Paediatric-Adolescent Cancer Ward (PAW) at Sir Anthony Mamo Oncology Centre (SAMOC).

The objectives of the research were to:

i. Develop a Pharmaceutical Care Model that could be implemented for patients attending the paediatric oncology unit
ii. Develop a Gap- Finding Tool on ward-based pharmacy services, utilizing SHPA Committee of Specialty Practice in Clinical Pharmacy (2013), ACCP (2014) and

EAHP (2014) publications to subsequently implement a Pharmaceutical Care Model tailored to our local setting

iii. Compile documentation tools required to run the service namely, the Pharmacy Patient Profile and the Discharge Medication Guide for parents

iv. Develop a classification system for PCIs, the pharmaceutical interventions to be proposed by the pharmacist to resolve the PCIs and the outcomes

v. Compile a questionnaire for parents to evaluate their level of satisfaction and perceived benefits of the service offered by the clinical pharmacist at the PAW regarding their child's treatment

vi. Compile a questionnaire to assess doctors' and nurses' satisfaction and perceived benefits of having a clinical pharmacist on the ward as part of the interdisciplinary team

CHAPTER 2
METHODOLOGY

2.1 Setting of the Pharmaceutical Care Model

The research was carried out at the Paediatric-Adolescent Cancer Ward (PAW) at Sir Anthony Mamo Oncology Centre (SAMOC). The PAW, also known as Rainbow Ward, admits children and adolescents of up to 18 years of age suffering from cancer and other diseases that require chemotherapy treatment.

In Malta, children and adolescents fall under the Paediatric Department until they are 16 years of age. At the PAW, patients up to this age are treated by Consultant Paediatric Oncologists. For the purpose of this research, the pharmaceutical care service targeted in-patients and day-case patients suffering from cancer and other diseases that require chemotherapy or a bone marrow transplant up to this age. The pharmaceutical care service also targeted the parents (especially in terms of patient education) of this patient cohort as well as the healthcare professionals (HCPs) caring for them with respect to clinical decision making and medicines information services.

At the PAW, day- case patients attend by appointment every week either for review only, or for review and chemotherapy treatment which is due as per protocol. Some patients are sometimes referred to reference oncology centres abroad such as Great Ormond Street Hospital in United Kingdom for further specialized treatment which is not available locally.

2.2 Research design

The methodology of this research was divided into two phases. The first phase was the development phase and the second phase was the implementation phase. Prior to initiation of the research, approval by the University Research Ethics Committee (UREC) was granted (Appendix 1).

2.3 Phase I- Development of the Pharmaceutical Care Model

This phase was carried out between April and May 2017. During this phase, the PAW was attended three times per week to observe the care practice delivered to the patients at the ward. Six tools were developed and validated for the purpose of this research. These were:

1. The Gap- Finding Tool
2. The Discharge Medication Guide for parents
3. The Pharmacy Patient Profile
4. The parents' satisfaction questionnaire
5. The healthcare professionals' satisfaction questionnaire
6. The classification system for Pharmaceutical Care Issues

This phase gave the opportunity to the pharmacist- researcher to start integrating with other members of the healthcare team to subsequently offer a pharmaceutical care service

based on an interdisciplinary team approach and addressing the needs of the paediatric oncology unit.

2.3.1 Development of the tools used for the study

In this section, the development of the tools used for the study is discussed.

The Gap- Finding Tool

The Standards of Practice for Clinical Pharmacy Services put forward by the SHPA Committee of Specialty Practice in Clinical Pharmacy (2013), the ACCP (2014) and the EAHP (2014) respectively were used to compile the Gap-Finding Tool (Appendix 2). The tool had to be filled in by the pharmacist-researcher during Phase I of the research. It had the following purposes;

- Determining and documenting the roles of a ward- based clinical pharmacist
- In the absence of a ward-based clinical pharmacist at the PAW, determining what pharmacy services were being offered and by who and what pharmacy services were lacking
- Comparing the pharmaceutical care practice delivered to patients at the PAW with international care practices

The Gap- Finding Tool was presented in tabular format. It comprised of nine sections with the following headings: Accurate History, Current Medication Management, Clinical Review, Therapeutic Drug Monitoring, Medicines Information, Adverse Drug Reaction (ADR) Management, Participating in Interdisciplinary Care, Information for

Ongoing Care and Documentation. Each heading corresponds to a pharmacy service which should be provided at ward level.

Each heading consisted of related statements which had to be ticked with either a very good or a cross symbol, depending on whether or not at the time of the observation phase, these services were provided at the PAW. A 'Comment' section was added so that the pharmacist-researcher could document who was providing the service in the absence of the pharmacist services.

The developed Gap- Finding Tool was tested for content validity by a panel of experts. The panel of experts involoved two Consultant Paediatric Oncologists, a Drug Information Pharmacist, a Quality Assurance Pharmacist and two Nursing Officers. The experts were asked to examine the proposed Gap-Finding Tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 3). The questions assessed the relevance of the sections with the purpose of the Gap-Finding Tool and the relevance of the statements for each heading. The panel was asked to suggest any changes that they considered necessary and whether they would add any sections or statements. Relevant amendments were applied and the Gap-Finding Tool was then finalized.

The Discharge Medication Guide for parents

A Discharge Medication Guide for parents was developed as a tool to run the service (Appendix 4). Its purpose was to enhance compliance, knowledge as well as safe and effective use of discharge medications of children and adolescents suffering from cancer. It is a tool which can be shared as patients move across transitional settings thereby ensuring continuity of care. An English and Maltese version were developed. The tool

had to be filled in by the pharmacist-researcher upon discharge of the patient from hospital.

The guide developed was presented in tabular format and was designed to fit over a single landscape oriented A4 sheet of paper. Both sides of the A4 sheet were used. The table consisted of two sections, the patient details and the medication details sections. The patient details section included the name, surname and identity card number of the patient, any allergies that the patient suffered from, consultant caring for the patient and date of discharge. The medication details section included the name of the medicine, the dosage form, the time and dose of the medication, what the medicine is for, other comments and the start and stop date of the medication. The 'other comments' sub-section was added so that the pharmacist-researcher could communicate in writing important information regarding the medication which did not fit under other sub-sections of the table. A characteristic of the guide is that it allowed the pharmacist- researcher to be specific with regards to the timing of medication administration. The medication details section was started at the front and was reproduced at the back of the A4 sheet. At the bottom of the medication guide, two fields- 'compiled by' and 'contact number'-, were added so that the pharmacist-researcher could write her personal information and be contacted by the parents in case they had any queries or issues regarding the medication.

The Discharge Medication Guide was tested for face and content validity by the same panel of experts used for the Gap-Finding tool. Also, a medical illustration expert who provided feedback specifically on the format of the documentation tool validated the Discharge Medication Guide. The experts were asked to examine the proposed tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 5). The panel was asked about the relevance of the content, what they

thought about the user-friendliness of the guide and to indicate their level of agreement with the idea of compiling the tool in both English and Maltese. The panel was also asked to suggest whether they would change anything in the format and to indicate any sections which they would add, omit or change. Relevant amendments were applied and the Discharge Medication Guide for parents was finalised.

The Pharmacy Patient Profile

A Pharmacy Patient Profile specific to paediatric cancer patients was developed so that the pharmacist-researcher would have a tool to document patient-related specific information including PCIs (Appendix 6). Apart from enabling the pharmacist-researcher to be fully informed about patient specific issues, development of the profile meant that the pharmacist-researcher had a paper-based patient record or medication-review tool to refer to in case she was not present at the ward and was contacted about a specific patient. This profile was filled in for every patient admitted at the PAW either as a day case or as an inpatient and was updated during the patient's stay or visit at the PAW. It was filled in using patient notes, treatment charts, laboratory investigations and during interviews with the parents.

The Pharmacy Patient Profile was presented in tabular format and was designed to fit over a single landscape oriented A3 sheet of paper. Both sides of the A3 sheet were used. The profile consisted of five sections, that is, the patient details section, the history section, the current medications section, the contact details and cards section and the PCIs section. It was made sure to include the patient's name and identity card number on every page of the patient profile.

The patient details section (first section) included patient specific information, namely, the name, surname, identity card number, date of birth, age, ward, consultant, weight in kilograms, height in metres, body surface area in metres squared, admission date, medical diagnoses, protocol, presence or absence of a central line and presence or absence of an enteral tube. If a central line was present, the type needed to be documented. If an enteral tube was present, the size and the type needed to be documented. In practice, when the body surface area of the patient changes, the Pharmacy Patient Profile needs to be changed as well.

The history section (second section) included information about the history of the patient, namely, family history, adverse drug reactions or sensitivities, past medical history and drug history. The past medical history and drug history part was further subdivided into date (date of diagnoses of condition), condition, medication (to list any past medications used for therapeutic or prophylactic purposes) and the respective dose and frequency.

The third section related to the current medication section. It included information about the list of the medications that the patient was taking on admission and during the hospital stay. This section was further subdivided into 'Chemotherapy and related medications' as per protocol and 'Other medications'. Other medications included supportive care medications and medications for the management of co-morbidities. The table for sub-section 'Chemotherapy and related medications' was divided into eight columns with the following headings respectively: phase, course/cycle, medication, days, dates (dd/mm/yyyy), dose, frequency and time and route. The table for sub-section 'Other medications' was divided into seven columns with the following headings respectively: start date (dd/mm/yyyy), medication, form, dose, frequency, route and stop date (dd/mm/yyyy).

The fourth section included information related to the parents of the patients, namely their name, surname, address and contact number just in case they needed to be contacted whilst their child was not admitted as an inpatient at the hospital. This section also included information related to schedule V, schedule II and drug control cards which entitle patients for free medications including dangerous drugs (DDAs) on a long-term basis. The procedure at the PAW is that every patient diagnosed with cancer needs to have a schedule II or V card. This section enabled the pharmacist- researcher to document and ensure that all the patients had a schedule II or V card. If not, the pharmacist-researcher reminded the consultant to fill in the necessary application form so that the necessary card is issued for the patient. Settling issues related to such cards ensures that upon discharge, the parents can go to the community pharmacy of their choice to collect the medications that their child requires for free.

The fifth section was the PCIs section. This section was added so that the pharmacist-researcher would be able to document all of the patient- related PCIs, the action or recommendation proposed to resolve each PCI and the outcome. Three columns, one to document the date when the PCI was identified, another one to document the date when the recommendation was proposed and another one to document the date of the outcome, were added respectively to the section.

The same panel of experts evaluating the Discharge Medication Guide was used to provide feedback on the Pharmacy Patient Profile. The experts were asked to examine the proposed tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 7). Questions targeted the relevance of the content and were asked to suggest whether they would change anything in the format and to indicate

any sections which they would add, omit or change. Relevant amendments were applied and the Pharmacy Patient Profile was finalised.

The parents' satisfaction questionnaire

As service users, a questionnaire was developed for parents to assess their satisfaction and perceived benefits of the pharmaceutical service offered by the pharmacist at the PAW regarding their child's treatment (Appendix 8). The questionnaire was developed in both English and Maltese languages (assessed by a language professional) in order for parents to select their preferred language. The questions drawn up and included in this questionnaire were direct and concise. The questionnaire was administered after that at least, one discharge medication counselling session was provided to the parents.

The questionnaire contained eighteen questions and took ten minutes to complete. Questions one to eleven and fourteen to sixteen were based on a Likert scale (5 item), questions twelve, thirteen and seventeen were closed ended questions, with question twelve being also a contingency question. Question eighteen was an open-ended question. Questions one to five (Section A) dealt with the advice provided by the pharmacist about their child's medications, questions six to ten (Section B) dealt with the abilities of the pharmacist and question eleven (Section C) dealt with the overall service provided by the pharmacist. Parents had to indicate their level of satisfaction with the latter.

The aim of questions twelve and thirteen was to learn whether the parents who had visited the PAW beforehand had ever discussed their children's medications with a pharmacist at the ward.

In questions foureteen to sixteen, parents had to indicate their level of agreement with the following statements respectively:

- the pharmacist helped them to increase their knowledge about their child's medications
- the pharmacist made sure that they understood all the information that she provided about their child's medications and
- the service offered by the pharmacist was beneficial.

Question seventeen aimed at assessing whether the parents were willing to discuss their child's medications with a pharmacist during future visits at the ward. Finally, question eighteen was added to enquire whether the parents had any comments or recommendations for the improvement of the service provided by the pharmacist at the PAW.

The same panel of experts evaluating the Discharge Medication Guide and the Pharmacy Patient Profile was used to provide feedback on the questionnaire for parents. The experts were asked to examine the proposed tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 9). This process was necessary to determine if the wording of the questionnaire was easy to understand, if the content of the questionnaire was relevant so that it fulfils its aims, whether the format and length were adequate and whether it was user-friendly. Relevant amendments were applied.

After face and content validity testing, reliability testing was carried out by adopting the test-retest method. This was carried out by a control group consisting of ten parents of children attending the PAW. The parents were informed about the importance of the test-retest procedure for this research. The English version of the questionnaire was filled in first, and after a seven- day interval, they filled in the same questionnaire in Maltese. The

Kappa test was used to assess test-retest reliability for questions having a nominal scale while the Kendall tau test was used to assess test-retest reliability for questions having an ordinal scale (Likert scale). For both tests, the null hypothesis specifies that there is weak test-retest reliability and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that there is satisfactory test re-test reliability and is accepted if the p-value is less than the 0.05 criterion.

The Friedman test was used to compare mean rating scores provided to statements within the parents' satisfaction questionnaire. The mean rating scores range from 0 to 4 where 0 corresponds to very dissatisfied and 4 corresponds to very satisfied. The larger the mean rating score, the higher is the agreement. The null hypothesis specifies that the mean rating scores provided to the statements are similar and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean rating scores vary significantly between the statements and is accepted if the p-values is less than the 0.05 criterion.

The healthcare professionals' satisfaction questionnaire

As service users, a questionnaire for clinicians and nurses caring for children at the PAW was developed to assess their satisfaction and perceived benefits of having a clinical pharmacist as part of the interdisciplinary team (Appendix 10). Similar to the questionnaire for parents, the questionnaire for HCPs was developed as part of the validation of the pharmaceutical care model developed and implemented. The questionnaire was developed in English language only (assessed by a language professional). The questions drawn up and included into this questionnaire were direct and concise.

The questionnaire for HCPs contained six questions and took ten minutes to complete. In question one, the HCPs were asked to indicate their profession to differentiate between the medical physician position and nurses. Question two which was further subdivided into statements a to m was based on a Likert scale (5 item). All the statements related to the roles played by the pharmacist at the PAW and the HCPs had to indicate their level of agreement with each statement. Question three was an open-ended question. It was added to enquire if, according to the clinicians and the nurses, the pharmacist should have any roles apart from the ones mentioned in question two. It was added to enquire about areas for improvement of the service provided by the pharmacist at the PAW. Question four and five were based on a Likert scale (5 scale). The former was added to enquire about the level of agreement of HCPs with the benefit of the presence of a pharmacist at the PAW whilst the latter was added to enquire about the level of satisfaction of the HCPs with the service provided by the pharmacist at the PAW. Question six was a yes or no question about whether they would like to see the pharmacist's role expanding within the paediatric oncology unit at the PAW and why.

The same panel of experts evaluating the questionnaire for parents was used to provide feedback on the questionnaire for HCPs. The experts were asked to examine the proposed tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 11). This process was necessary in determining if the wording of the questionnaire was easy to understand, if the content of the questionnaire was relevant so that it fulfils its aims, whether the format and length were adequate and whether the questionnaire was user-friendly. Relevant amendments were applied and the questionnaire for HCPs was subsequently distributed.

The Mann Whitney test was used to compare mean rating scores provided to a statement between two independent groups (clinicians and nurses) within the questionnaire for HCPs. The null hypothesis specifies that the mean rating scores provided by two groups are comparable and is accepted if the p- value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean rating scores provided by the two groups vary significantly and is accepted if the p-value is less than the 0.05 criterion.

The classification system for Pharmaceutical Care Issues

For the purpose of classifying and resolving the PCIs identified during Phase II of the research, an innovative easy-to-use classification system based on the PCNE Classification for drug related problems version 8 and the DOCUMENT system was developed, validated and used (Appendix 12). The development of such a system was important as it provided a standardized and consistent classification and documentation of PCIs and pharmaceutical interventions to be proposed by the pharmacist-researcher. The new classification system developed ensured the availability of a system which was robust enough to account for all the PCIs identified during the research.

The classification system was presented in tabular format. It consisted of five columns with the following headings respectively: category of PCI, category description, PCI, pharmaceutical intervention/s to resolve the PCI and outcome.

It consisted of eleven PCI categories, namely, drug selection, dose selection, dosage regimen selection, duration of treatment, unwanted drug effects, dispensing, compliance, drug administration, monitoring, counselling and seamless care.

Categories were discrete and unambiguous. A short description of every category was included to ensure that each category is comprehensible, to ease interpretation and assist

accurate classification of PCIs. Each category encompassed between one and ten subcategories or PCIs.

One or more pharmaceutical interventions to be proposed by the pharmacist to resolve the PCIs were determined and included in the classification system.

The outcome refers to the status of the pharmaceutical intervention proposed. Three possible outcomes were determined and included in the classification system, namely, accepted and implemented, accepted and not implemented and not accepted. Only one outcome was possible per pharmaceutical intervention proposed.

A panel of experts involving a drug information pharmacist and a community pharmacist validated the classification system. The experts were asked to examine the proposed tool and were given a set of questions which would enable them to express their opinion about the tool (Appendix 13). This process was necessary to determine;

- whether the categories of the PCI and PCIs respectively were satisfactory or not, that is, whether there were any categories or PCIs which needed to be added, omitted or changed
- whether the pharmaceutical intervention/s to be proposed by the pharmacist for every PCI was/were satisfactory or not, that is whether there was/were any pharmaceutical interventions which needed to be changed and
- whether there was any point from the outcome section which needed to be added, omitted or changed.

Relevant amendments were applied. Subsequently, the classification system was tested for its practicality and ability for it to be applied consistently by different pharmacists. Ten scenarios (Appendix 14) were selected from the dataset whereby each scenario

described one to three PCIs that occurred in the paediatric oncology unit. Two hospital pharmacists and one community pharmacist classified the PCIs using the developed classification system. The pharmacists were reminded about the importance of classifying each respective issue under a single sub-category or PCI.

2.4 Phase II- Implementation of the Pharmaceutical Care Model

This phase was carried out between June 2017 and January 2018, following ethics approval. Prior to initiation of the research, the parents were given a study information sheet in English or Maltese (Appendix 15). All the parents consented to participate in the study and signed the consent form.

During this phase, the PAW was attended three times per week. During these visits, the pharmacist-researcher focused on covering the gaps identified and services requiring optimisation. Activities carried out included:

- Active participation in ward rounds and interdisciplinary meetings. Ward rounds were held daily, were led by the most senior clinician present on the ward on the day and covered both in-patients and day-case patients. An interdisciplinary meeting was held every Friday and was attended by the two consultant paediatric oncologists, the resident specialists and higher specialist trainees present on the day, the nurses present on the day, a social worker, a speech therapist, a physiotherapist, a nutritionist and a teacher.

- Reviewing patients' files, treatment charts and chemotherapy prescriptions. Validation of treatment charts and chemotherapy prescriptions focused on confirmation of the correct dose of the drug according to the weight or body surface

area of the patient, the correct regimen of the drug, the suitability of the drug and its indication, dose adjustments recommended in the literature according to patient characteristics, the abscence of contraindications and clinically significant interactions, conformity with the therapeutic protocol and compliance with pharmacotechnical parameters (compatible diluent, infusion volume and concentration of the solution).

- Compilation of individualized Pharmacy Patient Profiles and identification of PCIs. Identified PCIs were discussed with the clinicians, nurses or parents respectively and subsequently, pharmaceutical interventions were proposed to solve them. The PCIs, pharmaceutical interventions proposed and outcome of the proposed pharmaceutical intervenetions were recorded in the Pharmacy Patient Profiles. The PCIs were classsified according to the classification system developed during Phase I of the research.
- Provision of counselling to parents including discharge medication counselling. Counselling captured indication, dosage regimen, method of administration, the duration of treatment, storage, possible side effects and details regarding further supply of the drug upon discharge. During the child's hospital stay, most of the counselling was provided verbally. Prior to discharge from hospital, written information (the Discharge Medications Guide) was always provided to the parents. Subsequently, the parents' satisfaction questionnaire was distributed.

- Development of other pharmaceutical services which were found to be lacking during Phase I of the research such as medicines information to HCPs. Amongst other sources of information, during the clinical fieldwork, the pharmacist-researcher

had access to the MedicinesComplete, UpToDate® and MicromedexSolutions® databases.

The questionnaire which was developed for HCPs caring for children at the PAW was distributed in January 2018. In order to ensure anonymity, the purpose of the questionnaire was explained to the secretary of the PAW. Then, multiple copies of the information letter, consent form and questionnaire were left on his desk. One copy of each was given to the doctors and nurses who agreed to participate. All the clinicians and nurses consented to participate in the study and signed the consent form (Appendix 16). HCPs were instructed to leave the filled questionnaire at the secretary's desk.

CHAPTER 3
RESULTS

The results are divided into two sections. The first section describes the validation of the tools (Phase I) and the second section describes the results pertaining to the running of the service (Phase II).

