IMPLEMENTATION OF A PHARMACEUTICAL CARE MODEL WITHIN HAEMATOLOGY

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

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In memory of Karen and Sharon, two haematology patients gone too soon

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Abstract

The complexity of haematological diseases together with complications that may arise during treatment, warrant the need for having a complete interdisciplinary team including the presence of a ward-based clinical pharmacist. The aim of this research was to develop and test the feasibility of a standardised pharmaceutical care model within the adult haematology ward at Sir Anthony Mamo Oncology Centre. The current practices within the ward were observed to develop a baseline against international standards of pharmacy practice care. The standards were used to devise an evidence-based clinical pharmacy service at the ward. During ward rounds and whilst reviewing treatment charts and patient files, the pharmacist identified pharmaceutical care issues (PCIs) and drug-related problems (DRPs). These were recorded in the pharmacist patient profile developed. Discussions to resolve these PCIs and DRPs were held with the other healthcare professionals (HCPs).

Ninety-three different patients were seen during 7 months of ward attendance. A total of 377 pharmaceutical care sessions were held, during which a total of 465 PCIs were identified. The DRPs were issues with drug selection (n=144) such as no indication for drug, monitoring needs (n=137), issues with dose selection (n=74) such as dose too low, the need for patient education (n=57), issues with treatment duration (n=24) such as duration of treatment too long, occurrence of side effects (n=13) and an issue related to the drug-use process (n=1). Eighty-seven percent of the interventions proposed for these PCIs were accepted by the other HCPs. The pharmacist also provided other pharmaceutical services to HCPs (n=398) including medicines information (n=180), administration advice (n=40), modifications on treatment charts (n=37), liaison with other pharmacy entities (n=37), dosage calculations (n=36), guiding doctors in filling the correct pharmacy-related forms (n=23), checking treatment against chemotherapy

protocols (n=14), checking for drug interactions (n=13), provision of medication tables on discharge (n=7) and medicines reconciliation (n=3).

This research demonstrated the feasibility of the developed standardised pharmacist intervention at ward level. The pharmacist interventions contributed to identifying PCIs occurring in patients which were, in the majority, accepted by the caring oncologists.

Keywords: clinical pharmacy, drug-related problems, haematology, pharmaceutical care issues, pharmaceutical care model, pharmaceutical interventions.

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List of Abbreviations

ACCP: American College of Clinical Pharmacists

DRP: Drug-Related Problem

EAHP: European Association of Hospital Pharmacists

HCP: Healthcare Professional

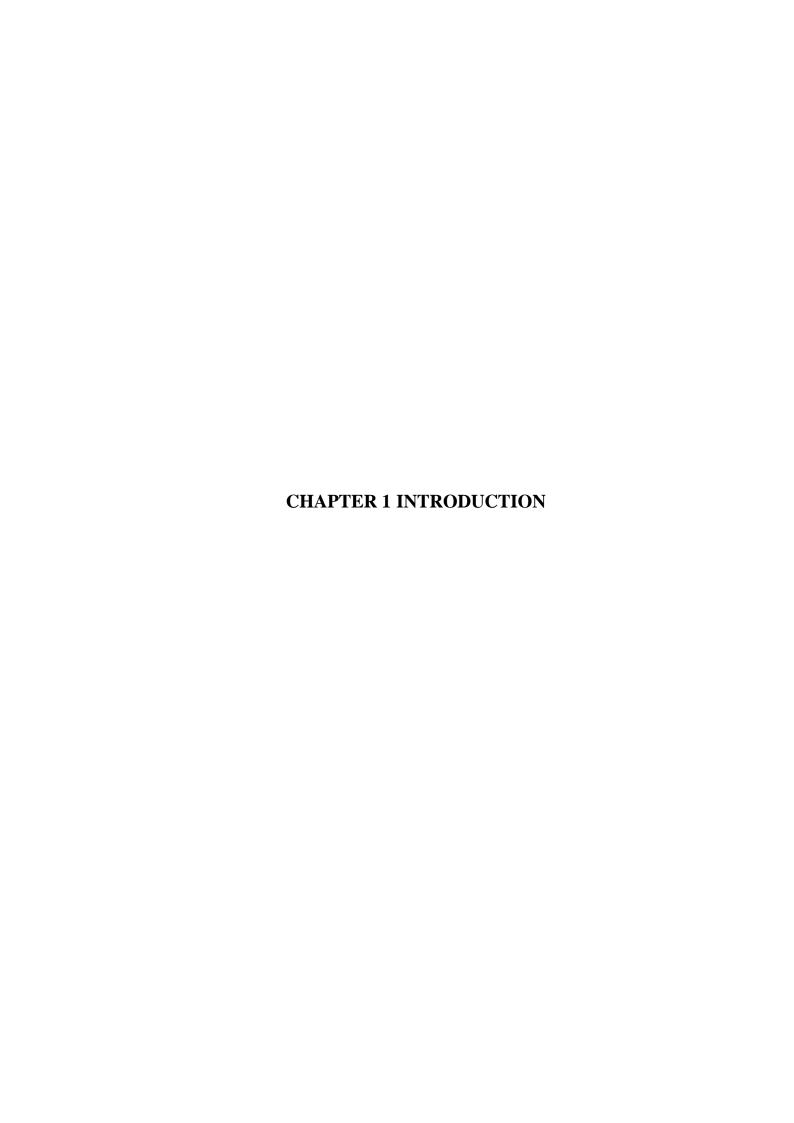
PCI: Pharmaceutical Care Issue

PCNE: Pharmaceutical Care Network Europe

PI: Pharmaceutical Intervention

SAMOC: Sir Anthony Mamo Oncology Centre

SHPA: Society of Hospital Pharmacists of Australia



The advances in pharmacological treatments throughout the years have led to an increase in life expectancy and an improvement in the quality of life and health of patients (Lichtenberg, 2015). These developments and advances in therapeutic medications, however, have also been accompanied by an increased risk of medication errors and drug-related-problems (DRPs). Ensuring drug safety throughout all the steps of the medication use process is therefore a vital component of patient management.

1.1 Pharmaceutical care models

Drug safety is a major concern for healthcare systems. Having sound pharmaceutical care services within a healthcare system can ensure drug safety and decrease the risk of medication errors. The development of the pharmacy profession led to a change from the pharmacist being a dispenser and a provider of medication to the pharmacist establishing a more patient-oriented role and thus being in a position to provide complete pharmaceutical care. A re-defined definition by the Pharmaceutical Care Network Europe (PCNE) in 2013, states that pharmaceutical care is "the pharmacist's contribution to the care of individuals in order to optimise medicines use and improve health outcomes" (Allemann, 2014). A pharmaceutical care model allows the delivery of medication management services keeping in mind the needs of the patient. The pharmacist, being the expert in the therapeutic use of medications, is responsible to handle the patients' drug-related needs in order to ensure that the pharmacotherapy administered is of good quality, safety, and efficacy (ACCP, 2014).

1.2 Clinical Pharmacy Service

In a hospital setting, one of the ways of putting a pharmaceutical care model into practice is through the provision of a clinical pharmacy service. The aim of a clinical pharmacy service is to provide patients and healthcare professionals (HCPs) with a drug therapy management plan that leads to safe medication use thereby minimising medication errors that may negatively impact the patient's outcomes (Leveque, 2014). In 2008, the American College of Clinical Pharmacy (ACCP) defined clinical pharmacy as "a health science discipline in which pharmacists provide patient care that optimises medication therapy and promotes health, wellness and disease prevention".

1.2.1 Characteristics of a Clinical Pharmacist

The ACCP also stated that this profession should be characterised by a caring attitude which together with intensive pharmaco-therapeutic knowledge, ensures effective patient outcomes. Clinical pharmacists should also aid in the creation of new knowledge for the ultimate improvement of health status and quality of life of the patients.

In 2014, the ACCP issued a document that highlighted the expectations of clinical pharmacists. The need to have the necessary qualifications, to provide an adequate process of care, to document correctly any pharmacy-related events and to work in collaboration with other HCPs were amongst the requirements (ACCP, 2014). An updated list of the core competencies and skills that a clinical pharmacist must possess in order to provide a good quality comprehensive medication management was devised by the ACCP in 2017. These competencies, summarised in Table 1.1, are similar to

¹ ACCP- American College of Clinical Pharmacy. The Definition of Clinical Pharmacy. Pharmacotherapy [Internet]. 2008 [cited 2018 Jan 19]; Available from:

https://www.accp.com/docs/positions/commentaries/Clinpharmdenfinal.pdf

those for clinicians; however, competencies for clinical pharmacists are more focused on pharmacotherapy (Sasseen *et al.*, 2017).

Table 1.1 Competencies of Clinical Pharmacists

Competency	Definition		
Direct Patient Care	Observe and evaluate the patient during ward rounds and assess		
Direct I attent Care	the patient's medications for efficacy, safety, and affordability		
Pharmacotherapy	Offer pharmacotherapy knowledge for an optimal choice of		
Knowledge	drug therapy		
System-Based Care	Identify areas for improvement to optimise individual patient		
and Population	and patient population care, using health informatics (Dobesh et		
Health	al., 2013).		
	Clearly communicating with patients, their caregivers a		
Communication	healthcare professionals, be it verbally or in a written manner,		
to ensure a safe and effective patient management			
	Constantly maintaining a level of appropriateness and		
Professionalism	professionalism whilst ensuring that the message being		
	conveyed is well understood (Lesse et al., 2010)		
	Apart from possessing the necessary qualifications, clinical		
Continuing	pharmacists must engage in continuing professional		
Professional	development such as participation in professional organisations,		
Development	providing training to students and educating other HCPs		
	(Sasseen et al., 2017)		

1.2.2 Duties of a Clinical Pharmacist

Clinical pharmacists can give their input throughout various phases of the patient's care process. According to the ACCP, a clinical pharmacist must be competent enough to carry out comprehensive medication management (ACCP, 2014). Assessing the patient directly, to collect essential subjective and objective information, is the first task of a clinical pharmacist (ACCP, 2014).

1.2.2.1 Clinical Medication Reviews

Secondly, the clinical pharmacist must perform comprehensive medication management through patient medication reviews. The PCNE defines medication reviews as "a structured evaluation of patient's medicines with the aim of optimizing medicines use and improving health outcomes. This entails detecting DRPs and recommending interventions²". Medication reviews allow the clinical pharmacist to contribute to rational and optimal drug use and to decrease the likelihood of DRPs (Krska, 2001; Graabaek and Kjeldsen 2013). As defined by Hepler and Strand, a DRP is "an event or circumstance involving drug treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care" (Hepler and Strand, 1990). Due to DRPs, many patients do not receive the full benefit of their drug therapy, therefore it is essential that DRPs are identified during medication reviews (Westerlund, 2009). There are many types of medication reviews that can be performed. The on-ward clinical participation of pharmacists in hospitals easily allows for clinical medication review to occur. This is because the patient himself/herself, his/her clinical notes and laboratory investigations are available at hand (Blenkinsopp, 2012). Clinical medication review was defined by Zermansky et al., as "the process where a health professional reviews the patient, the illness, and the drug treatment during a consultation. It involves evaluating the therapeutic efficacy of each drug and the progress of the conditions being treated. Other issues, such as compliance, actual and potential adverse effects, interactions, and the patient's understanding of the condition and its treatment are considered when appropriate. The outcome of the review will be a decision about the continuation (or otherwise) of the treatment" (Zermansky et al., 2006).

² PCNE:Pharmaceutical Care Network Europe. Medication review definition approved. [Internet]. [cited 2018 Mar 06]. Available from: http://www.pcne.org/news/35/medication-review-definition-approved

In practice, this can be translated into the below task points:

- Checking if the patient is on any unnecessary medicines
- Ensuring that the patient is being helped by all his/her medications
- Checking whether any harm is being caused by the drug therapy
- Making sure that the patient is willing to continue taking all the medications
- Offering treatment for untreated therapeutic indications (Blenkinsopp, 2012)

A complete evidence-based individualised pharmaceutical care plan is then devised to ensure that the most beneficial clinical outcome is achieved. Within the pharmaceutical care plan, apart from listing the pharmaceutical care issues (PCIs) and DRPs, the clinical pharmacist must offer pharmaceutical interventions (PIs) to solve these issues. The PI is the recommendation offered to the other HCPs within the interdisciplinary team, in order to solve the PCI or DRP³. Continuous collaboration and communication with the prescriber and other HCPs are vital to ensure acceptance of PIs.

Finally, outcomes are evaluated to ensure the patient's progress towards achieving all goals of therapy (ACCP, 2014).

1.3 The Setting

Presently, at Mater Dei Hospital (MDH) and Sir Anthony Mamo Oncology Centre (SAMOC) in Malta, pharmaceutical care models developed by clinical pharmacists are not yet established in all the wards and clinical areas. An example of a ward without a ward-based clinical pharmacist is the adult haematology ward at SAMOC. Chemotherapeutic prescriptions are vetted and checked by compounding pharmacists at

³ PCNE Conference.D-1461- Classification for pharmaceutical interventions in patient oriented care: a new concept. [Internet].2014.[cited 2018 Mar 15]. Available from: http://www.pcne.org/upload/other/D-1461.pdf

the Compounding Section of the Pharmacy Department prior to the reconstitution of chemotherapy preparations.

This practice of checking chemotherapy prescriptions prior to reconstitution, aids in identifying any errors with regards to the chemotherapy regimen being followed. It also helps in flagging errors in the dose of chemotherapy medications and in the checking of cumulative dosing of cytotoxic drugs such as the anthracyclines. The absence of a pharmacist at the patient's bedside, may however lead to the lack of identification of DRPs which may occur due to other medications, that although not chemotherapeutic in nature, are equally important. The haematology ward within SAMOC thereby provided the optimal setting to test the feasibility of a pharmaceutical care model. Adult inpatients are the focus of this research. Twenty-one beds are present within this ward and all these beds are occupied most of the time. Patient stay is usually a few days or weeks until the patient is given the first cycle of chemotherapy. If the patient has no/minimal accompanying conditions other than the malignancy, he/she is generally transferred to the day unit to continue receiving the remaining chemotherapy cycles. Patients are however re-admitted to the ward when complications such as infections arise and in these cases, their stay at the ward can last for several months.

1.4 The need of a Pharmaceutical Care Model within Haematology

The absence of a ward-based clinical pharmacist within haematology is not the only reason why this setting was chosen to test the feasibility of a pharmaceutical care model. The complexity of treating a patient for a haematological disease, the need for individualised treatment, together with the increased risk for medication errors with

chemotherapy drugs are all valid reasons that warrant the need for a complete interdisciplinary team.

