Drug Information Access for Pharmacists' Bedside Decision Making

Submitted in partial fulfilment
of the requirements of
the Doctorate in Pharmacy degree

Timothy Scicluna

Department of Pharmacy
2019

L-Università ta' Malta

FACULTY/INSTITUTE/CENTRE/SCHOOL

DECLARATION OF AUTHENTICITY FOR DOCTORAL STUDENTS

Student's I.D. /Code _____

Student's Name & Surname

_____

Course

_____

Title of Dissertation/Thesis

_____

_____

(a) Authenticity of Thesis/Dissertation

I hereby declare that I am the legitimate author of this Thesis/Dissertation and that it is my original work.

No portion of this work has been submitted in support of an application for another degree or qualification of this or any other university or institution of higher education.

I hold the University of Malta harmless against any third party claims with regard to copyright violation, breach of confidentiality, defamation and any other third-party right infringement.

(b) Research Code of Practice and Ethics Review Procedure

I declare that I have abided by the University's Research Ethics Review Procedures.

□ As a Ph.D. student, as per Regulation 49 of the Doctor of Philosophy Regulations, I accept that my thesis be made publicly available on the University of Malta Institutional Repository.

□ As a Doctor of Sacred Theology student, as per Regulation 17 of the Doctor of Sacred Theology Regulations, I accept that my thesis be made publicly available on the University of Malta Institutional Repository.

□ As a Doctor of Music student, as per Regulation 24 of the Doctor of Music Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

□ As a Professional Doctorate student, as per Regulation 54 of the Professional Doctorate Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

_____ _____

Signature of Student Name of Student (in Caps)

_____

Date

Acknowledgments

Heartfelt thank you to Prof Lilian M. Azzopardi, my tutor and Dr. Louise Grech, my co-tutor for their invaluable help and guidance during this study.

I am also grateful to Prof. Anthony Serracino Inglott and all the staff and lecturers at the Department of Pharmacy at the University of Malta.

This study would not have been possible without the help of Prof Alan Lau, Dr. Jennifer Pham, Dr. Christina Haaf and all the pharmacists at the drug information section at the University of Illinois in Chicago, the pharmacists who participated in the focus group and questionnaires and all the staff at the Intensive Care Unit at Mater Dei Hospital, in particular Dr. Michael Buttigieg.

Finally, I would like to thank my family, especially my parents, and Maria for always supporting me throughout the study.

Table of Contents

Abstract

The provision of Drug Information (DI) is a routine component of the daily practice of a pharmacist and the presence of a pharmacist at the patient bedside has been associated with decreased drug cost and reduction in hospital stays. The aim of this study was to evaluate and assess the access of DI by pharmacists at the patient bedside. A focus group was set up during which users and providers of DI at Mater Dei Hospital (MDH), Malta discussed limitations for DI access at bedside. An 8-week prospective study at the Intensive Therapy Unit (ITU) at MDH was carried out to identify challenges to offer a DI bedside service. Challenges to DI bedside access as identified from the focus group were Wi-Fi access at ward level and lack of online and updated resources. During the period at ITU, 140 bedside queries were forwarded to the pharmacist. Most were inquired by medical officers (43%), medical consultants (32%) and nurses (16%). Medical officers and consultants queried about pharmacotherapy such as ADRs and drug interactions (28%) while queries from nurses included drug administration and dosing (1%). Fifty-nine percent (59%) of the queries were answered in less than 5 minutes. Queries which required an in-depth search about a specific topic (14%) were forwarded to respective specialties. Micromedex was used to answer 60% of the queries while UpToDate had an answer to 36% of the queries. The presence of a pharmacist at patient bedside improves the time taken to answer DI queries at ward level. DI requests could be tackled by the pharmacist at bedside within 5 to 10 minutes using Micromedex and UptoDate.

List of Tables

List of Figures

List of Abbreviations

ASHP: American Society of Hospital Pharmacists

DI: Drug Information

DIC: Drug Information Centre

EMA: European Medicines Agency

FDA: Food and Drug Administration

FFS: Fee for Service

ISMP: Institute for Safe Medication Practices

MDH: Mater Dei Hospital

NW: Northwestern Hospital

P&T: Pharmacy and Therapeutics committee

UIC: University of Illinois in Chicago

ITU: Intensive Therapy Unit

WHO: World Health Organisation

List of Terms

Clinical Pharmacist: a ward-based pharmacist as part of the multi-disciplinary team. This pharmacist is involved in providing drug information at patient bedside and in patient interventions to prevent any drug related problems.

Drug Information: the act of providing information about drugs and therapy following a request from other healthcare providing organisations, committees, patients and community. It may also be defined as the knowledge of facts gathered through reading or experience concerning any medical substance used in the diagnosis, prevention and treatment of disease.

Drug Information Centre: an entity involved solely in the provision of drug information. Pharmacists working in this entity should have unlimited access to all possible resources, both online and as books, related to drug information.

Fee for Service: a payment model in which healthcare professionals are paid for the services performed. This is the current predominant payment method in the US. Users of the services provided by the DI centre make a pre-agreed contract with this same DIC which includes a yearly fee to be paid by the user in exchange for unlimited use of the service provided by the DIC. The yearly fee is set depending on the extent of the users – an extended pharmaceutical company or a large pharmacy chain have a higher fee than smaller ones.

New Drug Executive: a document compiled by the DIC at UIC and other hospitals in the US consisting of information about a new drug which needs to be included in the hospital formulary. This document includes data including Introduction, FDA-approved uses, Off-Label Use, Dosing & Product Availability, Clinical Efficacy, Safety, Guidelines & alternative agents, Conclusion and Formulary Recommendations. The information given in the New Drug Executive is brought from DI resources.

Pharmacy and Therapeutics Committee: a hospital-based committee or health plan which decides which drugs are to be introduced on the hospital formulary.

Shift Pharmacist: an after-hours pharmacist. In Malta, a shift pharmacist is the pharmacist present after pharmacy closure times and after normal shift hours. There are four groups of shift pharmacists at Mater Dei Hospital, each working on a day-night-rest-off basis. The day shift pharmacist works between 08:00 and 20:00 while a night shift pharmacist works between 20:00 and 08:00. This means that when the normal hours of pharmacy services at Mater Dei are over, these services are still covered by a pharmacist.

CHAPTER 1

INTRODUCTION

1.1 Drug Information Services

Drug Information (DI) involves the efficient retrieval, evaluation and communication of unbiased and factual information when a request from healthcare professionals or healthcare providing services is forwarded to a pharmacist in response to patient-related queries (Sridevi et al, 2017). DI includes the provision of subjective and objective information and also information which can be provided through scientific observations or practical experiences (Chhetri et al, 2008).

The World Health Organisation (WHO) defines the role of DI services *'as providing interventions to promote the rational use of medicines. The development of clinical guidelines, having hospital-based pharmacy and therapeutics (P&T) committee, promoting independent information and avoiding perverse financial incentives are among the interventions included'*. From 87 Drug Information Centres (DICs) around the US, 79 are combined to the Pharmacy and Therapeutics (P&T) Committee (Rosenberg et al, 1986). The basis of DICs is to provide independent and unbiased DI. The WHO refers to the DICs as *'tools to disseminate unbiased drug information and promoting the rational use of drugs'* [1]

In 1962, the first drug information service was started in the United States (US) at the University of Kentucky Medical Centre. This service was intended to be utilised as a source of accurate, unbiased, selected, comprehensive DI catering to the needs of the healthcare team (Sridevi et al, 2017). With the success of the University of Kentucky, additional DICs were set up during the 1960s. A survey by Rosenberg et al (1986) shows that pharmacist-operated DICs in the United States reached a maximum in 1986. Literature reports a continued growth in the number of formalised DICs until

[1] World Health Organisation, WHO. WHO policy and perspectives on medicines: Promoting rational use of medicines: core components. 2002 [cited 2018 October 8] http://apps.who.int/medicinesdocs/en/d/Jh3011e/1.html

the early 1990s (Beaird et al, 1992). Since the first DICs originated in the United States in the 1960s, such centres have evolved internationally. Most DICs are regional and provides DI services to a particular region in a country or local providing DI to a specific hospital. DICs may also be integrated with clinical services.[2]

In Australia, the first DICs was established in 1968 at the Royal Melbourne hospital while in the United Kingdom this was started in 1969 at the London hospital (Sridevi et al, 2017). In both countries, the DI services were initially combined and pharmacists carrying out ward rounds also had a role in the DIC. The Australian scenario was then changed in the late 1970s and provision of DI at patient bedside was separate from that provided at the DIC (Rajanandh et al, 2011).

In India, the first DIC was started in early 1970s. In this country, the concept of rational drug use is still undeveloped. Irrational use of drugs is common and this has led to antibiotics resistance, adverse drug reactions, drug interactions and other drug related problems (Rajanandh et al, 2011). Developing countries have lack of access to drug information due to limited availability of current literature, poor documentation and less dissemination of the information available (Beena et al, 2015; Sreekanth, 2015).

The number of operational DICs has been on the decline. The provision of drug information at patient bedside has increased and the pharmacist has become a major part of the multidisciplinary team reviewing patients in wards (Rosenberg et al, 2004).

[2] International Pharmaceutical Federation (FIP). Requirements for Drug Information Centres; 2015 http://www.cff.org.br/userfiles/file/cebrim/RequirementsforDrugInformationCentres%202005%20final.pdf

DICs answer drug related problems arising from health care professionals. Questions may be patient-related or for academic purposes. Health professionals forward DI requests to DICs due to lack of time or lack of skills when searching literature (Hedegaard et al, 2009).

A pharmacist at the bedside is also a source of DI. The presence of a pharmacist during ward rounds allows the opportunity for the multidisciplinary team to query concerns regarding specific patients. The pharmacist applies existing documentation and information found on accessible resources to the specific clinical case. Competence on disease states and therapy in addition to expertise in critical evaluation of the literature and translation of findings is required (Wojas et al., 2009).

DI encompasses information targeted at health care professionals as well as patients, with the primary aim of educating about medicines and carrying out a patient intervention in cases where this is requested at patient bedside during ward rounds. Medicines information for healthcare professionals aim to support them in their patient-care roles, while medicines information targeted at patients and consumers of medicines aims to ensure quality, safe and effective use of medicinal products.

Globally, a range of stakeholders are involved in the development and dissemination of DI to healthcare professionals. These groups range from pharmaceutical manufacturers, to health organisations, individual health care practitioners and online resources.

1.2 Goals and outcomes of effective access to drug information

Effective provision of DI by pharmacists to healthcare professionals is defined as information which improves the decision making of prescribers at patient bedside and eventually patients' treatment and health outcomes. Table 1.1 lists the goals and outcomes of effective access to DI.

Table 1.1 Outcomes of effective access to Drug Information

Outcomes	Result of outcome	Role of Pharmacist to achieve outcome
Rational use of Medicines	-Effective use of medicines -Increased adherence -Healthcare professionals (HCPs) take informed decisions	The presence of a clinical pharmacist ensures that the right medicine in the right dose is given to the right patient. Access to DI at patient bedside allows pharmacists and the multi-disciplinary team to discuss a patient and come up with a suitable intervention in the shortest time possible.
Medication Safety and Pharmacovigilance	-Safe use of medicines -Adverse drug events (ADRs) and medication errors prevented	A pharmacist at bedside drastically decreases drug-related problems. DI access allows for the recognition of a drug interaction or ADR. A pharmacist also ensures that the existence of an ADR is reported to the respective regulatory body.
Rational prescribing and dispensing	-DI integrated to relevant patient history -Communication of DI to patients and HCPs	Once an answer to a query is given to the HCP, the DI used to answer the patient-related query may be included in the patient medical records by the pharmacist to ensure transparency and clarity.

Table 1.1 shows the three main positive outcomes when DI access is effective. The third column shows the pharmacist intervention and how the presence of a pharmacist at bedside improves on these outcomes

1.2.1 Rational use of medicines

WHO defines the rational use of medicines as '*patients receiving medicines appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and the community'*.[3] The International Pharmaceutical Federation (FIP) states that *'the responsible use of medicines means that it is only used when necessary and that the choice of medicine is appropriate based on what is proven by clinical evidence to be most effective and cause least harm'*.[4] Drug choice should also consider patient preference and makes the best use of limited health care resources. Information that is better suited to the needs of the patient has the potential to improve patient medication adherence. For example, Australia's National Medicine Policy describes that information development, implementation and provision is paramount to facilitating quality use of medicine. Providing unbiased and effective DI to HCPs is a priority for pharmacists. The key challenge is access to DI in ways that meets the needs of patients and abilities of HCPs. A clinical pharmacist at patient bedside provides DI to the HCPs and based on this, a patient-related decision is made. The decision made ensures that the right medicine in the right dose is given to the right patient in the shortest time possible. A correct decision leads to less medication errors and rational use of medicines.

[3] World Health Organisation. The Rational Use of Drugs: Report of the Conference of Experts Nairobi. Geneva: World Health Organisation; 1987 [cited 2019 January 24] Available: http://apps.who.int/medicinedocs/documents/s17054e/s17054e.pdf

[4] International Pharmaceutical Federation (FIP). Growing the responsible use of medicines – FIP Annual Report; 2013-2014. Available from: https://fip.org/files/fip/publications/AnnualReport2013-14_for_print.pdf

1.2.2 Medication Safety and Pharmacovigilance

DI has a central role in preventing adverse drug effects. Communicating medication safety information is complex as it involves stakeholders with various degrees of risk perceptions, needs, knowledge and abilities (Bahri, 2010). Pharmacists have a fundamental role in the correction of identified medication errors and in the improvement of safety systems in clinical practice (Schnipper et al, 2012). Expanding the role of pharmacists such as including the presence of a pharmacist in inpatient services and increasing patient education through a pharmacist will improve safety in hospital settings (Vaida et al, 2014).