3.1 Phase I- Development of the Pharmaceutical Care Model

3.1.1 Validation of the tools developed for the study

In this section, results pertaining to the validation of the tools developed for the study are presented.

The Gap- Finding Tool

Positive feedback was given by the expert panel about the relevance of the sections to assess which pharmacy services were being provided in the absence of a pharmacist. Positive feedback was also provided when the experts were asked how much they thought that the statements of each section related to the heading of the section. No major changes were made in this regard. Table 3.1 summarises the suggestions put forward.

Table 3.1: Suggestions for the Gap-Finding Tool following validation

Suggestions	Modifications
Add a statement under the section 'Current medication management' regarding the need to ensure that the units of the medications prescribed are clearly indicated	Statement added
Change the first statement under the section 'Therapeutic drug monitoring'	Statement changed from 'Indicating the need for TDM when necessary' **to** 'When necessary, the pharmacist should give exact instructions when and how TDM is to be carried out'

Two suggestions were put forward by the expert panel. These were taken up and implemented.

The Discharge Medication Guide for parents

Positive feedback was given by the expert panel about the wording, relevance of the content, and user friendliness of the tool so no changes were made in this regard. Table 3.2 summarises the suggestions put forward.

Table 3.2: Suggestions for the Discharge Medication Guide following validation

Suggestions	Modifications
Create two different versions of the tool, one in English and one in Maltese rather than including both languages in one version	Two separate versions of the tool were created, one in English and one in Maltese. This was done to make the tool simpler and more understandable according to the language preference of the parents
Add the date to the patient details section	The field 'Date' was added to the patient details section of the guide. This refers to the date when the tool is compiled for the parents or the discharge date
Add the contact number of the pharmacist in case of difficulty encountered with the medication	The field 'Contact number' was added under 'Compiled by' at the bottom of the guide
Add logo of Mater Dei Hospital	Logo added

Four suggestions were put forward by the expert panel. These were taken up and implemented.

The Pharmacy Patient Profile

Positive feedback was given by the expert panel about the wording and relevance of the content so no changes were made in this regard. Table 3.3 summarises the suggestions put forward.

Table 3.3: Suggestions for the Pharmacy Patient Profile following validation

Suggestions	Modifications
Change the layout	Before validation, layout was such that the sheet would be folded upon itself, width wise. This was unpractical. Layout was changed and designed so that the profile fits over a single landscape oriented A3 sheet of paper.
Name the document	Document titled 'Pharmacy Patient Profile'
Specify the units for weight, height and body surface area	Units were specified
Indicate format of date where date is required	Format, that is, dd/mm/yyyy was specified where date is required
Add a tick box to confirm presence or absence of enteral tube. Also, type and size should be added	Tick box, type and size added
Add central line to patient details section. A tick box should be added to confirm its presence or absence. Also, type should be added	Central line added to patient details section. Tick box and type were also added.
Add the admission date to patient details section	Admission date added to patient details section
Separate the chemotherapy and related medications from the other medications	Current medications section was subdivided into 2 sub-sections, the chemotherapy and related medications section and other medications section
Add logo of Mater Dei Hospital	Logo added

Nine suggestions were put forward by the expert panel. These were taken up and implemented.

The parents' satisfaction questionnaire

Positive feedback was given by the expert panel about the wording, accuracy and user friendliness of the questionnaire so no changes were made in this regard. Table 3.4 summarises the suggestions put forward.

Table 3.4: Suggestions for the parents' satisfaction questionnaire following validation

Suggestions	Modifications
Make it shorter not in terms of the number of questions but in terms of the number of pages	Questionnaire shortened from 3 to 2 pages and printed double sided rather than single sided
Name the questionnaire	Questionnaire titled 'Parents' satisfaction questionnaire'
Split statement number 4 into two separate statements	Statement number 4, that is, 'Advice given by the pharmacist about the possible side effects of your child's medications and their management' was split as follows; Statement number 4: 'Advice given by the pharmacist about the possible side effects of your child's medications' Statement number 5: 'Advice given by the pharmacist about what you should do if your child develops any of these side effects'
Add an open-ended question to indicate any further recommendations or comments that the parents or legal guardians might have about the service provided by the pharmacist at Rainbow Ward	Question added

Four suggestions were put forward by the expert panel. These were taken up and implemented.

The healthcare professionals' satisfaction questionnaire

Positive feedback was given by the expert panel about the wording, content, accuracy and user friendliness of the questionnaire so no major changes were made in this regard. Table 3.5 summarises the suggestions put forward.

Table 3.5: Suggestions for the healthcare professionals' satisfaction questionnaire following validation

Suggestions	Modifications
Change the format from landscape to portrait	Format changed to portrait
Make it shorter not in terms of the number of questions but in terms of the number of pages	Questionnaire shortened from 3 to 2 pages and printed double sided rather than single sided
Name the questionnaire	Questionnaire titled 'Healthcare professionals' satisfaction questionnaire'
Add statements 'Preventing prescribing errors' and 'Participating in medical ward rounds' to question number 2	Statements added
Add another two questions: a. To obtain the opinion of the clinicians and nurses about any further roles that the Clinical Pharmacist should have at the PAW apart from the roles mentioned in question 2 b. To assess how far the clinicians and nurses agree that the presence of a Pharmacist at Rainbow Ward is beneficial	Questions added

Five suggestions were put forward by the expert panel. These were taken up and implemented.

The classification system for Pharmaceutical Care Issues

Fourty-three suggestions were put forward by the expert panel and incorporated in the final version of the classification system for Pharmaceutical Care Issues. Table 3.6 summarises the number of suggestions put forward per PCI category.

Table 3.6: Number of suggestions per PCI category following test for content validity

Category of PCI	Number of suggestions (n)
Drug selection	1
Dose selection	6
Dosage regimen selection	1
Duration of treatment	1
Unwanted drug effects	7
Dispensing	7
Compliance	4
Drug administration	10
Monitoring	1
Counselling	1
Seamless care	2
Route selection	1

Details of the suggestions put forward by the expert panel regarding the PCI classification system are included in Appendix 17. One of the suggestions put forward was not related to any of the PCI categories and therefore is not included in the table. The suggestion was to put forward a definition for the terms pharmaceutical care issue, pharmaceutical intervention and outcome respectively.

3.1.2 Practicality of the classification system for PCIs

To test the practicality of the adapted classification system, ten cases relating to paediatric oncology were selected from the data set and given to the expert panel consisting of two hospital pharmacists and a community pharmacist. Table 3.7 summarises the number of PCIs identified.

Table 3.7: Number of PCIs identified by the expert panel

Pharmacist	Total number of PCIs identified
Pharmacist-researcher (control)	22
Pharmacist 1	20
Pharmacist 2	20
Pharmacist 3	19

The total number of PCIs identified by the pharmacist-researcher on the ward (control) was 22. Upon comparing pharmacist 1, 2 and 3 with the control, these identified 20, 20 and 19 PCIs the in the same manner as the control. Pharmacists 1, 2 and 3 did not identify 2, 2 and 3 PCIs respectively when compared to the pharmacist-researcher. Overall, 89% of the PCIs were identified and classified in the same manner by the three pharmacists. Over and above, 6 new PCIs were identified: 2 by each pharmacist. For cases 1,2,4,5 and 8, all the PCIs identified by the pharmacist-researcher were identified by the three pharmacists. The missing and the newly identified PCIs were observed in cases 3,5,6,7,9 and 10. Details of the data and results pertaining to the testing of the practicality of the classification system are included in Appendix 17.

The practicality test showed that the classification system can be followed by trained pharmacists with minimal variation in the classification of Pharmaceutical Care Issues identified.

3.1.3 Completed Gap-Finding Tool

In this section, the results of the completed Gap-Finding Tool noted during Phase I of the research are presented. The completed Gap-Finding Tool is included in Appendix 17. The majority of the processes listed in the Gap-Finding Tool were covered by other HCPs, namely clinicians and nurses whose focus was not just the drug use process. Gaps in the local care practice were also identified.

The major gaps identified at the ward were:

- Interdisciplinary care was being provided in the absence of a clinical pharmacist
- Chemotherapy prescriptions prescribed were being vetted by a compounding pharmacist rather than by a clinical pharmacist on the ward. The compounding pharmacist did not provide a direct patient care service
- Lack of local pharmacological treatment guidelines such as guidelines on the acute and late effects of chemotherapy drugs in children
- No one checked for availability and access to medications and liaised with the unit responsible for patient access to treatment on the national health scheme
- No one provided medicines information to HCPs. However, if needed, they could contact the medicines information section of the Pharmacy Department

The processes that required optimisation were:

- Current medication management, clinical review, therapeutic drug monitoring, ADR management, discharge medication and documentation processes.
- Provision of medicines information and counselling to parents
- Liaison and coordination with other sections of the pharmacy department such as the dispensary and compounding sections.

3.2 Phase II- Implementation of the Pharmaceutical Care Model

The developed pharmaceutcial care model was implemented between June 2017 and January 2018.

3.2.1 Patient characteristics

The total number of patients that were reviewed during the study period was 25. Out of these 25, 14 were males (mean age: 8 years) and 11 were females (mean age: 6 years). Seventeen patients suffered from haematological malignancies, the most common of which was leukaemia, 4 suffered from solid tumours and 4 suffered from conditions which were not cancer, but which are treated with chemotherapy or require a bone marrow transplant (Figure 3.1).

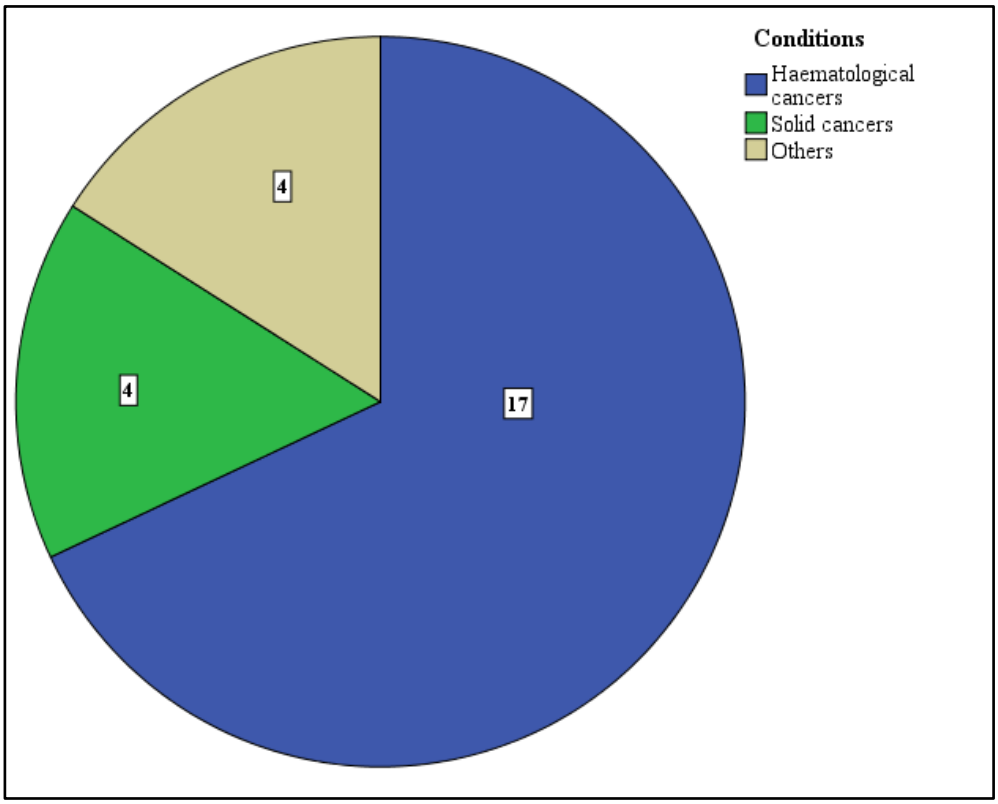


Figure 3.1: Patients' conditions (N=25)

3.2.2 Pharmaceutical Care Issues

During the study period, a total of 325 pharmaceutical care sessions were provided.[10] During these 325 care sessions, a total of 545 PCIs were identified. Most of the PCIs featured in the counselling [27.0% (n=147)], the drug selection [23.7% (n=129)], the dose selection [19.3% (n=105)] and the monitoring [15.4% (n=84)] categories (Figure 3.2)

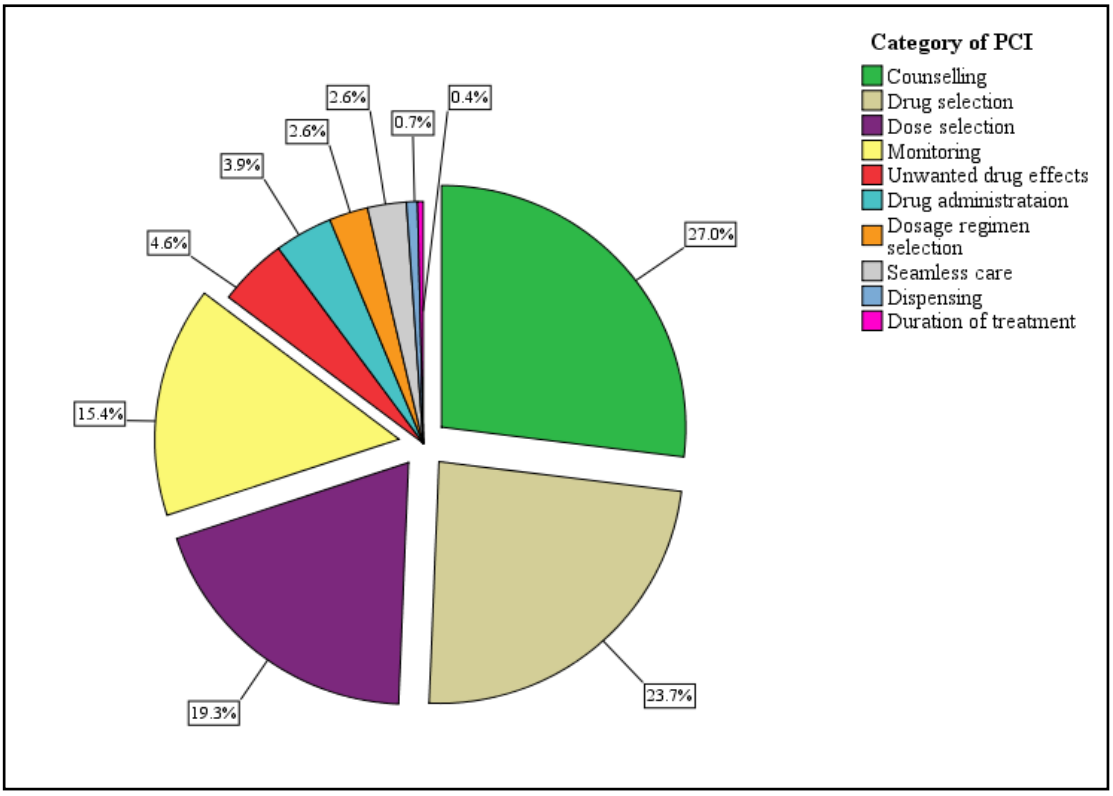


Figure 3.2: Categories under which the identified PCIs (N=545) were classified

[10] For the purpose of this research, a pharmaceutical care session is defined as the pharmaceutical service for an individual in-patient or day-case patient within one day capturing file review, discussion with HCPs and ward round.

3.2.2.1 Counselling

PCIs encountered for this category were ‘Counselling need to parents’ (N=147). Information was at times requested by the parents or else the pharmacist identified the need for the provision of the information. This captured discharge medication counselling as well.

Whenever the need for counselling to parents was identified, the pharmacist intervened by providing the necessary information. During the child’s hospital stay, either as an in-patient or as a day-case, most of the counselling was provided verbally. Prior to discharge from hospital, written information (the Discharge Medications Guide) was always provided to the parents.

3.2.2.2 Drug selection

The most common PCI within this category was ‘No indication for drug or indication no longer apparent’ (42.6%). This was followed by ‘No drug treatment despite existing indication requiring management or prevention’ (27.1%), ‘Drug interaction’ (7.8%), ‘Inappropriate dosage form’ (5.4%), ‘Other drug selection problem’ (5.4%), ‘Non-adherence to protocol or guidelines’ (4.7%), ‘Ineffective drug’ (3.1%) ‘Contraindication’ (1.6%), ‘Need for an additional drug to properly manage a condition (1.6%)’ and ‘Too many drugs prescribed for indication (0.8%)’.

The pharmaceutical interventions proposed by the pharmacist-researcher to solve the PCIs involved a change in therapy. The commonest pharmaceutical intervention was to stop unnecessary drugs, that is, to stop drugs which were being administered for no indication or indication was no longer apparent (Table 3.8).

Table 3.8: Drug selection: PCIs identified and proposed interventions

PCI (N=129)	Example of PCI	Proposed pharmaceutical intervention
No indication for drug or indication no longer apparent (n=55)	Patient admitted with febrile neutropenia is now afebrile (for 48 hours) and blood cultures negative. No need for further IV antibiotics	Stop unnecessary drugs
No drug treatment despite indication (n=35)	Patient suffering from Wilm's tumour- high risk. Not on prophylactic co-trimoxazole	Add drug as needed
Drug interaction (n=10)	Ondansetron and domperidone	Avoid combination
Inappropriate dosage form (n=7)	Ranitidine syrup prescribed and patient vomits every time she takes it	Change dosage form
Other drug selection problem (n=7)	Methotrexate written MTX on treatment chart	Correct name on treatment chart
Non- adherence to protocol or guidelines (n=6)	Leukaemic patient's bilirubin normalised so can restart oral methotrexate and 6-mercaptopurine. As per protocol, drugs should be restarted at 50% of previous dose. Instead, they were started at 75% of previous dose	Adhere to protocol
Ineffective drug (n=4)	Chronic leukaemia uncontrolled despite being on maximum doses of 6-mercaptopurine	Stop ineffective drug and prescribe an alternative
Contraindication (n=2)	Quinolones and epilepsy	Stop drug and prescribe alternative
Need additional drug to properly manage a condition (n=2)	Persistent pain despite maximum doses of paracetamol	Add drug as needed
Too many drugs prescribed for indication (n=1)	Patient suffering from dystonic movements and is on clonidine and trihexyphenidyl	Stop unnecessary drug

3.2.2.3 Dose selection

The most common PCI within this category was 'Dose too low for patient's age, weight and indication and/or severity' (44.8%). This was followed by 'Dose too high for patient's age, weight and indication and/or severity' (41.9%) and 'Other dose selection problem' (13.3%) (Table 3.9). The vast majority of the pharmaceutical interventions proposed by the pharmacist-researcher to solve the PCIs involved a change in therapy (86.7%). The interventions involving change in therapy were increasing or decreasing the dose of a drug (44.8% and 41.9% respectively). Pharmaceutical interventions for other dose selection problems proposed were to write any missing, wrong or unclear dose instructions on the treatment chart (13.3%).

Table 3.9: Dose selection: PCIs identified and proposed interventions

PCI (N=105)	Example of PCI	Proposed pharmaceutical intervention
Dose too low (n=47)	Dose of cotrimoxazole (240mg bd) too low for patient's body surface area (0.85)	Increase dose
Dose too high (n=44)	Dose of terbinafine (250mg) for treatment of tinea capitis too high for patient's age (4-year-old)	Decrease dose
Other dose selection problem (n=14)	Wrong dose written on treatment chart	Correct dose on treatment chart

3.2.2.4 Monitoring

PCIs encountered for this category were 'Monitoring need' related to necessary laboratory and non-laboratory monitoring (N=84). When the need for monitoring of

parameters such as liver function tests in a child suspected to have liver toxicity from hepatotoxic drugs and blood pressure in a child who is on blood pressure lowering medications was identified, the pharmacist-researcher proposed to undertake the necessary laboratory or non-laboratory parameters.

3.2.2.5 Unwanted drug effects

PCIs encountered for this category were 'Adverse drug reaction or side effect' (N=25). The pharmaceutical interventions proposed to solve the PCIs differed according to the side effect. Most of the side effects (92%) were related to chemotherapy and related drugs. The treatment options proposed to manage these side effects were as outlined in the 'Treatment modifications for toxicity' sections in the respective cancer protocols. In 20 (80%) of the cases, treatment involved decreasing doses or omitting chemotherapy drugs for a short period of time. On 2 occasions (8%), it was proposed to treat the side effect but continue the drug causing the side effect at the same dose. These were the cases of dexamethasone causing abdominal discomfort. The steroid was continued at the same dose but ranitidine was added. On another occasion (4%), it was proposed to treat the side effect and decrease subsequent doses of the drug. This was the case of vincristine following occurrence of seizures and severe constipation in a patient suffering from standard risk medulloblastoma. The other 8% of side effects identified occurred due to antibacterials, specifically piperacillin/tazobactam and itraconazole where they caused septic shock and melena respectively. The intervention proposed in these cases was to treat the ADR and to never re-challenge.

3.2.2.6 Drug administration

The most common PCI within this category was 'Inappropriate route' (47.6%). This was followed by 'Other drug administration problem' (23.8%) 'Wrong dilution' (14.3%) and 'Inappropriate infusion rate' (14.3%). The majority of the pharmaceutical interventions proposed to solve PCIs in this category involved changing the method of drug administration (76.2%) such as changing the route, correcting the method of dilution and correcting the rate of dose administration (Table 3.10). Interventions for other drug administration problems proposed were to write any missing, wrong or unclear drug administration instructions on the treatment chart or prescription.