1.4.1 Aetiology of Haematological Malignancies

Haematological malignancies and disorders consist of a number of heterogeneous conditions, all originating from cells of the bone marrow and the lymphatic system (Rodriguez-Abreu, 2007). These conditions and malignancies are different in prognosis, incidence and aetiology (Sant, 2010). The complexity of haematological diseases leads to a wide variety of treatment pathways. These treatment pathways are compiled into protocols, such as the commonly used R-CHOP-21 (Rituximab, Doxorubicin, Vincristine, and Prednisolone), for lymphoma. The treatment pathways differ not only in intensity but also in the purpose and duration (Smith, 2010). Such a scenario often leads to haematology patients needing individualised treatment which makes the pharmacological approach even more complex.

1.4.2 Complexity of Chemotherapy

Moreover, many of the anti-cancer drugs that are available for use are accompanied by a wide variety of drug-interactions and side-effects (Leveque *et al.*, 2014). When considering the complexity of chemotherapy protocols haematology patients follow, together with the multiple supporting medications they are on, there is an increased incidence of medication errors and DRPs. Within this context, improving safety and rational drug use whilst keeping in mind patients' requirements, depends on having a complete interdisciplinary team that manages these patients, including the presence of a ward-based clinical pharmacist (Chisholm-Burns *et al.*, 2010).

1.4.3 Medication Errors

The aim of a clinical pharmacy service is to provide patients and HCPs with drug therapy management that leads to safe medication use and thereby minimising medication errors that may negatively impact the patient's outcomes (Leveque et al., 2014). The input of clinical pharmacists has been proven to reduce medication errors (Chen et al., 2017). Medication errors, defined as "any preventable event that may lead to inappropriate medication use or patient harm", may occur due to various reasons (Patel, 2010). Chemotherapeutic agents are involved in 15.4% of fatal cases that occur due to a medication error (Knez et al., 2010). It has also been reported that approximately 5.3% to 11.4% of hospital admissions are related to the patient's drug therapy (Kongkaew, 2008). Keeping these two points in mind and the fact that oncohaematology patients take multiple other medications apart from their chemotherapy treatment, to treat co-morbidities and aid in their supportive care, one must take note of the increased possibility for the incidence of drug-drug interactions as well as adverse drug reactions to occur. (ASHP, 2006; Hanigian, 2010). This provides an excellent opportunity for clinical pharmacists to give their input and use their knowledge about medications to help in decreasing negative outcomes from occurring and thus lead to providing therapeutic outcomes that improve the quality of life of patients (Theophanous-Kitiri, 2012).

1.5 Advantages of having a Clinical Pharmacist on the Team

A study that aimed to provide strategies to reduce the incidence of medication errors and DRPs in hospitals, listed the "presence of a ward-based clinical pharmacist" as one of the top three strategies that can be implemented, together with computerised

physician order entries and better communication amongst doctors, nurses and pharmacists (Harlan and Gephart, 2003). Other studies show that PIs offered by ward-based clinical pharmacists effectively prevent medication errors and at the same time provide optimal pharmacotherapy (Langebrake and Hilgarth, 2010) (Hossein *et al.*, 2011).

1.6 Rationale of the Study

The clinical pharmacist was identified as a key HCP to liaise directly with the patient, with the other members of the interdisciplinary team and with the compounding pharmacists, thereby acting as a coordinator between all the processes involved in the medication use process. The clinical pharmacist at ward level can help improve the quality of care offered to onco-haematology patients who are highly vulnerable and susceptible to medication errors and DRPs.

1.7 Aims and Objectives

The aim of this research was to develop and test the feasibility of a standardised pharmaceutical care model within a haematology department.

The objectives of the research were to:

- i. Evaluate the care practice in haematology by implementing a checklist that serves as a gap-finding tool to identify gaps in the pharmaceutical service being offered
- ii. Support the use of innovative evidence-based medicine in haematology patients whilst ensuring optimal use of conventional treatment by identifying DRPs and offering pharmaceutical interventions (PI)
- iii. Develop and implement individualised pharmaceutical care plans including the development of an individualised pharmacy patient profile
- iv. Formulate and implement documentation tools that provide effective discharge counselling which can be used to ensure continuity of care as patients move across transitional settings including clinics and hospitals abroad
- v. Provide individualised patient counselling about treatment including directions for use, side effects management and lifestyle advice



2.1 Study Design: Phased Approach

An extensive literature review was conducted in order to familiarise with the latest terminology and concepts that make up a pharmaceutical care model. Keywords such as "pharmaceutical care model", "clinical pharmacy service" and "medication use process" were used to develop a care model in line with the latest evidence care practice.

The study was divided into two phases; the observation phase and the implementation phase. The objectives of the observation phase were to identify the routine practices within the haematology ward and to develop tools that aid with the implementation of a pharmaceutical care model in this clinical area. The expected outcomes of this phase were to equip the pharmacist researcher with the necessary skills and tools to run the clinical pharmacy service.

The objectives of the implementation phase were to develop and implement a pharmaceutical care model within haematology. The expected outcomes of the implementation phase were to report pharmacist interventions and pharmaceutical services that prompt this care model to be implemented on a full-time basis.

Ethics approval was obtained from the University Research Ethics Committee in July 2017 (Protocol 22/2017 Appendix 1).

2.2 Phase 1 - The Observation Phase

Two months were dedicated to the observation phase (July and August 2017). The haematology ward was attended three times per week. Each session lasted for an average of three hours. During this phase, the care practices at the haematology ward were observed.

A typical day started with a ward round by the interdisciplinary team, including the haematology consultant, the higher specialist trainee performing the patient examination and the house officer documenting notes in the patient's medical file. The doctors were accompanied by the nurse in charge as well as by other allied HCPs such as physiotherapists and nutritionists. One could observe the lack of presence of a pharmacist within this interdisciplinary team. The medical notes written throughout the patient stay at the ward and notes relating to recent medical history were kept in a separate file apart from the treatment chart, the chemotherapy protocol followed by the patient and the daily parameter charting. This made it more difficult to thoroughly analyse the patient's treatment chart, since time is often limited and there was no HCP solely dedicated to go through the treatment chart and the chemotherapy protocol, to ensure that there were no drug-therapy problems. New treatment or adjusting the current treatment was done by the doctors after the ward round. This could lead to medication errors. Moreover, one could observe that the doctors spent a lot of time filling in the necessary pharmacy related forms when required to use protocol regulated drugs or drugs ordered on a named-patient basis.

After the ward round, the necessary tests and procedures are ordered and consultations with other firms were carried out. Nurses in charge of patients were given a handover from the charge nurse with regards to what has changed from the treatment and subsequently the process of administering medications is started. It could be observed that nurses were at a loss on to how reconstitute, dilute or administer drugs, mostly the parenteral drugs or when new treatment was prescribed. It is important to have an observation phase where one could evaluate the current practices and establish a planned framework to clearly define goals prior to implementing a new service.

Throughout the observation phase, a gap-finding tool developed by Falzon (Falzon, 2018) was used to clearly define what pharmaceutical and medical care practices are being carried out and by which HCP are these performed (Appendix 2). This checklist tool was developed from standard practices of care such as those defined by the ACCP, the Society of Hospital Pharmacists of Australia (SHPA) and European Association of Hospital Pharmacists (EAHP). This tool is divided into nine sections (Table 2.1).

Table 2.1 Sections of the Gap-Finding Tool

Section	on Heading	
1	Accurate History	
2	2 Current Medication Management	
3	3 Clinical Review	
4	4 Therapeutic Drug Monitoring	
5	5 Providing Medicines Information	
6	6 Adverse Drug Reaction Management	
7	7 Participation in Interdisciplinary Care	
8	8 Information on Ongoing Care	
9	Documentation	

The sections of the Gap-Finding-Tool developed by Falzon (2018), explaining the roles of a ward-based clinical pharmacist within a pharmaceutical care model.

These main sections are then further divided into a total of seventy-three sub-sections that highlight in details the duties that should be performed by a clinical pharmacist. This gap-finding tool was filled in during the eight weeks of the observation phase. An average of one section per week was filled in. By ticking, the practices currently in place were determined. Any additional comments that were needed to correctly describe who is performing a particular action in the absence of a ward-based clinical pharmacist, were written down in the comments section.

2.2.1 Development of Tools to Aid in Documenting Patient Information at Ward

Two tools were developed during the observation phase to aid in the implementation phase of this study. These were the pharmacist patient profile and the discharge medication table for patients.

2.2.1.1 Pharmacist Patient Profile

The pharmacist patient profile (Appendix 3) consists of five sections namely patient details, current medications, investigations most significant for haematology patients, therapeutic drug monitoring and a section where PCIs and DRPs are recorded.

The section for current medications was designed especially for oncology patients and it was divided into chemotherapy medications, supporting medications and other medications. Investigations listed on the pharmacist patient profile conformed to the biochemical and haematology tests that are listed on iSOFT®; a program used at MDH and SAMOC. Apart from recording pharmacist's interventions in the pharmacist patient profile, these were also recorded in the patient file, together with other relevant information.

The pharmacist patient profile was validated by a panel of experts that consisted of two haematology doctors, two nurses and two hospital pharmacists. It was assessed for clarity, user-friendliness and content validity.

2.2.1.2 Discharge Medication Table for Haematology Patients

The discharge medication table (Appendix 4) for patients was developed by updating the current discharge medication table used at MDH and by making information more understandable for discharged patients.

The table was filled on the haematology ward by the pharmacist when present during a discharge process of a patient or when a patient was going home for a few days of leave. It was also filled in when the patient was transitioning to another care setting such as going abroad for bone marrow transplantation. This is especially important since it ensures seamless care, avoids medication errors and makes it easier for the patient to safely take the multiple medications he/she is on.

The discharge table was also validated by a panel of experts consisting of two doctors, two nurses and two pharmacists.

2.2.2 Healthcare Professionals Satisfaction Questionnaire

A questionnaire entitled "Healthcare Professionals Satisfaction Questionnaire" (Appendix 5) was developed to disseminate to the HCPs at the end of the fieldwork. This enables the researcher to assess their satisfaction and perceived benefits with the pharmaceutical care model developed by the pharmacist. A Likert Scale with five stages ranging from "Strongly Disagree" to "Strongly Agree" was provided with each question.

The questionnaire was validated by a panel of experts consisting of three pharmacists, one nurse and two doctors. The key domains assessed were length, clarity and relevance.

2.3 Phase 2 – The Implementation Phase

The implementation phase was spread over a total of seven months (September 2017 - March 2018). During this phase, the ward was also attended up to three times per week for an average of three hours per session. Patient information letters that briefly explained the purpose of this study in layman terms, were disseminated prior to reviewing the patients and their drug treatment. These were available both in English and Maltese to ensure patient understanding (Appendix 6). A consent form was also filled in by the patients (Appendix 7). Patients that had their treatment reviewed were selected via convenience sampling. Pharmaceutical care sessions were held in order to identify PCIs and DRPs. Activities during these sessions included participation in ward rounds and reviewing of patient files including both the treatment chart and the chemotherapy protocol.

The developed pharmacist patient profile was filled in during the pharmaceutical care sessions (Appendix 3). The patient details section and the current medications section were filled in during the first session with the patient. Investigations were copied from the iSOFT® program. Any biochemical or haematology tests that were out of the reference range were written down in red. The DRPs and PCIs identified, were also documented in the developed pharmacist patient profile. PIs were proposed to resolve these identified DRPs. The PI was subsequently discussed with the rest of the interdisciplinary team. These interventions were either accepted and implemented, or else rejected. Following acceptance of the intervention, the necessary therapy changes were carried out. The acceptance rate was recorded for each and every PI proposed and discussed.

2.3.1 Classifying Drug-Related Problems and Pharmaceutical Care Issues

DRPs were classified into major domains to aid in the collection of the results. Many validated classification systems for DRPs and PCIs are published in literature. Established systems such as the PCNE classification and the DOCUMENT system were used in this research.

2.3.1.1 The Pharmaceutical Care Network Europe Classification

'The PCNE Classification V8.02', is the most recent version of the PCNE tool⁴. Unlike other classifications, this classification separates the causes of the DRPs from the problems (Adusumilli and Adepu, 2014). This tool was chosen for this reason, as a DRP can be a result of both a cause and a problem. The cause is defined as "the action (or lack of action) that leads up to the occurrence of a potential or real problem⁴". Causes are divided into eight primary domains in the PCNE classification system. These are further subdivided into thirty-five grouped sub-domains. Domain eight was re-named as 'Monitoring Needs' instead of 'Others' since other reasons causing a DRP that were not listed, were further classified. Table 2.2 reproduces the primary domains together with the subdivisions.

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⁴ PCNE – Pharmaceutical Care Network Europe. The PCNE Classification V 8.02. [Internet]. 2017 [cited 2017 Dec 16]. Available from: http://www.pcne.org/upload/files/230_PCNE_classification_V8-02.pdf

 $Table \ 2.2 \ The \ PCNE \ Classification \ for \ Causes \ of \ Drug-Related \ Problems \ V8.02$

	Primary Domain	Code V8.02	Cause
		C1.1	Inappropriate drug according to guidelines / formulary
		C1.2	Inappropriate drug (within guidelines but otherwise contra-indicated)
	1. Drug selection	C1.3	No indication for drug
	The cause of the (potential) DRP is related to the	C1.4	Inappropriate combination of drugs or drugs and herbal medication
	selection of the drug	C1.5	Inappropriate duplication of the therapeutic group or active ingredient
		C1.6	No drug treatment in spite of existing indication
50		C1.7	Too many drugs prescribed for indication
Prescribing	2. Drug form The cause of the DRP is related to the selection of the drug form	C2.1	Inappropriate drug form (for this patient)
	3. Dose selection	C3.1	Drug dose too low
	The cause of the DRP is	C3.2	Drug dose to high
	related to the selection of the	C3.3	Dosage regimen not frequent enough
	dose or dosage	C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration	C4.1	Duration of treatment too short
	The cause of the DRP is related to the duration of treatment	C4.2	Duration of treatment too long
	5. Dispensing	C5.1	Prescribed drug not available
(The cause of the DRP is	C5.2	Necessary information not provided
Disp	related to the logistics of the	C5.3	Wrong drug, strength or dosage advised (OTC)
I	prescribing and dispensing process	C5.4	Wrong drug or strength dispensed
	6. Drug use process The cause of the DRP is	C6.1	Inappropriate timing of administration and/or dosing intervals
	related to the way the patient	C6.2	Drug under-administered
	gets the drug administered	C6.3	Drug over-administered
	by a health professional or	C6.4	Drug not administered at all
	carer, despite proper dosage	C6.5	Wrong drug administered
	instructions (on the label)	C6.6	Drug administered via wrong route
Use		C7.1	Patient uses/takes less drug than prescribed or does not take the drug at all
U	7 Dationt related	C7.2	Patient uses/takes more drug than prescribed
	7. Patient related The cause of the DRP is	C7.3	Patient abuses drug (unregulated overuse)
	related to the patient and his	C7.4	Patient uses unnecessary drug
	behaviour (intentional or	C7.5	Patient takes food that interacts
	non-intentional)	C7.6	Patient stores drug inappropriately
	· ·- ···	C7.7	Inappropriate timing or dosing intervals
		C7.8	Patient administers/uses the drug in a wrong way
		C7.9	Patient unable to use drug/form as directed
	8. Monitoring needs	C8.1	No or inappropriate outcome monitoring (incl.TDM)

Reproduced from: PCNE – Pharmaceutical Care Network Europe. The PCNE Classification V 8.02. 2017. Available from: http://www.pcne.org/upload/files/230_PCNE_classification_V8-02.pdf

To further classify DRPs that occurred due to a problem present, that may affect patient's outcomes, the PCNE classification scheme for problems, summarised in Table 2.3, was used. A problem is defined as "the expected or unexpected event or circumstance that is or might be wrong, in therapy with drugs" (PCNE, 2017). An example of a problem that may cause a DRP and affect the patient's outcome is the occurrence of a side-effect.