Pharmacovigilance involves monitoring the medication safety and taking appropriate action to minimise harm such as communicating drug safety information. Access to reliable, unbiased and updated DI resources especially related to drug safety, will allow pharmacists to provide reliable information to healthcare professionals and patients. When an Adverse Drug Reaction (ADR) is observed at patient bedside, the pharmacist should report this to the respective entity.

In the USA, resources are available online or via mobile technology (Gershman et al, 2014). These include the FDA Paediatric Labelling Information Database, a Paediatric Safety Reporting page, the Institute for Safe Medication Practices (ISMP) Risk Safety Manual and the ISMP Consumer Safety website.[5]

[5] Institute for Safe Medication Practices ISMP Drug Safety guidelines [cited 2019 January 25] Available: https://www.ismp.org/resources?field_resource_type_target_id%5B0%5D=33&field_resource_type_target_id%5B1%5D=33&field_resource_type_target_id%5B2%5D=33#resources--resources_list

In the European Union, the European Medicines Agency (EMA) guideline on good pharmacovigilance practices[6] emphasises the importance of communicating safety information to patients and healthcare professionals in order to promote the rational, safe and effective use of medicines prevent harm from adverse reactions and contribute to the protection of patients and public health.

1.2.3 Rational Prescribing and Dispensing

Rational Prescribing is a multi-step, iterative approach to prescribing that requires effective patient-provider communication. As the identification and review of available treatment options alongside treatment choice are core steps in the process of rational prescribing, DI becomes an important tool to achieve this goal (Maxwell, 2009).

DI can be used to facilitate, encourage and support rational prescribing practices across different health care contexts internationally. Educational intervention strategies are an example of a targeted approach that can be employed to optimize rational prescribing of medicines. It involves utilisation of medicine information, which would encompass DI. The role of DI, as part of initial education undertaken in the completion of qualifications and further specialization to qualify is apparent. DI is also important in continuing professional development to ensure that rational prescribing and dispensing practices reflect and consider best practice guidelines that are currently implemented (Wojas, 2009).

[6] EMA, European Medicines Agency guideline on good pharmacovigilance practices; 2017 [cited 2018 November 20] Available: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf

Pharmacists require a range of high quality, accurate, readily accessible and easy to use DI which is integrated into the relevant data systems in use to inform rational prescribing, particularly in the practice of evidence-based medicine. Integration of the use and provision of DI by pharmacists at patient bedside can directly improve and help ensure quality use of medicines.

DI is utilised by health care professionals while carrying out ward rounds to determine the safety and appropriateness of the prescribed medicines for the patient. Pharmacists provide DI to communicate adequate, safe and appropriate use of medicine.

1.3 Pharmacists and provision of DI

The 2008 FIP Statement of Policy on Medicines Information underlines the pivotal role of pharmacists in the provision of reliable and valid written and spoken DI.[7] National initiatives can encourage patients to engage with pharmacists and ask questions about their treatment. Pharmacists should also ensure that they collaborate with HCPs to make sure that the treatment prescribed is appropriate and consistent. Pharmacists help to provide objective, understandable, accurate and appropriate. Pharmacists should ensure that resources used are reliable by using tools to assess the sources. An example of a tool is the DARTS-checklist (Date, Author, References, Type and Sponsor) (Närhi et al, 2008). Pharmacists should also consider developing and providing drug information services making use of new information technology such as email, chat and mobile telephone applications to support provision of DI.

[7] International Pharmaceutical Federation. Statement of Policy. Medicines Information. The Hague: FIP; 2008. [cited 29 November 2018] Available at www.fip.org/www/uploads/database_file.php?id=290&table_id=

Clinical pharmacists are referred to as medicines experts since they are well trained in this section. Provision of drugs and therapeutics information to clinicians is one of the responsibilities of clinical pharmacists. Having access to updated and informative resources is an important asset for pharmacists due to increased patient load with co-morbid conditions and availability of more drugs on the market.

A variety of DI activities may be performed by pharmacists, depending on the particular practice setting and need. Table 1.2 gives a summary of such DI activities (Wang et al, 2006; Bernknopf et al, 2009).

Table 1.2: DI related activities carried out by pharmacists

Providing DI to patients and HCPs
Creating and maintaining print and online educational resources for patients and HCPs on optimal medication use, general health and selected clinical questions among other topics
Education of HCPs on safe and effective medication-use strategies and processes including development of resources
Leading or participating in continued education services for HCPs
Educating pharmacy students and precepting residents
Participating in quality improvement research projects and drug cost analyses
Contributing to the biomedical literature and providing peer review for other contributors

Adopted from American Society of Health-System Pharmacists. ASHP Statement on the Pharmacist's Role in Clinical Informatics. Am J Health-Syst Pharm. 2016; 73: 410-413

Table 1.2 summarises the DI activities carried out by any pharmacist. These are done by all pharmacists who are not necessarily involved directly with any DI service.

DI specialists who are enrolled in a job related specifically to DI carry out activities that may be carried out by other pharmacists or health care professionals. As a result of the advanced training and experience, pharmacists specialising in DI may be able to more efficiently retrieve, evaluate and disseminate information in order to develop evidence-based recommendations and assist in patient care decisions. Many DI specialists are also involved in medication-safety activities. Specific activities of the DI specialist may include those listed in table 1.3.

Table 1.3: Activities of DI specialists

Providing information when there is lack of time for other HCPs to properly research the DI question, when there is a knowledge gap, or when the question requires more thorough research
Establishing and maintaining a formulary based on scientific evidence of efficacy and safety and pharmacoeconomics
Educating health care professionals on safe and effective medication-use policies and processes, including development of resources to communicate this information.
Developing and participating in efforts to prevent medication errors and adverse drug events
Monitoring and assessing the clinical significance of medication safety alerts communicated by the Medicines Agencies of the respective country such as EMA and FDA, drug manufacturers and other sources
Performing health outcome and comparative effectiveness analyses

Adopted from American Society of Health-System Pharmacists. ASHP Statement on the Pharmacist's Role in Clinical Informatics. Am J Health-Syst Pharm. 2016; 73: 410-413

Table 1.3 gives the activities of pharmacists having a DI related job and employed with any type DI service, either at ward level or at a DIC.

1.3.1 Role of Pharmacists at DICs

The pharmacy informatics setting is an area of practice for DI specialists. Pharmacists providing DI focus on using technology to improve patient care by combining clinical and technologic skills to create useful applications in healthcare (Bernknopf, 2009). In the US, pharmacists at patient bedside may have a hand in various applications including computerized physician order entry (CPOE), health records and all resources needed to answer any DI queries forwarded by the healthcare professionals.

Pharmacists in DI services have the roles to communicate information about services available, respond to queries according to degree of urgency, maintain a documented system for recording details of the query and enquirer, maintain documents for recording responses to queries, record the query and response reference, store drug information service documents, ensure service is evaluated at regular intervals and perform quality assurance of the information provided for improved quality of service.

Pharmacists involved in clinical informatics must collaborate with other HCPs to support safe, effective, timely and best use of medication. Pharmacists contribute to the transformation of healthcare by analysing, designing, implementing, maintaining and evaluating information and communication systems that improve medication-related outcomes. The role of pharmacists revolves around their knowledge of pharmacy practice, safe medication use, clinical decision-making and the improvement of medication therapy outcomes (Fox et al, 2010).

1.3.2 Role of Pharmacists at patient bedside

Healthcare teams in the US include the presence of a clinical pharmacist who has a role in patient care at bedside. Pharmacists may be part of a multi-professional team for acute or ambulatory care populations but others have a private practice upon referral from physicians.

The main focus of pharmacists at bedside is medication management and the interventions carried out help improve the optimal use of medications and avoidance of adverse effects. The broad use of anti-hypertensive medications may lead to adverse outcomes if doses are not properly titrated. The benefit of clinical pharmacist education, monitoring and intervention was demonstrated in a prospective, randomized study of 800 heart failure or hypertension patients. The patients with a clinical pharmacist intervention had a 34% lower risk of any adverse drug effects or medication error including a significantly lower risk of ADRs, preventable ADR, potential ADR and medication errors compared to patients without a clinical pharmacist. The highest number of medications and cardiovascular events was present in patients with a complicated cardiovascular history. The role of the pharmacist was to interact, educate and communicate with the multidisciplinary team to improve medication adherence and reduce healthcare utilisation and direct costs of care. Additional benefits of clinical pharmacist monitoring and interventions on treatment endpoints such as blood pressure, lipid profile, weight and glycaemic control have been described in reviews (Jacobi et al, 2016). The benefits of a pharmacist at patient bedside has been endorsed by the American College of Cardiology which has recommended a strategy team-based care which includes a clinical pharmacist.

Clinical pharmacists in acute care teams such as the Intensive Therapy Unit have been shown to reduce preventable ADRs by 78% (Kucukarslan et al, 2013). A clinical pharmacist present at ward level with a critical care team effectively identified and prevented more ADRs leading to a decrease in potential costs of over €210,000 in 5 months (Kopp et al, 2017). The impact of DI service provided by clinical pharmacists in hospital inpatient settings was described in a review by 36 studies. This suggested that the inclusion of a clinical pharmacist to the acute care team resulted in improved care with no evidence of harm (Kaboli et al, 2006). Multidisciplinary team interaction during ward rounds, medication reconciliation from outpatients to inpatients, patient discharge education and follow-up all resulted in improved outcomes.

Clinical pharmacists have increased in number internationally and patients have benefited. A survey in 2015 described critical care clinical pharmacist roles in 24 countries outside North America. Seventy four percent of pharmacists indicated they attended medical rounds and almost all (90%) prospectively reviewed drug therapy and intervened to prevent drug interactions, ADRs, optimise doses and frequency or duration of treatment (Jacobi et al, 2016).

The presence of pharmacists on the wards has significantly reduced prescribing errors and related patient harm in Netherlands when compared to pharmacists carrying out standard pharmacy services (Klopotowska, 2010). Paediatric pharmacists in China demonstrated a significant reduction in ADRs, length of stay and drug costs compared with a similar control group without a rounding pharmacist (Zhang et al, 2012).

The primary roles and responsibilities encompass four defined categories (ASHP Pharmacy Informatics and Technology, 2016) and are given in table 1.4.

Table 1.4: Roles of Pharmacists practising DI

Data, information and knowledge management	Providing DI at bedside maintains data, information and knowledge assets.	Pharmacists can ensure that information provided is reliable and evidence-based. This minimises risks and warrants medication related safety.
Delivery of Information	DI is complex, vast and knowledge-dependent. It is challenging to absorb all literature and assimilate the growing volume of knowledge needed for effective patient care.	The clinical expertise of pharmacists can help deliver information during ward rounds proactively, interactively, asynchronously or passively. Pharmacists have the role of knowledge discovery, application and delivery.
Applied Clinical Informatics	DI has a significant role in giving research principles and best practices to the bedside.	Pharmacists work with healthcare teams to improve effectiveness, efficiency and safety of systems that support medication management.
Leading and Managing Change	DI has to support safe and effective medication use.	Knowledge and skills of pharmacists in managing change, working effectively in multidisciplinary teams, communicating and articulating health and DI allow them to have a significant role in attaining key leadership roles in provision of DI.

Adopted from American Society of Health-System Pharmacists. ASHP Statement on the Pharmacist's Role in Clinical Informatics. Am J Health-Syst Pharm. 2016; 73: 410-413

Table 1.4 gives the role of DI at patient bedside and how clinical pharmacists at ward level are responsible in giving the maximum assets of DI.

A pharmacist must exercise excellent oral and written communication to be an effective provider of DI. Pharmacists involved in DI must also be able to predict and assess the DI needs of patients and HCPs by carrying out a complete background check on the patient through the medical records. Once the request is forwarded, the pharmacist needs to use a systematic approach to tackle DI needs by making an effective search to retrieve literature which should be critically evaluated. Critical evaluation involves assessment of the study design, statistics bias, limitations and applicability. The response is the appropriately synthesised, communicated and documented depending on the patient care situation (Malone et al, 2012).

1.4 Systematic Approach for Responding to Drug Information Requests

Taking the features of an effective DI provider into consideration, guidelines on the pharmacists' role in providing drug information have been published by ASHP (Ghaibi et al, 2015). An approach to answering DI queries was first introduced in 1975 by Watanabe et al. but was eventually modified to ensure that all relevant information is considered before giving a response. Relevant patient data should be gathered and the context of a question must be understood before answering a DI request. A full systematic approach may not be practical for all requests, especially for urgent clinical needs in the direct patient care setting at bedside but the basis of the approach is still undertaken. The systematic approach is outlined in figure 1.1

1.	**Identifying the Requestor**
Health literacy and profession of the requestor needs to be established	
2.	**Defining the question and information needed**
Asking questions which may give important details of what is being asked. This helps the search processes and improves time of response	
3.	**Obtaining background information**
Examining medical record for patient data to individualise the response as much as possible	
4.	**Categorising the question**
Classifying requests as being patient-specific or academic and by type of question such as product availability, adverse drug event, compatibility, dosage/administration, drug interaction.	
5.	**Systematic Search**
Searching appropriate tertiary, secondary and primary resources including electronic resources	
6.	**Analysing the information**
Evaluating, interpreting and combining information from resources used	
7.	**Disseminating the information**
Providing a response, which is either written and oral, as needed by the requestor that applies the information to the particular situation	
8.	**Documentation**
Documenting the request, information resources used, the information found in each source, time spent and the response itself	
9.	**Follow-Up**
Assessing the utility of the information provided and whether the information resulted in changes in medication-use practice	

Figure 1.1: Systematic Approach for Responding to Drug Information Requests

Adopted from American Society of Health-System Pharmacists. ASHP Statement Pharmacist's Role in Clinical Informatics. Am J Health-Syst Pharm. 2016; 73: 410-413

1.5 Drug Information Access

Clinically relevant, updated, user-specific and objective information which is easily accessible is required to make appropriate decisions for medicine prescribing, dispensing and use. A healthcare system can provide access to the highest-quality medicines but if those medicines are not properly used, they may have negligible or harmful effects. Access to reliable DI does not guarantee appropriate decisions and use but it is a basic requirement for decision making.