Table 3.10: Drug administration: PCIs identified and proposed interventions

PCI (N=21)	Example of PCI	Proposed pharmaceutical intervention
Inappropriate route (n=10)	Immunocompromised patient suffering from shingles. Guidelines suggest starting treatment with IV aciclovir for at least five days and then switching to oral therapy. Clinician started treatment with the oral route	Change route
Other drug administration problem (n=5)	Wrong dilution written on chemotherapy prescription	Correct dilution on prescription
Inappropriate infusion rate (n=3)	Piperacillin/tazobactam should be infused over 30 minutes not over 60 minutes	Correct rate of administration
Wrong dilution (n=3)	800mg dose of co-amoxiclav was being diluted in up to 50ml of normal saline. At this dose, drug should be diluted in up to 80ml normal saline	If any doses have already been administered, monitor the patient and correct dilution for subsequent doses

3.2.2.7 Dosage regimen selection

The most common PCI within this category was ‘Dosage regimen too frequent’ (57.1%). This was followed by ‘Dosage regimen not frequent enough’ (21.4%) and ‘Other dosage regimen selection problem (21.4%).

The vast majority of the pharmaceutical interventions proposed to solve the PCIs within this category involved a change in therapy (78.5%). The interventions involving change in therapy were increasing or decreasing the dosage regimen frequency of a drug (57.1% and 21.4% respectively). Pharmaceutical interventions for other dosage regimen selection problems proposed were to write any missing, wrong or unclear dosage regimen instructions on the treatment chart (Table 3.11).

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

PCI (N=14)	Example of PCI	Proposed pharmaceutical intervention
Dosage regimen too frequent (n=8)	Cefpodoxime suspension prescribed to be administered three times daily when it should be given in two divided doses	Decrease dosage regimen frequency
Dosage regimen not frequent enough (n=3)	Miconazole oral gel for oral candidiasis prescribed to be applied two times daily when it should be applied four times daily for maximum efficacy	Increase dosage regimen frequency
Other dosage regimen selection problem (n=3)	Modifying treatment chart to cancel ondansetron prn as it was being administered regularly	Omit ondansetron prn on treatment chart

3.2.2.8 Seamless care

All the PCIs encountered for this category were ‘Counselling need to parents or legal guardians on the procedure to obtain medicine stocks upon discharge’ (N=14). Whenever the need for seamless care was identified, the pharmacist intervened by providing all the necessary information to parents on the bureaucratic procedures involved so that the child becomes entitled to free medications and the process of obtaining the required stock from the community pharmacy of their choice.

3.2.2.9 Dispensing

There were 4 PCIs related to dispensing, each one arising from different subcategories being ‘Wrong drug dispensed’, ‘Prescribed drug not available in the required strength’, ‘Prescribed drug not available in the required form’ and ‘Prescribed drug not available at all’. The pharmaceutical interventions proposed to solve the PCIs identified within this category were ‘Stop from administering a drug that has been dispensed wrongly and check that the correct drug has been prescribed and/or ordered’, ‘If it’s not a problem to administer dose using available strength, use available strength and if not possible, prescribe an alternative’, ‘If it’s not a problem to administer dose using available form, use available form as is’ and ‘Prescribe an alternative’ respectively (Table 3.12).

Table 3.12: Dispensing: PCIs identified and proposed interventions

PCI (N=4)	Example of PCI	Proposed intervention
Wrong drug dispensed (n=1)	Esomeprazole vials dispensed instead of omeprazole	Stop administration of wrongly dispensed drug. Check that the correct drug has been prescribed or ordered
Prescribed drug not available in the required strength (n=1)	Ranitidine 75mg tablets prescribed and not available on the hospital formulary	If not a problem, administer dose using available strength. If not possible, prescribe an alternative
Prescribed drug not available in required form (n=1)	Hyoscine hydrobromide required in tablet/liquid form but available as injection	If it is not a problem to administer dose using available form, use available form as is
Prescribed drug not available at all (n=1)	Maxitrol ® eye drops (dexamethasone, polymyxin B sulfate and neomycin sulfate) needed for a retinoblastoma patient until prosthesis is due	Prescribe an alternative

3.2.2.10 Duration of treatment

The PCIs encountered for this category were all 'Duration of treatment too short' (N=2). A case example was that of a patient suffering from *Pneumocystis Carinii* Pneumonia infection. Clinical guidelines suggest treatment with steroids and high dose cotrimoxazole for a total duration of 21 days. Steroids were going to be stopped after 14 days. The pharmaceutical intervention proposed to solve the PCIs identified within this category involved a change in therapy. The change was to increase the duration of treatment of the drug.

3.2.3 Outcome of the proposed interventions

Out of the total number of pharmaceutical interventions proposed, 95% (n=516) were accepted and implemented by the HCPs or the parents. The remaining 5% were discussed with the clinicians and not accepted.

3.2.4 Other services provided to complete the ward-based pharmacy service

Other pharmaceutical services provided to support the ward service included dosage calculations, medicines information to nurses and clinicians, guiding clinicians and nurses in identifying and filling the appropriate pharmacy related forms, liaison with other sections of hospital, mostly the dispensary and the compounding sections, liaison with the Directorate of Pharmaceutical Affairs for patients requiring medications on a named patient basis, preparation of chemotherapy flowsheets and proformas and participation in research studies (Table 3.13).

Table 3.13: Pharmaceutical services provided to complete the ward service

Pharmaceutical service	Number (n)
Dosage calculations	965
Drug information	374
Completion of pharmacy forms	52
Liaison with Pharmacy sections of MDH	48
Patient access to medications	8
Chemotherapy flowsheets preparation	8
Research studies	1

3.2.5 Parents' satisfaction questionnaire

In this section, the results pertaining to the parents' satisfaction questionnaire, including the test-retest reliability are presented.

3.2.5.1 Test re-test reliability

For all the ordinal questions of the questionnaire, that is, questions 1 to 11 and questions 14 to 16, the Kendall tau value was 1.000 and the respective p-value was 0.000. This implies that for these statements, the alternative hypothesis is accepted and there is satisfactory test re-test reliability. For all the nominal questions of the questionnaire, that is, questions 12, 13 and 17, the Kappa value was 1.000 and the respective p-value was 0.000. This implies that for these statements, the alternative hypothesis is accepted and there is satisfactory test re-test reliability.

3.2.5.2 Assessment of the pharmacist's service from the parents' perspective

Advice provided by the pharmacist

Table 3.14 summarises the mean rating scores to statements related to advice provided by the pharmacist. The mean rating score provided to 'Advice given by the pharmacist about the reasons why the medications are being given to your child' and 'Advice given by the pharmacist about how and when you should give your child his/her medications' (3.85) are the largest, indicating highest agreement. These are followed by 'Advice given by the pharmacist about how you should store your child's medications' and 'Advice given by the pharmacist about the possible side effects of your child's medications' (3.70) and 'Advice given by the pharmacist about what you should do if your child develops any of these side effects' (3.67).

Table 3.14: Mean rating scores for advice given by the pharmacist

Advice given by pharmacist about:	Mean	Std. Dev	Minimum	Maximum
The reasons why the medications are being given to your child	3.85	0.362	3	4
How and when you should give your child his/her medications	3.85	0.362	3	4
How you should store your child's medications	3.70	0.465	3	4
The possible side effects of your child's medications	3.70	0.542	2	4
What you should do if your child develops any of these side effects	3.67	0.620	2	4

$X^2(4) = 7.308, p = 0.120$

The mean rating scores for all the statements were very high. They ranged from 3 to 4 with 4 being the maximum, implying that on average, the parents were either satisfied or very satisfied with the advice provided by the pharmacist.

Abilities of the pharmacist

Table 3.15 summarises the mean rating scores to statements related to abilities of the pharmacist. The mean rating scores provided to 'Abilities of the pharmacist to explain things in a way that is easy for you to understand' and 'Abilities of the pharmacist to listen to all your questions about your child's medications' (4.00) are the largest, indicating highest agreement. These are followed by 'Abilities of the pharmacist to speak clearly and slowly', 'Abilities of the pharmacist to show sensitivity whilst providing advice' and 'Abilities of the pharmacist to answer all your questions about your child's medications' (3.96).

Table 3.15: Mean rating scores for abilities of the pharmacist

Abilities of the pharmacist to:	Mean	Std. Dev	Minimum	Maximum
Speak clearly and slowly	3.96	0.192	3	4
Explain things in a way that is easy for you to understand	4.00	0.000	4	4
Show sensitivity whilst providing advice	3.96	0.192	3	4
Listen to all your questions about your child's medications	4.00	0.000	4	4
Answer all your questions about your child's medications	3.96	0.192	3	4

$X^2(4) = 2.000, p = 0.736$

The mean rating scores for all the statements were very high. They ranged from 3 to 4 with 4 being the maximum, implying that on average, the participants were either satisfied or very satisfied with the abilities of the pharmacist.

Satisfaction with the overall service

When the parents were asked to indicate the level of satisfaction with the overall service provided by the pharmacist, the majority (96.3%) stated that they were very satisfied with the overall service provided by the pharmacist. When asked to state whether it was the first time that they were visiting Rainbow ward, the majority of the parents (92.6%, n=25) stated that it was not the first time that they were visiting Rainbow ward. The 25 participants who stated that it was not the first time that they were visiting Rainbow ward stated that during previous visits they had never discussed their child's treatment with a pharmacist.

Perceived benefits of having a clinical pharmacist on the ward

Table 3.16 summarises the mean rating scores for statements related to perceived benefits of having a clinical pharmacist on the ward. The mean rating scores provided to 'The Pharmacist made sure that you understood all the information that she provided regarding your child's medications' and 'The service offered by the Pharmacist at Rainbow Ward is beneficial' (4.00) are the largest, indicating highest agreement. These are followed by 'The Pharmacist has helped you to increase your knowledge about your child's medications' (3.93).

Table 3.16: Mean rating scores for perceived benefits of the clinical pharmacist

Kindly indicate how far you agree that:	Mean	Std. Dev	Minimum	Maximum
The Pharmacist has helped you to increase your knowledge about your child's medications	3.93	0.267	3	4
The Pharmacist made sure that you understood all the information that she provided regarding your child's medications	4.00	0.000	4	4
The service offered by the Pharmacist at Rainbow Ward is beneficial	4.00	0.000	4	4

$X^2(2) = 4.000$, $p = 0.135$

The mean rating scores for all the statements were very high. They ranged from 3 to 4 with 4 being the maximum, implying that on average, the participants agreed and strongly agreed with the fact that the pharmacist helped them to increase their knowledge about their child's medications, the pharmacist made sure that they understood all the information provided and the service offered by the pharmacist was beneficial.

Willingness to discuss treatment with a pharmacist during future visits

When the parents were asked to indicate whether they were willing to discuss their child's medications with a pharmacist during future visits at Rainbow ward, all of them (100%) unanimously answered positively.

Recommendations and comments about the service

When the parents were asked to mention further recommendations or comments about the service provided by the pharmacist at Rainbow ward, a total of 12 recommendations and comments were made (Table 3.17).

Table 3.17: Recommendations and comments about the pharmaceutical service

Recommendation (N=5)	**Frequency**
Provide written information on chemotherapy and side effects to be expected	10
Be present daily on the ward	5
Provide information about the long-term effects of chemotherapy	2
Be available out of working hours	1
Provide email address	1
Comments (N=7)	**Frequency**
Excellent service	8
Very helpful	5
Very organised	1
Very knowledgeable	1
Pharmacist eliminated doubts and clarified issues relating to medicines	1
Service allowed me to learn about my child's medications and what to expect	1

3.2.6 Healthcare professionals' satisfaction questionnaire

Out of the sixteen participants, seven were clinicians and nine were nurses.

The perceived benefits of having a clinical pharmacist on the ward

The mean rating scores provided by both the clinicians and the nurses were very high (Table 3.18). They ranged from 3 to 4 with 4 being the maximum, implying that on average, the clinicians and nurses either agreed or strongly agreed with the fact that at Rainbow ward, the clinical pharmacist played an important role in:

a. Discharge medication counselling
b. Monitoring patient response to drug therapy from a side effects perspective
c. Monitoring patient response to drug therapy from an effectiveness perspective
d. Providing drug information
e. Analysing patient treatment and suggesting changes in therapy when necessary
f. Indicating the need for monitoring when necessary
g. Preventing, identifying and managing side effects
h. Preventing, identifying and resolving drug interactions
i. Calculating drug doses for patients
j. Participating in medical ward rounds
k. Checking the correctness of the prescriptions
l. Preventing prescribing errors
m. Improving overall patient outcome/ quality of patient care

Table 3.18: Mean rating scores for the perceived benefits of a clinical pharmacist

At Rainbow Ward, the clinical pharmacist plays an important role in:	Profession	Mean	Std. Dev	P-value
Discharge medication counselling	Clinicians	3.86	378	0.681
	Nurses	4.00	0.000	
Monitoring patient response to drug therapy from a side effects perspective	Clinicians	3.57	0.535	0.174
	Nurses	4.00	0.000	
Monitoring patient response to drug therapy from an effectiveness perspective	Clinicians	3.14	0.900	0.055
	Nurses	4.00	0.000	
Providing drug information	Clinicians	4.00	0.000	1.000
	Nurses	4.00	0.000	
Analysing patient treatment and suggesting changes in therapy when necessary	Clinicians	3.71	0.488	0.351
	Nurses	4.00	0.000	
Indicating the need for monitoring when necessary	Clinicians	3.86	0.378	0.918
	Nurses	3.89	0.333	
Preventing, identifying and managing side effects	Clinicians	3.57	0.787	0.351
	Nurses	4.00	0.000	
Preventing, detecting and resolving drug interactions	Clinicians	3.86	0.378	0.681
	Nurses	4.00	0.000	
Calculating drug doses for patients	Clinicians	4.00	0.000	1.000
	Nurses	4.00	0.000	
Participating in medical ward rounds	Clinicians	3.86	0.378	0.681
	Nurses	4.00	0.000	
Checking the correctness of prescriptions (right patient, right drug, right time, right dose and right route)	Clinicians	3.86	0.378	0.681
	Nurses	4.00	0.000	
Preventing prescribing errors	Clinicians	3.86	0.378	0.681
	Nurses	4.00	0.000	
Improving overall patient outcome / quality of patient care	Clinicians	4.00	0.000	1.000
	Nurses	4.00	0.000	

The mean rating scores ranged between 3 and 4 with 4 being the maximum. All the p-values for the mean rating scores provided by the clinicians and the nurses to the statements related to the roles played by the clinical pharmacist at PAW exceeded the 0.05 level of significance. This implies that the mean rating scores provided to the statements related to the important roles played by the clinical pharmacist at PAW were comparable between the clinicians and the nurses. The score provided by the nurses was higher when compared to the score provided by the clinicians for all the statements.

Table 3.19 summarises the feedback given by the HCPs regarding other roles which the clinical pharmacist should have besides those already outlined in table 3.18.

Table 3.19: Feedback from HCPs on other roles of the clinical pharmacist

HCP	Feedback
Clinicians	Guide clinicians to identify the correct pharmacy related forms and filling them correctly, including the Schedule V, the off- licence, the unlicensed and exceptional treatment forms. Liaise with the Directorate of Pharmaceutical affairs for named patient medications. Prepare the Schedule V for patients and make sure that all the medicines that the children may need will be available. Contribute to strengthening antimicrobial stewardship practices.
Nurses	Guide clinicians and nurses to identify the correct pharmacy related forms and filling them correctly, including the Schedule V application forms, protocol regulated forms and covering letters. Liaise with other pharmacy sections of the hospital, ensuring smooth ordering and receipt of medications for the patients on the ward. Update treatment charts when necessary. Prepare Schedule V. Check availability of drugs on ward and dealing with any availability problems.

When the clinicians and the nurses were asked to indicate how far they agreed that the presence of a clinical pharmacist at Rainbow ward was beneficial, all of them (100%) unanimously answered that they strongly agreed that the presence of a clinical pharmacist at Rainbow ward was beneficial. When asked to indicate their level of satisfaction with the overall service provided by the clinical pharmacist at Rainbow ward, all stated satisfaction with the overall service provided, with 14 (87.5%) commenting that they were very satisfied.

CHAPTER 4
DISCUSSION

The final chapter of this dissertation consists of the discussion and the conclusion bringing together the core of the research. At this stage, one asks what has been undertaken, what has been achieved and where will this research lead us? What were the limitations of this research and how can these limitations be further improved upon, possibly eliminated in order to ameliorate the service provision?

The research departed with the rationale that a high intensity ward such as the PAW should benefit from the expertise of a clinical pharmacist co-ordinating the complex medication management process outlined in Figure 1.1. The aim of this research was to establish the role of the clinical pharmacist at the PAW within an interdisciplinary healthcare team.

Confucius (551-479BC) is quoted as saying that *"The mechanic that would perfect his work must first sharpen his tools*". Similarly, when starting a service, one needs to determine the tools required to develop, implement and run the service required. In this case one asks what tools were needed to ensure that the pharmacist-researcher establishes an innovative, world-class pharmaceutical care model which is tailored for the needs of paediatric patients attending the PAW and which helps pharmacy contribute towards a higher level of care in our paediatric patients? This question formed the rationale behind the inclusion of a Gap-Finding Tool in the research. Utilising clinical pharmacy practice standards developed by well renowned entities in the field of clinical pharmacy, namely the ACCP, the EAHP and the SHPA Committee of Specialty Practice in Clinical Pharmacy, the pharmacist-researcher developed a Gap-Finding Tool which captured nine domains related to pharmacy service provision at ward level. The developed Gap-Finding Tool enabled the comparison of local pharmaceutical care practice with care practices provided internationally. It was completed during the observation phase of the research

and enabled the identification of gaps as well as services which could be optimised by the pharmacist-researcher at the PAW.

4.1 Gaps and services requiring optimisation at the PAW

A number of gaps were identified through the developed Gap-Finding Tool. A gap which was identified in our local pharmaceutical care practice was lack of pharmacist participation in interdisciplinary care. Interdisciplinary care demands amongst others the physical presence of the pharmacist at the ward whereby the pharmacist can directly work in collaboration with the other members of the team for the ultimate benefit of the patients. Identification of this gap was crucial to be able to establish the importance of the pharmacist being actively present at the PAW and subsequently contributes towards establishment of other ward based pharmaceutical services.

Another gap which was identified was the provision of medicines information to healthcare professionals (HCPs). During the observation phase, it was noted that when nurses or doctors had a drug related query, they either relied on their knowledge, they looked up the information themselves (something which made them irritable at times due to the inability to find what they were looking for) or else they phoned the medicines information or the dispensary sections of the hospital pharmacy. This inadequate service of providing medicines information in an efficient, fast manner was overcome by the active presence of the pharmacist on the ward. During Phase II of the research, whereby the pharmacist was running the pharmaceutical care model service, medicines information was provided in a total of 374 occasions. Examples of medicines information enquiries included the method of reconstitution and dilution of drugs, drug dosages for specific indications, compatibilities, advice, choice of drug, monitoring, ADRs,

availability and administration of drugs via the enteral route. The presence of a pharmacist at the ward enabled the provision of more accurate information in a shorter amount of time, thus increasing the efficiency of the pharmaceutical care service provided to paediatric patients at the PAW and optimizing the quality use of medicines. It also allowed clinicians and nurses to focus on other patient care issues and increased the use of latest evidence-based medicines information since the pharmacist is the most trained HCP to look up drug information.

Another service which was optimised through this research was the discharge process. In order to optimise it, a Discharge Medication Guide for parents was developed. It is useless prescribing the appropriate drug to the right patient but then the parent is unable to make good use of the appropriately prescribed drug at home because there is lack of knowledge on its indication, how to administer it, the duration of treatment, how to store it, the possible side effects and details regarding further supply of the drug upon discharge. In a study conducted by Walsh et al (2009), administration errors were the most common medication errors detected amongst adults and children suffering from cancer in the outpatient setting, with home administration errors being more common in children than in adults. The Discharge Medication Guide was developed in this research to optimise the discharge process since prior to initiation of the research, discharge medications were written on a small white piece of paper and only the patient identifiers, the name, dosage regimen and duration of the drug were written. Other important information was limited to word of mouth given by the medical team. The guide also served as a documentation tool which could be shared as patients move across transitional settings thereby ensuring continuity of care. It is well documented in literature that written instructions on discharge

medications help to increase patient compliance and adherence (Kaestli et al, 2015; Glick et al, 2017; Horstman et al, 2017; Kemp et al, 2017; Thomas et al, 2018).

Another service identified which closely follows the dynamics of the Discharge Medication Guide and which was optimised during the implementation of this research was the documentation process. Documentation is central to the provision of high quality pharmaceutical care. It is an accepted method by which healthcare providers communicate with one another with respect to patient care decision making and clinical outcomes (DiPiro et al, 2011). To optimise the documentation process, a Pharmacy Patient Profile specific to paediatric cancer patients attending PAW was developed. The development of this tool, the Pharmacy Patient Profile was important as it meant that the pharmacist-researcher had a paper-based document on which patient- related specific information including PCIs could be documented. Apart from enabling the pharmacist-researcher to be fully informed about patient specific issues, development of the profile meant that the pharmacist-researcher had a paper-based patient record to refer to in case she was not present at the ward and was contacted about a specific patient. The Pharmacy Patient Profile is a document in itself and as such, once completed does not need to be transcribed to the patient's medical notes. A copy of it can be retained within the patients' medical notes as add on to the notes and information documented by clinicians in the patients' files.