Table 2.3 The PCNE Classification for Problems V8.02

Primary Domain	Code V8.02	Cause
1. Treatment effectiveness There is a (potential) problem	P1.1	No effect of drug treatment
with the (lack of) effect of the pharmacotherapy	P1.2	Effect of drug treatment not optional
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event	P2.1	Adverse drug event (possibly) occurring
3. Others	P3.1	Problem with cost-effectiveness of treatment

The PCNE classification for problems is subdivided into three main domains. These are further subdivided into domains, such as occurrence of an adverse drug event.

Reproduced from: PCNE – Pharmaceutical Care Network Europe. The PCNE Classification V 8.02. 2017. Available from: http://www.pcne.org/upload/files/230_PCNE_classification_V8-02.pdf

2.3.1.2 The DOCUMENT System

The DOCUMENT system was designed on other classification systems including the PCNE amongst others. The DOCUMENT system was used to classify the PCI 'Patient Education' that was not listed in the PCNE classification tool. The DOCUMENT system is usually used in a community pharmacy setting; however, this system includes issues such as the need for patient education that are also essential in a hospital setting

(Williams, 2011). Table 2.4 reproduces a section from the DOCUMENT classification system where the PCI 'Patient Education' is explained.

Table 2.4 DOCUMENT System Classification describing Patient Education

Category	Code	Sub-Category	Sub-Category Description
Education or	$\mathbf{E_1}$	Patient requests drug information	Patient requests information about their medication
Information (where a patient requests further	$\mathbf{E_2}$	Patient requests disease management advice	Patient requests information about the management or prevention of a condition
information about a drug or disease state)	E ₃	Confusion about therapy or condition	Patient has a poor understanding of their medical condition, but their medication compliance appears to be adequate according to the dispensing history
state)	$\mathbf{E_4}$	Demonstration of device	Patient has a technical problem with the administration of a device

DOCUMENT System Classification of Patient Education. This main domain is sub-divided into four sub-categories namely; drug information requests, disease management advice, clarifications about the therapy or condition and information on how to use a medical device.

Reproduced from: https://link.springer.com/article/10.1007%2Fs11096-011-9583-1

2.3.2 Other Pharmaceutical Services Offered

Whilst on the ward, the pharmacist offered other services apart from identifying and resolving PCIs. These included medicines information, administration advice to nurses and liaison with other pharmacy entities amongst others.

2.3.2.1 Medicines Information

Medicines information was a common service requested by the other HCPs on the ward especially doctors and nurses. Information given by the pharmacist was firstly confirmed by more than one source; usually with two or three sources. Databases used to obtain the information were Micromedex[®] (which uses Lexicomp for drug

interactions), UpToDate, Medicines Complete (that includes databases such as the British National Formulary, Stockley's Drug Interactions, Injectable Drugs Guide and Martindale - The Complete Drug Reference), the Renal Drug Handbook and the Summary of Product Characteristics obtained from the Malta Medicines Authority website to ensure that the latest approved product information is being consulted.

2.3.2.2 Liaison with Other Pharmacy Entities

Assistance was also given to nurses by liaising with the pharmacists at the hospital dispensary to confirm drug orders for the ward supply. The pharmacists at the dispensary were also consulted to check the necessary patient permits for medications that are protocol regulated or those that are ordered on a named-patient basis. Patient specific chemotherapy was also confirmed with the pharmacists at the reconstitution unit within the compounding section of the hospital pharmacy. Liaison with the pharmacy stores was offered when needed to check the availability of certain medications especially brand specific medications.

Where necessary, community pharmacists and pharmacy wholesale agents were contacted to check the availability of medications at retail pharmacists when patients needed medications that were not available on the hospital formulary. The Directorate for Pharmaceutical Affairs is the government entity that issues permits for exceptional use medications that are needed for patients with serious medical issues and specific conditions. Various paperwork and forms are needed for this entity to approve these medications and thus liaison with pharmacists at this branch, is of utmost importance since haematology patients use many medications that are listed as exceptional use. Examples of drugs used in haematology that require protocol-regulated procedures include lenalidomide, caspofungin and octreotide.

2.3.2.3 Reconstitution, Dilution and Administration Advice to Nurses

Advice with regards to how to reconstitute, dilute and administer parenteral medications was often requested by nurses. The Summary of Product Characteristics, Medusa[®] (which is an injectable medicines guide developed by the United Kingdom National Health Services) and Medicines Complete were used as references.

2.3.2.4 Checking Medications against Chemotherapy Protocols

The chemotherapy protocol that each haematology patient has to follow, is decided by the consultant haematologist according to the aetiology and type of haematological malignancy. Most of the haematology protocols used locally are those developed by the "Thames Valley Strategic Cancer Network" of Oxford University United Kingdom⁵. Patient chemotherapy doses were confirmed against these protocols and it was ensured that all the supporting medications were included on the patient's treatment chart.

2.3.2.5 Dosage Calculations and Confirmations

Doses of certain medications such as vancomycin, and amikacin are calculated according to the patient's body weight. When reviewing treatment charts, any doses worked out by other HCPs, or doses of drugs that the patient was on for a prolonged period of time, were re-checked by the pharmacist. This was done to ensure that the dose being given to the patient is within the indicated dose per kilogram. The weight of haematology patients fluctuates frequently due to the course of the disease and due to drugs, such as steroids and hence one can appreciate the value of this exercise of rechecking of doses and constant monitoring. Patient weight is recorded regularly in this

⁵ Network Site Specific Group - Haematology. [Internet]. Oxford. Thames Valley Strategic Clinical Networks. c2014. [cited 2017 Nov 5]. Available from: http://nssg.oxford-haematology.org.uk/

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setting. In order to ensure safe medication use, one should not only work out the chemotherapy doses according to the patient's weight, but also the doses of other drug treatment.

2.3.2.6 Modification on Treatment Charts

When mistakes were encountered whilst reviewing treatment charts, these were modified and arranged accordingly. The treatment charts were reviewed in particular for the points below:

- Legibility
- Completeness
- Timing
- Annotating correctly, for example, which drugs are patient's own
- Using the correct abbreviations that are commonly used and easily understood⁶

2.3.2.7 Filling the appropriate Pharmacy-related Forms

When applying for patient permits for the use of protocol-regulated drugs or exceptional use medications, non-pharmacy HCPs were sometimes at a loss on how to fill the correct paperwork. As a consequence, this led to time wasted re-filling the correct forms. With the pharmacist as part of the interdisciplinary team, this exercise was important as it freed doctor's time that could be used for other more pertinent tasks.

 $http://www.healthywa.wa.gov.au/\sim/media/Files/Corporate/general\%\,20 documents/Quality/PDF/NIMC-WAGuidelines\,2012.ashx$

⁶ Guidelines for the WA National Inpatient Medication Chart. [Internet] Aug 2012 [cited 2018 Apr 02]. Available from:

2.3.2.8 Filling the Developed Discharge Medication Table

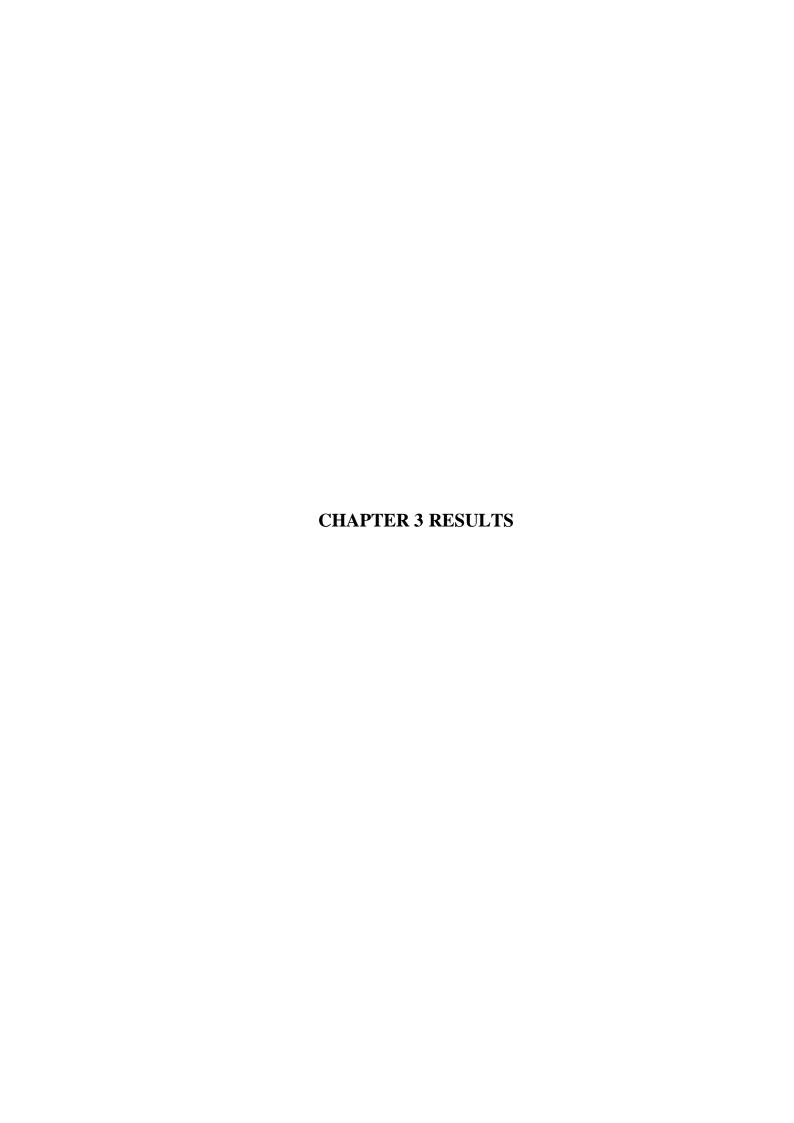
Apart from giving the patient a discharge letter, a discharge medication table was filled in for the patient, so that the patient or carer could easily follow instructions for medication intake when at home. Many drugs used as supportive medication in haematology patients, such as prophylactic use of an anti-viral, an anti-fungal and a proton pump inhibitor are taken during chemotherapy cycles and up to three months after chemotherapy cessation. One therefore needs to ensure that the patient is taking the correct dose of the medication and at the correct time and this is explained easily on the discharge medication table.

2.3.2.9 Checking for Drug Interactions

During ward rounds, treatment charts were analysed for drug interactions. The most common database program used to check for drug interactions was that provided by Micromedex[®], which makes use of Lexicomp[®], which is a program that provides clinical information solutions.

2.3.2.10 Medicines Reconciliation

Whenever possible, medicines reconciliation was performed upon patient's admission to the ward. The past medical records were analysed thoroughly to identify any discrepancies and missing medical information. Checks against the Pharmacy of Your Choice Scheme (POYC) paperwork were made to ensure that all the patient's current chronic treatment was listed on the ward treatment chart.



3.1 Observation Phase

The results of the observation phase, namely the results of the gap-finding tool, the developed pharmacist patient profile and the developed discharge medication table are discussed in this section.

3.1.1 Analysis of the Gap-Finding Tool

Out of the 73 sub-sections of the gap-finding tool (Appendix 2), 20 of the duties of a ward-based clinical pharmacist, were not performed at the haematology ward, neither by a pharmacist nor by any other HCP (Table 3.1).

Table 3.1 Duties of a Ward-based Clinical Pharmacist that are Not Performed

1. Accurate History	Tick
Asking about the use of adherence aids	×
Asking about storage of current medications at home	×
Assessing the need to refer to medical staff	×
2. Current Medications	Tick
All drugs are prescribed by their active ingredient	×
Drug names and directions are not abbreviated	×
Providing information on extemporaneous oral formulations	×
5. Providing Medicines Information	Tick
Providing medicines information to health professionals	×
6. Adverse Drug Reaction Management	
Developing and implementing pharmacological treatment guidelines on acute and late effects of chemotherapy drugs	×
7. Participating in Interdisciplinary Care	Tick
Being physically present to participate in ward rounds, clinics and meetings	×
Preparing accurate and comprehensive patient profiles for assistance when preparing for a ward round	×
Contributing information about the patient's medicines and medicines management	×

7. Participating in Interdisciplinary Care	Tick
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 or planning for ongoing care	×
8. Information for ongoing care	
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 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	×
Liaising with other HCPs 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 health professional	×

20 out of the 73 duties of a ward-based clinical pharmacist highlighted by the gap-finding tool were not fulfilled at the haematology ward.

Seventy-three percent (n= 53) of the roles of a ward-based clinical pharmacist, were either performed by pharmacists working in other sections of the hospital pharmacy, or other HCPs; mostly doctors and nurses. Tables 3.2-3.11 summarise the duties of the gap-finding tool that were being undertaken by other HCPs, in the absence of a ward-based clinical pharmacist. Comments for each sub-domain explain who performed the activity.