DI is available as printed and electronic forms with the need for DI varying among different types of health care providers and patients. For example, physicians and pharmacists need access to the full range of information about generic and branded, indications and contraindications for use, medicines of choice and therapeutic alternatives, dosing, precautions for use, drug interactions, side effects, adverse effects, clinical features and treatment of overdose, dosage forms and strengths and cost of treatment (Management Sciences for Health, 2012).

1.5.1 Drug Information Resources

Appropriate, updated and credible resources should be used by pharmacists when responding to a DI query. Medical knowledge has grown considerably and access to DI has changed over the last few decades. Traditional print resources are being replaced by electronic databases, online resources and mobile applications (Fass et al, 2012). Convenient and timely access to DI has improved with the internet and mobile technology. Pharmacists should critically evaluate all resources prior to use to ensure accuracy, unbiased and up-to-date.

Pharmacists should be familiar with the features of each resource to make searching more efficient so that more time can be used to analyse, apply and communicate the information needed. Factors which should be considered when purchasing DI resources including electronic subscriptions, for the pharmacy practice setting include features of resource including the frequency of updates, affiliations of authors, year of publication, method of delivery and cost, practice setting such as the type of facility and needs of health care professionals with that same environment and accessibility of resource and its location of print resources and number of users allowed by subscription (Wojas et al, 2009).

1.5.2 Types of Resources available

A DI service should aim to provide a direct service to patient related drug information queries. Clinical pharmacists should be available at ward level to provide this drug information service. Clinical training and experience are essential for effective pharmacist communication with health care professionals. Pharmacists should have other important attributes including computer skills, literature analysis, editing and library management (Ghaibi, 2016).

An efficient drug information service and centre should maintain a library of commonly used resources. Additional books and publications should be accessible in hardcopy or electronically from external sources. When providing information, data can be extracted from textbooks, databases, data sheets, reports and scientific journals. Previous inquiries are usually recorded and data from these can also be used. An adequate literature search requires an understanding of available sources and their limitations (Adibe, 2010). Pharmacists should work closely with others within the organisation to ensure that current resources including peer-reviewed original studies which are types of primary resources, indexing or abstracting services such as MEDLINE which are

secondary resources and databases, textbooks and guidelines which are types of tertiary resources. These resources are available to assist in answering a variety of DI requests.

Lag time between writing and time of publication, limitations of space that may prevent discussing a topic in-depth, the potential for author biases and the fact that the information may be incomplete, misleading or inaccurate are all limitations to using tertiary literature.

1.5.3 Electronic Resources

Availability and popularity of mobile devices has increased greatly. Most DI resources are available as a mobile app or as an online version. Apart from being more easily accessible by pharmacists and DI users, online versions are better updated. Clinical pharmacists may encounter various methods of access including full websites, mobile-compatible website and mobile applications. Newer technologies allow browsing of uniform resource locators from tablet devices and smartphones. Mobile-compatible websites are redesigned for handheld devices to enable content delivery to the smaller screen. Mobile applications are downloaded to the handheld device. Live connection is mostly not necessary with the exception of downloading updates and uploading gathered data.

1.6 Economic Impact of DI services

The benefits of drug information services in a sample of more than 1,000 hospitals have been shown in a study by Bond et al (2006). DI services are associated with a decrease in medication cost, total cost of care, medication errors and patient mortality rates. One study by Lyrvall et al retrospectively examined medical records by comparing two similar cases of patients who were taking neuroleptic drugs and had amenorrhea and elevated prolactin levels. A psychiatrist wanted

to order a CT scan for one patient, but before consulted the pharmacist at bedside. The pharmacist recognised the elevated prolactin levels as a documented adverse drug reaction to the neuroleptic medication and the scan was eventually cancelled saving $2500 in direct costs. In the second patient, for whom the pharmacist was not consulted, unnecessary costs for diagnostic investigations and drug treatment totalled $42,890 (Lyrvall et al, 1993). In the hospital setting, drug information services are associated with reduced costs of $1,960 per occupied bed per year or $430,580 to $1.7 million per hospital per year (Kinky et al, 2009).

DI services are currently trying to optimise resources with limited finances available. Like any other speciality areas of pharmacy practice, a DI service must validate its existence to remain a viable and worthy component of the healthcare system. Few cost analyses have been completed thus far in the speciality of drug information (Kinky et al, 2009). Strand et al addressed the obstacles related to drug therapy, which is helpful in addressing costs of services provided (Strand et al, 1990). Potential negative outcomes in the drug use process that could be considered as potential pharmacists' interventions were categorised (Kinky et al, 2009). These categories and their cost implication are given in table 1.5.

Table 1.5: Severity rating model and corresponding hospital costs

Description	Cost ($)
No medication related problems	0
Change in therapy	40
Physician visit	65
Additional tests	95
Non-invasive procedure	184
Additional treatment	230
Additional treatment + Non-invasive procedure	411
Increased length of stay	2590
Increased length of stay + Invasive procedure	2500
Transfer to ICU	2640
Long term admission	4571
Death	10000

Adopted from Kinky DE et al. Economic Impact of a Drug Information Service

Table 1.5 gives a description of all the possible severity models with the related costs which the hospital goes into when the described action occurs

A retrospective medical record analysis was carried out to determine potential savings of a DI service. The management and resultant direct and indirect costs of two patients receiving neuroleptic agents were compared based on timing of DI service use. The study examined the need for additional tests and consultations resulting from a high prolactin concentration in one patient whose healthcare professionals did not turn to a DI service, compared with a patient whose physician called a DI service before embarking on further evaluation of the patient. The DI service identified the adverse event early thus saving healthcare resources (Kinky et al, 2009; Lyrvall et al, 2013).

Patient-specific questions received by clinical pharmacists at bedside and by DI services were reviewed and evaluated in Spain (Kinky et al, 2009). A panel determined whether a drug-related problem may have occurred if the pharmacists DI service was not consulted. Seventy-seven of the 570 DI requests received in the six-week study had quantifiable potential cost savings to the institution. Ten percent of the requests avoided additional tests, 5% avoided procedures, 25% avoided additional treatment, 10% prevented the combined use of additional treatment and procedures, 20% prevented change in therapy while the remaining 30% prevented long-term admission and increased length of stay by recognising a drug interaction or an adverse drug effect (Bond et al, 1999). The pharmacist prevented these drug-related problems after the multidisciplinary team referred the queries at bedside to a DI service. Potential cost savings were estimated to be $195,000. Projected to one year, cost savings add up to $1.7 million. Based on the estimated annual costs related to maintaining a DI service of $145,950, the resultant range of benefit/cost ratio is 13:1 (Kinky et al, 2009).

1.7 Aim and Objectives of the Study

The aim of the study was to propose improvements to the current drug information service provided at Mater Dei Hospital (MDH) at patient bedside. The objectives were to compare and contrast drug information platforms used locally and the US, to review and assess the drug information centre at MDH and to evaluate the nature and extent of DI requests from a clinical inpatient hospital setting both from patient bedside and shift perspective.

CHAPTER 2

METHODOLOGY

The methodology for the research study was divided into three main phases:

i. Analysis of existing DI models internationally

ii. Assessment of DI services at Mater Dei Hospital

iii. Evaluation of DI service and access at patient bedside

2.1 Analysis of existing DI models internationally

The analysis of different drug information models was undertaken via two methods namely through literature review and through an observation study at DICs in Chicago, USA. The literature review was carried out to identify DI models used internationally. Standards and guidelines pertaining to DI services which are used in hospitals namely in the United States and Europe were reviewed. The models and standards identified were analysed comparatively in order to determine which factors are ideal for the eventual implementation of a bedside DI service at Mater Dei Hospital.

2.1.1 The Setting in Chicago

During May 2018, a 3-week observation study was carried out at the University of Illinois Hospital (UIC) and Northwestern (NW) Memorial Hospital, in Chicago, USA where DI pharmacists working in the two institutions were shadowed.

The UIC Hospital is a 1,900-bed hospital with 820 beds catering for emergency and acute patients. The NW Memorial Hospital has a total of 894 beds. Both hospitals offer centralised DI services and DI services at patient bedside. Each service is a separate and independent entity. DI pharmacists receive queries from other hospitals, retail pharmacy chains and healthcare professionals within Chicago or within the state of Illinois. These services are given as a Fee for Service (FFS) and the

individuals placing a query are in a contract with the UIC and can put forward any type of queries. Queries from patients are not taken by this same DI centre but 24/7 units specifically dedicated to patients are available in Chicago and the US. Patients can contact these units via phone or electronically.

The centralised DI service offered by the DIC responds to queries from third parties such as pharmaceutical companies, retail pharmacies, dentists, physicians or patients. This service is not offered to the wards of the same hospital since such wards use the service of the clinical pharmacists doing ward rounds. The NW Memorial Hospital DIC also offers a DI service to third parties but since the respective hospital is on a smaller scale, the DIC also provides answers to DI requests forwarded from wards when the respective clinical pharmacist at bedside is not able to respond to the query. The tendency for this to happen is, however, less than 5 times a week. During the 3-week observation study, the DIC and the clinical services offered at ward level in paediatrics, oncology and neurosurgery at UIC were visited. One day from the 3-week observation study was spent at NW Memorial Hospital, during which an overview of the DI process, both at the DIC and at ward level, was given.

2.1.2 Activities carried out at the Drug Information Centre during observation study

Different hospitals in the US have different drug formularies which includes different drugs. The drugs included in the formulary are then offered for patient treatment by the hospital. Whenever the Food and Drug Administration (FDA) introduces and accepts a new drug, hospitals need to eventually determine whether it should be included in the hospital formulary. In-depth research from DI resources is carried out by the DIC and included in a document referred to as the 'New Drug Executive'. Both the DI centre at UIC and NW Memorial Hospital are responsible for the

compilation of a new drug executive. The new drug executive includes all the necessary information regarding the new drug such as 'Dosing, Administration and Availability', 'Use in Special Populations', 'Clinical Efficacy', 'Contraindications', 'Warnings and Precautions', 'Adverse Effects' and 'Drug Interactions'. During the observation study at UIC, the compilation of a new drug executive for Tremfya® was carried out (Appendix 1). Information resources available at the UIC DIC were considered when compiling this document. The medication formulary data is then reviewed by the committee and recommendations are offered to the medical staff before inclusion in the formulary.

The DICs at UIC and NW Memorial Hospital are also combined to the P&T committee. The P&T committee formulates policies regarding evaluation, selection, diagnostic and therapeutic use, and monitoring of medications and medication-associated products and devices. The P&T committee establishes and assists in programs and procedures that ensure safe and effective medication therapy such as clinical care plans, treatment guidelines, critical pathways and disease management protocols. The P&T committee meets once every week at UIC and during the 3-week observation study, the pharmacist leading the P&T committee was shadowed and two meetings were followed. During the P&T committee, the participants, who are involved in the medicine scenario, but not necessarily pharmacists, discuss any issues which arise with patients. During the committee, a conference call can also be carried out to involve health care professionals outside of Chicago but within the Illinois state.

2.1.3 Activities carried out at ward level during the observational study

The University Of Illinois Hospital has 35 different wards which are spread throughout the University of Illinois Medical district. All wards at UIC have one or two pharmacists as part of the team. Three of these wards were visited for one day every week. Clinical services visited at UIC were paediatrics, oncology and neurosurgery.

During these ward rounds, the clinical pharmacists were shadowed while carrying out clinical roles at patient bedside. The multidisciplinary team consists of the ward consultant, nurse and pharmacist who are always responsible for the same patients and then a specialist consultant from other wards (eg. respiratory, gastroenterology) and other members such as anaesthesiologist depending on the need of the patient. The healthcare team carries out ward rounds during which the pharmacist reviews the medical history and treatment chart and depending on the state of the patient, makes the corresponding changes. Any member of the team can forward all the queries encountered at patient bedside to the pharmacist. A mobile bedside computer which has access to all the online resources used at the DIC, is used by the pharmacist to give an answer to the query.

2.2 Assessment of DI services at Mater Dei Hospital

Mater Dei Hospital (MDH) in Malta offers both a centralised DI service from a DIC and a DI service at patient bedside, with both services being combined unlike those at UIC. This means that clinical pharmacists are available at ward level to respond to any DI query presented at patient bedside but whenever resources at bedside are not enough to answer such queries at bedside, the queries are forwarded to the DIC.

This second part of the study consisted of assessment of DI services at MDH and how DI is accessed both at the DIC and at patient bedside. This step was carried out by setting up a focus group consisting of users and providers of DI. The focus group participants were recruited via email (Appendix 2).

2.2.1 Focus Group

A focus group consisting of users and providers of DI at MDH namely 3 clinical pharmacists from Infectious Diseases, Paediatrics and Nephrology; 1 shift pharmacist; 3 DI pharmacists; 1 Quality Assurance Officer and 2 medical consultants was set up to assess and review the current DI service provided at Mater Dei Hospital. Necessary approvals from the University Research Ethics Committee was granted (Appendix 2). Participants who accepted to take part in the focus group were then given a consent form to be filled by each individual concerning the recording of the focus group session (Appendix 2).

The participants who accepted the invitation for the focus group were consulted regarding a day and time to set up the meeting which was held on a Friday at 1500. Since all participants work at Mater Dei Hospital, the venue was within Mater Dei specifically at the Hospital Pharmacy Dispensary.

The focus group was asked to reflect on access to DI from a shift pharmacist and from a clinical pharmacist basis. This was carried out to evaluate the efficiency of DI services offered by MDH and limitations to accessing DI from these users. The main question which the focus group was expected to answer was whether clinical pharmacists should respond to the patient bedside DI query directly without the need to refer to the DI centre. The focus group activity reflected on the

essential information required by clinical pharmacists, whether clinical pharmacists are to respond directly to bedside DI queries, what should happen in those clinical areas where no clinical pharmacist is available and whether there should be a standard source containing all the information required by DI providers. The limitations to accessing DI and respective recommendations were put forward by participants of the focus group.