The Discharge Medication Guide and the Pharmacy Patient Profile that were developed during this research were both tailored for the needs of the local setting, making the developed and subsequently implemented pharmaceutical care model innovative.

Current medication management was another process which required optimisation to ensure safe and effective medication use as identified during the Gap-Finding Tool exercise. Prior to initiation of the research, clinicians had no choice but to prescribe drugs in the absence of a drug expert who would otherwise scrutinize the appropriateness of the drugs prescribed and ensure that prescriptions and treatment charts are clear, valid and tailor-made for each individual paediatric patient. Chemotherapy prescriptions were vetted by pharmacists at the compounding section prior to reconstitution who however were unaware of the individual patient's needs and co-morbidities. This was a gap itself as ideally chemotherapy prescriptions become vetted by a clinical pharmacist on the ward prior to reaching the compounding section; the clinical pharmacist being the person who knows all about the patient. During Phase II of the research, this process was optimised by attending ward rounds and by reviewing all the prescriptions and treatment charts, including chemotherapy prescriptions. Through thorough review of prescriptions and dosage calculations, these interventions enabled the pharmacist researcher to identify pharmaceutical care issues according to each patient's needs.

Other pharmacy services which were found to be lacking and were subsequently provided were liaison with other sections of the pharmacy department at the hospital, liaison with the Directorate of Pharmaceutical Affairs for patients requiring medications on a named patient basis and participation in research studies. All these services were tailored and provided to support the ward service. Amongst others, they ensured that patients had access to all the medications that they needed. The need and provision of these services substantiates the importance of the presence of the clinical pharmacist at the PAW. As outlined in the SHPA Standards of Practice for the provision of Clinical Oncology Pharmacy Services, participation in research studies is a requirement for all oncology

pharmacists (SHPA, 2002). The research in which the pharmacist-researcher participated during the study period was conducted by the World Health Organisation in collaboration with McMaster University (Canada) and University of Pennsylvania (USA). The aim was to assess the extent of shortages of essential cytotoxic agents for treating children with cancer in low, middle and high-income countries. Participation helped to add on to literature to subsequently improve availability of medicines and cancer management in this patient cohort.

4.2 Novel classification system for identified PCIs

Once the gaps were identified and the tools (the Discharge Medication Guide and the Pharmacy Patient Profile) to run the service set, the pharmaceutical care model could be implemented. One final step was required to be undertaken to ensure that the service run could aptly document the pharmaceutical care issues identified within a quality care model. An easy-to-use classification system was developed with the rationale of achieving standardization and consistency in the way pharmaceutical care issues identified are classified and documented in the Pharmacy Patient Profiles during the research. It also served as a guide with regards to the pharmaceutical interventions or recommendations to be proposed for every pharmaceutical care issue. The novel PCI classification system was based on categorisations developed by the Pharmaceutical Care Network Europe Foundation (the Pharmaceutical Care Network Europe Foundation classification for drug related problems version 8) and the Pharmaceutical Society of Australia (the DOCUMENT system). Practicality testing showed that the innovative classification system was relevant, robust and practical for use, making the model feasible to run at the PAW.

4.3 Validation of the interventions of the pharmacist through PCIs

The most common PCI category identified during the study period was the counselling category, with 'Counselling need to parents' being the most common PCI. The result is similar to that of a study conducted by Randolph et al. (2016) where the highest percentage of interventions documented were also related to patient counselling. In the local research there were instances where information about medications was requested by the parents. There were other instances were information about medications was provided simply because the pharmacist felt it necessary to share it with the parents such as at the time of initiation of a drug or complex chemotherapy regimen, when there was a change in drug therapy and prior to discharge from hospital. Counselling by the pharmacist captured the reasons for use, administration, side effects and their management, handling, storage and drug interactions.

The second most common PCI category was the drug selection category, with the majority involving 'No indication for drug or indication no longer apparent'; 'No drug treatment despite existing indication requiring management or prevention i.e. untreated actual or potential indication' and 'Drug interaction'. Examples of no indication for drug or indication no longer apparent were those involving failure to stop intravenous antibiotics when no longer indicated such as after patients admitted with febrile neutropenia would have been afebrile for 48 hours and blood cultures would be negative (recommendation as per protocol). Prolonged use of antibiotics may increase the risk of adverse effects whilst increasing the risks of resistance. A case example of no drug treatment despite existing indication requiring management or prevention i.e. untreated actual or potential indication is that of a 3-year-old boy suffering from graft versus host disease post bone marrow transplant. The patient was severely immunocompromised and

thus, needed to be started on antifungal and antiviral prophylaxis. The issue was discussed with the clinician and initially the drug was not started due to the concern that the patient was in a palliative stage. Eventually, the patient developed herpes zoster amongst other multiple bacterial mixed infections and received the relevant treatment. A case example of drug-drug interaction which was identified whilst at the ward was that between ondansetron and domperidone, a potentially major drug-drug interaction. Literature suggests that concomitant use of these two drugs is expected to substantially increase the risk of serious toxicities, including the development of torsade de pointes or other severe ventricular tachyarrhythmias. Pharmacists play a major role in checking for drug interactions and assessing their clinical significance. This helps to detect and prevent major interactions which could otherwise have potentially serious consequences and cause patient harm. These scenarios all highlight the importance of the pharmacist as the drug expert exerting the pharmaceutical advice for the benefit of the patient.

The third most common PCI category was the dose selection category. The most common PCIs which featured under this category were ‘dose too low for patient’s age, weight and indication and/or severity’ and ‘Dose too high for patient’s age, weight and indication and/or severity’. A case example of dose too low was that of a 5-year old boy suffering from acute lymphoblastic leukaemia. Patients suffering from leukaemia need to be on a medication for Pneumocystis Carinii Pneumonia (PCP) prophylaxis and the most commonly used drug is co-trimoxazole. Doses vary according to body surface area and are specified in the protocol. In this case, the boy had put on weight, his body surface area had changed but the dose of co-trimoxazole had not been increased accordingly. PCP is a very serious opportunistic infection in immunocompromised patients and was the most common cause of death amongst children receiving chemotherapy prior to the inclusion

of PCP prophylaxis (Shankar and Nania, 2007). Ensuring that the right dose of co-trimoxazole is prescribed is crucial as otherwise potentially serious consequences can occur.

A case example of dose too high was that of a 3-year old boy suffering from graft versus host disease post bone marrow transplant. Bacterial cultures and sensitivities for an abscess that had developed on his head showed sensitivity to flucloxacillin. Initially, the patient was given intravenous treatment (500mg every 6 hours) as an in-patient. When he was stable and fit to go home, the doctor discharged him on oral flucloxacillin at a dose of 500mg every 6 hours. For flucloxacillin, intravenous to oral conversion is not 1:1. The dose of the oral drug is approximately half that of the intravenous dose. Upon being identified, the issue was flagged by the pharmacist and subsequently, the dose of flucloxacillin was decreased to 250mg every 6 hours. Such high dose could have resulted in unwanted side effects including profuse diarrhoea. Another example was that of a 5-year-old boy suffering from ALL who was in the maintenance phase of leukaemia treatment. He lost weight and subsequently his body surface area decreased. Patient came for review at the PAW and upon calculating the doses of 6- mercaptopurine and methotrexate, it was noted that the doses were too high for his body surface area. Implications of high doses of chemotherapy are increased risks of haematological toxicity and subsequently interruption of doses. Dose interruptions decrease the rate of therapeutic success and can result in treatment failure and relapse. The presence of a pharmacist on the ward to ensure an optimal therapeutic plan, limiting these side effects and subsequently achieving optimal treatment outcomes is of utmost importance. Other PCIs related to this category dealt with missing, wrong or unclear dose instructions on the

treatment chart or prescriptions such as dose of drug written unclearly on the treatment chart.

In paediatrics, dosing errors are one of the most frequent prescribing errors (Alenezi et al, 2016; Ramadaniati et al, 2016). These PCIs may have potentially serious consequences, either via enhanced toxicity or impaired disease control (Ma, 2004; Davis, 2011; Watts and Parsons, 2013). As shown in this research, pharmacists play a key role by ensuring that drug doses are appropriate (Ma, 2004; SHPA, 2013, ACCP, 2014, EAHP, 2014). Their intervention has a major impact on detecting and reducing dosing errors (Wong and Gray, 1999; Dean et al, 2000; Prot-Labarthe et al, 2008; Davis, 2011; Tuffaha and Abdelhadi, 2012; Fernandez Llamazares et al, 2012; Bauters et al, 2014; Ma, 2014; Ramadaniati et al, 2016).

The fourth most common PCI category was the monitoring category related to laboratory and non-laboratory parameters. A case example of laboratory monitoring was that of a 5-year-old girl suffering from chronic myelomonocytic leukaemia who had been started on digoxin by her consultant abroad due to heart failure post chemotherapy treatment. Laboratory results following request for monitoring of electrolytes, in particular magnesium, potassium and calcium showed persistently low magnesium levels. Subsequently, magnesium supplementation was started to prevent potential digoxin toxicity due to hypomagnesaemia.

A case example of non-laboratory monitoring was that of a 14-year-old boy suffering from Langerhans cell histiocytosis. Part of his treatment regime entailed three weeks of high dose steroids. The issue of the need for monitoring of fasting and post- prandial blood glucose was raised upon steroid treatment initiation. On one occasion, his random

blood glucose result was 11mmol/L. Subsequently, fast acting soluble insulin was prescribed as an ‘as required medication’.

Amongst other cases of monitoring need, the two cases described above continue to prove that the pharmacist has an important role in detecting potential and hence preventing actual drug-related problems (Cipolle et al, 1998). Especially within this speciality of paediatric oncology, clinical pharmacists in collaboration with other members of the healthcare team can help to optimize drug therapy administered to children suffering from cancer (SHPA, 2013; Ma, 2014)

Other PCI categories encountered included the unwanted drug effects and the drug administration categories. A case example of side effect, a PCI which is classified under the unwanted drug effects category was that of an 8-year-old girl suffering from standard risk medulloblastoma. Following chemotherapy treatment initiation which included vincristine, the patient suffered from severe constipation and epileptic seizures. It was brought to the attention of the consultant that these side effects were most likely to be due to the vincristine and as per protocol, subsequent doses of the drug should be decreased from 1.5mg/m^2 to 1mg/m^2. This instigated the consultant to discuss the patient’s case with the consultant from abroad where it was decided to omit the vincristine from future cycles completely. This example confirms that having a pharmacist as part of the interdisciplinary health care team to provide evidence-based professional advice regarding medications including side effects is imperative if it is to be ensured that patients receive the best possible care holistically and ensuring the safest use of medications.

A case example of inappropriate route, a PCI which is classified under the drug administration category was that of a three-year-old immunocompromised boy suffering from shingles. As per clinical guidelines, treatment involves starting with intravenous aciclovir for at least five days and then switch to oral aciclovir for 2 days after crusting of the lesions. Clinician decided to start treatment with oral aciclovir rather than intravenous. Subsequently, clinician was advised that starting treatment with the oral route was inappropriate and if so, that was a case of undertreatment and that shingles could manifest again. The intervention was taken up at a later stage. The pharmacist plays an important role in ensuring the appropriateness of all drugs prescribed. This was a case of inappropriate prescribing which was subsequently flagged up by the pharmacist. Implication is prevention of a potential drug related problem, that is undertreatment of a serious infection in immunocompromised patients and which could result in mortality.

4.4 The clinical pharmacist: an asset to patients?

The implemented pharmaceutical care model was validated by means of the parents' and healthcare professionals' satisfaction questionnaires. The parents' and healthcare professionals' satisfaction questionnaire results were encouragingly positive. The majority of the parents were very satisfied with the advice provided by the pharmacist about their child's medications, with the abilities of the pharmacist and with the overall service provided by the pharmacist. Moreover, the parents strongly agreed with the fact that the pharmacist helped them to increase their knowledge about their child's medications and that the service offered by the pharmacist was beneficial. Some of the parents clearly claimed that the clinical pharmacist was an asset to the service being provided from PAW.

Similar results were obtained in the healthcare professionals' questionnaire. The clinicians and nurses either agreed or strongly agreed with the fact that at PAW, the clinical pharmacist played an important role in providing drug information, calculating drug doses for patients, improving overall patient outcome/ quality of patient care, discharge medication counselling, indicating the need for monitoring when necessary, preventing, identifying and resolving drug interactions, participating in medical ward rounds, checking the correctness of the prescriptions, preventing prescribing errors, analysing patient treatment and suggesting changes in therapy when necessary, monitoring patient response to drug therapy from a side effects perspective, preventing, identifying and managing side effects and monitoring patient response to drug therapy from an effectiveness perspective. All the clinicians and nurses strongly agreed that the presence of the pharmacist at Rainbow ward was beneficial, making them feel safer when working in such a scenario. All of them were very satisfied with the overall service provided by the pharmacist. The lead-clinician claimed that stopping or interrupting the service would result in a disservice to the patients attending PAW.

The results of the questionnaires provided evidence that as service users, parents, clinicians and nurses experienced high satisfaction with the pharmaceutical services offered by the pharmacist. This gives a strong indication that the pharmaceutical care model implemented by the pharmacist was of a very high quality. Furthermore, the research documented a 95% acceptance rate for the pharmaceutical interventions put forward by the pharmacist. This may be looked as a quantitative indicator of the effectiveness of the pharmacist at PAW. It also indicates the establishment of a good working relationship with the medical team as well as the parents which is the basis of successful clinical practice.

4.5 Recommendations

Every research undertaken brings to light a number of recommendations for further studies. In this research, recommendations for service and research development were identified.

4.5.1 Service development

The vision of the Ministry of Health is to expand clinical pharmacy services. This research has shown positive outcomes, indicating the need to implement the pharmaceutical care model on a permanent basis in a setting such as the PAW. Another service development which needs looking into is the development of chemotherapy monographs in English and Maltese. These monographs should be aimed for parents to enhance their knowledge about their child's medications, teaching them the expected side effects and more importantly how to deal with them both physically and emotionally. The development of local guidelines, taking into consideration currently available pharmacotherapy, such as guidelines for the management of febrile neutropenia, nausea and vomiting in our paediatric oncology patients would help increase the standardisation of care and the quality of service offered to our patients.

4.5.2 Research development

As part of further research which could be carried out, one could extend the clinical pharmacy service to other wards lacking a clinical pharmacist. The innovative Gap-Finding Tool could be used in a similar manner to identify gaps and subsequently provide a pharmaceutical service aimed at closing the gaps. The tools used within this research, including the developed PCI classification system can also be extended and adapted for implementation in another clinical area such as paediatric surgery, paediatric emergency

and paediatric anaesthesia. This model will thereby analyse the significance of the PCIs so as to evaluate the impact of the presence of the pharmacist at other clinical areas. Taking the research model a step further, one can design a model to analyse the cost-effectiveness of a pharmacist-led service as described by this research study.

The recommendations put forward for service development namely the development of monographs and the development of local guidelines for certain clinical conditions can be used as recommendations for research development thereby linking the research aspect to the service development.

4.6 Limitations

The limitations of the research were logistics, a small patient population and a limited team of HCPs. Regarding the logistics, the limited amount of time permitted to attend the PAW at times made it difficult to follow up all patients. A small patient population and a limited team of HCPs reflected in a small number of parents and HCPs who were included in the study.

4.7 Conclusion

Every beginning has an end even though the end can be the beginning or transformation into something else. At the end of this research, one can reflect on the relevant contribution of the pharmacist at ward level within the interdisciplinary healthcare team which was made possible through the implementation of an innovative pharmaceutical care model focusing on pharmaceutical care issues individualised according to each patient specific needs. The research used a novel Gap-Finding Tool to identify gaps and tools designed specifically for the local setting at the PAW which made it possible to run

a feasible pharmaceutical care model with the clinical pharmacist managing medication processes in a quality care service.

Results of this research show that pharmaceutical care issues including drug related problems are frequent and may result in reduced quality of life, and even morbidity and mortality. Clinical pharmacists can effectively identify and prevent clinically significant drug-related problems and clinicians, nurses and parents acknowledge and act on the clinical pharmacist's suggestions for interventions to the drug-related problems. This model adds to the continuous improvement of the standard of care provided to patients attending the paediatric oncology unit at Sir Anthony Mamo Oncology Centre.

REFERENCES

Alenezi S, Abramson J, Smith C, Sammons H, Conroy S. Interventions made by UK pharmacists to minimise risk from paediatric prescribing errors. Archives of Disease in Childhood. 2016;101(9):A1-A37.

American College of Clinical Pharmacy. Standards of Practice for Clinical Pharmacists. Pharmacotherapy. 2014; 34(8):794-797.

American Society of Hospital Pharmacists. ASHP statement on pharmaceutical care. American Journal of Hospital Pharmacy.1993;50:1720–1723.

Avery M, Williams F. The importance of pharmacist providing patient education in oncology. Journal of Pharmacy Practice. 2014;28(1):26-30.

Beavers B. New Practitioners Forum: Specialising in paediatric haematology and oncology. American Journal of Health-System Pharmacy. 2007;64:812-13

Bhatt-Mehta V, Buck M, Chung A, Farrington EA, Hagemann T, Hoff D et al. Recommendations for meeting the paediatric patient's need for a clinical pharmacist: A joint opinion of the paediatrics practice and research network of the American College of clinical pharmacy and the paediatric advocacy group. The Journal of Paediatric and Therapeutics. 2012;17(3):281-291.

Bauters T, Vinent-Genestar J, Delaney J, Mycroft J, Vandenbroucke J. Role of the clinical pharmacist in a paediatric haemato-oncology stem cell transplantation ward. European Journal of Hospital Pharmacy. 2014;21(5):309-312.

Belson M, Kingsley B, Holmes A. Risk factors for acute leukaemia in children: a review. Environmental Health Perspectives. 2007;115(1):138-145.

Calvagna V. Paediatric cancer in Malta. The Chronic ill. 2003;7:14-16.

Cehajic I, Bergan S, Bjordal K. Pharmacist assessment of drug-related problems on an oncology ward. European Journal of Hospital Pharmacy. 2015;22(4):194-197.

Cipolle R, Strand L, Morley P. Pharmaceutical Care Practice. New York; NY: McGraw-Hill; 1998.

Cipolle R, Strand LM, Morley P, Frakes M. Pharmaceutical Care Practice; the clinician's guide. New York; McGraw Hill; 2004: 78-79, 165.

Davis T. Paediatric prescribing errors. Archives of Disease in Childhood. 2011;96(5):489-491.

Dean B, Barber N, Schachter M. What is a prescribing error? Quality in Health Care. 2000;9(4):232-237.

Defoe K, Jupp J, Leslie T. Integration of clinical pharmacists into an ambulatory, paediatric haematology/oncology/transplant clinic. Journal of Oncology Pharmacy Practice. 2018;0(0):1-6.

Delpeuch A, Leveque D, Gourieux B, Herbrecht R. Impact of clinical pharmacy services in a haematology/ oncology inpatient setting. Anticancer Research. 2015;35(1):457-460.

DiPiro J, Talbert R, Yee G, Matzke G, Wells B, Posey L. Pharmacotherapy: a pathophysiologic approach. 8th ed. New York: McGraw-Hill Education; 2011.

Donald G, Scott S, Broadfield L, Harding C, Meade A. Optimizing patient education of oncology medications: A descriptive survey of pharmacist-provided patient education in Canada. Journal of Oncology Pharmacy Practice. 2017;0(0):1-8.

Erdlenbruch B, Lakomek M, Bjerre LM. Editorial: chemotherapy errors in oncology. Med Pediatr Oncol. 2002;38(5):353–356.

Eisenhut M, Sun B, Skinner S. Reducing prescribing errors in paediatric patients by assessment and feedback targeted at prescribers. ISRN Paediatrics. 2011:1-5.

European Association of Hospital Pharmacy. The European Statements of Hospital Pharmacy. European Journal of Hospital Pharmacy. 2014;21(5).

Farias T, Aguiar K, Rotta I, Belletti K, Carlotto J. Implementing a clinical pharmacy service in haematology. Einstein (São Paulo). 2016;14(3):384-390.

Fernandez-Llamazares C, Calleja-Hernandez M, Manrique-Rodriguez S, Pérez-Sanz C, Duran-García E, Sanjurjo-Saez M. Impact of clinical pharmacist interventions in reducing paediatric prescribing errors. Archives of Disease in Childhood. 2012;97(6):564-568.

Fernandez-Llamazares C, Pozas M, Feal B, Cabanas J, Villaronga M, Hernandez- Gago Y et al. Profile of prescribing errors detected by clinical pharmacists in paediatric hospitals in Spain. International Journal of Clinical Pharmacy. 2013;35:638-646.

Fisher C, Kim A, Elder J. Impact of a pharmacist-led chemotherapy education program on the knowledge of paediatric haematology/oncology nurses. The Journal of Paediatric Pharmacology and Therapeutics. 2017;22(5):332-337.

Fosbrook C. Rates and types of prescribing errors and related interventions in paediatric oncology. Archives of Disease in Childhood. 2016;101(9): A1-A37.