Table 3.2 Accurate History Domain - The Roles of a Ward-Based Pharmacist

1. Accurate History	Tick	Comment
Obtaining and documenting a complete Drug History	✓	Carried out by doctors
Obtaining and documenting a complete Past Medical History	✓	Carried out by doctors
Confirming and documenting ADR's/sensitivities	✓	Carried out by doctors
Reconciliation of medication therapy	✓	Carried out by doctors but sometimes omitted due to time constraints
Asking about recently stopped/changed medications	✓	Carried out by doctors but sometimes omitted due to time constraints
Assessing parent's/ patient's understanding of their child's/ their illness and determining if there is need for further education about the illness	✓	Carried out by doctors
Assessing parent's/ patient's understanding and attitude to their child's/ their current drug therapy	✓	Carried out by doctors
Assessing parent's/ patient's ability to use drugs as prescribed	✓	Sometimes carried out by doctors or nurses

Activities such as obtaining a complete drug and medical history and performing medicine reconciliation are carried out by doctors, in the absence of a ward-based pharmacist at the haematology ward.

Table 3.3 Domain 2A: Current Medication: Ensuring Clarity and Validity - The Roles of a Ward-Based Pharmacist

2. Current medication management	Tick	Comment			
A. Reviewing all prescriptions and treatment charts to ensure clarity and validity					
Prescriber's intention is clear to enable the safe supply and administration of medicines	√	Carried out by nurses and by compounding pharmacists for chemotherapy			
Prescriptions and treatment charts are comprehensive and unambiguous	✓	Carried out by nurses when giving treatment. Sometimes treatment charts are re-copied by clinicians			
Date and time of administration are written	✓	Carried out by doctors and nurses especially for chemotherapy and antibiotics in particular			
Time at which the dose should be given is endorsed in the relevant section of the chart	√	Carried out by doctors			
Checking that patient identifiers are documented	✓	Carried out by doctors and compounding pharmacists for chemotherapy			
Order is signed and the prescriber can be identified	✓	Carried out mostly by nurses			

Reviewing treatment charts and chemotherapy prescriptions to ensure clarity and validity, is carried out by the clinicians, in the absence of a pharmacist.

Table 3.4 Domain 2B: Current Medication: Ensuring Appropriateness of Drugs - The Roles of a Ward-Based Pharmacist

2.Current medication management		Comment
B. Reviewing all prescriptions and treatment	cha	
drugs	CIIU	to to ensure appropriateness of an
Confirming a clear indication for each drug	√	Carried out by doctors depending on time
Confirming that the medicine is prescribed for		Carried out by doctors. For chemotherapy
an approved indication. If not, ensuring that the	✓	 compounding pharmacists. For protocol
necessary forms are filled		regulated drugs – dispensary pharmacists
Protocols and guidelines (local where	✓	Carried out by doctors
appropriate) are considered during prescribing		Carried out by doctors
Latest evidence regarding the medicine's		Carried out by doctors and compounding
efficacy, and likelihood of side effects	✓	pharmacists for chemotherapy
compared to therapeutic alternatives		F
Method of administration selected is the most	✓	Carried out by doctors and nurses
appropriate		•
Infusion solution and concentration are		Sometimes carried out by nurses, but
appropriate for parenteral drugs	✓	depending on time constraints, it is not
Checking that drugs and doses are appropriate		done for all drugs
with respect to patient specific considerations,		Carried out by doctors and compounding
therapeutic goals of each drug and licensed dose	•	pharmacists for chemotherapy
Checking dose conversions with changes to	✓	Carried out by doctors
route or formulation Checking that drug achieved goals of therapy	✓	Carried out by doctors
	▼	•
Checking for duplications		Sometimes carried out by other HCPs
Checking for contraindications	✓	Sometimes carried out by doctors
Checking for drug interactions and assessing their clinical significance.	✓	Rarely carried out by doctors. Depends on time constraints
Units of the drug doses prescribed are clearly		Sometimes carried out by doctors and
indicated	✓	nurses
Tracking the cumulative doses of anti-cancer		
drugs	√	Carried out by compounding pharmacists
Liaising with the cytotoxic manufacturing		
service to coordinate the timely supply of	✓	Carried out by doctors
chemotherapeutics		•
Drugs are available at the ward and where	<	Carried out by nurses
necessary are ordered	Ĺ	Carried out by nurses
Checking the medication administration record		
to ensure that all doses ordered have been	✓	Carried out by nurses
administered		
Annotating treatment charts as necessary	✓	Carried out by doctors
Ensuring that the order is cancelled when	✓	Mostly carried out by doctors
medicine therapy is intended to cease Considering cost of the medicine and		
Considering cost of the medicine and considering therapeutic alternatives	✓	Mostly carried out by doctors
considering dicrapeduc attenuatives		Carried out by doctors or other
Checking availability and access to medications	✓	pharmacists in other sections of the
Checking availability and access to incurcations		hospital pharmacy
	1	noopiui piuriiuo j

Comprehensive medication management such as reviewing doses, checking medications against protocols, checking for contraindications and filling the necessary forms for off-formulary medications are mostly carried out by other HCPs on the ward.

Table 3.5 Domain 3: Clinical Review - The Roles of a Ward-Based Pharmacist

3. Clinical Review	Tick	Comment
Reviewing and monitoring patient-specific clinical information including patient's signs and symptoms, parameters, biochemical tests and other tests to evaluate the response to the drugs and adjust therapy accordingly	✓	Carried out by doctors
Identifying actual and potential medicines-related problems	✓	Carried out doctors but optimisation is needed
Performing follow-up evaluations in collaboration with other members of the health care team	✓	Carried out by doctors

Identifying actual and potential DRPs and monitoring patient-specific information such as biochemical tests are mostly performed by doctors, however these activities are not always performed well due to time-constraints.

Table 3.6 Domain 4: Therapeutic Drug Monitoring - The Roles of a Ward-Based Pharmacist

4. Therapeutic drug monitoring (TDM)	Tick	Comment
When necessary, the pharmacist should give exact instructions when and how TDM is to be carried out	✓	Sometimes carried out medicines information pharmacists
Informing the prescriber of the results of TDM in a timely manner, including recommended action and future monitoring requirements	✓	Sometimes carried out medicines information pharmacists

Therapeutic drug monitoring of narrow-therapeutic index drugs such as digoxin is only performed by Medicines Information pharmacists when they are notified by the ward doctors.

Table 3.7 Domain 5: Providing Medicines Information - The Roles of a Ward-Based Pharmacist

5. Providing medicines information		Comment
Providing medicines information to patients	✓	Carried out by doctors
Educating the patients/caregivers	✓	Carried out by doctors

In the absence of ward pharmacists, educating patients and their carers about the treatment, is carried out by ward clinicians.

Table 3.8 Domain 6: Adverse Drug Reaction Management - The Roles of a Ward-Based Pharmacist

6. Adverse drug reaction (ADR) management	Tick	Comment
A. Detection and prevention of ADRs		
Identifying and monitoring susceptible patients such as patients on multiple drugs	✓	Carried out by doctors
B. Suspected ADR		
Assessing the details of the ADR in the context of patient-specific and medication-related factors	✓	Carried out by doctors
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).	1	Carried out by doctors
Recommending treatment options for the ADR	✓	Carried out by doctors
Involvement in the management of all cancer and drug related complications	✓	Carried out by doctors

Adverse-drug reactions are managed by doctors on the ward; however, time constraints sometimes inhibit thorough assessment of the likelihood and clinical significance of ADRs.

Table 3.9 Domain 7: Participation in Interdisciplinary Care - The Roles of a Ward-Based Pharmacist

7. Participating in interdisciplinary care		Comment
Giving advice on the administration , taking into account the availability of access lines, compatibilities and possible pharmaceutical interactions. Advice on possible alternative drugs that can be given more quickly or less frequently if appropriate	✓	Sometimes carried out by pharmacists at the medicines information section that forms part of the hospital pharmacy

When contacted by ward doctors, medicines information pharmacists give advice on administration of drugs; however, any problems that are not communicated, are not assessed by a pharmacist.

Table 3.10 Domain 8: Information for Ongoing Care - The Roles of a Ward-Based Pharmacist

8. Information for ongoing care (Promoting seamless care by contributing to transfer of information about medicines whenever patients move between and within healthcare settings)	Tick	Comment
A. Managing the patient's medicines and communica or legal guardians on transition	ting with	them/ their parents
Discussing the medicines that need to be supplied or sourced on discharge or transfer with the patient	✓	Carried out by doctors
Providing the patients with the medicines that they require	✓	Carried out by nurses
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	✓	Sometimes carried out doctors with discharge letters
Educating patients on how they should take any new medication prescribed, how to identify side effects and what to do if they occur after being discharged	✓	Carried out by doctors

When haematology patients go home for a few days on leave, nurses provide them with the medications they need. When patients are discharged, doctors fill out the necessary paperwork so that patients can get the medications from their community pharmacy. There is no pharmacist that however coordinates all these processes to ensure seamless care.

Table 3.11 Domain 9: Documentation - The Roles of a Ward-Based Pharmacist

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 in the documentation; A. Patient medication record B. Active medication problem C. Pharmaceutical care issues D. Medication therapy plan	√	Any information is documented by doctors as no pharmacist is assigned to the ward

Any information with regards to therapy is only documented on the patient's file by doctors as no pharmacist is present on the ward.

Table 3.12 shows the number of activities of a ward-based pharmacist that were performed by other HCPs for each of the nine main domains of the gap-finding tool.

Table 3.12 Number of Roles of the Gap-Finding Tool Performed

Domain Number	Description of Domain	Number of Roles Performed (N=53)
1	Accurate History	73% (n=8)
2	Current Medication Management	90% (n=27)
3	Clinical Review	100% (n=3)
4	Therapeutic Drug Monitoring	100% (n=2)
5	Providing Medicines Information	67% (n=2)
6	Adverse Drug Reaction Management	83% (n=5)
7	Participation in Interdisciplinary Care	12.5% (n=1)
8	Information on Ongoing Care	44% (n=4)
9	Documentation	100% (n=1)

Two of the nine domains of the Gap-finding tool namely: information on ongoing care and participation in interdisciplinary care, scored less than 50%. This means that these two areas are not being provided by the present HCPs at the ward which further highlights the need for a pharmacist as part of the interdisciplinary team.

3.1.2 Developed Pharmacist Patient Profile

The pharmacist patient profile (Appendix 2) consists of five main sections, namely patient demographics, current medications, investigations, therapeutic drug monitoring and PCIs. The patient profile was developed in such a way that all sections fit on an A3 paper to ensure that no section gets misplaced. The patient details section (Table 3.13) is composed of the necessary patient characteristics, such as the weight and height, needed for calculating the body surface area. This measurement is usually used to calculate the required chemotherapy dose. This section contains double patient identifiers; the name and the identification number.

The panel of experts validating this profile, suggested that the name of the caring consultant is added to this section. The section where weight, height and body surface

area are recorded, should include more columns since haematology patients have variations in these parameters due to the course of the disease and the treatment they are taking (Table 3.14).

Table 3.13 Patient Details Section before Validation

Surname		Name		ID No.
Age	Weight (kg)	l	Height (cm)	Body Surface Area (m ²)
Diagnosis		Protocol		Known sensitivities/ADRs

Before validation, weight, height and body surface area sections only had space for one entry. These were modified accordingly.

Table 3.14 Patient Details Section after Validation

Surname			Name		ID No.		
Age	Diagno	osis		Protocol	Consult	ant	
Date							
Weight (kg)							
Height (cm)							
BSA (m ²)							

A section where the caring consultant can be written down, was added post-validation. The section where the pharmacist can record any drug allergies was moved with the 'Current Medications' section to have space for weight, height and body surface area.

Other information recorded in this section includes the age of the patient, the patient's diagnosis and the name of the chemotherapy protocol being followed.

The second section of the pharmacist patient profile is that of the current medications.

After being validated by the panel experts, it was agreed that in this section, a space

where the cycle number can be recorded, is added. The section where adverse drug events can be recorded, was transferred to this part of the patient profile and the word "regimen" was replaced by the word "frequency" to avoid any misinterpretations. Table 3.15 shows the final version of this section. For chemotherapy medications, instead of writing a start date and a stop date, is was suggested by the expert panel, that it would be better to write down the date that the medication is given and ticking the adjacent column. This is because chemotherapy drugs are mostly given on specific cycle days and not for an extended number of days as other medications.

Table 3.15 Current Medications

Cycle No:			Known Sensitivities/ADRs:					
Chemotherapy	Dose	Cycle Day/s to be Taken	Duration of Administration	Route	Date	Tick		
Supporting Medications	Form	Dose	Frequency	Route	Start Date	Stop Date		
Other Medications	Form	Dose	Frequency	Route	Start Date	Stop Date		

Section on the patient profile where the pharmacist can record the current medications, including chemotherapy drugs.

The section for current medications was designed especially for oncology patients as it was divided into chemotherapy medications, supporting medications and other medications. For chemotherapy medications, the day of the cycle on which a particular chemotherapy is administered is listed to ensure continuation of treatment. This also enables easy referencing to avoid referring back to the protocol each time.

Serum drug levels for narrow therapeutic index drugs such as vancomycin, gentamicin and digoxin were recorded in the section seen in Table 3.16, to make sure that the dose is changed accordingly. Sub-therapeutic and supra-therapeutic situations are minimised or avoided. The panel of experts validating this patient profile, suggested the addition of a column where the pharmacist can add the frequency of administration of the drug as this can also change according to the serum drug level.

Table 3.16 Therapeutic Drug Monitoring

M - 32 - 42	Serum Levels	Dose:			Blood Sample		Dose:		
Medication	Ref Range	Date	Time	Frequency	Date	Result	Date	Time	Frequency
Madiastian	Serum Levels	Dose:		l	Blood Sample		Dose:		
Medication	Ref Range	Date	Time	Frequency	Date	Result	Date	Time	Frequency

The dose, frequency and serum drug levels for narrow therapeutic index drugs are recorded in this table.

Investigational results such as electrolyte levels and serum blood counts were recorded in the section seen in Table 3.17 and can be referred to during ward rounds. Trend views for a particular investigation can be easily observed. Levels that are out of normal range were recorded in red ink.