The 10 focus group participants were set up around a table and each chair was labelled with a code for confidentiality purposes when focus group recordings are transcribed. The lead researcher led the focus group by asking the questions. Three sets of questions (Appendix 3) were put forward, one set aimed at providers of DI, one set aimed at users of DI and one set aimed at both. All participants took part in the discussion. The focus group lasted about 1.5 hours. There was no need for another session since all the requested questions were answered and discussed.

2.2.2 Feedback from experts

Nine participants who were invited to the focus group but could not attend, formed the expert group. These included clinical pharmacists at Rheumatology and Endocrine, 2 DI pharmacists working at the DIC at MDH, 1 shift pharmacist at MDH, the head of the DI services section and 1 nurse. Two pharmacists, each working in two other local private hospitals, were also invited to participate but could not attend. These experts were sent a questionnaire having the same questions as the focus group (Appendix 3) so that their feedback was also inputted in the study.

The questionnaire was compiled to collect data about frequency of DI queries, types of queries received, requestor type, resources used, time taken to respond a DI query and the limitations and recommendations encountered when answering queries. The questions were inputted on Google

form® and sent to the expert group via email. The expert group was requested to answer all questions by choosing from the options provided.

2.3 Evaluation of DI service and access at patient bedside

The evaluation of the DI service and DI access at patient bedside was carried out in two steps:

I. Prospective study at the Intensive Therapy Unit (ITU) at MDH to assess hands-on the access of DI from a patient bedside scenario. This was done by using conventional resources and subsequently by using Ask Watson feature
II. Evaluation of DI services provided to wards after-hours when clinical pharmacist is not available at ITU

The points brought out in the focus group were assessed and reviewed while implementing any recommendations provided. This was done in a DI system which is set up to support pharmacists' bedside decision making at the patient bedside. An 8-week study was set up to assess the proposed framework.

2.3.1 DI service at patient bedside in acute setting

The ITU at MDH was chosen for this study phase. At the ITU no inhouse clinical pharmacist is available. The importance of accessing drug information at patient bedside can be highlighted mostly in this area since it is the most acute setting in the hospital where responses to queries to any drug information are required as soon as possible.

During the 8-week study phase, daily morning ward rounds carried out by the multidisciplinary team, led by the ITU consultant and consisting of ITU medical officers and the ITU nurses, were

attended to. Besides following each patient's pharmacotherapeutic review, any drug information queries requested during the ward round were forwarded to the pharmacist-researcher attending the ward round. The pharmacist-researcher used a personal digital assistant having the same resources to the MDH DIC including Micromedex®, UptoDate® and Medicines Complete. A documentation template was compiled using Excel to record and follow-up each query requested during the prospective study at ITU. For study purposes, all DI queries details were collected and noted. Forwarding of queries to the DI centre was also noted. The queries presented at patient bedside may be forwarded to different entities depending on specialisation of the query. Unlike queries presented at bedside and answered by the pharmacist-researcher during the ward ward round, the follow-up for the forwarded queries was not recorded since the individual entities dealt themselves with the ITU healthcare team.

The details included in the template consisted of query requested, requestor, reason for query, type of query, time taken to answer query, resources used and pharmacist intervention carried out, if any. Apart from receiving queries from the multidisciplinary team, the pharmacist also intervened and questioned any uncertainty in the patient treatment chart. The points brought out from the focus group including procedure followed when answering a DI query at bedside and limitations found when doing so and respective recommendations were compared to those found at the ITU.

2.3.2 Analysis of Ask Watson™ platform

Ask Watson™ is a newly available platform launched during this study, in August 2018. This combines the artificial intelligence of IBM Watson with the evidence-based clinical decision support of Micromedex®. Ask Watson™ platform hastens access to DI by avoiding the keyword-based research process and uses a Watson Assistant which accepts natural language queries. It answers drug questions from specific content within Micromedex®, including answers for drug classes, IV compatibility, dosing and administration, medication safety, mechanism of action, pharmacokinetics and drug interactions. Ask Watson™ is a platform similar to a chat function where the user inserts the keywords of the drug information query. From these keywords, the software itself guides the user to the correct webpage within Micromedex® containing the answer, which can then be provided to the healthcare professional requesting the query. Ask Watson helps give more access to information in a timelier manner to healthcare professionals, especially pharmacists at patient bedside. A seminar which gave an overview of the Ask Watson platform held in October 2018 at the University of Malta was attended. This seminar gave an overview of the functions of Micromedex®. During this seminar, a clinical training consultant showed the participants all the features within this DI source with an emphasis on Ask Watson™ since this feature was added recently to the online DI platform.

The queries requested at patient bedside during the 8-week study at ITU were reviewed and re-answered using Ask Watson™. The number of queries answered with this platform and the time taken for each question were recorded. The results were then compared to those previously obtained using contemporary resources.

2.3.3 DI service at patient bedside during after hours

The final step of this phase took place between December 2018 and February 2019. During this period, data regarding DI queries received from shift pharmacists after hours was collected. Drug information queries arising from all wards, including ITU, forwarded to shift pharmacists were considered for this study. A questionnaire similar to the one distributed to focus group and expert group participants, was sent as a Google Form to all shift pharmacists (Appendix 4). Details of drug information requests received were recorded similarly to those received during ward round. Data collected included number of queries requested per shift, requestor, reason for query, type of query, time taken to answer query and resources used. This data collection, together with the results published by Cassar and Azzopardi in 2016, was eventually used to compare the number of queries received from ITU during normal hours with those received after hours.

CHAPTER 3

RESULTS

3.1 Observational Study to analyse existing DI models internationally

The DI services provided at the University of Illinois Hospital and Northwestern Memorial Hospital, in Chicago were compared to each other and to those provided in Malta. Table 3.1 gives the differences of DI services in the three entities.

DI services include the services provided by the DI centre and the services provided at patient bedside. In Chicago, these services are standalone while in Malta, the DI centre is centralised and the clinical services at ward level are combined therefore any queries whose answer is not found at the bedside resources are eventually forwarded to the DIC. Some clinical pharmacists who carry out daily ward rounds in the morning provide also DI services at the DI centre after ward rounds are over.

DI pharmacists at Chicago amount to 12 with the help of pharmacy residents. Pharmacy residents are newly graduated pharmacists specialising in a pharmacy section and at the time of the observational study, there were two residents giving DI services at the DI centre. NW Memorial Hospital takes less DI requests since the hospital is on a smaller scale and has 7 DI pharmacists and 3 pharmacy residents.

Eight DI pharmacists are available at MDH DI centre, 3 of whom also provide DI service at patient bedside during ward rounds these being rheumatology, paediatric and infectious disease. The shift for pharmacists providing DI is the same in all three hospitals as seen in Table 3.1, however, UIC and NW Memorial Hospital have a dedicated DI pharmacist for after hours.

Table 3.1: Comparisons and Differences of UIC, NW Memorial Hospital and MDH

	UIC	NW Memorial Hospital	MDH
Hospital Capacity	700 beds	400 beds	1000 beds
Shift	6 days a week; shift on other days and after hours. Dedicated DI pharmacist for after hours	6 days a week; shift on other days and after hours. Dedicated DI pharmacist for after hours	6 days a week; shift on other days and after hours
Pharmacists	Around 12 DI pharmacists and 2 pharmacy residents; clinical pharmacists in all wards	7 DI pharmacists and 3 pharmacy residents; 15 clinical pharmacists in all wards	8 DI pharmacists 3 Clinical pharmacists
Resources	70 online; multiple access points 150 books continually updated	70 online; multiple access points 40 books continually updated	10 online resources; one access point for Micromedex® 25 books
Clients	Fee for Service; clients with a contract	Free Service; used only by NW Hospital healthcare professionals	Free service; open to everyone
Requestors	Mostly pharmacists	Practitioners, nurses and pharmacists working at NW Hospital	Practitioners, nurses, pharmacists, patients, other hospitals
Mode of Requests	Mostly via email	Mostly via telephone	Mostly via telephone
Mode of response	Answered by pharmacists or pharmacy residents	Answered by pharmacists or pharmacy residents	Answered by pharmacists
Access at patient bedside	Direct access to all electronic resources via bedside computer	Direct access to all electronic resources via bedside computer	Limited access; referral to DIC

Table 3.1 gives the similarities and differences of the UIC and NW Hospital, which are the two hospitals observed in Chicago, to MDH, which is the main public hospital in Malta.

DI resources in all hospitals are available in an electronic format or book format. At UIC, more than 70 online resources and 150 books are available. Online resources have multiple access points and more than one pharmacist can access the online resource at the same time. The books are continually updated depending on the version available and published. The same applies at NW Memorial Hospital, though the number of books available in this entity are 40.

The number of available resources is drastically decreased and is limited in Malta with less than 10 online resources and less than 25 books. Micromedex and Up to Date are the online resources mostly used at the DIC and also at patient bedside, as shown in figure 3.4. Micromedex is available to only one pharmacist at a time since there is only one access point to this resource.

Twenty-eight (28) queries were presented at patient bedside during 3 ward rounds at UIC. This gives a mean of about 9 DI queries per ward round. All DI queries presented were answered during the ward round and were not forwarded to the DI centre. No ward rounds were observed at NW Memorial Hospital.

All the online DI resources available at the DI centre at UIC and NW Memorial Hospitals are also available at patient bedside. Two portable bedside computers having all these DI resources are available in all wards at the hospitals in Chicago.

3.2 Assessment of DI services at Mater Dei Hospital - Focus Group

The resources used by pharmacists at patient bedside are given in table 3.2. Micromedex® and UpToDate are the resources mostly used by healthcare professionals and pharmacists who provide DI services at the DI centre and at patient bedside. The BNF is accessed by pharmacists at patient bedside through their own personal copy. A clinical pharmacist personally takes a copy of the updated version of the BNF during ward round. One clinical pharmacist stated that at patient bedside, the use of an updated hard copy of the BNF and Micromedex is enough. The nephrology clinical pharmacist uses the online version of the Renal Drug Handbook to complement the use of BNF and Micromedex®.

Certain queries related to a particular condition require the use of specific resources. A DI centre pharmacist suggested the use of NHS or NICE guidelines since these give the place in therapy for a particular treatment and helps in providing appropriate treatment. The same pharmacist suggested that accessing this resource is, however time consuming and may not be feasible to be used at patient bedside. Up to Date is used in cases where a clinical pharmacist at patient bedside needs to refer to evidence-based recommendations in a condition. The 'Search' function in this platform eases DI access when used at patient bedside.

Table 3.2: Resources used at DI services in Malta

Resource	Type	Reason for Accessing	Use
BNF	Hardcopy	Drug Related queries such as ADRs, Drug Interactions, Dose and Clinical Use	At patient bedside
Medicines Complete	Online	Latest and most relevant medicines information from peer-reviewed publications. Available resources are BNF, Martindale, Stockley's Drug Interactions, Drug Administration via Enteral Tubing, Drugs in Pregnancy and Lactation, Handbook of Injectable Drugs	At patient bedside DI centre
Micromedex	Online	Drug Related queries such as ADRs, Drug Interactions, Doses and Drug Comparisons Calculations	At patient bedside DI centre
Up to Date	Online	Recommendations provided by peer-reviewed literature and evidence-based recommendations	At patient bedside DI centre
NHS guidelines	Online	Queries related to conditions and treatment guidelines	DI centre
SPC	Online	Drug Related queries such as ADRs, Drug Interactions, Dose and Clinical Use	At patient bedside DI centre

Table 3.2 gives a brief description of the types of resources used in Malta by clinical pharmacists, shift pharmacist or both. This table was compiled from data gathered from focus group and expert group.

Table 3.3 gives a list of the requestors which mostly present queries to pharmacists, type of query forwarded and the entity the query is mostly forwarded to.

Drug Administration and Compatibility issues are forwarded mostly by nurses. The pharmacists at the DI centre and the shift pharmacists are presented with this type of query after nurses start administering treatment. Treatment administration takes place after the ward round is finished and therefore any queries related to this cannot be forwarded to the pharmacists at patient bedside. Patients may be admitted with liver or renal impairment. Treatment given may not always be applicable to such patients and doses may need to be adjusted. Doctors and Consultants may need to know how drugs should be adjusted in such cases. Dose Adjustments are therefore very common at patient bedside but a clinical pharmacist stated that these types of queries are not usually answered at ward level but eventually forwarded and responded after some time. The DI centre has the resources, which are not available at patient bedside, to give a response to these types of queries. Community pharmacists and other entities such as the prison pharmacy or other local private hospitals forward their requests, though not very common, to the DI centre or shift pharmacists depending on the time of day the query is brought up, with most queries being on drug availability or to confirm a dose from the former and overdosage and treatment available from the latter.

Table 3.3: Requestors and Type of Request

Requestor	Type of DI query	Entity
Nurses	- Drug Administration - Drug Compatibility	Mostly to DI centre and shift pharmacists after hours Few forwarded at bedside
Doctors and Consultants	- Dosage Regimens - Drug Use in certain conditions - Drug Availability - Dose Adjustments in Liver and Renal impairment, Pregnancy and Lactation - Drug Comparison	At patient bedside
Pharmacists	- Availability of drug in hospital - Confirmation of doses	DI centre
Patients	- Availability of drug in hospital - Drug information such as dosing and possible ADRs	DI centre Shift Pharmacists
Other Entities	Overdosing and respective treatment	DI centre

Table 3.3 summarises the most common DI requestors which forward a DI query to clinical pharmacists, shift pharmacist or both. This table was compiled from data gathered from focus group and expert group.

DI pharmacists at the DI centre at MDH receives about 15 queries daily between 07:30 and 15:00. Two out of 3 DI pharmacists present during the focus group stated that queries presented from clinical pharmacists at bedside are unlikely, with only about 2 queries received weekly. The clinical pharmacists present stated that DI requests are only forwarded when the answer is not available in the resources accessible at patient bedside and an urgent response is required. In other cases where no answer is available at bedside but the response is not urgent, the clinical pharmacist answers the query after the ward round when at the DI centre. During the focus group, clinical pharmacists stated that an average of 5 requests per ward round are forwarded to the DI centre and not answered at patient bedside.