Gatta G, Botta L, Rossi S, Aareleid T, Bielska-Lacosta M, Clavel J et al. Childhood cancer survival in Europe 1999-2007: results of EUROCARE-5-a population-based study. The Lancet Oncology. 2014;15:35-47.

Glick A, Farkas J, Nicholson J, Dreyer B, Fears M, Bandera C et al. Parental Management of discharge instructions: A Systematic Review. Paediatrics. 2017;140(2):e20164165.

Guy J, Persaud J, Davies E, Harvey D. Drug errors: What role do nurses and pharmacists have in minimizing the risk? Journal of Child Health Care. 2003;7(4):277-290.

Hamel C, Tortolano L, Bermudez E, Desmaris R, Klein S, Slimano F et al. Computerized paediatric oncology prescriptions review by pharmacist: A descriptive analysis and associated risk factors. Paediatric Blood & Cancer. 2017;65(4):1-6.

Hepler C. A dream deferred. American Journal of Health-System Pharmacy. 2010;67.

Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. American Journal of Hospital Pharmacy. 1990;47 (3): 533-543.

Holle L, Harris C, Chan A, Fahrenbruch R, Labdi B, Mohs J, et al. Pharmacists' roles in oncology pharmacy services: Results of a global survey. Journal of Oncology Pharmacy Practice. 2016;23(3):185-194.

Holle L, Michaud L. Oncology pharmacists in health care delivery: Vital members of the cancer care team. Journal of Oncology Practice. 2014;10(3):142-145.

Horstman M, Mills W, Herman L, Cai C, Shelton G, Qdaisat T et al. Patient experience with discharge instructions in post discharge recovery: A qualitative study. BMJ Open. 2017;7(2):e014842.

Hudson M, Meyer W, Pui C. Progress born from a legacy of collaboration. Journal of Clinical Oncology. 2015;33:2935-2937.

Kaatsch P. Epidemiology of childhood cancer. Cancer Treatment Reviews. 2010;36:277-85.

Kaboli P, Hoth A, McClimon B, Schnipper J. Clinical pharmacists and inpatient medical care. Archives of Internal Medicine. 2006; 166:955-964.

Kaestli L, Noble S, Combescure C, Lacroix L, Galetto A, Gervaix A et al. Drug information leaflets improve parental knowledge of their child's treatment at paediatric emergency department discharge. European Journal of Hospital Pharmacy. 2015;23(3):151-155.

Kaushal R. Medication errors and adverse drug events in paediatric inpatients. Journal of the American Medical Association. 2001;285(16):2114-2120.

Kemp K, Santana M, Jolley R, Southern D, Quan H. Discharge communication and patient involvement are associated with unplanned hospital readmissions: results from a validated hospital experience survey. International Journal for Population Data Science. 2017;1(1).

Krska J, Cromarty J, Arris F, Jamieson D, Hansfor D. Providing pharmaceutical care using a systematic approach. 2000;265(7120):656-660.

Krska J, Jamieson D, Arris F, McGuire A, Abbott S, Hansford D et al. A classification system for issues identified in pharmaceutical care practice. International Journal of Pharmacy Practice. 2002;10(2):91-100.

Leveque D, Delpeuch A, Gourieux B. New Anticancer Agent: Role of Clinical Pharmacy Services. Anticancer research. 2014; 34:1573-1578.

Liekweg A, Westfeld M, Jaehde U. From oncology pharmacy to pharmaceutical care: New contributions to multidisciplinary cancer care. Support Care Cancer. 2004;12:73-79.

Lin Q, Wang G, Ma G, Shen Q. The role of pharmaceutical care in the oncology department. European Journal of Hospital Pharmacy. 2015;22:128-131.

Ma C. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. Integrated Pharmacy Research and Practice. 2014;3:11-24.

MacDonald T. Paediatric Cancer: A Comprehensive Review. Part I: Biology, Epidemiology, Common Tumours, Principles of Treatment and Late Effects. Canadian Pharmacists Journal. 2010;143(4):176-183.

Mancini R. Implementing a standardized pharmacist assessment and evaluating the role of a pharmacist in a multidisciplinary supportive oncology clinic. J Support Oncol. 2012;10(3):99-106.

Maxwell S. Rational prescribing: The principles of drug selection. Clinical Medicine. 2016;6(5):459-464.

Murphy M, Bithell J, Stiller C, Kendall G, O'Neill K. Childhood and adult cancers: Contrasts and commonalities. Maturitas. 2013;76(1):95-98.

O'Neill K, Murphy M, Bunch K, Puumala S, Carozza S, Chow E et al. Infant birthweight and risk of childhood cancer: International population-based case control studies of 40000 cases. International Journal of Epidemiology. 2015;44(1):153-168.

Pedersen C, Schneider P, Scheckelhoff D. ASHP national survey of pharmacy practice in hospital settings: Monitoring and patient education--2015. American Journal of Health-System Pharmacy. 2016;73(17):1307-1330.

Porter E, Barcega B, Kim T. Analysis of medication errors in simulated paediatric resuscitation by residents. Western Journal of Emergency Medicine. 2014;15(4):486-490.

Prot-Labarthe S, Therrien R, Demanche C, Larocque D, Bussières J. Pharmaceutical care in an inpatient paediatric hematopoietic stem cell transplant service. Journal of Oncology Pharmacy Practice. 2008;14(3):147-152.

Ramadaniati H, Lee Y, Hughes J, Emmerton L. Pharmacists' Interventions in a Paediatric Haematology-Oncology Pharmacy: Do They Matter to Minimise Medication Misadventure? Indonesian Journal of Clinical Pharmacy. 2016;5(1):1-10.

Randolph L, Walker C, Nguyen A, Zachariah S. Impact of pharmacist interventions on cost avoidance in an ambulatory cancer centre. Journal of Oncology Pharmacy Practice. 2016;24(1):3-8.

Ries L, Smith M, Gurney J, Linet M, Tamra T, Young J et al. Cancer Incidence and survival among children and adolescents: United States SEER Program 1975-1995. Bethesda; 1999.

Schmidt C. Childhood cancer: A growing problem. Environmental Health Perspectives. 1998;106(1):A18-23.

Sessions J, Valgus J, Barbour S, Iacovelli L. Role of Oncology Clinical Pharmacists in Light of the Oncology Workforce Study. Journal of Oncology Practice. 2010;6(5):270-272.

Shankar S, Nania J. Management of Pneumocystis jiroveci Pneumonia in children receiving chemotherapy. Paediatric Drugs. 2007;9(5):301-309.

SHPA Committee of Specialty Practice in Clinical Pharmacy. Standards of Practice for Clinical Pharmacy Services. Journal of Pharmacy Practice and Research. 2013; 43(2). Available from: https://www.shpa.org.au/resources/standards-of-practice-for-clinical-pharmacy-services.

SHPA Committee of Specialty Practice in Oncology. Standards of Practice for the provision of Clinical Oncology Pharmacy Services. Journal of Pharmacy Practice and Research. 2002; 32(2). Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1002/jppr2002322115.

Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2018. CA: A Cancer Journal for Clinicians. 2018; 68:7-30.

Spector L, Pankratz N, Marcotte E. Genetic and nongenetic risk factors for childhood cancer. Paediatric Clinics of North America. 2015;32(1):11-25.

Steliarova- Foucher E, Stiller C, Lacour B, Kaatsch P. International Classification of Childhood Cancer, Third Edition. Cancer. 2005;103(7):1457-1467.

Steliarova- Foucher E, Colombet M, Ries L, Moreno F, Dolya A, Bray F, et al. International incidence of childhood cancer, 2001-10: a population-based registry study. The Lancet Oncology [Internet]. 2017 [cited 2018 May 5]. Available from: https://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(17)30186-9.pdf.

Taylor J, Winter L, Geyer L, Hawkins D. Oral outpatient chemotherapy medication errors in children with acute lymphoblastic leukaemia. Cancer. 2006;107(6):1400-1406.

Thomas D, Bradley L, Servi A, Reilly S, Niskala Apps J, McCrea M et al. Parental knowledge and recall of concussion discharge instructions. Journal of Emergency Nursing. 2018;44(1):52-56.

Tuffaha HW, Abdelhadi O. Clinical pharmacy services in the outpatient paediatric oncology clinics at a comprehensive cancer centre. International Journal of Clinical Pharmacy. 2012;34:27-31.

Tulip S, Campbell D. Evaluating pharmaceutical care in hospitals. *Hosp Pharm.* 2001; 8: 275-279.

Valgus J, Faso A, Gregory K, Jarr S, Savage S, Caiola S et al. Integration of a clinical pharmacist into the haematology-oncology clinics at an academic medical centre. American Journal of Health-System Pharmacy. 2011;68(7):613-619.

van Mil F. Drug-related problems: a cornerstone for pharmaceutical care. Journal of the Malta College of Pharmacy Practice. 2005;10:5-8.

Viktil K, Blix H. The impact of clinical pharmacists on drug-related problems and clinical; outcomes. Basic & Clinical Pharmacology & Toxicology. 2008;102:275-280.

Walsh K, Dodd K, Seetharaman K, Roblin D, Herrinton L, Von Worley A et al. Medication errors among adults and children with cancer in the outpatient setting. Journal of Clinical Oncology. 2009;27(6):891-896.

Watts R, Parsons K. Chemotherapy medication errors in a paediatric cancer treatment centre: Prospective characterization of error types and frequency and development of a quality improvement initiative to lower the error rate. Paediatric Blood & Cancer. 2013;60(8):1320-1324.

Williams M, Peterson G, Tenni P, Bindoff I, Stafford A. DOCUMENT: A system for classifying drug-related problems in community pharmacy. International Journal of Clinical Pharmacy. 2011;34(1):43-52.

Wong I, Ghaleb M, Franklin B, Barber N. Incidence and Nature of Dosing Errors in Paediatric Medications. Drug Safety. 2004;27(9):661-670.

Wong S, Gray E. Clinical pharmacy services in oncology clinics. Journal of Oncology Pharmacy Practice. 1999;5(1):49-54.

Appendix 1

UREC Approval Letters

L-UNIVERSITÀ TA' MALTA

Msida – Malta
Skola Medika
Sptar Mater Dei

UNIVERSITY OF MALTA

Msida – Malta
Medical School
Mater Dei Hospital

Ref No: **15/2017**

Tuesday 30th May 2017

Ms. Sephorah Falzon
4, Saint Pearl Flats, Flat 2
Triq Sir Paul Boffa
Marsascala

Dear Ms. Sephorah Falzon,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Development of a Pharmaceutical Care Model within Paediatric Oncology

The University Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

L-Università ta' Malta

Faculty of
Medicine & Surgery

University of Malta
Msida MSD 2080, Malta

Tel: +356 2340 1879/1891/1167
umms@um.edu.mt

www.um.edu.mt/ms

Ref No: **15/2017**

Monday 15th January 2018

Ms. Sephorah Falzon
4, Saint Pearl Flats, Flat 2
Triq sir Paul Boffa
Marsascala

Dear Ms. Sephorah Falzon,

Please refer to your application to gather an extension of the ethics approval submitted to the Research Ethics Committee in connection with your research entitled:

Development of a Pharmaceutical Care Model within Paediatric Oncology

The University Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

Appendix 2

Gap Finding Tool

Gap Finding Tool- The roles of a Ward-Based Pharmacist

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 in Pharmacy, April 2017

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		
Asking about the use of **adherence** aids		
Asking about **storage** of current medications at home		
Assessing parent's/ patient's understanding of their child's/ their illness and determining if there is need for further **education about the illness**		
Assessing parent's/ patient's understanding and attitude to their child's/ their **current drug therapy**		
Assessing parent's/ patient's ability to **use drugs as prescribed**		
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		
Ensuring that drug names and directions 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 recognized 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 **duplications**		
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		
Tracking the cumulative doses of anti-cancer drugs		
Providing information on extemporaneous oral formulations		
Liaising with the cytotoxic manufacturing service to coordinate the timely supply of chemotherapeutics		
Ensuring drugs are available at the ward and where necessary are ordered, e.g. current medicine, premedication, 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 prioritizing these per their risk and urgency		
Performing **follow-up** evaluations in collaboration with other members of the healthcare team to continually assess patient outcomes		

4. Therapeutic drug monitoring (TDM)	Tick	Comment
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** and future **monitoring requirements**		

5. Medicines information	Tick	Comment
Providing medicines information to **healthcare professionals** to provide patient-centred care and optimise quality use of medicines		
Providing medicines information to patients and their **parents/legal guardians** to improve their capacity for involvement, engage them in their health care and encourage the safe and appropriate use of medicines, thereby, enhancing therapeutic outcomes. This includes assuring the safe handling of hazardous drugs		

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 medication-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		
Involvement in the management of all cancer and drug related complications (e.g. nausea, infection, pain etc. in paediatric oncology patients)		
Developing and implementing pharmacological treatment guidelines on acute and late effects of chemotherapy drugs		

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 **discharge planning**		

8. Information for ongoing care	Tick	Comments
A. Managing the patient's medicines and communicating with them/ their parents or legal guardians on transition		
Discussing the medicines that need to be supplied or sourced on discharge or transfer with the parent/legal guardian/ patient		
Annotating which medicines need to be supplied on discharge on the patient profile		
Removing ceased medicines for destruction with the parent's/legal guardian's/ patient's permission		
Providing the parents/legal guardians/ patients with the medicines that their child/ they require/s		
Providing a written list of the discharge medications as well as directions of how they should be taken, why they are used, start and stop date as well as a hospital contact name and telephone number		
Providing information about adherence aids		
Encouraging parents/legal guardians/ patients to contact their hospital pharmacist at any time, even after discharge as they may require further information despite comprehensive counselling		
Educating parents/legal guardians/ patients on how their child/ they should take any new medication prescribed, how to identify side effects and what to do if they occur after being discharged.		
A. Liaising with other Healthcare Professionals on transition		
Obtaining consent and then communicating all medicines-related information in a timely manner to the patient's GP,		

community pharmacist, residential care provider or other healthcare professional; • details of medicines prescribed on discharge or 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**	**Comment**
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, ADRs/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		

Adopted from:

European Association of Hospital Pharmacy. The European Statements of Hospital Pharmacy. European Journal of Hospital Pharmacy. 2014;21(5)

SHPA Committee of Specialty Practice in Clinical Pharmacy. Standards of Practice for Clinical Pharmacy Services. Journal of Pharmacy Practice and Research. 2013; 43(2). Available from: https://www.shpa.org.au/resources/standards-of-practice-for-clinical-pharmacy-services

American College of Clinical Pharmacy. Standards of Practice for Clinical Pharmacists. Pharmacotherapy. 2014; 34(8):794-797

Appendix 3

Validation questions for the Gap Finding Tool

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the ***Gap-Finding Tool*** *which has been compiled as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The following are questions which enable you to express your opinion about the Gap- Finding Tool, which shall be completed by the Pharmacist- Researcher during the research.*

The aim of this tool is to assess and document what Pharmacy services are offered at Rainbow Ward and what Pharmacy services are lacking.

Please answer the following 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 Rainbow Ward 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				
Do not relate at all	**Relate Slightly**	**Relate Moderately**	**Relate**	**Relate Considerably**
0	1	2	3	4
Comments _____ _____ _____				
SECTION 2: CURRENT MEDICATION MANAGEMENT				
Do not relate at all	**Do not relate at all**	**Do not relate at all**	**Do not relate at all**	**Do not relate at all**
0	1	2	3	4
Comments _____ _____ _____				

SECTION 3: CLINICAL REVIEW

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 4: THERAPEUTIC DRUG MONITORING

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 5: PROVIDING MEDICINES INFORMATION

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 6: ADR MANAGEMENT

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 7: PARTICIPATING IN INTERDISCIPLINARY CARE

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 8: INFORMATION FOR ONGOING CARE

Do not relate at all	Relate Slightly	Relate Moderately	Relate	Relate Considerably
0	1	2	3	4

Comments

_____

_____

_____

SECTION 9: DOCUMENTATION				
Do not relate at all	**Relate Slightly**	**Relate Moderately**	**Relate**	**Relate Considerably**
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 help.

Sephorah Falzon

Doctorate of Pharmacy Student

Appendix 4

Discharge Medication Guide for parents in English and Maltese

Medications on Discharge: Guide to parents or legal guardians

Name:	Surname:	ID No:	Allergies:	Consultant:	Date:

Name of Medicine	Dosage Form	Time (T) / Dose (D)				What the medicine is for	Other Comments	Date	
								Started	Stopped
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				

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 in Pharmacy, 2017

Name of Medicine	Dosage Form	Time (T) / Dose (D)				What the medicine is for	Other Comments	Date	
								Started	Stopped
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				
		T	T	T	T				
		D	D	D	D				

Compiled by:
Contact no:

Mediċini wara Ħruġ mill-Isptar: Gwida għall-Ġenituri jew Gwardjani Legali

Isem:	Kunjom:	Numru ta' l-ID:	Allerġiji:	Konsulent:	Data:

Isem tal-mediċina	Forma tal-mediċina	Ħin (Ħ) / Doża (D)				Għalfejn tintuża l-mediċina	Kummenti oħra	Data	
								Bidu	Tmiem
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				

Magħmula minn S. Falzon bħala parti mir-riċkerka intitolata "Żvilupp ta' mudell tal-kura farmaċewtika fil-qasam ta' l-onkoloġija pedjatrika" sabiex jiġu sodifatti r-rekwiżiti tal- lawrja ta' dottorat, 2017

Isem tal-mediċina	Forma tal-mediċina	Ħin (Ħ) / Doża (D)				Għalfejn tintuża l-mediċina	Kummenti oħra	Data	
								Bidu	Tmiem
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				
		Ħ	Ħ	Ħ	Ħ				
		D	D	D	D				

Mimlija minn:

Kuntatt:

Appendix 5

Validation questions for the Discharge Medication Guide for parents

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the ***Discharge Medication Guide to Parents or Legal guardians*** *which has been compiled as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The following are questions which enable you to express your opinion about the Guide, which shall be completed by the Pharmacist- Researcher during the research.*

The aim of the Discharge Medications Guide to Parents or Legal guardians is to enhance compliance, knowledge and safe and effective use of discharge medications of children and adolescents with cancer

---

Please answer the following questions:

1. Is there anything that you would like to change in the **format** of the Discharge Medications Guide?

   Yes ☐ No ☐

   If yes, kindly specify.

   _____

   _____

   _____

   _____

   _____

   _____

2a. From a scale of 0 to 4, how much do you think that the **content** of the table is relevant so that the Discharge Medications Guide will fulfil its aims?

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

2b. Kindly indicate any sections which you would add, omit or change in the table below.

Sections to add	
Sections to omit	
Sections requiring change	

3. From a scale of 0 to 4, how much do you think that the **wording** of the Discharge Medications Guide is easy to understand by the parents or legal guardians?

Not Easy at All	Slightly Easy	Moderately Easy	Easy	Very Easy
0	1	2	3	4

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

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

5a. Do you think that the fact that the Discharge Medications Guide was compiled in both English and Maltese was a good idea?

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
0	1	2	3	4

5b. Kindly indicate any changes that you would recommend in this regard.

_____

_____

_____

6. Did the Discharge Medications Guide create a positive impression?

Yes ☐ No ☐

Further comments and recommendations which you wish to suggest regarding the Discharge Medications Guide to Parents or Legal guardians.

_____

_____

Thank you for your time and help.

Sephorah Falzon

Doctorate of Pharmacy student

Appendix 6

Pharmacy Patient Profile

Appendix 7

Validation questions for the Pharmacy Patient Profile

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the ***Pharmacy Patient Profile*** *which has been compiled as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The following are questions which enable you to express your opinion about the Pharmacy Patient Profile, which shall be completed by the Pharmacist- Researcher during the research.*

The aim of the Pharmacy Patient Profile is so that the Pharmacist- Researcher would have a tool to document patient- related information including patient treatment and interventions in terms of pharmaceutical care issues.

Please answer the following questions:

2. Is there anything that you would like to change in the **format** of the Pharmacy Patient Profile?

   Yes ☐ No ☐

   If yes, kindly specify.

   _____

   _____

   _____

   _____

   _____

   _____

2a. From a scale of 0 to 4, how much do you think that the **content** of the Pharmacy Patient Profile is relevant so that it will fulfil its aims?

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

2b. Kindly indicate the sections which you would add, omit or change in the table below.

Sections to add	
Sections to omit	
Sections requiring change	

3. Did the Pharmacy Patient Profile create a positive impression?

Yes ☐ No ☐

Further comments and recommendations which you wish to suggest regarding the Pharmacy Patient Profile.

_____

_____

Thank you for your time and help.

Sephorah Falzon

Doctorate of Pharmacy student

Appendix 8

Parents' satisfaction questionnaire in English and Maltese

Dear parent/legal guardian,

Thank you for your participation. The purpose of this questionnaire is to evaluate parents' level of satisfaction and perceived benefits of the service offered by the Pharmacist at Rainbow Ward regarding their child's treatment.