Table 3.17 Investigations

	Date	:		
Test				
Urea (1.7-8.3mmol/L))				
Cr (44-80F/62-106M µmol/L)				
Cr Cl (60-120ml/min)				
eGFR (>60ml/min/1.73m ²)				
K (3.5-5.1mmol/L)				
Na (135-145mmol/L)				
Bilirubin (0-21µmol/L)				
ALP (40-104F/40-129M U/L)				
GGT 5-36F/8-61M U/L)				
ALT (5-33F/5-41M U/L)				
LDH Serum (135-220U/l)				
Ca (2.15-2.55mmol/L)				
Corrected Ca (2.05-2.60mmol/L)				
Phosphate (0.87-1.45mmol/L)				
Magnesium (0.65-1.05mmol/L)				
Albumin (32-52g/L)				
Protein (66-87g/L)				
CRP (0-5mg/L)				
CK (26-192F/39-308M U/L				
WBC (4.30 -11.0 x 10 ⁹ /L)				
Neutrophils Abs (2.1-7.2x10^9/L)				
Immature Granulocytes(0-0.09x10^9/L)				
Lymphocytes Abs(1.3-3.6x10^9/L)				
Monocytes Abs (0.4-1.10x10^9/L)				
Eosinophils Abs (0.1-0.7x10^9/L)				
Basophils Abs (0.000.01x10^9/L)				
RBC (3.9-5.6F/4.6-5.9M x 10 ¹² /L)				
HgB(11.5-16.5F/14.1-17.2M g/dL)				
Hematocrit (40.4-50.4%)				
MCV (76-95F/76-100M fL)				
Mean Cell Hb (27.0-32.0pg)				
Mean Cell Hb Conc (33-36g/dL)				
Platelets (146-302 x 10 ⁹ /L)				
ESR (33-37F/28-32M mm 1st hr)				
B12 (156-672pmol/L)				
Ferritin (10-291F/22-322M ng/ml)				
Folate (>12.19nmol/L)				
Fe (5.83-34.5µmol/L)				
Transferrin Sat (20-50%)				

Investigations most relevant to haematology patients, such as white cell count, platelet count and haemoglobin levels are recorded in this section of the pharmacist patient profile.

PCIs and DRPs detected, were recorded in the section seen in Table 3.18.

Table 3.18 Pharmaceutical Care Issues and Drug-Related Problems

Date	PCI/DRP	Proposed Action	Desired Outcome

The date of detection of the PCI/DRP, the type of issue with the intervention proposed and the outcome desired are recorded in a similar table as above.

3.1.3 Developed Discharge Medication Table

Figure 3.1 is a template of the discharge medication table developed for use when patients were going to be discharged, sent home for a few days on leave or transferred to other sections such as the day unit (Appendix 3).

Double identifiers were also recorded for this table namely the name and the identification number. Apart from the dose, the number of tablets that had to be taken by the patient each time of the day, was also documented. For example, if a particular medication is available as 100mg tablets at hospital and the patient needs to take 200mg in the morning, the number 2 would be recorded in the morning box.

The start and stop date gives an exact indication to the patient when the medications need to be started and stopped as these may not need to be taken throughout all the patient's stay at home.

	Haematology Discharge Medication Table									
Patient:								ID Number:		
MEDICATION NAME	DOSE (mg)	DOSAGE FORM	REGIMEN		TIMIN	G		REMARKS	START DATE	STOP DATE
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			

Figure 3.1 The Developed Haematology Discharge Medication Table

The haematology discharge medication table is to be filled by the ward-based pharmacist when the patient is going to leave the ward. It serves as an aid to the patient or carer as to how to take the medications in the absence of a HCP.

3.1.4 Healthcare Satisfaction Questionnaire

Questionnaires were given to HCPs to assess their satisfaction with the ward pharmacy service provided (Appendix 4). The expert panel validating this questionnaire suggested the deletion of two questions to end up with a 2-pager questionnaire. Avoiding the use of a lengthy questionnaire minimises the likelihood of having participants not filling all the questions of the questionnaire. They were asked about the ability of the pharmacist to provide specific services including:

- providing drug information in a timely manner
- identifying DRPs

- resolving DRPs
- recommending the ideal therapy
- providing patients with the necessary education
- giving nurses the correct information regarding drug administration

HCPs were also asked if the pharmacist had sufficient knowledge to function in the haematology ward setting. The final question was asked to investigate whether the HCPs working at the haematology ward feel the need to have the presence of a clinical pharmacist on the ward on a full-time basis, considering that for the purpose of this research, this service was not offered on a full-time basis. 100% response rate was obtained (N=15). As can be seen from Figure 3.2, the vast majority of the responses were either "Strongly Agree" or "Agree".

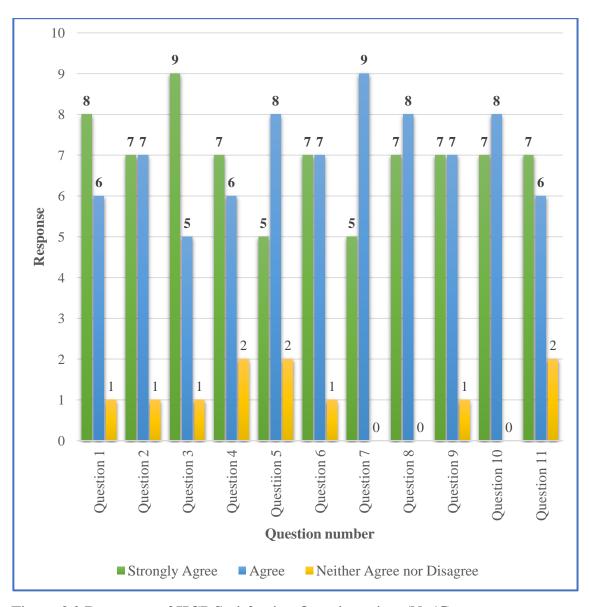


Figure 3.2 Responses of HCP Satisfaction Questionnaires (N=15)

- Q 1: Ability of pharmacist to answer drug information questions in a timely manner
- Q2: Ability of pharmacist to identify DRPs
- Q3: Ability of pharmacist to resolve DRPs
- Q4: Ability to recommend appropriate therapy
- Q5: The pharmacist has sufficient knowledge to function in the haematology setting
- Q6: Ability of pharmacist to give correct reconstitution/administration advice to nurses
- Q7: Ability to check availability of medicines and liaise with correct entities if not
- Q8: Ability to educate patients/relatives/carers about the drug treatment
- Q9: The clinical pharmacist enhances my understanding of medication use
- Q10: Overall satisfaction with the service provided by the pharmacist
- Q11: The presence of a full-time clinical pharmacist at haematology is essential

3.2 Implementation Phase

This section gives details relating to the implementation phase of the pharmaceutical care model.

3.2.1 Pharmaceutical Care Issues and Drug-Related Problems

Ninety-three different patients were seen during 7 months of ward attendance. The pharmacist saw each patient an average of five times during their stay at the haematology ward. The patients included 53 males with a mean age of 57.77 and 40 females with a mean age of 62.15. Table 3.19 shows the demographic profile of patients.

Table 3.19 Demographic Profile of Patients

	Male (%)	Female (%)	Total (%)
Number of patients	53 (43)	40 (56)	93 (100)
Age [years (mean±SD)]	57.77±16.56	62.15±16.40	59.66±16.55
Range [years]	26 – 87	21 – 95	21 – 95
Median [years]	58	62	60

Female patients were slightly older than male patients. The age range for female patients was slightly wider than that of male patients, with the youngest and oldest patients being both females.

A total of 377 pharmaceutical care sessions were held with these patients, during which a total of 465 PCIs were identified. These were divided according to the eight primary domains for causes of the PCNE classification of DRPs, the domain for problems of the PCNE classification (Occurrence of Side Effect) and the main domain 'Patient Education' of the DOCUMENT system (Figure 3.3). No DRPs or PCIs that fall under the two main domains for causes of the PCNE classification namely; 'Dispensing' and 'Patient-related', were identified.

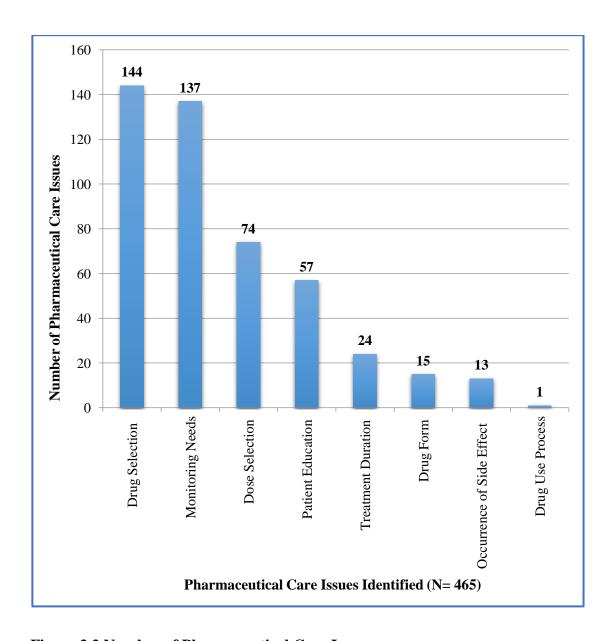


Figure 3.3 Number of Pharmaceutical Care Issues

The most common issues identified during the care sessions, were issues with drug selection, followed by monitoring needs and issues with dose selection. The least common DRPs were issues with drug form, occurrence of side effects and issues with the drug use process.

The most common DRPs identified were issues with drug selection (31.0%). Table 3.20 shows how these identified issues are divided according to the sub-domains of the PCNE classification.

Table 3.20 Drug Selection

DRUG SELECTION (n=144)	
Inappropriate drug according to guideline	23
No indication for drug	34
Inappropriate combination of drugs	18
No drug treatment despite existing indication	60
Too many drugs prescribed for one indication	9

'No drug treatment despite an existing indication' was the most common issue identified with respect to drug selection. This was followed by 'no indication for drug' and 'inappropriate drug according to guidelines'.

'Monitoring needs' was the second most common PCI identified (29.5%) This was then followed by 'dose selection' (15.9%). Table 3.21 shows how issues with dose selection were sub-divided according to PCNE classification.

Table 3.21 Dose Selection

DOSE SELECTION (n=74)		
Dose too low	14	
Dose too high	25	
Dosage regimen not frequent enough	8	
Dosage regimen too frequent	17	
Dosage timing instructions wrong, unclear or missing	10	

Giving too high a dose was the most common issue with respect to dose selection. This was followed by having a dosage regimen that was too frequent and have a dose that was too low.

'Patient education' (Table 3.22) was the fourth most common PCI identified (12.3%). Patient education was either offered directly by the pharmacist researcher or information was passed on to the clinician to inform the patient himself/herself.

Table 3.22 Patient Education

EDUCATION OR INFORMATION (n=57)	
Patient requires drug information	40
Patient requires disease management advice	8
Confusion about therapy or condition	6
Demonstration of a medical device	3

Education given to the patients includes drug information about the chemotherapy treatment and supportive medications, how to manage the disease and side-effects of treatment and information about how to use a medical device such as a spacer.

The next most common issues identified were those that had to do with duration of treatment (5.2%). Table 3.23 shows how these issues are subdivided according to the PCNE classification.

Table 3.23 Treatment Duration

TREATMENT DURATION (n=24)	
Duration of treatment too short	2
Duration of treatment too long	22

Giving a drug for too long or for too little time are drug-therapy issues that were also identified during pharmaceutical care sessions.

The last three PCIs with the lowest percentage identification were issues with 'drug form' (3.2%), 'occurrence of side-effects' (2.8%) and issues with the 'drug-use process' (0.2%).

3.2.1.1 Pharmaceutical Interventions

The acceptance rate of the pharmaceutical PIs offered and discussed with the other HCPs was 87% (n=405).

3.2.2 Other Pharmacy Services Offered

Medicines information (n=180; 45%) was the most common pharmaceutical service offered to the HCPs whilst on the ward. Frequent questions asked were queries about doses of drugs, maximum doses that can be given, drug dose adjustments in renal and hepatic impairment and availability of medication on the local formulary.

Reconstitution, dilution and administration advice to nurses was the second most common pharmaceutical service offered (n=40; 10%). The most common queries brought forward by nurses were on which solvent to use to dissolve a powder, what is the maximum amount of diluent one can use, especially when patients are fluid restricted, and for how long could a drug be administered. This service was particularly important and the presence of the pharmacist was appreciated by the nurses. In one instance, the nurses wanted to administer immunoglobulins (Privigen®) and they were unaware of the rate of administration. When they administered it in the absence of the pharmacist, the medication was administered too fast, and the patient experienced infusion-related adverse events including fever and hypersensitivity reactions. The next day, when the same medicine was administered in the presence of the ward-pharmacist,

the correct method rate of administration was pointed out (initial rate of 0.3mL/kg/hr for 10 minutes with monitoring and if tolerated rate is increased to 0.6mL/kg/hr for 30 minutes, then increased to a maximum rate of 4.8mL/kg/hr) and the patient did not experience any infusion-related side-effects.

A specific gap was identified during the care sessions at the haematology ward. The nurses were taking care of a particular patient that needed to use the biosimilar Enbrel[®]. This medication is not routinely used in this ward and therefore the need was felt to give a brief educational session on the administration of this subcutaneous medication. A video from the product's website⁷ itself was shown to nurses to better explain the administration technique and an informative leaflet was prepared for the nurses to follow during reconstitution. The leaflet was prepared using the official websites of the products, as well as the Summary of Product Characteristics, Patient Leaflets, guidelines and published articles. The ward pharmacist was also present during the reconstitution and administration of the first dose.

Modifications on treatment charts was the third most common pharmaceutical service offered (n= 37; 9%). The following is a list of the most common errors encountered on treatment charts:

- Duplicated medicines with some treatment written in both "as required medications" section and the "regular medications" section
- Trade names written down instead of active ingredients (excluding biosimilar medications)
- Spelling mistakes when writing medication names
- Treatment not crossed off when having a stop date

⁷ Enbrel®. [Internet]. California: Amgen®; c2018 [cited 2018 Jan 04]. Available from: https://www.enbrel.com/

.

 Od used as an abbreviation for once daily and was mistaken for twice daily. In fact, guidelines on treatment chart annotations recommend writing mane, nocte or a specific time instead of od.⁸

Figure 3.4 summarises the other pharmaceutical services that were provided to the haematology ward.