As concluded from the focus group, 60% of the clinical pharmacists (n=3) at patient bedside receive most queries from consultants, with the remaining 40% of requests being brought up by house officers or the pharmacists themselves. The queries brought up by pharmacists are usually as a result of a pharmacist intervention. At patient bedside, the pharmacist reviews patient drug chart and medical history, searches resources when there is uncertainty and intervenes in cases of drug related problems. One pharmacist during the focus group said that this occurrence is common at patient bedside. Shift pharmacists receive no requests from clinical pharmacists at patient bedside.

Table 3.4 gives an overview of the limitations encountered by DI providers and users as brought up in the focus group and expert group. DI pharmacists are not trained enough before given a role in DI at Mater Dei. Abroad, DI pharmacists spend some time in DI as residents which helps them in training and in carrying out satisfactory DI roles. In Malta, this is not the case and at first, pharmacists may not provide effective DI services. Slow IT systems is also an issue at the DI centre as discussed by the focus group and expert group. Resources used are mostly online and having

slow IT systems limits the efficient access to DI. Another issue with resources was one which all DI pharmacists, clinical pharmacists and shift pharmacists agreed on. Resources currently available in book form at the DIC is outdated with certain issues dating back to 2015 or 2016. Since the current issues available are the only ones present at the DI centre, pharmacists may still use them since certain DI requests are only available in those books. This may result in outdated DI since evidence-based information in continually changing.

Online resources are also limited. Micromedex is the source mostly used by all pharmacists providing DI. The information in this source is continually updated however only one access point to be used by all pharmacists at MDH is available. This means that if one pharmacist is using Micromedex, another pharmacist who requires it cannot use it at the same time. This may eventually result in pharmacists, especially those at patient bedside, to make a personal subscription to these DI sources. One clinical pharmacist stated that 'the BNF she has is the most current one since it is bought every six months and the one available at MDH is not updated'. Another clinical pharmacist 'personally subscribed to three online resources used at bedside since the ones available may not always be accessible'. Clinical pharmacists do not have a source from which they can access DI at patient bedside. No bedside portable computer is available at ward level or if available, is mostly used by nurses and consultants. This results in the pharmacists having to carry a personal digital assistant, using own smartphones or tablets.

Time constraints is an issue faced by shift pharmacists. Apart from DI provision, shift pharmacists have other duties including dispensing of medications to wards and discharged patients, reconstitution of any newly prescribed medicine not available in the dosage form required and emergency medicine deliveries. Not enough time is therefore dedicated to DI during shift hours

and queries, especially those arising from ward level, might not be responded well enough resulting in lack of DI access to patient care.

A pharmacist should always form part of the multidisciplinary team carrying out ward rounds at patient bedside. Apart from providing DI to any queries requested by the team, pharmacists may intervene in patient care, in case of drug related problems or medication errors carried out by the team. The consultants during the focus group brought up the limitation of 'lack of pharmacists at ward level. The presence of a pharmacist assists in care decision-making, helps develop evidence-based recommendations and eventually improves patient outcomes. The availability of a pharmacist has been associated with decreased drug costs and reduction in hospital stays.'

Table 3.4: Limitations for Drug Information Access

DI pharmacists	Lack of efficient training Outdated and limited resources Slow IT systems
Clinical Pharmacists	Outdated and limited resources; personal subscription to online resources No bedside computer; use of personal digital assistant
Shift Pharmacists	Time Constraints Outdated and limited resources
Consultants	Lack of pharmacists during ward rounds

Table 3.4 gives the limitations for DI access as put forward by DI pharmacists at the DI centre, clinical pharmacists at patient bedside, shift pharmacists working after hours and clinical consultants.

3.3 Evaluation of DI service and access at patient bedside

Three sets of results were gathered from this phase of the study since this was divided into three main parts:

- Results from 8-week study at the ITU at Mater Dei Hospital
- Results from the assessment of the Ask Watson platform when queries presented to this platform
- Results from questionnaire regarding queries received to shift pharmacists after-hours

3.3.1 8-week study at the ITU at Mater Dei Hospital

During an 8-week period at the ITU at Mater Dei Hospital, 140 bedside queries were forwarded to the pharmacist (mean of 7 queries daily and range of 5 to 12 queries).

Figure 3.1 summarises the requestors of DI queries presented at patient bedside. Medical officers presented the most queries totalling up to 43%. ITU consultants presented 32% of the queries while nurses 16%. The pharmacist-researcher at the ITU reviewed patient medical charts and treatment prescribed while at the ward round. Eight percent of DI queries resulted from the intervention of the pharmacist while reviewing drug treatment charts Medical students undergoing a placement at the ITU forwarded their queries on the patient case, resulting in only 1% of the cases.

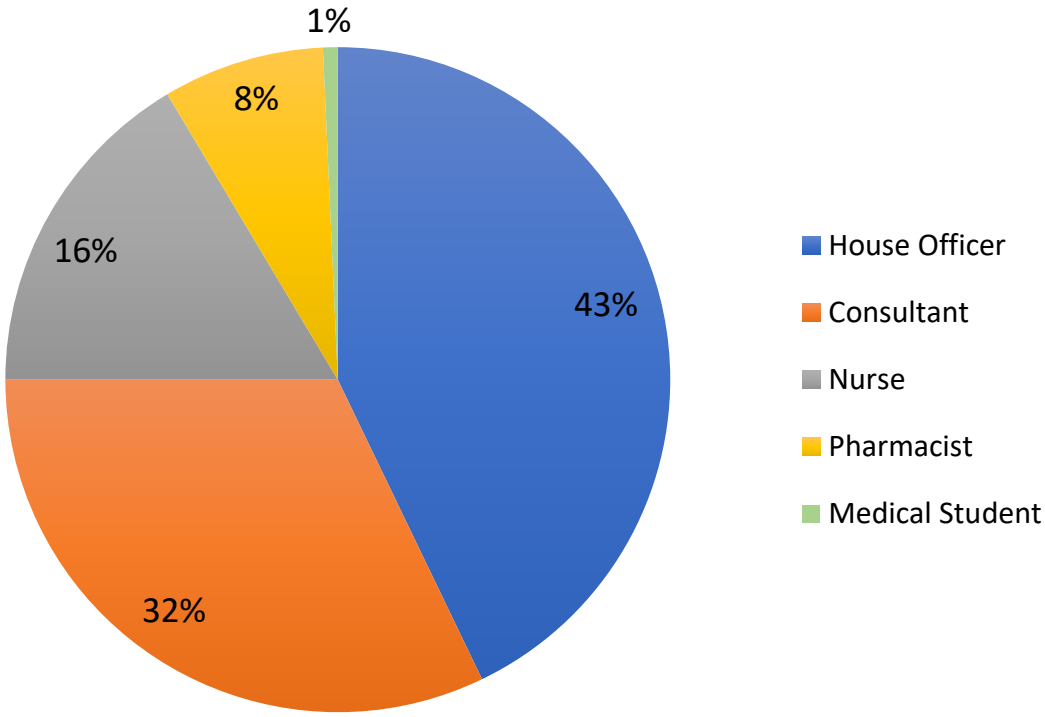

Figure 3.1: Requestor for DI queries at patient bedside during 8-week study at ITU (N=140)

House Officers accounted for the highest requestors of DI queries. The least were the nursing staff. Medical students also forwarded their own DI queries to the pharmacist-researcher.

Drug information queries may be patient specific, academic for educational purposes or population based to aid in the decision-making process for evaluating medication use for groups of patients. The goal of providing carefully evaluated, evidence-based recommendations to support specific medication-use practices is to enhance the quality of patient care, improve patient outcomes and ensure the efficient use of resources. DI queries presented at the ITU were either patient-related or academic. One hundred queries (71%) were patient related, while the remaining 40 (29%) were for educational purposes.

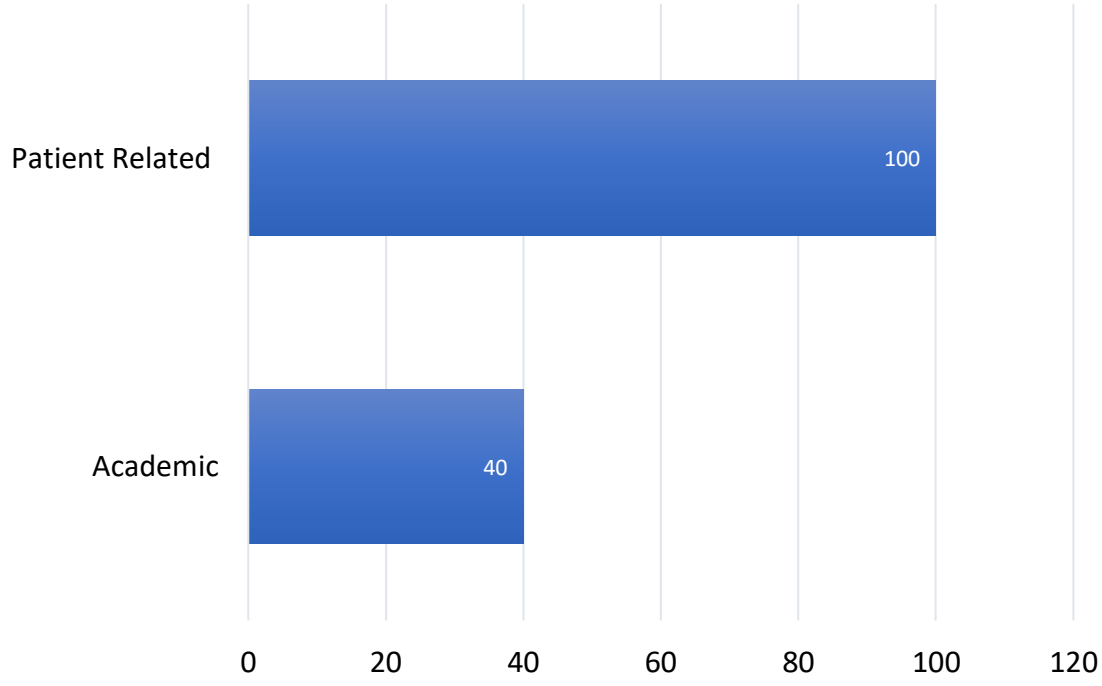

Figure 3.2: Reason for Queries forwarded at patient bedside during 8-week study at ITU (N=140)

Different types of drug Information requests were received at patient bedside varied in type and for this reason, they were categorised accordingly. The different categories and the frequencies of them being requested at patient bedside are given in figure 3.3.

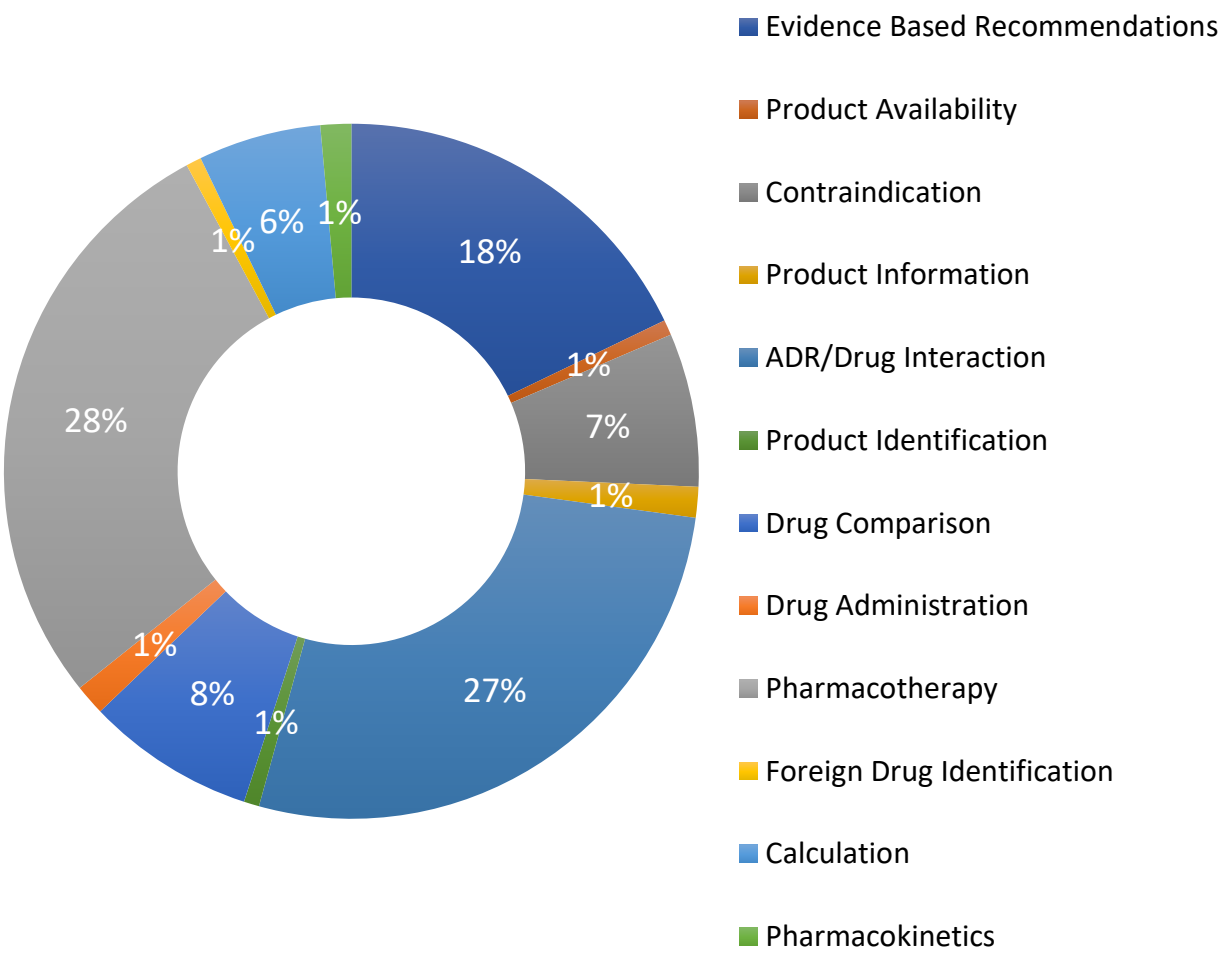

Figure 3.3: Types of DI Queries requested at patient bedside during 8-week study at ITU (N=140)

The highest types of queries were Pharmacotherapy related (28%) followed by ADR and drug interaction related queries (27%)

Requestors at patient bedside may need to know the use of a medicinal drug in treatment giving rise to pharmacotherapy queries. Out of 140 queries presented at patient bedside, 39 queries (28%) were about pharmacotherapy. Thirty-seven queries (27%) were about Adverse Drug Reactions (ADRs) and Drug Interactions of drugs. Evidence-based recommendations from literature resources were requested in cases where it was not known if a treatment is effective in a condition or to make a correct diagnosis from the test results of the patients. Evidence-based recommendations queries included:

- What does a decreasing level of lactate indicate?
- Use of vitamin K in a patient not taking warfarin
- Serotonin syndrome symptoms, reasons and treatment
- Patient involuntary moving hand due to seizure - what type of seizure and ideal treatment

The healthcare team may need to compare drugs used in different medical conditions especially regarding effectiveness and tendency to cause ADRs. Eleven queries (8%) were regarding drug comparison. The mostly requested drugs needed to be compared were antibiotic drugs and anaesthetic drugs. Other DI requests presented at patient bedside included drugs contraindications (7%) and calculations (6%). Drug Administration, Product Identification, Product Availability, Pharmacokinetics and Foreign Drug Identification are the least requested types of queries with each amounting to 1% of the queries.