Kindly indicate your level of satisfaction with each of the following statements:

A. Advice given by the Pharmacist about:	**Very dissatisfied**	**Dissatisfied**	**Neutral**	**Satisfied**	**Very Satisfied**
1. The reasons why the medications are being given to your child.	0	1	2	3	4
2. How and when you should give your child his/her medications.	0	1	2	3	4
3. How you should store your child's medications.	0	1	2	3	4
4. The possible side effects of your child's medications.	0	1	2	3	4
5. What you should do if your child develops any of these side effects.	0	1	2	3	4

B. Ability of the Pharmacist to:	**Very dissatisfied**	**Dissatisfied**	**Neutral**	**Satisfied**	**Very Satisfied**
6. Speak clearly and slowly.	0	1	2	3	4
7. Explain things in a way that is easy for you to understand.	0	1	2	3	4
8. Show sensitivity whilst providing advice.	0	1	2	3	4
9. Listen to all your questions about your child's medications.	0	1	2	3	4
10. Answer all your questions about your child's medications.	0	1	2	3	4

C. Overall Service	**Very dissatisfied**	**Dissatisfied**	**Neutral**	**Satisfied**	**Very Satisfied**
11. Overall service provided by the Pharmacist.	0	1	2	3	4

Kindly answer the following questions:

12. Is this the first time you are visiting Rainbow Ward?

Yes ☐ No ☐

If the answer to question 12 is 'Yes', kindly proceed to question 14. If the answer to question 12 is 'No', kindly proceed to question 13.

13. Have you ever discussed your child's treatment with another Pharmacist at Rainbow Ward?

Yes ☐ No ☐

Kindly indicate how far you agree that:

	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
14. The Pharmacist has helped you to increase your knowledge about your child's medications.	0	1	2	3	4
15. The Pharmacist made sure that you understood all the information that she provided regarding your child's medications.	0	1	2	3	4
16. The service offered by the Pharmacist at Rainbow Ward is beneficial.	0	1	2	3	4

17. During future visits, would you like to discuss your child's medications with a Pharmacist?

Yes ☐ No ☐

18. Kindly indicate below any further recommendations or comments that you might have about the service provided by the pharmacist at Rainbow Ward.

_____

Għażiż ġenitur/gwardjan legali,

Grazzi tal-parteċipazzjoni tiegħek. Dan il-kwestjonarju qed isir sabiex jiġi evalwat kemm il-ġenituri kienu sodisfatti u kemm jaħsbu li kien ta' beneficċju is-servizz li tagħthom l-ispiżjara ta' Rainbow Ward dwar it-trattament tat-tifel/tifla tagħhom.

Jekk jogħġbok indika kemm inti sodisfatt b'dawn li ġejjin:

A. Il-pariri mogħtija mil-ispizjara dwar:	**Assolutament Mhux Sodisfatt/a**	**Mhux Sodisfatt/a**	**Newtrali**	**Sodisfatt/a**	**Sodisfatt/a Ħafna**
1.Ghalxiex il-mediċini qegħdin jingħataw lit-tifel/tifla tiegħek.	0	1	2	3	4
2. Kif u meta għandek tagħti l-mediċini lit-tifel/tifla tiegħek	0	1	2	3	4
3. Kif għandek terfa l-mediċini tat-tifel/tifla tiegħek	0	1	2	3	4
4. L-effetti mhux mixtieqa (side effects) li l-mediċini jistgħu ikollhom fuq it-tifel/tifla tiegħek.	0	1	2	3	4
5. X'għandek tagħmel f'każ li t-tifel/tifla tiegħek jibda/tibda isofri/issofri minn dawn l-effeti mhux mixtieqa.	0	1	2	3	4

B. Il-kapacità tal-ispiżjara sabiex:	**Assolutament Mhux Sodisfatt/a**	**Mhux Sodisfatt/a**	**Newtrali**	**Sodisfatt/a**	**Sodisfatt/a Ħafna**
5. Titkellem b'mod ċar u bil-mod.	0	1	2	3	4
6. Tispjega b'mod u manjiera li jkun faċli għalik li tifhem	0	1	2	3	4
7. Turi sensittività waqt li qed titkellem miegħek.	0	1	2	3	4
8. Tisma' l- mistoqsijiet dwar il-mediċini tat-tifel/tifla tiegħek kollha	0	1	2	3	4
9. Twieġeb għall-mistoqsijiet dwar il-medicini tat-tifel/tifla tiegħek kollha.	0	1	2	3	4

C. Is-servizz b'mod ġenerali	**Assolutament Mhux Sodisfatt/a**	**Mhux Sodisfatt/a**	**Newtrali**	**Sodisfatt/a**	**Sodisfatt/a Ħafna**
10. Is-servizz b'mod ġenerali offrut mill-ispiżjara	0	1	2	3	4

Jekk jogħġbok, wieġeb il-mistoqsijiet li ġejjin:

11. Din hija l-ewwel vista tiegħek ġewwa *Rainbow Ward*?

Iva ☐ Le ☐

Jekk it-tweġiba għall-mistoqsija 11 hija 'Iva', jekk jogħġbok kompli minn mistoqsija 13. Jekk it-tweġiba għall-mistoqsija 11 hija 'Le', jekk jogħġbok kompli minn mistoqsija 12.

12. Gieli tkellimt ma' spiżjar/a ieħor/oħra dwar it-trattament tat-tifel/tifla tiegħek ġewwa Rainbow Ward?

Iva ☐ Le ☐

Jekk jogħġbok indika kemm taqbel illi:

	Assolutament Ma Naqbilx	**Ma Naqbilx**	**Newtrali**	**Naqbel**	**Naqbel Ħafna**
13. L-ispiżjara għenitek sabiex ittejjeb l-għarfien tiegħek dwar il-mediċini tat-tifel/tifla tiegħek.	0	1	2	3	4
14. l-ispiżjara rat illi fhimt l-informzzjoni li tagħtek dwar il-mediċini tat-tifel/tifla tiegħek.	0	1	2	3	4
15. Is-servizz mogħti mill-ispiżjara ġewwa Rainbow Ward hu ta' benefiċċju	0	1	2	3	4

16. Waqt visti ohra fil-futur, tixtieq illi tiltaqa' u tiddiskuti il-mediċini tat-tifel/tifla tiegħek mal-ispiżjar/a?

Iva ☐ Le ☐

17. Indika hawn taħt rakkomandazzjonijiet jew kummenti oħra dwar is-servizz mogħti mill-ispiżjara ġewwa Rainbow Ward.

_____

Appendix 9

Validation questions for the parents' satisfaction questionnaire

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the ***Questionnaire for Parents or Legal Guardians*** *which has been compiled as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The following are questions which enable you to express your opinion about the questionnaire, which shall be completed by the parents or legal guardians at the end of the discharge medication counselling session and after that they have been provided with the Discharge Medications Guide.*

The aim of this questionnaire is to assess parents' satisfaction and perceived benefits of the interaction with the pharmacist.

Please answer the following questions:

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

Not Easy at All	Slightly Easy	Moderately Easy	Easy	Very Easy
0	1	2	3	4

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

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

2b. Kindly indicate any questions which you would add or omit.

_____

_____

_____

_____

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

   Yes ☐ No

   If yes, kindly specify.

   _____

   _____

4. 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

5. 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

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

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

7. Did the questionnaire create a positive impression?

   Yes No ☐

Further comments and recommendations which you wish to suggest regarding the Questionnaire for Parents/ Legal Guardians.

_____

_____

Thank you for your time and help.

Sephorah Falzon

Doctorate of Pharmacy student

Appendix 10

Healthcare professionals' satisfaction questionnaire

Healthcare professionals' satisfaction questionnaire

The purpose of this questionnaire is to assess the clinician's and nurse's satisfaction and perceived benefits of having a Clinical Pharmacist at Rainbow ward as part of the interdisciplinary team.

Kindly answer the following questions:

1. What is your profession?

Consultant Paediatric Oncologist	
Resident Specialist	
Higher Specialist Trainee	
Basic Specialist Trainee	
House Officer	
Nurse	
Other	

If other, kindly specify _____

Kindly indicate how far you agree with the following statements:

2. At Rainbow ward, the Clinical Pharmacist plays an important role in:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. Discharge medication counselling.	0	1	2	3	4
b. Monitoring patient response to drug therapy from a side effects perspective.	0	1	2	3	4
c. Monitoring patient response to drug therapy from an effectiveness perspective.	0	1	2	3	4
d. Providing drug information such as compatibility, stability, storage, availability, doses, appropriate route of administration, reconstitution, dilution and method of administration.	0	1	2	3	4
e. Analysing patient treatment and suggesting changes in therapy when necessary.	0	1	2	3	4
f. Indicating the need for monitoring when necessary.	0	1	2	3	4
g. Preventing, identifying and managing side effects.	0	1	2	3	4

h.	Preventing, detecting and resolving drug interactions.	0	1	2	3	4
i.	Calculating drug doses for patients.	0	1	2	3	4
j.	Participating in medical ward rounds.	0	1	2	3	4
k.	Checking the correctness of prescriptions (right patient, right drug, right time, right dose and right route).	0	1	2	3	4
l.	Preventing prescribing errors.	0	1	2	3	4
m.	Improving over-all patient outcome/quality of patient care.	0	1	2	3	4

3. In your opinion, apart from the roles mentioned above (question 2), what other roles should the Clinical Pharmacist have at Rainbow Ward?

_____

_____

_____

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
4. Kindly indicate how far you agree that the presence of a Pharmacist at Rainbow Ward is beneficial	0	1	2	3	4

	Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
5. Kindly indicate your level of satisfaction with the overall service provided by the Pharmacist at Rainbow ward	0	1	2	3	4

6. Would you like to see the Clinical Pharmacist's role expanding at Rainbow Ward?

Yes	
No	

Please give a reason for your answer.

_____

_____

_____

Appendix 11

Validation questions for the healthcare professionals' satisfaction questionnaire

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the ***healthcare professionals' satisfaction questionnaire*** *which has been compiled as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'. The following are questions which enable you to express your opinion about the questionnaire, which shall be completed by Health Care Professionals working at Rainbow Ward after that the Pharmaceutical Care Model has been developed.*

The aim of this questionnaire is to assess medical doctors' and nurses' satisfaction and perceived benefits of having a clinical pharmacist on the ward as part of the interdisciplinary team.

Please answer the following questions:

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

Not Easy at All	Slightly Easy	Moderately Easy	Easy	Very Easy
0	1	2	3	4

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

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

2b. Kindly indicate any questions which you would add or omit.

_____

_____

_____

_____

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

   Yes ☐ No ☐

   If yes, kindly specify.

   _____

   _____

9. 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

10. 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

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

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

12. Did the questionnaire create a positive impression?

Yes ☐ No ☐

Further comments and recommendations which you wish to suggest regarding the Questionnaire for Health Care Professionals.

_____

_____

Thank you for your time and help.

Sephorah Falzon

Doctorate of Pharmacy student

Appendix 12

Classification system for PCIs

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 13

Validation questions for the classification system for PCIs

Validation of the Pharmaceutical Care Issues (PCIs) classification system developed by S. Falzon as part of the dissertation entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology', 2017

1. Kindly indicate any categories which you would add, omit or change to the classification system in the table below.

Categories to add	
Categories to omit	
Categories requiring change	

2. Each category is made up of one or more PCIs.
For every category, kindly

(i) Indicate if there are any PCIs which you would change or omit
(ii) Give a **reason** for any changes and/or omissions in the 'Comments' section
(iii) Indicate **how** you would change the PCI in the 'Comments' section in case you propose any changes
(iv) State any PCIs which you would add in the 'Add' section

Category 1: Drug selection

PCI	Change	Omit	Comments
1.1 Drug interaction			
1.2 Inappropriate dosage form			
1.3 Incorrect strength			
1.4 Contraindication			
1.5 No indication or indication no longer apparent			
1.6 Too many drugs prescribed for indication			
1.7 No drug treatment despite existing indication requiring management or prevention			
1.8 Need for an additional drug to properly manage a condition (undertreated condition)			
1.9 Ineffective drug			
1.10 Non-adherence to protocol or guidelines			
Add:			

Category 2: Dose selection

PCI	Change	Omit	Comments
2.1 Dose too low for patient's age and weight			
2.2 Dose too high for patient's age and weight			
2.3 Overtreatment but when drug was introduced the dose selected was correct			
2.4 Undertreatment but when drug was introduced the dose selected was correct			
Add:			

Category 3: Dosage regimen selection

PCI	Change	Omit	Comments
3.1 Dosage regimen too frequent			
3.2 Dosage regimen not frequent enough			
Add:			

Category 4: Duration of treatment

PCI	Change	Omit	Comments
4.1 Duration of treatment too short			
4.2 Duration of treatment too long			
Add:			

Category 5: Route selection

PCI	Change	Omit	Comments
5.1 Inappropriate route			
Add:			

Category 6: Unwanted drug effects

PCI	Change	Omit	Comments
6.1 Adverse Drug Reaction (ADR)			
6.2 Toxicity			
6.3 Allergic reaction			
Add:			

Category 7: Dispensing

PCI	Change	Omit	Comments
7.1 Wrong drug dispensed			
7.2 Wrong strength dispensed			
7.3 Wrong formulation dispensed			
7.4 Prescribed drug not available in the required strength			
7.5 Prescribed drug not available in the required form			
7.6 Prescribed drug not available at all			
Add:			

Category 8: Compliance

PCI	Change	Omit	Comments
8.1 Inappropriate compliance			
Add:			

Category 9: Drug administration

PCI	Change	Omit	Comments
9.1 Inappropriate timing of administration and/or dosing intervals			
9.2 Drug under- administered			
9.3 Drug over- administered			
9.4 Drug not administered at all			
9.5 Wrong drug administered			
9.6 Wrong dilution			
9.7 Wrong rate of dose administration of an intravenous drug			
Add:			

Category 10: Monitoring

PCI	Change	Omit	Comments
10.1 Monitoring need			
Add:			

Category 11: Counselling; patient related

PCI	Change	Omit	Comments
11.1 Counselling need to parents or legal guardians			
Add:			

3. For every PCI, a **pharmaceutical intervention** is proposed. Kindly indicate whether you agree with the intervention proposed or not. If the answer is no, kindly Indicate **how** you would change it in the 'Comments' section.

Category 1: Drug selection

Pharmaceutical Intervention	**Agree**	**Do Not Agree**	**Comments**
1.1 Depends on severity: If **contraindicated**-avoid combination. If **major**-consider therapy modification. If **moderate**- monitor therapy. If **minor**- no action needed			
1.2 Change dosage form			
1.3 Prescribe the correct strength			
1.4 Stop drug and prescribe an alternative			
1.5 Stop unnecessary drug			
1.6 Stop unnecessary drugs			
1.7 Add drug as needed			
1.8 Add drug as needed			
1.9 Stop ineffective drug and prescribe a more effective drug if indication still apparent			
1.10 Adhere to protocol or guidelines			

Category 2: Dose selection

Pharmaceutical Intervention	**Agree**	**Do Not Agree**	**Comments**
2.1 Increase dose			
2.2 Decrease dose			
2.3 Decrease dose			
2.4 Increase dose			

Category 3: Dosage regimen selection

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
3.1 Decrease dosage regimen frequency			
3.2 Increase dosage regimen frequency			

Category 4: Duration of treatment

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
4.1 Increase duration of treatment			
4.2 Decrease duration of treatment			

Category 5: Route selection

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
5.1 Change route			

Category 6: Unwanted drug effects

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
6.1a. Treatment options for the ADR & 6.1b. Stop drug and never re- challenge. Consider an alternative or 6.1c. Continue drug and decrease subsequent doses or 6.1d. If ADR less serious than effects of disease, continue drug			
6.2a. Treatment options for the Toxicity & 6.2b. Stop drug or 6.2c. Decrease subsequent doses or 6.2d. Increase interval of administration			
6.3a. Treatment options for the reaction & 6.3b. Stop drug and try re- challenging with pre- medications or 6.3c. Stop drug and never re- challenge. Consider an alternative			

Category 7: Dispensing

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
7.1 Stop from administering a drug that has been dispensed wrongly			
7.2 Stop from administering a drug that has been dispensed wrongly			
7.3 Stop from administering a drug that has been dispensed wrongly			
7.4 If it's not a problem to administer dose using available strength, use available strength. If not possible, prescribe an alternative			
7.5 If not a problem to administer dose using available form, use available form. May require extemporaneous compounding.			
7.6 Prescribe an equivalent alternative if possible			

Category 8: Compliance

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
8.1 Verbal drug counselling to parents or legal guardians including provision of written information to resolve compliance issues. Refer to prescriber when necessary			

Category 9: Drug administration

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
9.1 Administer drug at the right time			
9.2 Correct the frequency of drug administration			
9.3 Correct the frequency of drug administration			
9.4 Start administering a drug			
9.5 Stop the administration of a wrong drug			
9.6 Correct the dilution of a drug			
9.7 Correct the rate of dose administration of an intravenous drug			

Category 10: Monitoring

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
10.1 Undertake necessary laboratory and non- laboratory monitoring			

Category 11: Counselling; patient related

Pharmaceutical Intervention	Agree	Do Not Agree	Comments
11.1 Provision of drug and disease-related information to parents or legal guardians including written information			

4. Regarding the outcome section, is there any point which you would add, change or omit?

Point to add	
Point to omit	
Point requiring change	

5. Further comments and recommendations which you wish to suggest

_____

_____

_____

_____

Appendix 14

Case scenarios for practicality testing of the classification system for PCIs

Dear Colleague,

Thank you for agreeing to form part of the expert panel for the validation of the robustness of the Classification system for Pharmaceutical Care Issues (PCIs), which has been developed as part of the research entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology'.

Hereunder, kindly find ten case scenarios related to paediatric cancer. Each scenario describes one to three pharmaceutical care issues. You are kindly requested to analyze each scenario in detail, identify the pharmaceutical care issue/s and classify each issue using the developed classification system. It is important to classify each respective issue under a single sub-category or PCI.

Case 1

VB is an 8-year-old girl suffering from Acute Lymphoblastic Leukaemia. She is on Regimen C and is receiving maintenance chemotherapy (cycle 5). Her weight and body surface area are 36kg and 1.2m^2 respectively.

Protocol: UKALL 2011

Current medications:

- Methotrexate: 25mg orally on Monday (104%)
- 6-mercaptopurine: 100mg orally on Monday, Wednesday, Friday and Saturday & 75mg orally on Tuesday, Thursday and Sunday (99%)
- Co-trimoxazole: 480mg orally twice daily on Thursday and Friday

a. VB came to the Paediatric- Adolescent ward as a day-case for review and bloods. Upon examination, she was noted to be jaundiced so her LFTs were checked. Results showed a Bilirubin level of 67 micromoles/L. As per protocol (see excerpt in red below), methotrexate and 6- mercaptopurine were stopped.

Protocol states that for oral methotrexate and 6- mercaptopurine, "if bilirubin >50 micromoles/L, both drugs should be omitted until it is less than 20 micromole/L, and then restarted at half of the previously attained dose. Escalate from 50% to 75% to 100% dose at 10-day intervals provided hyperbilirubinaemia does not occur. Do not modify dosage for elevated aminotransferases".

b. One week later, VB came to the ward for a review and to have her bloods repeated. LFTs were checked. Results showed a Bilirubin level of 19 micromoles/L.

Case 2

AG is a 5-year-old boy suffering from Acute Lymphoblastic Leukaemia. He is on Regimen C and is receiving maintenance chemotherapy (cycle 4). His weight and body surface area are 22kg and 0.85m^2 respectively.

Protocol: UKALL 2011

Current medications:

- Methotrexate: 17.5mg orally on Monday (103%)
- 6-mercaptopurine: 75mg orally on Monday and Thursday & 50mg orally on Tuesday, Wednesday, Friday, Saturday and Sunday (90%)
- Co-trimoxazole: 240mg orally twice daily on Thursday and Friday

As per protocol, the dose of Co-trimoxazole is:

Surface area	***Co- trimoxazole dose***
0.5-0.75 m^2	*240mg bd*
0.76-1.0 m^2	*360mg bd*
Over 1.0 m^2	*480mg bd*

Case 3

JZ is a 4-year- old boy suffering from Acute Lymphoblastic Leukaemia. He is on Regimen A and is receiving maintenance chemotherapy (cycle 6). His weight and body surface area are 21kg and 0.82m^2 respectively. The boy does not have any problems with swallowing whole tablets.

The patient came to the Paediatric- Adolescent ward as a day-case for review and bloods. Upon examination, he was noted to have a raised red ring with a central area of clearing on his forehead. An infectious disease consultant confirmed the diagnoses of tinea capitis and prescribed terbinafine 250mg tablets to be taken once daily for 2 to 4 weeks.

Case 4

LF is a 5-year-old boy suffering from Acute Lymphoblastic Leukaemia. He is on Regimen A and is receiving maintenance chemotherapy (cycle 3). His weight and body surface area are 23kg and 0.87m^2 respectively.

Protocol: UKALL 2011

Current medications:

- Methotrexate: 15mg orally on Monday (86%)
- 6-mercaptopurine: 75mg orally on Monday, Wednesday and Friday & 50mg orally on Tuesday, Thursday, Saturday and Sunday (93%)
- Co-trimoxazole: 360mg orally twice daily on Thursday and Friday

The patient came to the Paediatric- Adolescent ward accompanied by his mother as a day-case to take Vincristine 1.5mg/m^2 by bolus intravenous injection and prednisolone 40mg/m^2 for five days as per protocol. Prior to discharge, the clinician prescribed the prednisolone regimen as follows: once daily for five days.

Protocol states that "prednisolone administration: 40mg/m^2 orally daily in two divided doses, with or after food."

Case 5

GME is a 5-year-old girl suffering from chronic myelomonocytic leukaemia and heart failure post azacytidine treatment. The patient was admitted to the Paediatric Adolescent ward by the consultant due to fever and lethargy.