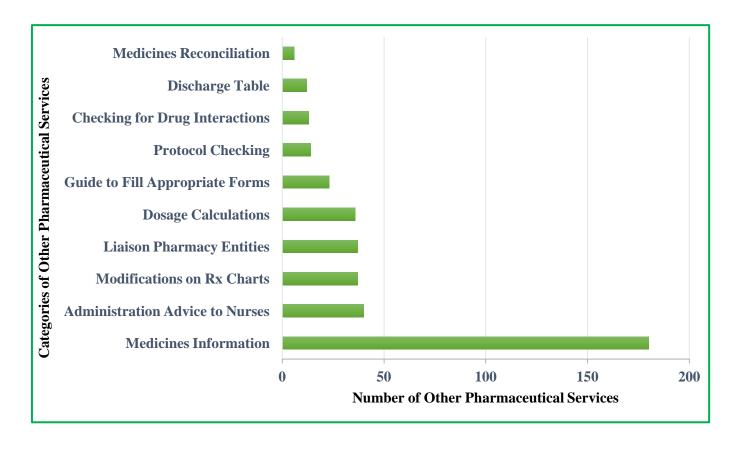


Figure 3.4 Other Pharmaceutical Services Offered (N=398)

⁸ Guidelines for the WA National Inpatient Medication Chart. [Internet] Aug 2012 [cited 2018 Apr 02]. Available from: http://www.healthywa.wa.gov.au/~/media/Files/Corporate/general%20documents/Quality/PDF/NIMC-WAGuidelines2012.ashx

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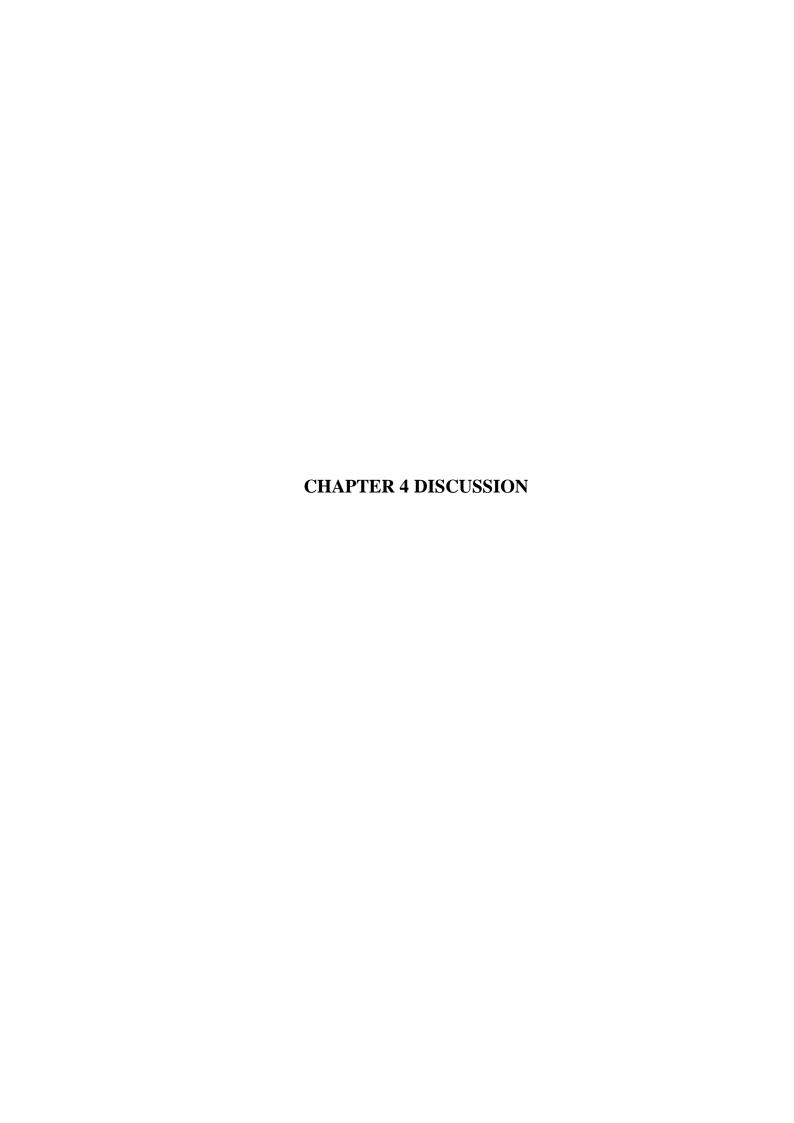
Medicines Information was the most common pharmaceutical service offered. This was followed by giving administration and reconstitution advice to nurses and performing modifications on treatment charts when mistakes or ambiguous annotations were detected.

Liaison with other pharmacy entities was also the third most common pharmaceutical service offered (n= 37; 9%). Liaison was sought with both pharmacy entities within the hospital and other pharmacy entities outside the hospital, such as community pharmacies. Collaboration with the Quality Assurance Department of MDH was sought when one of the refrigerators of the haematology ward exceeded temperature limits. With the help of a quality assurance pharmacist, all the stock present in the fridge was put in quarantine. The maximum temperature reached and the total period of time in which the cold chain excursion occurred was established in collaboration with ward staff. The products suffering storage conditions outside the temperature range specified in their Summary of Product Characteristics were identified. The marketing authorization holders for these products were contacted through their Responsible Person in order to obtain information regarding the safety of use of these products following the experienced temperature excursion.

When the haematology pharmacy technician was absent from the ward, expiry dates were checked, stock was rotated and weekly scheduled orders were made via the online database system that connects the wards with the dispensing pharmacy. Any expired medications were removed from the ward and given to pharmacists at the pharmacy stores to correctly dispose of them. This ensured continuity of service that is offered to the ward by the dispensing pharmacy.

Community pharmacists were contacted to check about the availability of items patients get through the Pharmacy of Your Choice Scheme (POYC) once they return back home. When patients had missing permits, or stocks of medications were not available, the correct entities, including the Directorate for Pharmaceutical Affairs were contacted.

Dosage calculations and confirmations (n=36; 9%), guiding doctors in filling the correct pharmacy–related forms (n=23; 6%), checking of treatment charts against chemotherapy protocols (n=14; 4%), and checking for drug interactions (n=13; 3%), were the next most common pharmaceutical services offered. These were followed by filling of the discharge medication table (n=12; 3%) and medicines reconciliation (n=6; 2%).



4.1 Gaps Identified and Fulfilled and Services Optimised

The observation phase through the gap-finding tool, allowed for the evaluation of the practices at the haematology ward and for the identification of gaps that needed to be fulfilled. An article comparing various new healthcare services implemented, showed that when a service was implemented prior to evaluating its effectiveness, the service was often not sustainable and provided little benefit (McDonnell, 2006). The pharmaceutical care model implemented at the haematology ward, based on international standards of care practice, was successfully developed. The gap-finding tool also helped the pharmacist researcher to set a baseline of what the duties of a ward-based clinical pharmacist should be. Some of the duties were being omitted because of time constraints, lack of presence of an actual pharmacist on the ward, or failure by the other HCPs to identify a specific need.

Duties pertaining to the domain 'Accurate History' of the gap-finding tool, such as asking about the storage of medications at the patient's home, was provided during interventions to resolve the PCI 'Patient Education'.

The provision of medicines information was another gap that was identified and subsequently fulfilled. In fact, this was the most requested pharmaceutical service on the ward. Responding to medicines information queries (16%) was reported in a study as one of the pharmacy services that was frequently provided by clinical pharmacists (Harrison *et al.*, 2012). It was more practical for healthcare professionals to have a pharmacist on the ward who provides medicines information on the spot rather than having to call the Medicines Information Unit of MDH Pharmacy. This service was made more efficient since the pharmacist made use of an electronic tablet that is easy to

carry around and can be freely used; unlike the computers available at the ward. Medicines information queries that were frequently asked included the provision of the latest evidence-based guidelines on the use of anti-emetics with chemotherapy. Clinicians, did not always have the time to look up guidelines and thereby the ward pharmacist aided doctors and nurses with this exercise. Providing medicines information to health professionals to provide evidence-based patient-centred care and optimise quality use of medicines, was one of the roles highlighted by the gap-finding tool. This was successfully provided in a timely and efficient manner. Administration advice to nurses was another common service provided. Examples include giving information about the correct diluents, the correct concentration and the correct infusion rate for intravenous drugs. This ensured safe administration of medications to patients.

Information for ongoing care was another duty from the gap-finding tool that was fulfilled. Patients were encouraged to contact their ward pharmacist, even when they were discharged. Previously, this was not possible as haematology patients did not have a ward pharmacist. Communicating with the patient's community pharmacist and with other clinical pharmacists of hospitals the patients were being transferred to, helped in ensuring seamless care during the transition process. This is especially important since in Malta, there is no bone marrow transplant centre and haematology patients have to travel overseas to benefit from this life-saving procedure. The main domain of the gap-finding tool 'information on ongoing care', was now being accomplished. This was appreciated by doctors and nurses alike, as the majority of HCPs strongly agreed, when asked about the ability of the clinical pharmacist to provide the above service. Ongoing care was even more facilitated due to the improvement of the discharge planning process. Having the pharmacist present on the ward at the time of discharge, provided the patient with discharge counselling, a personalised discharge medication table, and

coordination of all the processes that had to take place to ensure that the patient had access to all the medications needed.

Some processes identified by the gap-finding tool as being provided by other HCPs such as nurses, were now done by the pharmacist present on the ward. Considering that pharmacists are the experts of drugs, ideally activities relating to drug treatment are performed by the pharmacist. This freed nursing time and as a result increased the nurses' contact time with the patient that is very limited in this ward due to shortage of nurses. Such activities included medicines reconciliation and checking for drug interactions. The reviewing of treatment charts to check for clarity and validity, including checking for duplications, contraindications and changing brand names into active ingredients, were now carried out by the ward pharmacist. Abbreviations for active ingredients, such as ATRA, were changed to full names (alpha-trans retinoic acid) and clinicians were educated about the importance of writing full names. These modifications were vital to reduce the risk of medication errors.

Some roles were undertaken by other pharmacists working in other sections of the hospital pharmacy. They were all able to perform the assigned activity well; however considering that these pharmacists are not actively present at the ward, and do not interact directly with patients and other HCPs, they were sometimes limited with the extent of service they could provide. The service was sometimes not provided in a timely manner and according to the patient's individual needs. Checking for the availability and access to medicines, previously done by the dispensing pharmacists, was now the job of the ward pharmacist.

Another process that was optimised, was the service offered by medicines information pharmacists on therapeutic drug monitoring. The Medicines Information Unit within MDH Pharmacy has pharmacokinetic programs available that allow doses to be calculated according to the individual's pharmacokinetics. When medicines information pharmacists were not notified about drugs that needed monitoring, they could not help with this process. The ward pharmacist liaised with medicines information pharmacists to ensure optimal dosing of these drugs that are frequently used within the haematology ward.

Documentation was another activity evidently optimised during the implementation of this pharmaceutical care model. Documenting the clinical activities undertaken by the pharmacist during the time spent at the ward, was possible due to the development of the pharmacist patient profile. Documenting is important to demonstrate the pharmacist's impact on patient's outcomes, to track the pharmacist's actions and to provide information to healthcare administrators. Trends can also be identified and strategies to improve the services can also be highlighted (Fox et al., 2011).

4.2 Assessment of the Pharmacist's Interventions through Pharmaceutical Care Issues

During the implementation phase, DRPs and PCIs were identified through pharmaceutical care sessions. Pharmaceutical care sessions held in this study consisted in participation at ward rounds and reviewing of medical charts. A study carried out in Spain, showed that many of the PIs start during these two activities (Fernandez-Llamazares *et al.*, 2012). Another study compared the acceptance of PIs by clinicians when pharmacists were present for ward rounds (93%) versus when pharmacists were not present for rounds (76%) (Patel *et al.*, 2010). This further highlights the need of the

presence of a full-time in-house pharmacist within the haematology ward that proactively provides rational drug therapy. Eighty-seven percent of the HCPs at the haematology ward also agreed or strongly agreed that a clinical pharmacist's presence on the ward should be on a full-time basis. As demonstrated by this research, a study held by Kucukarslan *et al.*, showed that when pharmacists participate in interdisciplinary care such as ward rounds, they reduce the occurrence of preventable drug events (Kucukarslan et al., 2003). A growing body of literature demonstrates that the presence of clinical pharmacists in ward settings result in positive outcomes for the patients (Kaboli *et al.*, 2006; Bond and Raehl, 2007; Chisholm-Burns *et al.*, 2010; Mekkonen *et al.*, 2013). Being close to the prescriber and having full access to the clinical notes of the patient aids in providing successful PIs. The physical presence on the ward put the pharmacist researcher at an advantage on other pharmacists, such as the compounding and the dispensing pharmacists, as the patient could be evaluated holistically.

The most common issues identified were those related to 'drug selection' (31%). The most common sub-domain within this category was that of 'No drug treatment despite an existing indication' such as leaving out drugs like omeprazole and prophylactic acyclovir that are listed on the chemotherapy protocols. Checking the patient's treatment chart according to the protocol the patient is following, was an important exercise to identify any missing medications the patient is not prescribed. If these issues were not detected by the pharmacist, the patient would have remained without anti-viral and gastro-protection that could have resulted in additional complications. The need for drug addition was also one of the most common DRPs identified in a study carried out at an onco-haematology setting by Shah *et al* (Shah et al., 2006). This was followed by 'no indication for drug'. Examples of drugs that were left by clinicians on the treatment

chart, after that the patient's condition was resolved, include nystatin oral drops and xylomethazoline nasal spray. These are still administered by the nurses to the patients, increasing the risk of organism resistance and side effects. Another example in this category of drug selection was 'Too many drugs for one indication'. A common example that the pharmacist researcher encountered frequently, was that of having a patient being on a macrogol, a stimulant laxative and an osmotic laxative for constipation when the patient was passing normal stools. 'Inappropriate drug according to guidelines' was another issue often encountered within this domain of DRPs. An example of such issue is the switching of xylomethazoline nasal spray to a steroid nasal spray for long-term use in allergic rhinitis.

The second most common pharmaceutical care issue documented was 'monitoring needs' such as the need to monitor blood glucose levels with high doses of steroids, the need to monitor serum vancomycin levels and the need to monitor serum potassium levels with angiotensin-converting enzyme inhibitors. Another example included the need to monitor serum potassium and magnesium levels in a patient on both a loop diuretic and digoxin. Having low potassium and magnesium levels may lead to digoxin toxicity. Such scenarios are ideally avoided in critical and vulnerable patients such as the haematology patients.

Dose selection was the third most common pharmaceutical care issue identified. This category included sub-domains such as dose too high, dosage regimen too frequent and errors in the timing and dosing instructions. An example of giving a dose that was too high, was with teicoplanin in a 33 kilogram cerebral palsy patient. The recommended dose for teicoplanin is 12mg/kg and for this patient a 400mg dose would be ideal. If this had not been flagged by the ward-pharmacist, the patient could have had an increased

risk for side-effects. Examples of errors in this category also include giving paroxetine in the evening that may result in insomnia.