A personal digital assistant was available at patient bedside with 3 preinstalled DI resources apps. Micromedex and Up to Date are the DI resources applications accessible for pharmacists at ward level at Mater Dei Hospital since access points are available to these resources only. During the 8-week study at the ITU, 62% of queries were answered using Micromedex platform. Micromedex contains Micromedex Drug Ref which is the main DI resource page which giving information on any searched drug. Each searched drug has short answers or in-depth answers depending on the degree of detail needed by the requestor. Different sections of DI resources are also found in Micromedex including a section regarding Drug Comparisons, a Calculator and Drug Interactions. The mobile version of Micromedex has an application for each section. Thirty-two queries (23%) were answered using the Micromedex Drug Ref since these queries were specific to a certain drug. The 27 requests (19%) which were about the comparison of two or more drugs were inputted in the Drug Comparison section of Micromedex. Drug Interactions queries, which had a total of 25 (18%) were answered using the 'Drug Interactions' feature in Micromedex. Three queries (2%) were Calculations regarding anion gap, creatinine clearance and ideal body weight were answered using the Micromedex calculators.

Up to Date is a drug information source having peer-reviewed articles and studies. Fifty queries (35%), especially those which needed evidence-based recommendations, were answered using this DI resource. The summary of product administration (SPC) and the hospital formulary were used in 2% of all 140 DI queries. The SPC was referred to in the query regarding blood levels testing in a patient on valproate while the hospital formulary was needed to check whether nicotine patches are available on the Maltese Government drug formulary.

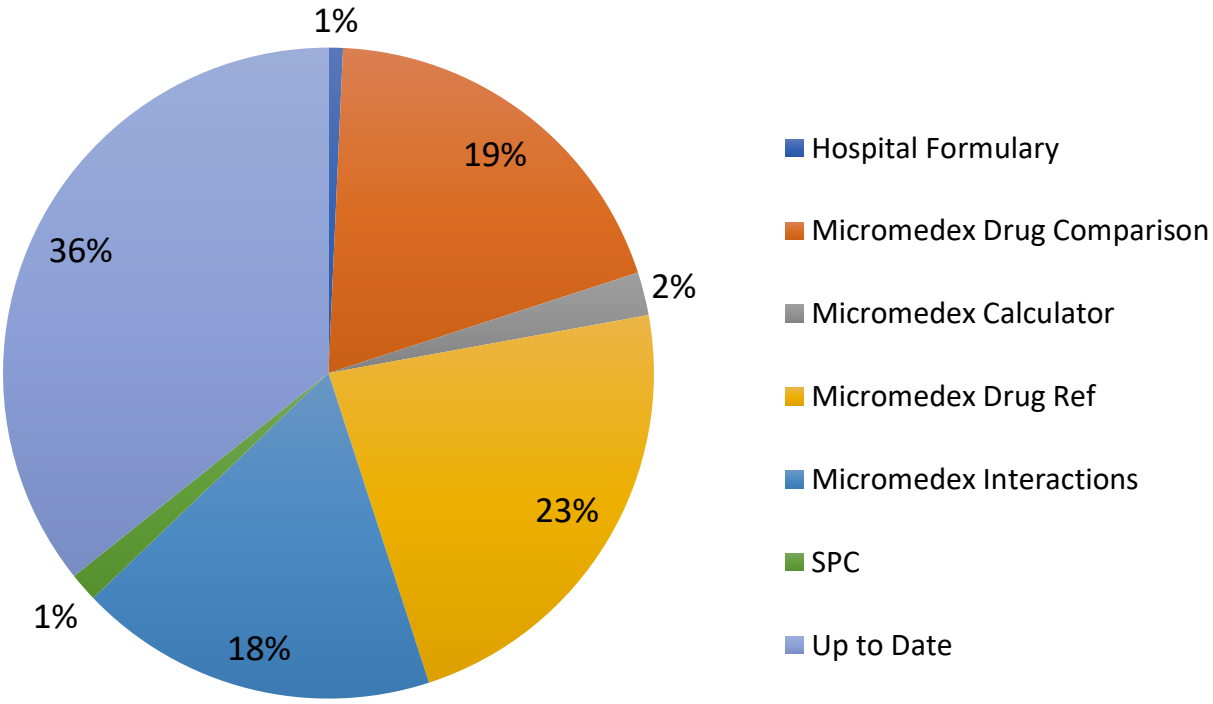

Figure 3.4: Resources used at Patient Bedside during 8-week study at ITU (N=140)

The time taken to answer each DI query presented at patient bedside was recorded. Most queries were answered in less than 5 minutes using the available resources at patient bedside. The queries which were answered in this short time were simple and straightforward whose response was easily accessible from the resources available. Some examples of such queries include:

- Is thrombocytopenia a contraindication of enoxaparin?
- Nebivolol vs Carvedilol for Heart Failure
- Pradaxa vs Rivaroxaban for Atrial Fibrillation

Queries which required about 5 to 10 minutes to be answered amounted to about 26%. These included queries which needed a more in-depth search or simple calculations which could be answered using the Micromedex calculator such as:

- Ideal antibiotic between itraconazole and meropenem for septic patient on daunorubicin
- Calcuation of Creatinine Clearance

Twenty queries (14%) answered at bedside had to be referred to different sections according to the need and to the area of specialization of the same query. 10 queries (7%) were about dosing calculations or dosing total parenteral nutrition and were referred to the DIC and answered by the pharmacists at the DIC. Such queries could not be answered at patient bedside since the resources used to usually answer such queries are found in the DIC resources which are not accessible at patient bedside.

During the ward round, others health care professionals are usually present near some patients depending on the case. A specialist consultant may be required at patient bedside to give further advice regarding a condition which cannot be handled by the ITU team. For example, a patient

developing COPD while in ITU is referred to a respiratory consultant and the respective team. In cases where the DI request was about a particular condition or due to an action taken by the patient's specialist consultant, they were referred. These added up to only 2% of the queries. An example of these includes the calculation of respiratory rate and action needed.

An antibiotic pharmacist carried out ward rounds at a time period during the day. This pharmacist reviews patients who are on antibiotics and discusses with the ITU team regarding the progress of the respective patient. Any queries the ITU team might have regarding antibiotics are therefore forwarded to this pharmacist. During the 8-week study at the ITU, 5% of queries fell in this category. Some queries which were forwarded to the antibiotic pharmacist included:

- Ideal antibiotic for bacterial diffuse consolidation in lungs
- Hospital acquired sepsis antibiotics treatment - previously on co-amoxiclav and erythromycin
- Community Acquired Pneumonia patient taking rifampicin and levofloxacin - ideal treatment?

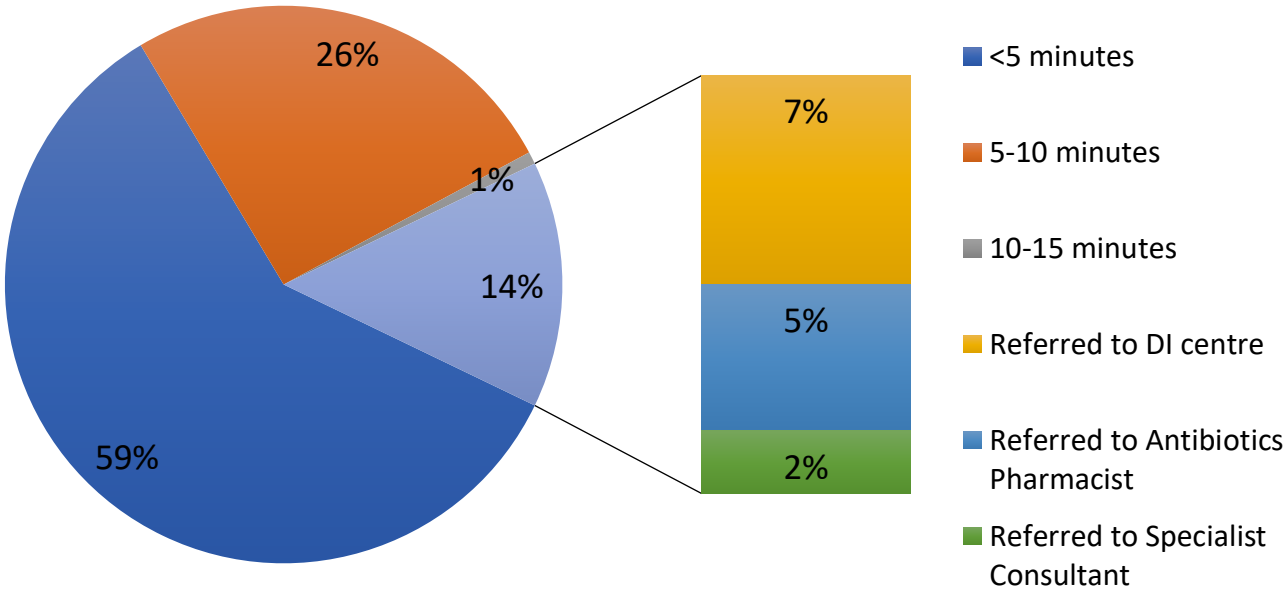

Figure 3.5: Time taken to answer a DI query at patient bedside during 8-week study at ITU (N=140)

3.3.2 DI accessibility when same queries requested more than once

The Intensive Therapy Unit healthcare team is made up of the ITU consultant, 1 Specialist Trainer (BST), 2 House Officers (HO) and 1 nurse with each patient. There are 8 ITU consultant, each changing every week while the HOs and the BST work on a shift basis. Queries arising at patient bedside may therefore repeat themselves whenever the team changes. The pharmacist was the same throughout the whole 8 weeks.

During the 8-week period at the ITU, 8 same or similar queries (5%) were requested again to the pharmacist. Table 3.5 gives the list of all the queries which were repeated.

For most cases, the response to the query when requested for the second time was given in shorter time by the pharmacist since the resource was already searched and therefore the pharmacist could access it in a shorter time. Certain queries still had to be forwarded to its respective entity since resource at patient bedside was not available. Queries related to calculations are an example of this. Another which was initially forwarded was answered by the pharmacist at bedside after accessing the proper resource.

Table 3.5: DI queries requested more than once at patient bedside during 8-week study at ITU (n= 8)

Query No.	Frequency	DI query Forwarded	Requestor	Resource used	Time taken
1	Two	Teicoplanin vs Tazocin vs Fluconazole	Consultant	Micromedex	5-10 minutes
		Teicoplanin vs Tazocin	HO	Micromedex	< 5 minutes
2	Two	Use of mannitol 15% and ideal dose in CKD patient	HO	Referred to DIC	>15 mintues
		Dose of mannitol 15% in 53 y/o patient with CKD	HO	Referred to DIC	>15 minutes
3	Two	Clonidine vs Midazolam vs Propofol as sedation	Consultant	Micromedex	5-10 minutes
		Clonidine vs Alfentanil vs Propofol as sedation	Consultant	Micromedex	< 5 minutes
4	Two	Drop in CRP from 167 on Day 1 to 92 on Day 2. Can this drop be due to tazocin which was started on Day 1?	HO	Referred to antibiotics pharmacist	>15 minutes
		Teicoplanin, Gentamicin and Tazocin started Day 0. CRP up by 100 on Day 2. Are antibiotics causing this rise? How to proceed?	Consultant	Referred to antibiotics pharmacist	>15 minutes
5	Three	Hospital acquired sepsis antibiotics treatment - previously on co-amoxiclav and erythromycin	HO	Referred to antibiotics pharmacist	> 15 minutes
		Hospital acquired sepsis antibiotics treatment - tazocin?	HO	Up to Date	< 5 minutes
		Ceftriaxone vs Tazocin in Hospital Acquired Pneumonia	HO	Micromedex	< 5 minutes
6	Two	Levels of amikacin	HO	Up to Date	5–10 minutes
		Levels of amikacin	Nurse	Up to Date	< 5minutes
7	Two	Thiopental levels	Consultant	Up to Date	< 5 minutes
		Levels of thiopental	Nurse	Up to Date	< 5 minutes
8	Two	Which is longer acting? Noradrenaline vs terlipressin	Consultant	Micromedex	<5 minutes
		Vasopressin vs Terlipressin	HO	Micromedex	< 5 minutes

Table 3.5 gives the list of the 8 queries which were requested more than once at patient bedside. The first column shows the query number from 1 to 8 while the second column gives the frequency number of that respective query. The exact DI query as asked by the requestor is given in the third column

3.3.3 Pharmacist Intervention at patient bedside

Nine queries (6%) from the 140 presented at bedside resulted in the eventual pharmacist intervention. All these interventions were carried out after the pharmacist at the ITU queried about the treatment or intervention being carried out by the healthcare team. The presence of a pharmacist drastically reduced the time taken for a decision to be taken at patient bedside as seen in table 3.6. Only one DI request which was intervened by the pharmacist had a decision taken in more than 15 minutes since it was a calculation. Access to calculation related DI requests is limited at patient bedside.