Medications upon admission:

Co-trimoxazole 240mg bd on Monday and Tuesday

Levothyroxine 25mcg daily

Enalapril 2.5mg twice daily

a. GME was started on empiric antibiotics, that is, piperacillin/ tazobactam 90mg/kg (1400mg) four times daily and teicoplanin 10mg/kg every 12 hours for three doses and then 10mg/kg every 24 hours (156mg). After two days, the blood cultures became positive for Gram negative rods, specifically *Pseudomonas aeruginosa*. The organism was sensitive to piperacillin/tazobactam.
b. Whilst in hospital and receiving treatment for the infection, GME had an exacerbation of heart failure and subsequently, she was started on furosemide syrup 10mg twice daily.

Case 6

KB is a 14-year-old boy suffering from Langerhans cell histiocytosis and diabetes insipidus. Currently, he is receiving continuation maintenance treatment (week 29). He was admitted at the PAW as he was due to take Vinblastine as per protocol.

Medications upon admission:

Levothyroxine 150 micrograms

Ranitidine 150mg twice daily

Hydrocortisone 2.5 mg twice daily at 07:00 and 12:00

Hydrocortisone 5mg twice daily 17:00 and 22:00

Desmopressin 250micrograms in the morning and 150micrograms in the evening

During his inpatient stay, KB's parameters and blood results including urea and electrolytes remained normal until morphine was started due to severe pain in his knee. One day after morphine was started, KB became very hyponatraemic.

Case 7

KA is a two-year-old girl suffering from retinoblastoma in her left eye. Upon diagnoses, the tumour was so large that the she required surgery to remove the whole eye as well as part of the optic nerve. Following surgery, the clinician from abroad prescribed Maxitrol eye drops, an antibiotic eye drop containing dexamethasone, neomycin and polymyxin. The regimen was one drop three times daily to be applied topically to the eye until the prosthesis.

During KA's visit at the Paediatric adolescent ward for review, her mother complained that Maxitrol eye drops were about to finish and she still did not have a date for the prosthesis, so required further eye drops. Upon checking, it was noted that Maxitrol eye drops were not available neither on the government formulary nor in retail community pharmacies.

Case 8

KS is a 15-year-old-boy suffering from acute myeloid leukaemia (AML). As per AML protocol, for the whole treatment duration, KS needs to be on a prophylactic antifungal agent, so he was started on itraconazole syrup. Two weeks after that he was started on itraconazole, KS had an episode of melaena. Subsequently, itraconazole was stopped and sucralfate, ranitidine and omeprazole were started as treatment for possible GI ulcer and related bleeding. Liposomal Amphotericin B was prescribed as an alternative antifungal agent.

Whilst the nurse was reconstituting the omeprazole that had just been ordered by the ward and dispensed by the hospital pharmacy, it was noted that the drug dispensed and being reconstituted was esomeprazole.

Case 9

GM is a 6-year-old boy suffering from Acute Lymphoblastic Leukaemia. He is on Regimen C and is receiving maintenance chemotherapy (cycle 1). GM together with his

mother came to the Paediatric Adolescent Ward as a day-case for review and bloods. His weight and body surface area are 23.3kg and 0.87m^2 respectively.

Current medications:

- Methotrexate: 15mg orally on Monday (86%)
- 6-mercaptopurine: 75mg orally on Monday and Wednesday & 50mg orally on Tuesday, Thursday, Friday, Saturday and Sunday (88%)
- Co-trimoxazole: 360mg orally twice daily on Thursday and Friday

Upon discussion of GM's current treatment with the mother, it was transpired that 6-mercaptopurine was being given to the child in the morning after that he takes his breakfast cereal.

Protocol states "6-mercaptopurine doses are to be taken once a day one hour after food in the evening"

SPC states "the dose should not be taken with milk or dairy products. 6-mercaptopurine should be taken at least 1 hour before or 2 hours after milk or dairy products"

Case 10

LG is an 8-year-old girl suffering from standard risk medulloblastoma. She was admitted at the Paediatric adolescent cancer ward as she was due to take chemotherapy cycle 2. Drugs administered were Mesna, Vincristine and Cyclophosphamide as per protocol.

a. Five days post- chemotherapy, LG was still in hospital as despite being on Senna 7.5mg daily at night and Movicol Paediatric 2 sachets per day, she was still severely constipated.
b. Eight days post treatment, LG managed to pass stools. On day ten, she was still on Senna and Movicol and was passing diarrhoea.

Appendix 15

Information letters and consent forms for parents in English and Maltese

Dear parent/s or legal guardian/s,

I am Sephorah Falzon, a pharmacist and a student reading for a Doctorate in Pharmacy. For the fulfillment of the requirements for the Doctorate Degree, I am working on a research project entitled "Development of a Pharmaceutical Care Model within Paediatric Oncology". The research is being carried out under the supervision of Professor Lilian Azzopardi and Dr. Louise Grech in collaboration with Dr. Victor Calvagna and Dr. Nathalie Galea, Consultant Paediatric Oncologists.

The purpose of this research is to develop pharmacy services to cover Rainbow Ward at Sir Anthony Mamo Oncology Centre.

This research involves the pharmacist- researcher contributing to the safe and optimum use of the medications used in the management of your child's illness. This is done in collaboration with the doctors and nurses taking care of your child at Rainbow ward.

This research also involves the pharmacist- researcher verifying the drug history of your child with you as well as providing you with discharge medication counselling and information about chemotherapy agents and other drug therapies, including the reasons for use, how to take, potential side effects, drug interactions and proper handling and storage. To assess your satisfaction and perceived benefits of the interaction with the pharmacist- researcher, you are asked to fill in a questionnaire.
The identity of your child will not be revealed in anyway, any information collected will be kept anonymous throughout the research and you and your child may quit the study at any time.

Thank you in advance.

Għażiż/ għeżież ġenitur/i jew gwardjan/i legali,

Jiena Sephorah Falzon, spiżjara u studenta tal-kors tad- dottorat tal-farmacija. Sabiex jigu sodifatti r-rekwiżiti tal- lawrja ta' dottorat, jiena qiegħda naħdem fuq riċerka intitolata "Żvilupp ta' mudell tal-kura farmaċewtika fil-qasam ta' l-onkoloġija pedjatrika". Din ir-riċerka qiegħda issir taħt is- superviżjoni tal-Professoressa Lilian Azzopardi u d-Dott. Louise Grech flimkien mal-Konsulenti onkoligisti tal- pedjatrika Victor Calvagna u Nathalie Galea.

L-għan ta' din ir-riċerka huwa l-iżvilupp ta' servizzi tal-farmaċija sabiex tiġi koperta s-sala *Rainbow* ġewwa ċ-ċentru ta' l-onkoloġija Sir Anthonty Mamo.

Din ir-riċerka tinvolvi lill-ispiżjara riċerkatriċi tikkontribwixxi għall-użu sikur u l-aħjar tal- mediċini li jintużaw fil-ġestjoni tal-marda tat- tifel/tifla tiegħek. Dan ser isir b' kollaborazzjoni mat-tobba u l- infermiera li jieħdu ħsieb lit-tifel/ tifla tiegħek ġewwa s-sala *Rainbow*.

Din ir-riċerka tinvolvi wkoll lill-ispiżjara riċerkatriċi tivverifika l-mediċini li jieħu/tieħu t- tifel/ tifla tiegħek miegħek kif ukoll tipprovdik b' pariri u informazzjoni dwar kimoterapija u terapiji ta' drogi oħra, inkluż ir-raġunijiet għall- użu, istruzzjonijiet għall-użu, effetti potenzjali, interazzjonijiet bejn mediċini u mmaneġġjar u ħażna korretta ta' mediċini. Sabiex jiġi evalwat is-sodisfazzjon tiegħek u l-benefiċċji maħsuba mill-interazzjoni ma' l-ispiżjara riċerkatriċi, inti ser tiġi mitlub/a timla kwestjonarju.

L-identita tat-tifel/ tifla tiegħek mhux ser tiġi rivelata bl-ebda mod, l-informazzjoni li ser tinġabar ser tinżamm anonima matul ir-riċerka u inti u t-tifel/tifla tiegħek tistgħu tieqfu milli tieħdu sehem f' din ir-riċerka meta trid.

Grazzi bil-quddiem.

Consent Form

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

The purpose and details of the research entitled '**Development of a Pharmaceutical Care model within paediatric oncology**' have been explained to me by Sephorah Falzon and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator 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 child and I are participating may be reported or published: however, myself and my child shall not be personally identified in any way, either individually or collectively, without my express written permission.

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

My child 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 child.

I and my child are not receiving any remuneration for participating in this study.

For any further details or queries, I may contact Sephorah Falzon on 79309671 or via email at sephorah.falzon.10@um.edu.mt

Signature of Parent/ Legal Guardian _____

Name of Parent/ Legal Guardian and ID number _____

Signature of Chief Investigator _____

Name of Chief Investigator and ID number _____

Signature of Supervisor _____

Date _____

Formola tal- kunsens

Jien, is- sottofirmat niċċertifika li jiena l- ġenitur jew gwardjan legali ta' _____ (Numru ta' l- *ID*: _____) u jiena għandi d-dritt illi nieħu deċiżżjonijiet għat-tifel/tifla tiegħi li jirriflettu il-benesseri tieghu/tagħha.

L-għan u d-dettalji tar- riċerka ntitolata "Żvilupp ta' mudell tal- kura farmaċewtika fil-qasam ta' l- onkoloġija pedjatrika" spjegathomli Sephorah Falzon li wkoll iċċaratli xi mistoqsijiet li għamilt.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal-din ir-riċerka 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, la jiena u lanqas it tifel/ tifla tiegħi, ma nistgħu nkunu identifikati, individwalment jew bħala parti minn grupp, mingħajr il-kunsens tiegħi bil-miktub.

Jiena u t-tifel/ tifla tiegħi m' għandna l-ebda obbligu li nieħdu sehem f'din ir-riċerka u dan qed isir b'mod volontarju.

Jiena u t- tifel/ tifla tiegħi nistgħu, meta rrid, ma nkomplux nieħdu sehem fir-riċerka, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk, it-tifel/tifla xorta jibqa'/ tibqa' tieħu l-kura li ssoltu tingħatalu/a.

Jiena u t- tifel/ tifla tiegħi mhux qed nitħallasu biex nieħu sehem f'din ir-riċerka.

Jekk ikolli xi diffikulta nista' nikkuntatja lil Sephorah Falzon fuq 79309671 jew bl- email fuq sephorah.falzon.10@um.edu.mt

Firma tal- ġenitur jew gwardjan legali _____

Isem tal- ġenitur jew gwardjan legali u Numru ta' l- *ID* _____

Firma tal- persuna responsabbli għal din ir- riċerka _____

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

Firma tas- Superviżur _____

Data _____

Appendix 16

Information letter and consent form for healthcare professionals

Dear Colleague,

I am a Pharmacist working at MDH Pharmacy and a third-year student reading for a Doctorate in Pharmacy (Pharm D). For the fulfillment of the requirements for the Doctorate Degree, I am working on a research entitled "Development of a Pharmaceutical Care Model within Paediatric Oncology". The research is being carried out under the supervision of Professor Lilian Azzopardi and Dr. Louise Grech.

The aim of this research is to develop and implement a novel pharmaceutical care model within Rainbow Ward at Sir Anthony Mamo Oncology Centre. To validate this pharmaceutical care model, the clinician's and nurse's satisfaction and perceived benefits of having a ward- based pharmacist as part of the interdisciplinary team are sought. As a clinician or nurse working at the Paediatric- Adolescent Cancer Ward, you are requested to complete a questionnaire that is two pages long and will not take more than ten minutes to complete.

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 accessible to the researcher. The information may be published as part of this study but the information will never be traceable to you.

Thank you in advance for your participation,

Sephorah Falzon

B.Sc. Pharm. Sci. (Hons.) (Melit.) M.Pharm. (Melit.)

Consent Form

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 '**Development of a Pharmaceutical Care model within paediatric oncology**'

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

I give my consent to the Principal Investigator 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 are 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 Sephorah Falzon on 79309671 or via email at sephorah.falzon.10@um.edu.mt

Signature of Participant _____

Name and ID number of Participant _____

Signature of Chief Investigator _____

Name of Chief Investigator and ID number _____

Signature of Supervisor _____

Date _____

Appendix 17

Phase I data

Suggestions for the classification system for PCIs following test for content

Suggestions
Add another category- Seamless Care
Omit 'Route selection' category
The dose selection category: - Change PCIs 2.1 and 2.2, that is, 'Dose too low for patient's age and weight' and 'Dose too high for patient's age and weight' respectively **to add** 'and indication and/or severity' - Omit PCIs 2.3 and 2.4, that is 'Overtreatment but when the drug was introduced the dose selected was correct' and 'Undertreatment but when drug was introduced the dose selected was correct' respectively - Change wording of pharmaceutical intervention (PI) 1.9 from 'Stop ineffective drug and prescribe a more effective drug if indication still apparent' **to** 'Stop ineffective drug and prescribe an alternative if indication still apparent'
The unwanted drug effects category: - Since category number 5 was omitted, to change its category, PCI and PI number from 6 to 5 - Change PCI 5.1 (formerly 6.1) from 'Adverse Drug Reaction (ADR)' **to** 'Adverse Drug Reaction (ADR)/ Side Effect (SE)' - Change PCI 5.2 (formerly 6.2) from 'Toxicity' **to** 'Toxicity (Overdose)' - Subsequently, make changes to the PI proposed for these two PCIs; o PI 5.1 (formerly 6.1): ▪ Add another option- 5.1.e 'Stop drug and try re- challenging with pre- medications' o PI 5.2 (formerly 6.2): ▪ Omit options 5.2.b, 5.2.c, and 5.2.d (formerly 6.2.b, 6.2.c, and 6.2.d), that is, 'Stop drug or', 'Decrease subsequent doses or' and 'Increase interval of administration' respectively. ▪ Change wording of 5.2.a (formerly 6.2.a) from 'Treatment options for toxicity' **to** 'Stop drug, evaluate situation and consider treatment options for toxicity' - Omit the PCI 'Allergic reaction
The dispensing category: - Since category number 5 was omitted, to change its category, PCI and PI number from 7 to 6 - Change PIs 6.1, 6.2 and 6.3 (formerly 7.1, 7.2 and 7.3 respectively) from 'Stop drug that has been administered wrongly' **to add** 'Check that the correct drug/strength/formulation has been prescribed and/or ordered and fill in an incident report' - Change PI 6.5 (formerly 7.5) from 'If not a problem to administer dose using available form, use available form. May require extemporaneous compounding' **to** '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'

- Change PI 6.6 (formerly 7.6) from 'Prescribe an equivalent alterative if possible' **to** 'Prescribe an alternative'
The compliance category: - Since category number 5 was omitted, change its category, PCI and PI number from 8 to 7 - Change PCI 7.1 (formerly 8.1) from 'Inappropriate compliance' **to** 'Non-compliance' - Change PI 7.1 (formerly 8.1) **to add** another option- 7.1.b 'Suggest an alternative to the clinician'
The drug administration category: - Since category number 5 was omitted, to change its category, PCI and PI number from 9 to 8 - Change PCI 8.7 (formerly 9.7) from 'Wrong rate of dose administration of an intravenous drug' **to** 'Inappropriate rate' - Change PI 8.1 (formerly 9.1) from 'Administer drug at the right time' **to** 'Discuss with prescriber. If ok, administer drug at the right time' - Change PI 8.2 (formerly 9.2) from 'Correct the frequency of drug administration' **to** 'Discuss with prescriber. If ok, correct the frequency of drug administration' - Change PI 8.3 (formerly 9.3) from 'Correct the frequency of drug administration' **to** 'Discuss with prescriber. If ok, correct the frequency of drug administration' - Change PI 8.4 (formerly 9.4) from 'Start administering a drug' **to** 'Discuss with prescriber. If ok, start administering a drug' - Change PI 8.5 (formerly 9.5) from 'Stop the administration of a wrong drug' **to** 'Stop the administration of a wrong drug. Discuss with prescriber' - Change PI 8.6 (formerly 9.6) from 'Correct the dilution of a drug' **to** '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' - Change PI 8.7 (formerly 9.7) from 'Correct the rate of dose administration of an intravenous drug' to 'Correct the rate of dose administration of the parenteral drug. Discuss with clinician'
Add 'Other' as PCI for every drug category. Subsequently, add a PI
Define Pharmaceutical care issue, pharmacist intervention and outcome

All suggestions put forward were taken up and implemented.

PCIs identified by the three pharmacists using the adapted classification system

Case	Control (real case scenario)	Pharmacist 1	Pharmacist 2	Pharmacist 3
1	1.1 No drug treatment despite existing indication requiring management or prevention 5.1 Adverse Drug Reaction (ADR)/ Side effect (SE) 9.1 Monitoring need	1.1 No drug treatment despite existing indication requiring management or prevention 5.1 Adverse Drug Reaction (ADR)/ Side effect (SE) 9.1 Monitoring need	1.1 No drug treatment despite existing indication requiring management or prevention 5.1 Adverse Drug Reaction (ADR)/ Side effect (SE) 9.1 Monitoring need	1.1 No drug treatment despite existing indication requiring management or prevention 5.1 Adverse Drug Reaction (ADR)/ Side effect (SE) 9.1 Monitoring need
2	2.1 Dose too low for patient's age, weight and indication and/or severity	2.1 Dose too low for patient's age, weight and indication and/or severity	2.1 Dose too low for patient's age, weight and indication and/or severity	2.1 Dose too low for patient's age, weight and indication and/or severity
3	2.2 Dose too high for patient's age, weight and indication and/or severity 6.4 Prescribed drug not available in the required strength 9.1 Monitoring need X	2.2 Dose too high for patient's age, weight and indication and/or severity 6.4 Prescribed drug not available in the required strength 9.1 Monitoring need X	2.2 Dose too high for patient's age, weight and indication and/or severity 6.4 Prescribed drug not available in the required strength 9.1 Monitoring need X	2.2 Dose too high for patient's age, weight and indication and/or severity X 9.1 Monitoring need 10.1 Counselling need to parents
4	1.10 Non- adherence to protocol or guidelines	1.10 Non- adherence to protocol or guidelines	1.10 Non- adherence to protocol or guidelines	1.10 Non- adherence to protocol or guidelines
5	1.5 No indication for drug or indication no longer apparent 9.1 Monitoring need X	1.5 No indication for drug or indication no longer apparent 9.1 Monitoring need 10.1 Counselling need to parents	1.5 No indication for drug or indication no longer apparent 9.1 Monitoring need X	1.5 No indication for drug or indication no longer apparent 9.1 Monitoring need X

6	9.1 Monitoring need 1.7 Drug interaction X	9.1 Monitoring need 1.7 Drug interaction X	9.1 Monitoring need 1.7 Drug interaction X	9.1 Monitoring need X 5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE)
7	6.6 Prescribed drug not available at all 10.1 Counselling need to parents	6.6 Prescribed drug not available at all X	6.6 Prescribed drug not available at all 10.1 Counselling need to parents	6.6 Prescribed drug not available at all 10.1 Counselling need to parents
8	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 6.1 Wrong drug dispensed 9.1 Monitoring need	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 6.1 Wrong drug dispensed 9.1 Monitoring need	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 6.1 Wrong drug dispensed 9.1 Monitoring need	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 6.1 Wrong drug dispensed 9.1 Monitoring need
9	1.7 Drug interaction 7.1 Non-compliance X X	1.7 Drug interaction 7.1 Non-compliance X X	X X 1.10 Non-adherence to protocol or guidelines 10.1 Counselling need to parents	1.7 Drug interaction 7.1 Non-compliance X X
10	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 2.1 Dose too low for patient's age, weight and indication and/or severity 1.5 No indication for drug or indication no longer apparent X	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 2.1 Dose too low for patient's age, weight and indication and/or severity X 2.2 Dose too high for patient's age, weight and indication and/or severity	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) 2.1 Dose too low for patient's age, weight and indication and/or severity 1.5 No indication for drug or indication no longer apparent X	5.1 Adverse Drug Reaction (ADR)/ Side Effect (SE) X 1.5 No indication for drug or indication no longer apparent X

The total number of PCIs identified by the pharmacist-researcher on the ward (control) was 22. Upon comparing pharmacist 1, 2 and 3 with the control, they identified 20, 20 and 19 PCIs the same respectively. Therefore, it can be inferred that pharmacist 1, 2 and 3 did not identify 2, 2 and 3 PCI respectively. Overall, 89% of the PCIs were identified and classified the same by all the three pharmacists. Over and above, it can be observed that 6 new PCIs were identified: 10.1 in case 5 and 2.2 in case 10 by pharmacist 1; 1.10 and 10.1 in case 9 by pharmacist 2 and 10.1 in case 3 and 5.1 in case 6 by pharmacist 3. It can be noted that for cases 1,2,4,5 and 8, all PCIs were identified by all the pharmacists. The missing PCIs and the newly identified PCIs were analysed and evaluated. The differences were observed in cases 3,5,6,7,9 and 10. For case 3, pharmacist 1 and 2 identified all the PCIs of the control whilst pharmacist 3 identified 2 PCIs as the control, failed to identify PCI 6.4 and identified a new PCI, 10.1. For case 5, pharmacist 1 identified a new PCI, 10.1. With regards to case 6, the difference was observed in the answers of pharmacist 3 where PCI 1.7 was not identified whilst a new PCI, 5.1 was identified. Pharmacist 1 did not identify PCI 10.1 for case 7. For case 9, pharmacist 2 identified two new PCIs, 1.10 and 10.1 whist Pharmacists 1 and 3 identified all the PCIs as the control. For case 10, pharmacist 2 identified all the PCIs, pharmacist 1 omitted PCI 1.5 and identified PCI 2.2 and pharmacist 3 failed to identify PCI 2.1.