Another PCI identified concerned 'patient education'. Education sessions were carried out both prior to initiation of chemotherapy and at discharge. Patients were educated on the chemotherapy remigen and side effects expected. Education of patients was also carried out when the patients were going to be discharged home or going home for a few days on leave no healthcare professional is present to assist the patient. The provision of patient education was further optimised through the use of the developed discharge medication table. Before intiation of this service by the pharmacist, these sessions were carried out by clinicians and nurses, minimising their time to carry out their duties. This is a common service provided by clinical pharmacists within an oncohaematology setting (Vulgus *et al.*, 2011).

Other PCIs defined during this exercise were those falling under the category of 'treatment duration', such as duration of treatment too short and duration of treatment too long. With chemotherapy protocols involving the use of cytarabine, dexamethasone or prednisolone eye drops are co-prescribed until day nine of the cycle, to decrease the risk of haemorrhagic conjunctivitis. These were often not stopped after day nine, and so the pharmacist educated the clinicians in inserting a stop date to ensure that treatment duration is not too long.

4.3 Other Services Offered to complete the Pharmaceutical Care Model

Calculating and confirming drug doses helped doctors in using their valuable time for other duties. This exercise also provided a second check for calculated doses which also ensures safe medication use and avoids sub-therapeutic or supra-therapeutic situations.

Educational sessions were held for nurses when deemed necessary. These educational sessions were also sometimes requested by the nurses themselves when they felt the need for further education and information about a particular technique or procedure. Reconstitution and administration advice to nurses was now provided efficiently by the ward pharmacist that took into consideration all the treatment the patient was on, rather than focusing only on the drug in question.

The pharmacist researcher also served as a link between the external entities and the ward as in the case of liaison with other pharmacy entities such as the dispensing pharmacy, the Directorate for Pharmaceutical Affairs and the compounding pharmacy. As outlined by the ACCP, the pharmacist through direct patient care and with the adequate pharmacotherapy knowledge, was able to provide comprehensive medication management.

4.4 Validation of the Pharmacist's Interventions at the Haematology Ward

The high acceptance rate of the PIs proposed, shows that the identification of important pharmaceutical care issues was appreciated by the rest of the healthcare team. The acceptance rate of 87% is comparable to that of other similar studies carried out in oncology centres that quote an acceptance rate of 85.4% (Davies *et al.*, 1992) and 94.5% Wong and Gray, 1999).

The other healthcare professionals of the interdisciplinary team agree that the presence of a pharmacist is essential and appreciated on the ward. Thirteen out of fifteen responses of the questionnaire, strongly agreed or agreed that the presence of a full-time clinical pharmacist on the haematology ward is an asset to the team managing these

patients. This further substantiates the need for a ward-based clinical pharmacist at the haematology ward.

4.5 Limitations of the Study

- Logistical limitations: the pharmacist researcher did not attend the haematology ward on a full-time basis and therefore not all drug-related problems were pointed out. On the days when the pharmacist researcher was not present on the ward, the patients did not have their treatment reviewed by the pharmacist and may have left the ward before the pharmacist returned.
- Time constraints: the significance and impact of the PIs due to time limitations were not evaluated.
- Due to time constraints, some of the pharmacist's interventions on the ward may have been under-reported.
- The pharmacist researcher was not informed beforehand on the type of cases
 that would be present on the day that she would be attending the ward and
 therefore could not prepare beforehand.
- Cost evaluations were not performed. The cost reductions as a consequence of the input of the pharmacist researcher were not carried out due to time constraints.

4.6 Recommendations for Further Studies

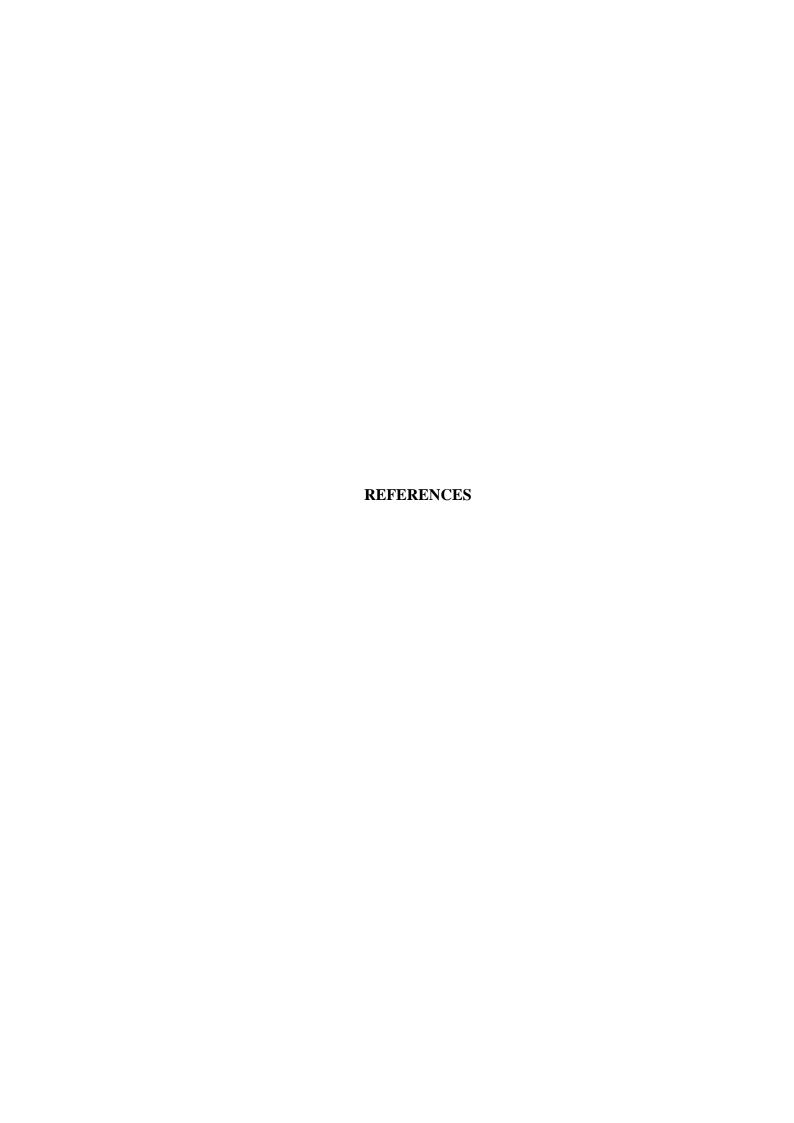
- The cost reductions as a consequence of the pharmacist's presence on the ward could be evaluated. Reduction in length of stay and introgenic re-hospitalisations can be recorded if the economic impact is evaluated.
- Although this study evaluated the pharmacist's contribution within a haematology settings, this standardised pharmaceutical care model can be implemented in other oncology areas and in other non-oncology areas of the hospital. There are various areas within the hospital that do not have the presence of a ward-based clinical pharmacist.
- Considering the positive outcome of this study, this pharmaceutical care service can be permanently implemented on a full-time basis within the haematology ward.
- The feasibility economic impact of a bone marrow transplant centre in Malta could be studied. The role of the pharmacist within this setting can be established during this study and how pharmacists could contribute within this setting.

4.7 Conclusion

The lack of presence of the clinical pharmacist before the start of this study, may not have been hindering the normal functioning of the ward, however, one can conclude that many of the gaps identified were fulfilled, and other services that were already being provided, were optimised. This research provided a new healthcare service within the haematology setting and overall, the pharmacist provided specific drug interventions. When the pharmacist was actively present on the ward, the availability of

evidence-based pharmacological knowledge to patients and fellow healthcare professionals, was increased. This therefore opened up not only opportunities to improve patient care, but to also enhance the knowledge of colleagues.

This study demonstrates the importance of integrating a ward-based clinical pharmacist. By assuming the role of the drug-therapy expert, and by collaborating with other healthcare professionals, the pharmacist ensures safe and optimal care for haematology patients.



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Appendix 1
Ethics 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: 22/2017

Tuesday 18th July 2017

Ms. Diane Saliba

'Gharix'

Dun Spir Gauci Street

Munxar, Gozo

MXR 1361

Dear Ms. Diane Saliba,

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

Implementation of a Pharmaceutical Care Model within Haematology

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

Yours sincerely,

Dr. Mario Vassallo

Chairman

Research Ethics Committee

Email: umms@um.edu.mt • Web: http://www.um.edu.mt/ms



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: 22/2017

Friday 2nd March 2018

Ms. Diane Saliba 'Gharix' Dun Spir Gauci Street Munxar Gozo MXR2361

Dear Ms. Diane Saliba,

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:

Implementation of a Pharmaceutical Care Model within Haematology

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

1. Accurate History	Tick	Comment
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	Comment
A. Reviewing all prescriptions and treatment charts to ensure of	larity a	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 all prescriptions and treatment charts to ensure a all drugs	ppropi	riateness of
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	
Considering cost of the medicine to the patient and hospital and considering therapeutic alternatives	
Checking availability and access to medications, i.e. government restrictions, marketing approval, hospital formulary limitations, methods of obtaining further supply outside the facility	

3. Clinical Review	Tick	Comment
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 health care team the need for intervention and prioritizing these per their risk and urgency		
Performing follow-up evaluations in collaboration with other members of the health care 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. Providing medicines information	Tick	Comment
Providing medicines information to health 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		
Educating the patient/caregivers (both verbally and in writing) to ensure understanding of the care plan, to optimize adherence, and to improve therapeutic outcomes		

6. Adverse drug reaction (ADR) management	Tick	Comment
A. Detection and prevention of ADRs		
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	Comment
Being physically present to participate in ward rounds, clinics and meetings attended by other health 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 or planning for ongoing care		
Giving advice on the administration , taking into account the availability of access lines, compatibilities and possible pharmaceutical interactions. Advise on possible alternative drugs that can be given more quickly or less frequently if appropriate		

8. Information for ongoing care (Promoting seamless care by contributing to transfer of information about medicines whenever patients move between and within healthcare settings)	Tick	Comment
A. Managing the patient's medicines and communicating with or legal guardians on transition	them/ t	heir parents
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.		
B. Liaising with other Health 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 provides or other health 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 in the documentation;		
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. PCIs		
Date when PCI arose, care issue, date when action is taken, action taken, date of outcome, outcome		
D. Medication Therapy Plan		
Implemented collaboratively by the health care 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		

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

Adopted from:

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

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

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Appendix 3 Pharmacist Patient Profile

PATIENT DETAILS

Surname			Name		ID No.			
Age	Diagno	osis Protocol Consultant						
Date								
Weight (kg)								
Height (cm)								
BSA (m ²)								

CURRENT MEDICATIONS

Cycle No:			Known Sensitivities/ADRs:					
Chemotherapy	Dose	Cycle Day/s to be Taken	Duration of Administration	Route	Date	Tick		
Supporting Medications	Form	Dose	Frequency	Route	Start Date	Stop Date		
Other Medications	Form	Dose	Frequency	Route	Start Date	Stop Date		
		1	1		1			

INVESTIGATIONS	Date				
Test					
Urea (1.7-8.3mmol/L))					
Cr (44-80F/62-106M µmol/L)					
Cr Cl (60-120ml/min)					
eGFR (>60ml/min/1.73m ²)					
K (3.5-5.1mmol/L)					
Na (135-145mmol/L)					
Bilirubin (0-21µmol/L)					
ALP (40-104F/40-129M U/L)					
GGT 5-36F/8-61M U/L)					
ALT (5-33F/5-41M U/L)					
LDH Serum (135-220U/l)					
Ca (2.15-2.55mmol/L)					
Corrected Ca (2.05-2.60mmol/L)					
Phosphate (0.87-1.45mmol/L)					
Magnesium (0.65-1.05mmol/L)					
Albumin (32-52g/L)					
Protein (66-87g/					
CRP (0-5mg/L)					
CK (26-192F/39-308M U/L					
WBC (4.30 -11.0 x 10 ⁹ /L)					
Neutrophils Abs (2.1-7.2x10^9/L)					
Immature Granulocytes(0-					
0.09x10^9/L)					
Lymphocytes Abs(1.3-3.6x10^9/L)					
Monocytes Abs (0.4-1.10x10^9/L)					
Eosinophils Abs (0.1-0.7x10^9/L)					
Basophils Abs (0.000.01x10^9/L)					
RBC $(3.9-5.6F/4.6-5.9M \times 10^{12}/L)$					
HgB(11.5-16.5F/14.1-17.2M g/dL)					
Hematocrit (40.4-50.4%)					
MCV (76-95F/76-100M fL)					
Mean Cell Hb (27.0-32.0pg)					
Mean Cell Hb Conc (33-36g/dL)					
Platelets (146-302 x 10 ⁹ /L)					
ESR (33-37F/28-32M mm 1st hr)					
B12 (156-672pmol/L)					
Ferritin (10-291F/22-322M ng/ml)					
Folate (>12.19nmol/L)					
Fe (5.83-34.5µmol/L)					
Transferrin Sat (20-50%)					

THERAPEEUTIC DRUG MONITORING

	THERALEECTIC DRUG MONTORING								
Serum Levels Ref Range	Dose:			Blood Sample		Dose:			
	Date	Time	Frequency	Date	Result	Date	Time	Frequency	
Serum Levels Ref Range	Dose:			Blood Sample		Dose:			
	Date	Time	Frequency	Date	Result	Date	Time	Frequency	
Serum Levels Ref Range	Dose:			Blood Sample		Dose:			
	Date	Time	Frequency	Date	Result	Date	Time	Frequency	
	Serum Levels Ref Range Serum Levels Ref Range	Serum Levels Ref Range Serum Levels Ref Range Dose:	Levels Ref Range Date Time Serum Levels Ref Range Dose: Date Time Serum Levels Ref Range Dose: Date Time	Levels Ref Range Date Time Frequency Serum Levels Ref Range Date Time Frequency Frequency Date Time Frequency Frequency Time Frequency	Levels Ref Range Date Time Frequency Date Serum Levels Ref Range Date Time Frequency Date Bl Sat Frequency Date Date Time Frequency Date Date Time Frequency Date Date Time Frequency Date	Levels Ref Range Date Time Frequency Date Result Serum Levels Ref Range Date Time Frequency Date Result Blood Sample Result Frequency Date Result Blood Sample Result Frequency Date Result Frequency Date Result	Levels Ref Range Date Time Frequency Date Result Date Serum Levels Ref Range Date Time Frequency Date Date Dose: Serum Levels Ref Range Date Time Frequency Date Result Dose: Serum Levels Ref Date Time Frequency Date Result Date Date Time Frequency Date Result Date	Levels Ref Range Date Time Frequency Date Result Date Time Serum Levels Ref Range Date Time Frequency Date Result Date Time Serum Levels Ref Range Date Time Frequency Date Result Date Time Serum Levels Ref Date Time Frequency Date Result Date Time	

PCIs and DRPs

Date	PCI/DRP	Proposed Action	Desired Outcome

Developed by Diane Saliba as part of the dissertation entitled 'Implementation of a Pharmaceutical Care Model within Haematology' as partial fulfilment for the Doctorate in Pharmacy, August 2017.