Table 3.6: Pharmacist's Interventions at Patient Bedside during 8-week study at ITU (n=9)

Query	Intervention carried out	Time taken for decision
Use of vitamin K in a patient not taking warfarin	Vitamin K stopped	Immediately. Removed from patient treatment chart.
Patient on bumetanide 1mg 8 hourly IV. Acute Kidney Injury present as concluded from the decreasing urea values. No oedema. Bumetanide?	Bumetanide stopped	< 5 minutes
Patient with STEMI taking no aspirin or statin. Can they be started?	Aspirin and Statin started	Immediately. Included in patient treatment chart
Reason for patient taking hydrocortisone	Stopped	Immediately. Removed from patient treatment chart.
Oseltamivir given for community acquired pneumonia	Stopped	Immediately. Removed from patient treatment chart.
Clarithromycin + Simvastatin	Clarithromycin changed to Ciprofloxacin	5-10 minutes
Volume of 3% Na in low sodium	60ml of 3% Na n 10 minutes. Na levels every hour	> 30 minutes since referred to DIC
Amiodarone with warfarin	Decrease the warfarin dose by one-half and monitor INR	5-10 minutes
Enoxaparin and heparin given together - drug interactions?	Stop Heparin	Immediately. Removed from patient treatment chart.

Table 3.6 gives the list of 9 queries which eventually resulted in a pharmacist intervention. The query forwarded is in the first column, with the respective intervention given in the second column. The time taken for a decision is in the last column.

3.3.4 Assessment of the Ask Watson platform when queries presented to this platform

All 140 queries presented at patient bedside were inputted and reanswered using a feature integrated within Micromedex called Ask Watson.

IBM Micromedex with Watson combines the artificial intelligence of IBM Watson with the evidence-based clinical decision support of IBM Micromedex. It accelerates access to information by bypassing the keyword-based research process in favor of a Watson Assistant accepting natural language queries. It can answer drug questions from specific content within Micromedex, including quick answers for drug classes, IV compatibility, dosing and administration, medication safety, mechanism of action, pharmacokinetics and drug interactions.[8]

[8] IBM. Put the power of AI to work [Internet]. 2018 [cited 2018 December 12]. Available from: https://www.ibm.com/us-en/marketplace/micromedex-with-watson

Ask Watson was able to give an answer to 110 queries presented at patient bedside, therefore a total of 79%. The remaining 21% could not be answered, either because the platform did not have the sufficient information to provide a satisfactory query or because the query was a calculation.

Out of 110 queries answered using Ask Watson platform, 87% were answered in less than 5 minutes and 9% still had to be forwarded to the respective entities since the information was not available in Ask Watson. When compared to queries answered without this platform, Ask Watson improved time taken for a drug information response to be given. Only 59% were answered in less than 5 minutes and 14% in more than 15 minutes when not using Ask Watson platform.

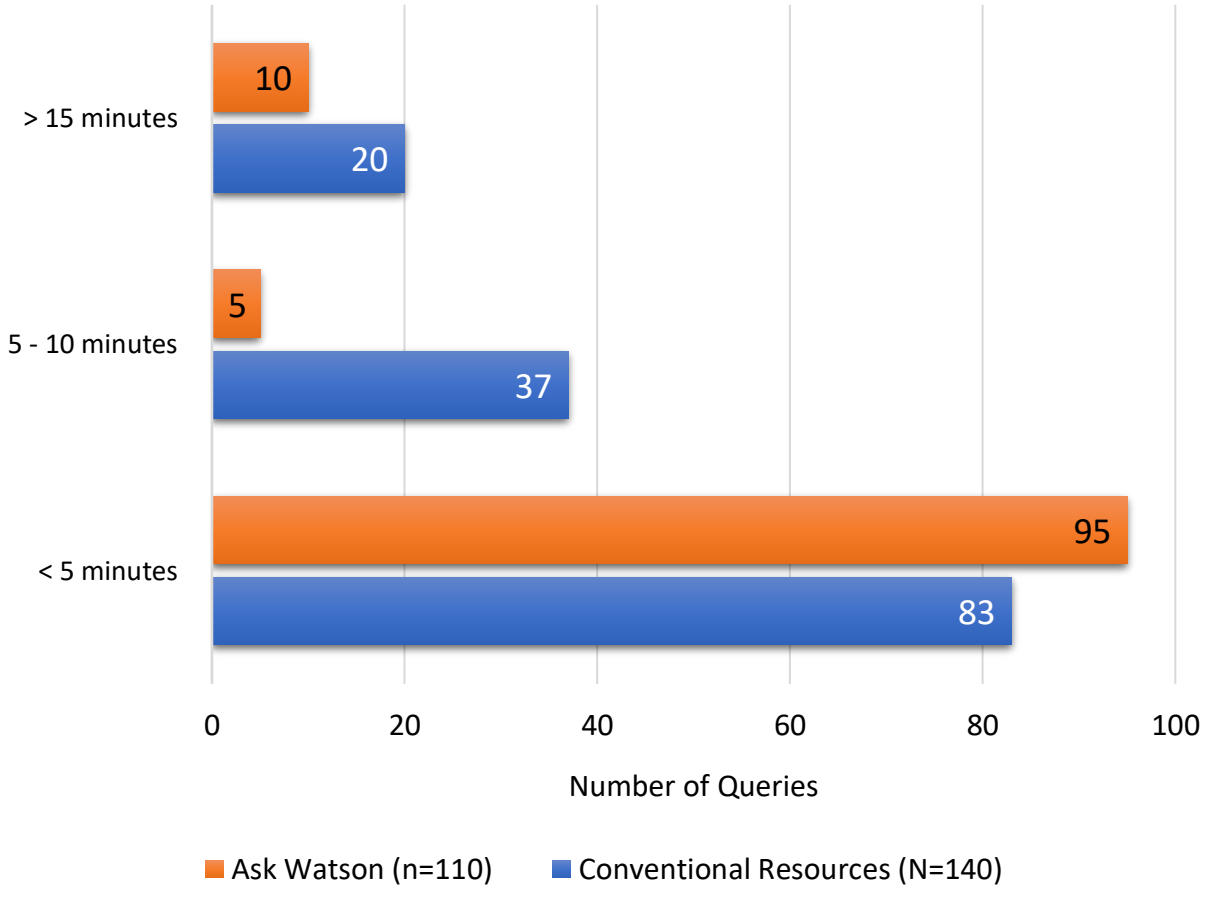

Figure 3.6: Time taken to answer Drug Information queries with Ask Watson available (n=110)

3.3.5 Queries received to shift pharmacists after-hours

Four shift pharmacists from the possible 8 answered the questionnaire distributed regarding collection of bedside DI queries after hours. An average of 13 queries are received after hours during each shift with all requests being forwarded by nurses. All shift pharmacists (N=4) responded that queries are answered in between 5 – 10 minutes.

Figure 3.7 gives the type of DI queries mostly received during shift hours. The most common query requested to shift pharmacists is regarding Drug Administration. This complies with the most common requestor since nurses are involved in administering drugs and when doing so, they might have queries which cannot be requested to the clinical pharmacist since the ward round would have already finished. Three shift pharmacists stated that they receive queries regarding drug dosing mostly about calculations of doses and posology. Shift pharmacists answer DI queries from patients or community pharmacists who usually ask about a product and its availability in hospital and 2 shift pharmacists stated they such queries are forwarded during shift hours. Other queries include drug identifications, pharmacotherapy and drug contraindications.

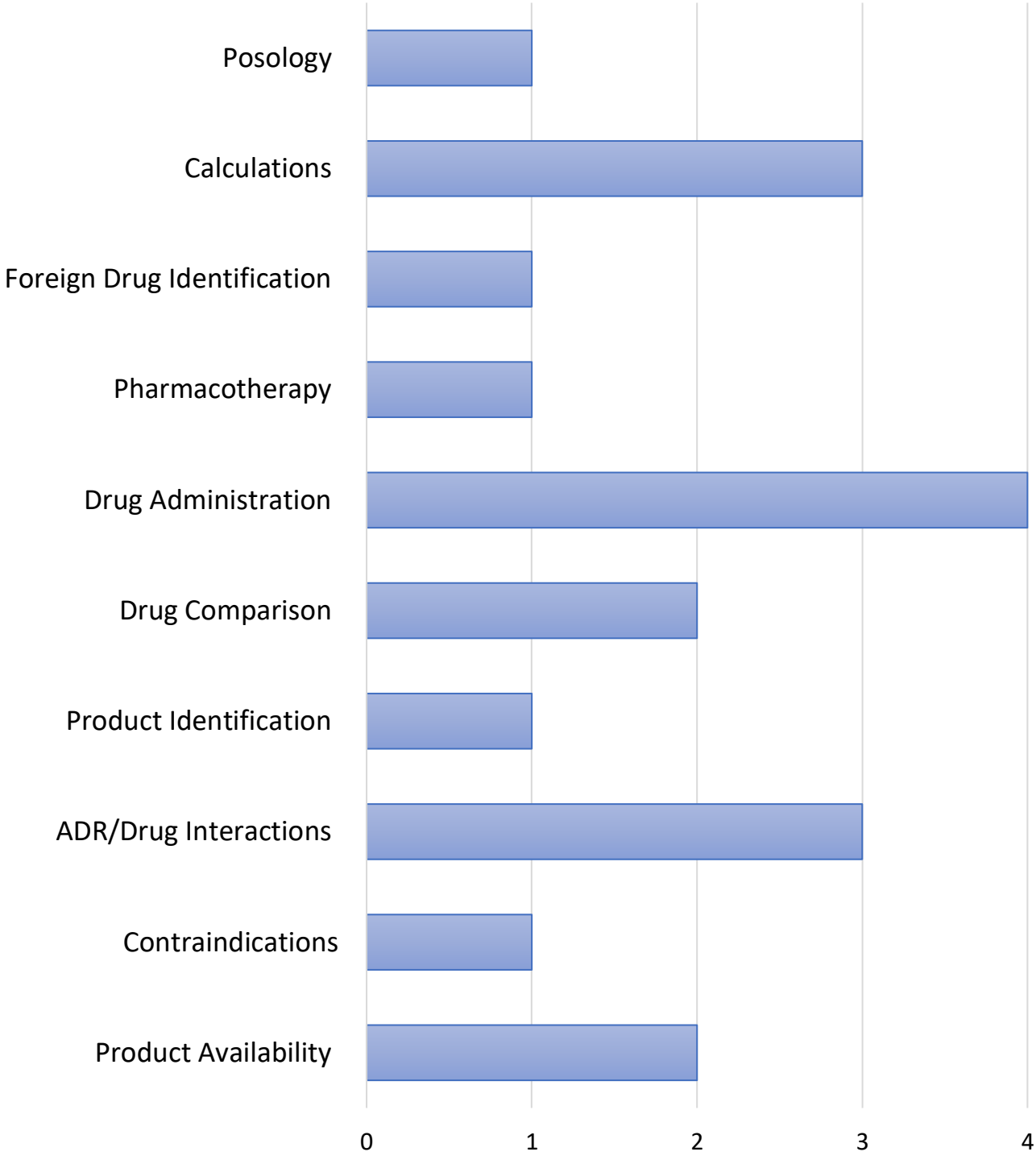

Figure 3.7: Type of DI queries received during shift hours (N=4)

Resources used are only those available online since according to 2 shift pharmacists 'drug information book resources are available at the DI centre which is not accessible after hours.' Figure 3.8 gives a chart of the resources used by shift pharmacists. These include Micromedex, Up to Date and the Summary of Product Characteristics with the majority of shift pharmacists who answered the questionnaire using these resources. Two shift pharmacists have their own personal BNF which they refer to when DI queries are forwarded. Medicines Complete, especially the Injectable Drugs section, and the Drug Monographs are also used as a source of DI by shift pharmacists.