Completed Gap- Finding Tool

1. Accurate History	Tick	Comments
Obtaining and documenting a complete **Drug History**	✓	Done by Clinicians
Obtaining and documenting a complete **Medical History**	✓	Done by Clinicians
Confirming and documenting **adverse drug reactions/sensitivities**	✓	Done by Clinicians
Reconciliation of medication therapy	✓	Done by Clinicians
Asking about recently **stopped/changed medications**	✓	Sometimes omitted
Asking about the use of **adherence** aids	X	Not done
Asking about **storage** of current medications at home	X	Not done
Assessing parent's/ patient's understanding of their child's/ their illness and determining if there is need for further **education about the illness**	✓	Done by Clinicians
Assessing parent's/ patient's understanding and attitude to their child's/ their **current drug therapy**	✓	Done by Clinicians
Assessing parent's/ patient's ability to **use drugs as prescribed**	✓	Done by Clinicians
Assessing the need to refer to medical staff	X	Not done

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	✓	C**hemotherapy** and related drugs: other clinicians and compounding pharmacist **Other** drugs: other clinicians and sometimes nurses.
Ensuring that prescriptions and treatment charts are comprehensive and unambiguous	✓	C**hemotherapy** prescriptions: electronically prepared by a clinician and double checked by another. They are also checked by a compounding pharmacist Prescriptions for **other drugs:** prescribing clinician only. **Treatment Charts:** sometimes clinicians and sometimes nurses.
Ensuring all drugs are prescribed by their active ingredient	X	Not done. Some medications are prescribed by brand name and no action is taken.
Ensuring that drug names and directions are not abbreviated	X	Not done
Ensuring that the date and time at which medicine administration is to commence and cease are written	✓	Done by clinicians and nurses
Ensuring that the time the dose should be given is endorsed in the relevant section of the chart	✓	Done by nurses.
Checking that patient identifiers are documented	✓	Done by clinicians, nurses and for chemotherapy prescriptions, also done by a compounding pharmacist
Ensuring that the order is signed and the prescriber can be identified	✓	C**hemotherapy** prescriptions: done by prescriber himself, the clinician double checking the prescription and the compounding pharmacist. **Medications ordered using the ward booklet**: the nurse. Prescriptions for **other drugs**: written by one clinician and not checked by anyone else.
B. Reviewing prescriptions and treatment charts to ensure appropriateness of all drugs		
Confirming drugs have an **indication**	✓	Done by clinicians

Confirming drug is prescribed for an **approved** or recognized indication.	✓	**Chemotherapy** drugs: Compounding pharmacist. **Other** drugs: clinicians and/or dispensing pharmacist
Ensuring protocols/guidelines are considered	✓	Done by clinicians and compounding pharmacist for cytotoxics
Considering **latest evidence** regarding drug's efficacy and toxicity	✓	Done by clinicians
Ensuring best **method of administration**	✓	Done by clinicians, nurses and compounding pharmacist for cytotoxics
Ensuring infusion solution and concentration are appropriate for IV drugs	✓	**Chemotherapy** drugs: clinicians and compounding pharmacist. **Other** drugs: nurses
Checking **drugs and doses** are appropriate	✓	**Chemotherapy** drugs: clinicians and compounding pharmacist. **Other** drugs: mostly clinicians
Checking **dose conversions** with changes to route or formulation	✓	Done by clinicians
Checking drug's achieving **therapy goals**	✓	Done by clinicians
Checking for **duplications**	✓	Sometimes done by clinicians
Checking for **contraindications**	✓	Sometimes done by clinicians
Checking for **drug interactions**	X	Not done
Ensuring drug **units** are clear	✓	Done by clinicians
Tracking cumulative doses	✓	Compounding pharmacist
Providing information on extemporaneous oral formulations	X	Clinicians/nurses phone compounding/medicines information
Liaising with compounding unit	✓	Done by clinicians and nurses
Ensuring drugs are available at the ward and where necessary are ordered	✓	Done mostly by nurses & sometimes clinicians
Checking treatment chart to ensure all doses have been administered	✓	Done mostly by nurses and sometimes clinicians
Annotating treatment charts	✓	Done by clinicians and nurses
Ensuring drug is cancelled on treatment chart when stopped	✓	Done mostly by clinicians & sometimes nurses
Checking availability and access to medications	✓	Done by clinicians or compounding pharmacist
Considering cost of drugs to patient and hospital and considering alternatives	✓	Done by clinicians

3. Clinical review	Tick	Comments
Reviewing and monitoring patient-specific clinical information to evaluate the response to the drugs and adjust therapy accordingly	✓	Done by clinicians and nurses
Identifying **actual and potential drug-related problems**	✓	Done by clinicians and nurses
Performing **follow-up** evaluations in collaboration with other members of the healthcare team	✓	Done by clinicians

4. Therapeutic drug monitoring (TDM)	Tick	Comment
Giving instructions as to **when** and **how** TDM must be carried out	✓	Done by clinicians
Informing clinician of TDM **results** in a timely manner, including recommended **action** and future **monitoring requirements**	✓	Done by clinicians

5. Medicines information	Tick	Comment
Providing medicines information to **healthcare professionals**	X	Clinicians and nurses liaise with medicines information/ compounding pharmacist
Providing medicines information to patients and **parents/legal guardians** verbally and in writing	✓	Clinicians and nurses but not in so much detail

6. Adverse drug reaction (ADR) management	Tick	Comments
A. Detection and prevention of an ADR		
Identifying and monitoring susceptible patients	✓	Done by Clinicians
B. Suspected ADR		
Assessing ADR details in the context of patient-specific and medication-related factors	✓	Done by Clinicians
C. Management of an ADR		
Considering the likelihood of the suspected drug having caused the reaction and the clinical significance when assessing whether to continue treatment with the suspected drug	✓	Done by Clinicians
Recommending treatment options for the ADR and, if appropriate, recommending alternative treatments	✓	Done by Clinicians
Involvement in the management of all cancer and chemotherapy related complications	✓	Done by Clinicians
Developing and implementing pharmacological treatment guidelines on acute and late effects of chemotherapy drugs	X	Not done

7. Participating in interdisciplinary care	Tick	Comments
Being physically present to **participate in ward rounds, clinics and meetings** attended by other HCPs	X	No clinical pharmacist assigned to do so
Preparing accurate and comprehensive **patient profiles**	X	No clinical pharmacist assigned to do so
Contributing **information** about patient's drugs and their management	X	No clinical pharmacist assigned to do so
Making suggestions for **selecting** and **monitoring** medicines	X	No clinical pharmacist assigned to do so
Be fully informed about **current patient-specific issues**	X	No clinical pharmacist assigned to do so
Prioritising **patients requiring further review or education** by the pharmacist	X	No clinical pharmacist assigned to do so
Participating in **discharge planning**	X	No clinical pharmacist assigned to do so

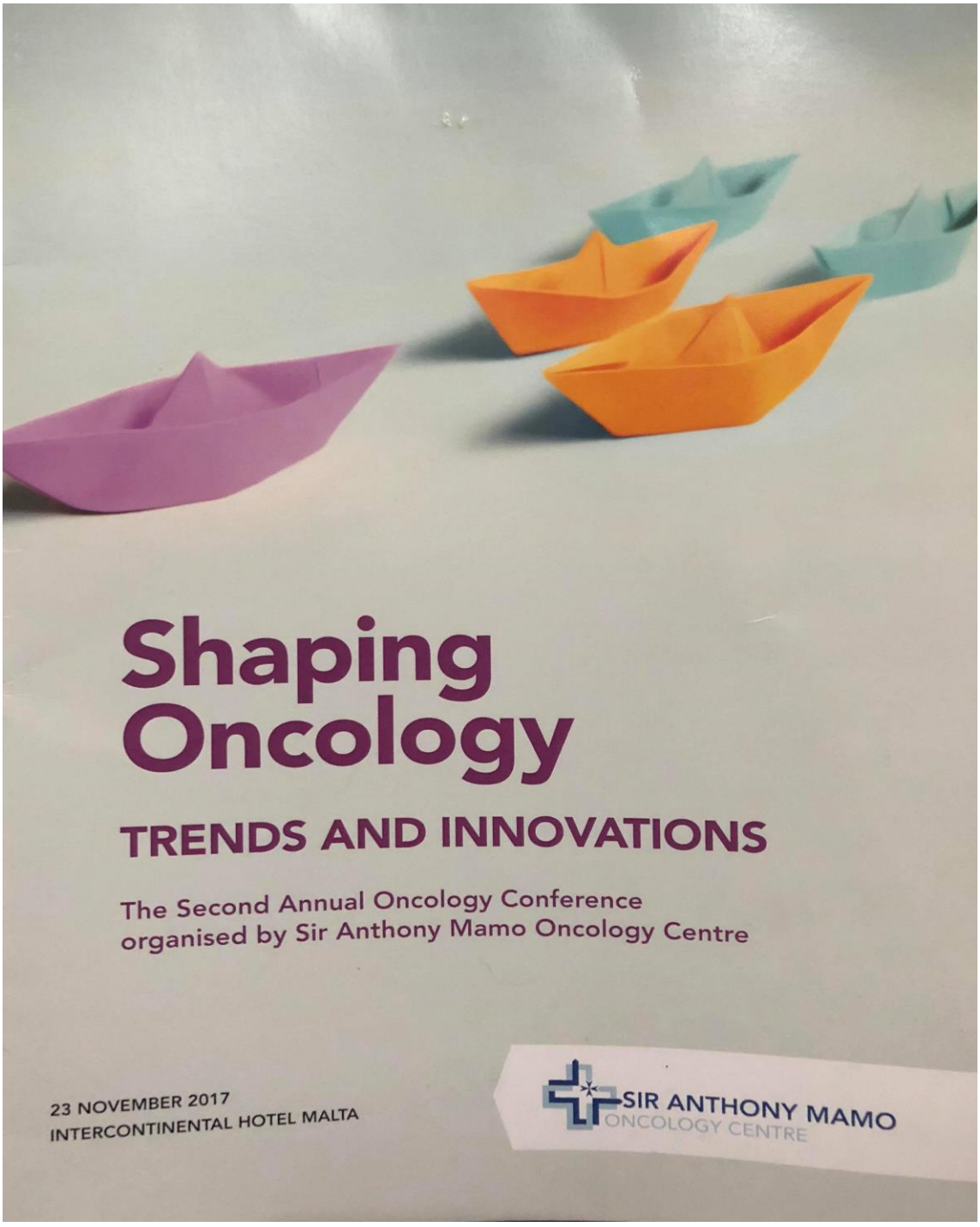
8. Information for ongoing care	Tick	Comments
A. Managing patient's drugs and communicating with them/ their parents on transition		
Discussing the drugs that need to be supplied or sourced on discharge or transfer	✓	Done by clinicians, nurses and dispensing pharmacists
Annotating drugs which need to be supplied on discharge on the patient profile/file	✓	In patient's file- done by clinicians
Removing ceased medicines for destruction	X	For drugs brought from home, the policy of Mater Dei Hospital is to return these medicines to the patients or their parents. The patients or their parents have to go to waste facilities so that these can be discarded. Regarding hospital drugs, if there are other patients on the same drugs, they are not discarded
Providing patients with drug/s required	✓	Nurses or dispensary
Providing information (written and verbal) about discharge medications, including directions, indication, start and stop date, contact name and number, how to identify side effects of new drugs and what to do if they occur	✓	Clinicians but not in detail. Discharge medications are written on a white piece of paper and only the name and dosage regimen are written. Other details are provided verbally.
Providing information about adherence aids	X	Not done
Encouraging parents/ patients to contact their hospital pharmacist at any time after discharge	X	No Pharmacist assigned to the ward
B. Liaising with other Healthcare Professionals on Transition		
Obtaining consent and then communicating all drug-related information in a timely manner to the patient's GP, community pharmacist, residential care provider or other HCP	X	Not done. Information is usually communicated to the parents/ patients who then communicate any information to other HCPs. In special circumstances, clinicians write letters addressing different HCPs but not routinely.

9. Documentation	Tick	Comment
Documenting medication related assessment and plan of care to optimise patient outcomes	✓	Done by clinicians in patient files

Appendix 18

Publications

Abstract entitled 'Development of a Pharmaceutical Care Model within Paediatric Oncology' submitted and accepted for presentation at the Second Annual Oncology Conference organised by Sir Anthony Mamo Oncology Centre, November 2017.



SEPHORA FALZON
Pharmacist, Department of Pharmacy, MDH

Sephorah Falzon graduated from the University of Malta in 2015 obtaining an MPharm Degree. In 2016, she joined the Pharmacy Department at Mater Dei Hospital working within the Compounding section. She strongly believes that pharmacists in collaboration with clinicians should be at the forefront and play an active role with respect to clinical decision making in terms of pharmacotherapy based on patients' individual needs. Ms Falzon is currently reading for a level 8 postgraduate degree, the PharmD degree. As part of her studies, she is working on a dissertation that involves establishing a clinical pharmacy therapeutics service at the Paediatric/Adolescent Ward at Sir Anthony Mamo Oncology Centre.

Development of a Pharmaceutical Care Model within Paediatric Oncology

Sephorah Falzon, Dr Victor Calvagna, Dr Nathalie Galea, Dr Louise Grech, Professor Lilian Azzopardi

Introduction: The pharmacotherapy of cancer in children and adolescents is challenging. Pharmacists can help improve the patients' health outcomes and quality of care by contributing to the safe and optimum use of the pharmacotherapy used in paediatric cancer.
Objective: To develop and implement a Pharmaceutical Care Model at the Paediatric Adolescent Ward at Sir Anthony Mamo Oncology Centre.

Method: Following ethics approval, the pharmacist attended ward rounds where patients' files, treatment charts and prescriptions were reviewed to identify pharmaceutical care issues (PCIs). The identified PCIs were discussed with the clinicians and the outcomes were recorded. Other pharmaceutical services identified to be lacking were developed.

Results: A total of 192 PCIs were identified during 180 pharmaceutical care sessions provided over 4 months. The most common PCIs identified were classified as monitoring needs (n=52); counselling needs to parents/legal guardians (n=45); need for treatment discontinuation (n=36); incorrect dose (n=30) and adverse drug reaction and drug interaction (n=27). Other pharmaceutical services provided (n=265) included drug information to healthcare professionals; accessibility of drugs and liaison with the compounding section.

Conclusion: This study reflects the important role of the Clinical Pharmacist at ward level adding to the continuous improvement of the standard of care provided to oncology patients.

Abstract entitled 'Development of a pharmaceutical care model within paediatric oncology' submitted and accepted for poster presentation at the ACCP Global Conference on Clinical Pharmacy 2018 to be held from 20 to 23 October 2018.

Introduction

Pharmacists contribute to improved health outcomes and quality of care of paediatric oncology patients by supporting safe and optimum use of complex pharmacotherapy.

Research Question

To develop and implement a pharmaceutical care model at the Paediatric Adolescent Ward at Sir Anthony Mamo Oncology Centre.

Study design

A cross- sectional prospective study.

Methods

Following ethics approval, the pharmacist investigator attended ward rounds where patients' files, treatment charts and prescriptions were reviewed to identify pharmaceutical care issues (PCIs). The PCIs identified were discussed with the clinicians and the outcomes were recorded. Other pharmaceutical services found to be lacking were developed.

Results

A total of 545 PCIs were identified during 325 pharmaceutical care sessions provided over 8 months. These included counselling need to parents/legal guardians about medications (n=147); incorrect dose (n=91); monitoring need (n=84); no indication for drug (n=55); no drug treatment despite existing indication (n=35); missing, wrong or unclear instructions on treatment chart or prescription (n=29); side effect (n=25); seamless care need (n=14); incorrect dosage regimen frequency (n=11); drug interaction (n=10); inappropriate route of administration (n=10) and inappropriate dosage form (n=7). Other pharmaceutical services provided to support the ward service included dosage calculations (n=965); drug information to healthcare professionals (n=374); guiding clinicians and nurses in filling the appropriate pharmacy related forms (n=52); liaison with other pharmacy sections at the hospital (n=48); checking availability and accessibility of drugs (n=31); attending interdisciplinary meetings (n=27); liaison with the unit responsible for patient access to treatment on the national health scheme (n=8); preparing chemotherapy flow sheets (n=8) and participation in research studies (n=1).

Conclusion

This study reflects the relevant contribution of the pharmacist at ward level within the interdisciplinary healthcare team through the implementation of a novel pharmaceutical care model which focuses on PCIs and patient specific needs.

abstracts@accp.com via confex.com

16 Apr

to me, seph.falzon

Dear Sephorah Falzon,

Congratulations! Your abstract, titled "Development of a pharmaceutical care model within paediatric oncology", is ACCEPTED as a POSTER PRESENTATION at the 2018 ACCP Global Conference on Clinical Pharmacy. The meeting will take place October 20-23, 2018, at the Washington State Conference Center, Seattle, Washington, USA.

IMPORTANT PRESENTATION/PUBLICATION REQUIREMENTS:

- Posters *must* be presented to have the abstract published in an official journal of ACCP.
- The poster presenter *must* be an author listed on the abstract (including encore posters).
- All poster presenters *must* be registered* for the Global Conference to present their poster.
- You will receive a second e-mail today providing a link to confirm your understanding of these requirements.

Poster notes and specifications:

- Your poster presentation day and time will be emailed in late August.
- All poster boards are 4 feet high by 8 feet wide; your poster must fit within these dimensions.
- All relevant conflicts of interest must be disclosed on each poster.
- All forms of financial support for projects must be displayed on the poster.
- Encore abstracts are included full-text in the meeting app, but only the title, authors, and original place of presentation/publication are published.

Reviewers' scores and comments may be reviewed at http://accp.confex.com/accp/2018am/authorratingview.cgi?username=45576&password=131560. This feature is not available for Encore abstracts.

*All poster presenters *must* be registered for the meeting in order to present their poster. Presenters must either be registered for the full meeting or have a one day registration for the day of their presentation. For registration information and details on the 2018 ACCP Global Conference on Clinical Pharmacy, go to https://www.accp.com/meetings/gc18/index.aspx.

We look forward to your presentation. If you have any questions in the upcoming months please contact ACCP at abstracts@accp.com.

Abstract entitled "Pharmacy service at a paediatric-adolescent cancer ward" submitted and accepted for the 78th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2018 to be held from 2 to 6 September 2018

Background

A high intensity ward such as a paediatric-adolescent cancer ward (PAW) is a setting that requires a pharmacist to participate in direct-patient care.

Purpose

To implement a pharmacy service within the interdisciplinary health care team caring for children attending the PAW at Sir Anthony Mamo Oncology Centre.

Method

A Gap-Finding Tool utilising clinical pharmacy practice standards developed by the American College of Clinical Pharmacy, the European Association of Hospital Pharmacy and the SHPA Committee of Specialty Practice in Clinical Pharmacy was developed to compare local practice at the PAW to international care practices and enable the identification of gaps. Subsequently a pharmaceutical service was developed focusing on covering the gaps identified.

Results

The tool captured nine domains related to pharmacy service provision at ward level. The gaps identified and implemented included participation in interdisciplinary care by being physically present to attend ward rounds and meetings, provision of medicines information to health care professionals and parents and co-ordinating patient access to treatment. Services which were optimised included the discharge process by developing a discharge medication guide for parents, the documentation process by developing a Pharmacy Patient Profile and the current medication management process by reviewing prescriptions and treatment charts, ensuring that they are clear and valid and that the prescribed drugs are appropriate.

Conclusion

The pharmaceutical service developed ensures that rather than duplicating services that are being provided by other healthcare professionals in the team, the pharmacist developed a service which optimizes patient care

FIP Congress Registration & Abstract Handling Office <FIP@mci-group.com> 30 Apr (13 days ago)

to me

Abstract Submission Number: FIPSUB-2270
Abstract topic: Hospital pharmacy
Abstract title: Pharmacy service at a paediatric-adolescent cancer ward

Dear Ms Falzon,

Thank you for having submitted the abstract listed above for the 78th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2018, to be held in Glasgow, Scotland from 2-6 September 2018.
On behalf of the Scientific Committee, it is our great pleasure to inform you that this abstract **has been accepted** for **POSTER presentation.**
Further information regarding the display dates of your poster and the poster guidelines will be communicated at a later stage.

Please note that the presenting author needs to register **before 15 May 2018** to keep your abstract in the Congress programme. If you have not yet registered, we kindly invite you to register as soon as possible. For registration and more information on the various fees and deadlines, please visit the Congress website: https://www.fip.org/glasgow2018/registration-forms/.

Please also note that residents from some countries require a visa. An official support letter can be requested during online registration. We recommend that you start the visa process as soon as possible. Do not hesitate to contact us if you encounter any difficulty.

For questions regarding your presentation or registration, please contact fip@mci-group.com.

We look forward to meeting you in Glasgow, Scotland and remain at your disposal for any further information you may require.