Appendix 4
Discharge Medication Table

Haematology Discharge Medication Table										
Patient:						ID Number:				
MEDICATION NAME	DOSE (mg)	DOSAGE FORM	REGIMEN	TIMING			REMARKS	START DATE	STOP DATE	
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			
				MORN	NOON	EVE	BED			

Appendix 5

Healthcare Professional Satisfaction Questionnaire

Dear Healthcare Professional,

The scope of this questionnaire is to assess your satisfaction with the clinical pharmacy service provided by myself during these months at the Haematology Ward as part of my dissertation entitled "Implementation of a Pharmaceutical Care Model within Haematology" as partial fulfilment for the Doctorate of Pharmacy I am currently following. Rate your level of agreement for the below statements by ticking one box only per question.

1. Ability to answer drug information questions in a timely manner:							
Strongly Agree	□ Agree	☐ Neither Agree nor Disagree	□ Disagree	☐ Strongly Disagree			
•	to identify medi ions, detect inco		•	ample detect drug			
Strongly Agree	□ Agree	□ Neither Agree nor Disagree	□ Disagree	☐ Strongly Disagree			
3. Ability to resolve medication related problems (for example offer alternative therapies):							
Strongly Agree	□ Agree	☐ Neither Agree nor Disagree	□ Disagree	☐ Strongly Disagree			
4. Ability	to to recommend	d appropriate the	erapy:				
Strongly Agree	□ Agree	☐ Neither Agree nor Disagree	□ Disagree	☐ Strongly Disagree			
5. Sufficient knowledge to function in this setting:							
Strongly Agree	□ Agree	☐ Neither Agree nor Disagree	□ Disagree	☐ Strongly Disagree			

	6. Ability to provide nurses with the correct information regarding reconstitution, dilution and administration of parenteral drugs:							
	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
	-			• •				nd liaise with the ations they need:
	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
	=	to provide the atment::	nece	ssary educati	ion t	o patients a	nd/o	r relatives regarding
<u></u>	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
		nical pharmacient of the diseas		-		standing of	med	ication use in the
_	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
	10. Overall satisfaction with the service provided by the pharmacist:							acist:
	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
	11. The pro-	esence of a fulla al:	-time	clinical pha	rma	cist at the ha	aema	tology ward is
	Strongly Agree	□ Agree		Neither Agree nor Disagree		Disagree		Strongly Disagree
val	•	ery much for ta	_		con	nplete this s	surv	ey. Your feedback is
		r III, Universit epartment of Ph	•		ei H	[ospital		

Appendix 6 Patient Information Letters in English and Maltese

English

Dear Patient,

I am Diane Saliba, a pharmacist and a student reading for a Doctorate in Pharmacy. For

the fulfilment of the requirements for the Doctorate Degree, I am working on a research

project entitled "Implementation of a Clinical Pharmacy Service within Haematology".

The research is being carried out under the supervision of Professor Lilian Azzopardi

and Dr. Louise Grech in collaboration with Dr. David Busuttil, Dr. Alexander Gatt and

Dr. David James Camilleri, Consultant Haematologists.

The purpose of this research is to develop pharmacy services to cover the Haematology

Ward at Sir Anthony Mamo Oncology Centre.

This research involves the pharmacist-researcher contributing to the safe and effective

use of the medications used in the management of your illness. This is done in

collaboration with the doctors and nurses taking care of you at the Haematology ward.

This research involves the pharmacist-researcher verifying your drug history with you

as well as providing you with discharge medication counselling and information about

the chemotherapy agents and other drug therapies, including the reason for use, how to

take, potential side effects, drug interactions and proper handling and storage.

Your identity will not be revealed in anyway, any information collected will be kept

anonymous throughout the research and you may quit the study at any time.

Thank you for your time and co-operation,

Diane Saliba

Pharmacist

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Maltese

Għażiż/a Pazjent/a,

Jiena Diane Saliba, spiżjara u studenta ghad-Dottorat fil-Farmacija u qed naghmel

ricerka intitolata "L-Implimentazzjoni tas-Servizz tal-Farmacija Klinika

fl-Ematologija". Din ir-ricerka qed issir taht is-supervizjoni tal-Professur Lilian

Azzopardi u Dr Louise Grech, bil-kollaborazzjoni ta' Dr David Busuttil, Dr Alexander

Gatt u Dr David James Camilleri, Konsulenti tal-Ematologija.

L-ghan ta' din ir-ricerka huwa l-iżvilupp tas-servizzi farmacewtici fis-sala ematologa

fiċ-Ċentru tal-Onkologija Sir Anthony Mamo.

B'din ir-ricerka, l-ispizjar-ricerkatur ser janalizza l-użu sigur u effettiv tal-medicini

użati fil-kura tal-marda tieghek. Dan kollu ged isir b'kollaborazzjoni mat-tobba u

1-infermiera li qed jieħdu ħsiebek fis-sala tal-Ematologija.

Bhala parti minn din ir-ricerka, l-ispizjar-ricerkatur li se jwettaq dan l-istudju ser

jivverifika mieghek l-istorja farmačewtika tieghek, filwaqt li jaghtik pariri u

informazzjoni siewja dwar forom ta' kemoterapija u medićini ohrajn. Din

1-informazzjoni tinkludi wkoll raģunijiet għall-għoti ta' dan it-trattament, kif irid

jittiehed mill-pazjent, x'jistghu jkunu l-effetti negattivi u kollaterali ta' dan it-trattament

u kif wiehed ghandu jippreserva u juża dawn il-medićini.

L-identità tieghek ser tibqa' kunfidenzjali u kull tip ta' informazzjoni miġbura waqt din

ir-ricerka ser tibqa' anonima. Inti tista' tiddeciedi li twaqqaf il-partecipazzjoni tieghek

minn dan l-istudju meta trid.

Grazzi tal-ħin u l-koperazzjoni tiegħek,

Diane Saliba

Spiżjara

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Appendix 7Patient Consent Forms in English and Maltese

Consent Form

I am a Maltese citizen and am over eighteen (18) years of age.

I have been asked to participate in a research study entitled:

Implementation of a Pharmaceutical Care Model within Haematology

The purpose and details of the study have been explained to me by Diane Saliba and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator and his delegate either to make the appropriate observations/tests or both or take the necessary samples. I am aware of the inconveniences which this will cause.

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

I am under no obligation to participate in this study and am doing so voluntarily.

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

I understand that any complications and/or adverse effects which may arise during or as a consequence of the study will be recorded and any treatment which this may entail will be given within the Government Health Services.

In case of queries during the study I may contact Diane Saliba on 79306582 or via email on

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

diane.saliba.10@um.edu.mt.	
Signature of participant	<u> </u>
Name of participant	
ID of participant	
Signature of Chief Investigator	
Name of Chief Investigator	
ID of Chief Investigator	
Signature of Supervisor	
Date	

Proposta ghall- formola tal-kunsens

Jien/a cittadin/a Malti/ja u għalaqt tmintax (18)-il sena.

Talbuni biex niehu sehem fi studju rićerka bl-isem ta':

Implimentazzjoni ta' mudell tal- kura farmčewtika fil-qasam tal- ematoloģija

II-ghan u d-dettalji ta' I-istudju spejgathomli Diane Saliba li wkoll iččaratli xi mistoqsijiet li ghamilt.

Naghti l-kunsens tieghi lill-persuna responsabbli ghal-din ir-ricerka u l-assistenti taghha biex jaghmlu l-osservazjonijiet li hemm bžonn jew inkella jiehdu l-kampjuni u nifhem li dan jista' jkun ta' skomdu ghalija.

Jiena niftem li r-rizultati ta' dan l-istudju jistghu jintuzaw ghal skopijiet xjentifići u jista' jigi ppubblikat rapport bil-miktub: jekk isir hekk b'ebda mod ma nista' nkun identifikat/a, individwalment jew bhala parti minn grupp, minghajr il-kunsens tiehħi bil-miktub.

Jiena ma ghandi I-ebda dmir li niehu sehem f'dan 1-istudju u dan qed naghmlu minn rajja.

Jiena nista', meta rrid, ma nkomplix niehu sehem fl-istudju, u minghajr ma' naghti raguni.

Jiena nifhem li jekk ikun hemm xi kumplikazzjoniji jew effetti mhux mistennija waqt l-istudju, dawn jigu mniżżla bil-miktub u jekk ikun hemm bżonn xi kura, tigi mghotija fis-Servizz Nazjonali tas-Sahha.

Jiena mhux qed nithallas biex niehu sehem f'dan I-istudju.

Jekk ikolli xi diffikulta' waqt I-istudju, nista' nistaqsi ghal Diane Saliba fuq 79306582 jew fuq diane.saliba.10@um.edu.mt,

Firma tal-participant	W
Isem tal-participant	
Numru ta' I-identita	
Firma tal-persuna responsabbli ghal din ir-ricerka	
Isem tal-persuna responsabbli ghal din ir-ričerka	
Numru ta' I-identita	
Firma tas- superviżur	
Data	



Oncology Conference Malta - November 2017





DIANE SALIBA Pharmacist, Department of Pharmacy, MDH

Diane Saliba is a pharmacist working at the compounding section within the Department of Pharmacy at Mater Dei Hospital. She graduated from the University of Malta in October 2015 after completing the course of Master of Pharmacy. Ms. Saliba is currently following a Doctorate in Pharmacy course offered by the Department of Pharmacy at the University of Malta in collaboration with the University of Illinois in Chicago and is presently in her third and final year. Her dissertation within the haematology unit has enabled her to further expand her knowledge in this field.

Implementation of a Pharmaceutical care model within Haematology Diane Saliba, Dr. Louise Grech, Prof. Lilian Azzopardi

Intoduction: The complexity of haematological diseases together with the complications that may arise during treatment warrants the need of having a complete interdisciplinary team including a clinical pharmacist.

Aim: To develop a standardised pharmaceutical care model within the haematology ward at Sir Anthony Mamo Oncology Centre.

Method: During phase one, a gap finding tool was developed using international standards of clinical pharmacy practice care to establish the current practices within the ward. Phase two involved the implementation of the standards of care to develop an evidence-based clinical pharmacy service at the haematology ward. During ward rounds, the pharmacist reviewed treatment charts and identified pharmaceutical care issues. Suggestions to resolve drug therapy problems were put forward to the other healthcare professionals.

Results: A total of 191 drug related problems were identified over 4 months. These included monitoring needs (n=59), treatment discontinuation (n=32), need for additional drug (n=36), drug dosing adjustments (n=14), more appropriate route of administration (n=12), more appropriate drug (n=8), change in dosing schedule (n=17) and drug-drug-interactions (n=6). Other pharmaceutical services offered included medicines information (n=61), administration advice (n=9), dosage calculations (n=16) and patient education (n=8).

Conclusion: The development of a standardised clinical pharmacist service within a collaborative management model contributes to rationale and safe patient management

2018 ACCP Global Conference

2018 Global Conference Scholars Workshop Invitation Indiox





Dear Diane Saliba,

Congratulations, your abstract #45577 has been accepted for presentation during the 2018 ACCP Global Conference Scholars Workshop. This special, <u>by invitation only</u>, session held during the Global Conference on Clinical Pharmacy will provide you with the unique opportunity to present your written abstract titled "Implementation of a pharmaceutical care model within haematology" to ACCP Master Scholars.

One or more Master Scholars will then work directly with you to optimize your abstract for submission to the 2019 ACCP Virtual Poster Symposium or a future ACCP Meeting. The goal of the ACCP Scholars Workshop is to further develop your abstract submission to achieve both successful poster presentation and manuscript publication in the near future.

Requirements for participation:

- 1. Invitation to participate in the Global Conference Scholars Workshop
- Completion of the online Workshop Acceptance Form a link to this form will arrive in a second email from ACCP today.
- 3. Registration for the 2018 ACCP Global Conference www.accp.com/gc
- 4. Attendance at the ACCP Global Conference May 20-23, 2018 in Seattle, Washington USA
- Presentation of abstract's contents, background literature, and details of methods, analyses, and results during the Scholars Workshop.

Sincerely,

Michael S. Maddux, Pharm.D., FCCP Executive Director American College of Clinical Pharmacy 13000 W. 87th Street Parkway Lenexa, KS 66215-4530

Abstract for ACCP Conference 2018

Implementation of a Pharmaceutical Care Model within Haematology

Diane Saliba, Louise Grech, Lilian Azzopardi

Introduction:

The complexity of haematological diseases together with complications that may arise during treatment, warrant the need of having a complete interdisciplinary team including the presence of a ward-based clinical pharmacist.

Hypothesis:

To develop and implement a standardised pharmaceutical care model within a haematology ward

Study Design

A cross-sectional prospective study was undertaken within Sir Anthony Mamo Oncology Centre

Methods:

Current practices within the ward were observed to develop a baseline against international standards of pharmacy practice care. The standards were used to devise an evidence-based clinical pharmacy service at the ward. During ward rounds and whilst reviewing treatment charts and patient files, the pharmacist identified pharmaceutical care issues (PCIs). These were recorded in the pharmacist patient profile developed. Interventions to resolve these PCIs were discussed with the other healthcare professionals.

Results:

Ninety-three different patients were seen during 7 months of ward attendance. A total of 377 pharmaceutical care sessions were held, during which a total of 465 PCIs were identified. The DRPs were issues with drug selection (n=144) such as no indication for drug, monitoring needs (n=137), issues with dose selection (n=74) such as dose too low, the need for patient education (n=57), issues with treatment duration (n=24) such as duration of treatment too long, occurrence of side effects (n=13) and an issue related to the drug-use process (n=1). Eighty-seven percent of the interventions proposed for these PCIs were accepted by the other HCPs. The pharmacist also provided other pharmaceutical services (n=398) including; medicines information (n=180), administration advice (n=40), modifications on treatment charts (n=37), liaison with other pharmacy entities (n=37), dosage calculations (n=36), guiding doctors in filling the correct pharmacy-related forms (n=23), checking treatment against chemotherapy protocols (n=14), checking for drug interactions (n=13), provision of medication tables on discharge (n=7) and medicines reconciliation (n=3).

Conclusions:

This study demonstrated the benefits of an integrated interventional pharmaceutical care model at the haematology ward that resulted in improvement of individualisation of drug therapy and supporting patient care within the clinical ward.