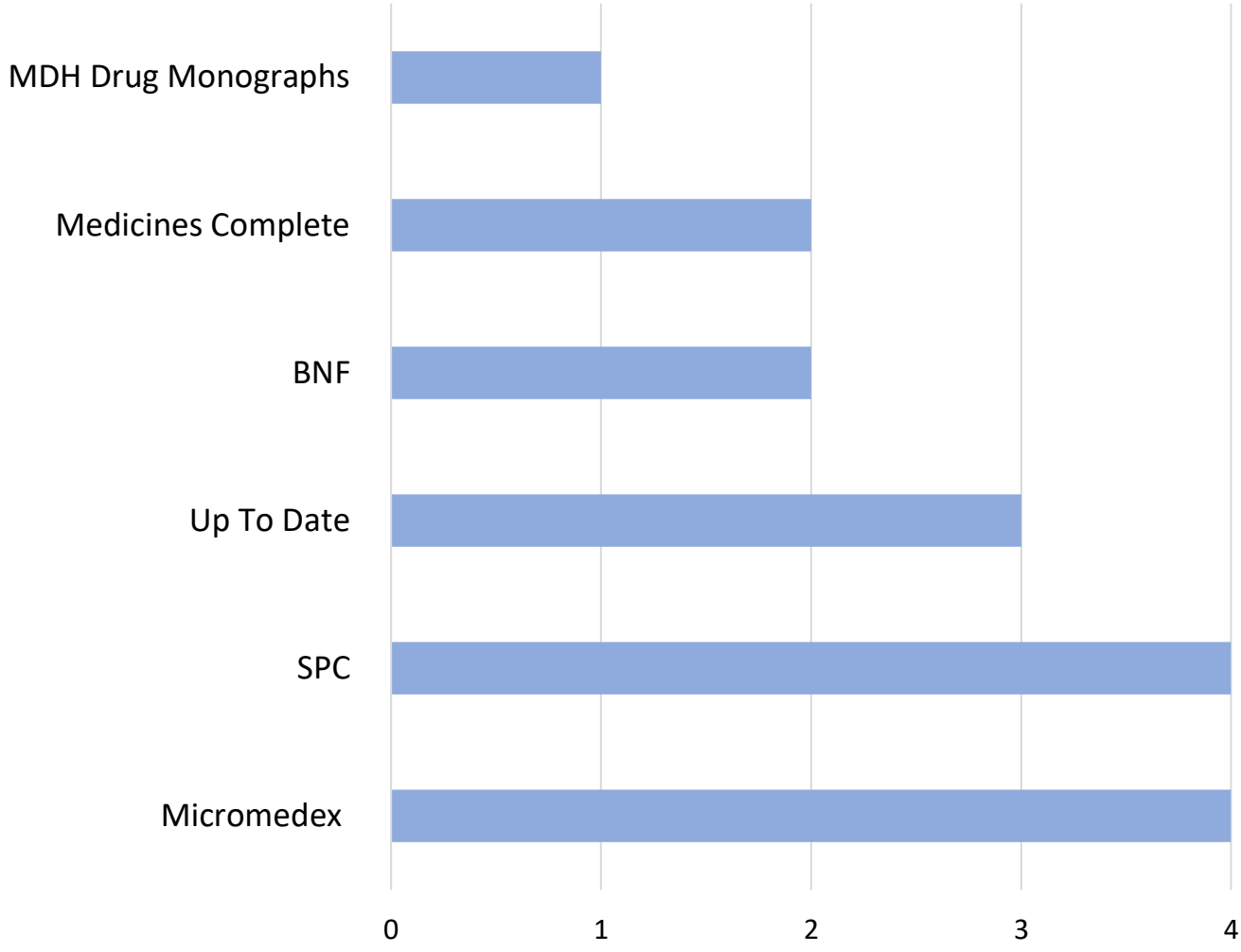

Figure 3.8: Resources used for shift DI queries (N=4)

The results obtained from the questionnaires distributed to shift pharmacists were compared to those obtained from the 8-week observational study at ITU.

Two hundred eighty-four queries were requested by wards during shift hours. Four shifts are available at MDH, resulting in a mean of 71 queries per shift for a total of 8 weeks

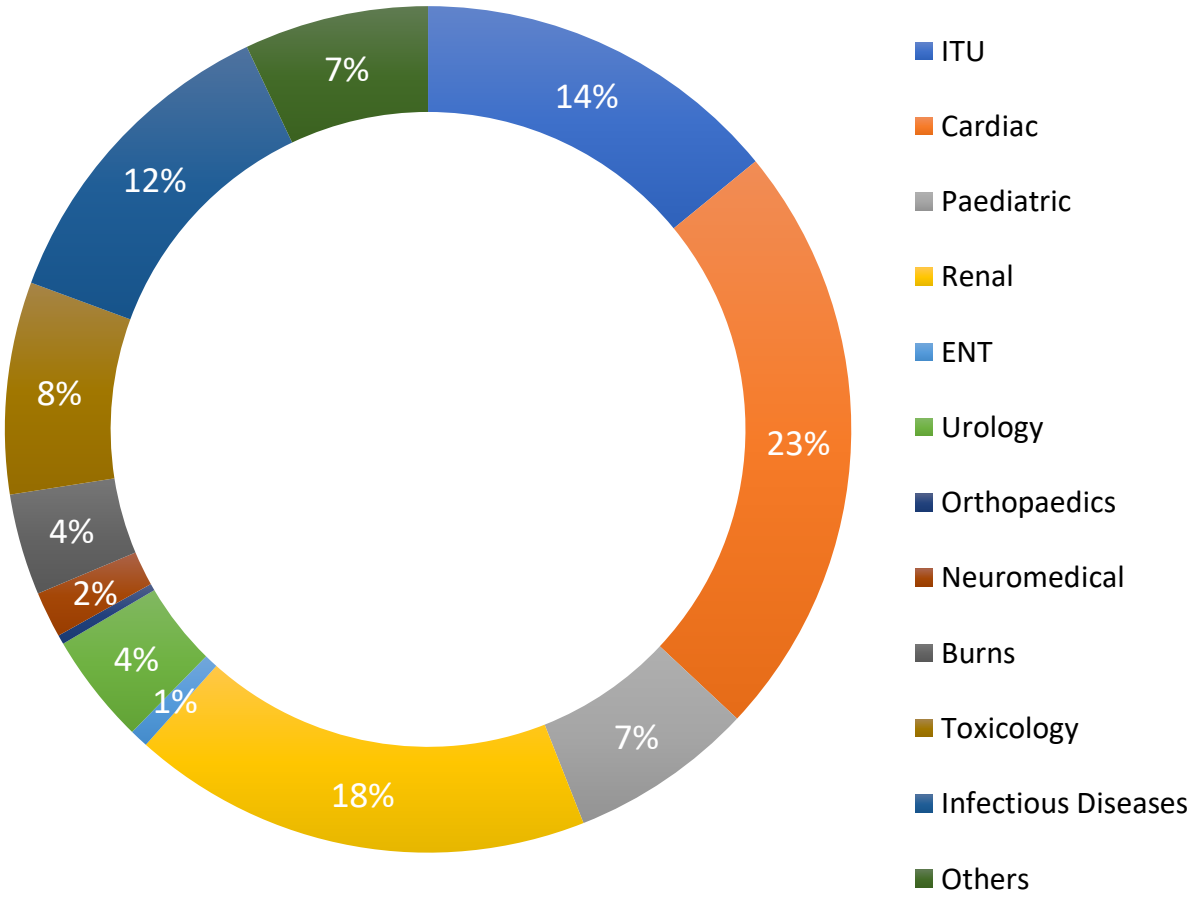

Figure 3.9: Wards request DI queries during shift hours (N=284)

DI queries were most commonly forwarded by Cardiac ward (23%) followed by Renal ward (18%), ITU (14%) and Infectious Diseases ward (12%)

Most queries were forwarded from the Cardiac ward followed by the Renal ward amounting to 23% and 18% respectively. Fourteen percent (14%) were forwarded from ITU and 12% from Infectious Diseases Unit. Other wards which request DI queries include Paediatric, ENT, Urology, Orthopaedics and Toxicology.

All queries to shift pharmacists are forwarded by nurses. Consultants and Medical Officers are not present in wards after hours so queries do not arise from these healthcare professionals.

During the 8-week observational study at the ITU, 140 queries were forwarded to the pharmacist at patient bedside. During an 8 week shift analysis, 40 queries were forwarded to the pharmacist working after hours.

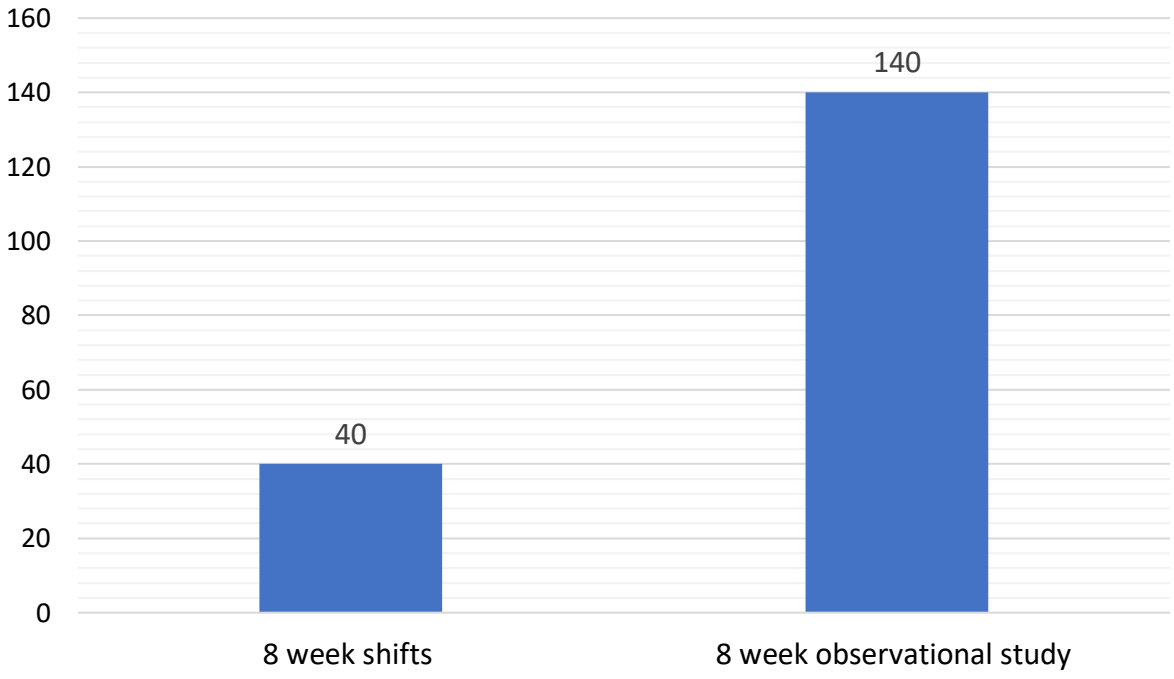

Figure 3.10: Queries arising from ITU

CHAPTER 4

DISCUSSION

4.1 Bedside DI point of care system

Improving medical service at the bedside point of contact is the most important aim of healthcare. Healthcare professionals working at patient bedside need the greatest access to all the available information. Pharmacists at bedside have the main role to provide the necessary information on drugs and intervene in cases where treatment of patient is not ideal. To ensure medication safety and prevent errors and data losses, many hospitals have converted their bedside point of care processes from paper-based charts to integrated electronic systems.

Improving patient safety and accuracy throughout a hospital or clinic has become a prime concern throughout the healthcare industry. Medication administration errors result in drug related problems, which sometimes may be fatal. The role of the pharmacist at bedside is to prevent these drug related problems. Accessing evidence-based and up-to-date information at ward level is essential.

Bedside point of care systems utilise several core components:

i. Mobile Computer: pharmacists doing wards rounds need a portable bedside computer with easy access to all available resources
ii. Wireless Infrastructure: Information needs to be accessible at all times and updated, for which a robust wireless infrastructure is required
iii. Resources: most online resources have a login point to have access to full range of information. Having more than one access point is needed so that different pharmacists in different wards can access the same resource at the same time. The more resources available, the more easily accessible the information is at patient bedside

iv. Patient History: accessing patient history, test results and medication list at bedside is important. This ensures that all changes made to a patient intervention are updated and easily accessible to users. Having a computerised system, rather than paper based, ensures that all patient history is available without the risk of it becoming lost. This is mostly useful when the patient has been in hospital for a long time and many interventions have occurred during the stay.

4.2 Evidence-based Medicine Information

Evidence-based medicine information places emphasis on the use of literature to guide recommendations in clinical practice. Evidence-based medicine is defined as the conscientious use of current best evidence in making clinical decisions about the care of patients. The practice of evidence-based medicine means integrating individual clinical evidence from a systematic research (Sackett et al, 1996). Evidence-based medicine applies current evidence in practice with clinical expertise and patient values as given in figure 4.1.

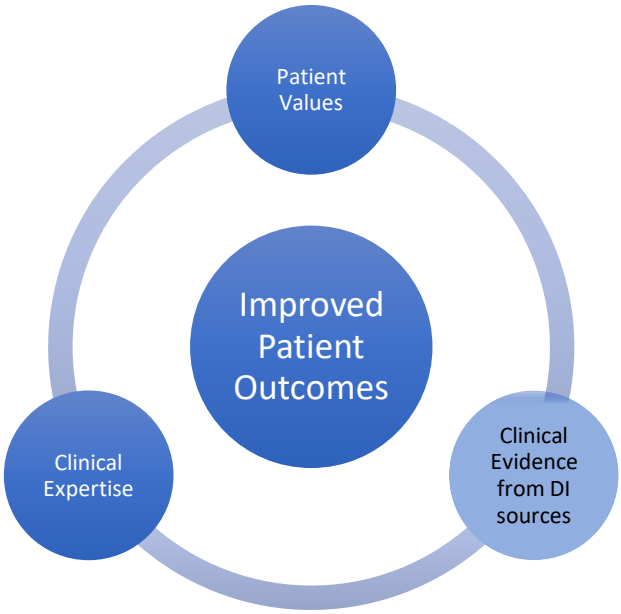

Figure 4.1: Principles of evidence-based medicine practice

Literature and efficient retrieval and assessment of drug information sources play a vital role in improving patient outcomes. It is also essential to use clinical expertise gained through practice to evaluate the DI sources found in the least time possible to eventually have an answer which can be presented to healthcare professionals at patient bedside to come up with the best way forward regarding the patient. Without clinical expertise, practice risks becoming overcome by evidence because evidence presented may not always be applicable and appropriate to the individual patient. In the same way, without current best evidence, practice may become rapidly outdated to the detriment of the patient.

Healthcare professionals especially consultants and medical officers may question the recommendations put forward during ward rounds and find evidence for their reasoning. They might also want to know if there is a more favourable intervention as recommended by literature and evidence. The pharmacists' main role at patient bedside is therefore to search the available literature, evaluate the evidence found and incorporating this evidence with the expertise about medicines into patient care (Guyatt et al, 2012).

Clinical practice has changed to focus on the quality of care the patient receives with the use of evidence-based drug information. The use of DI resources by pharmacists at bedside provide a response focused on patient-oriented evidence rather than disease states since giving recommendations on disease states may not result in the best long-term patient outcomes.

4.3 Barriers to Evidence-Based Medicine Information Access

Incorporation of evidence-based medicine information in practice is growing due to the number of benefits seen when applying this information. It promotes recommendations that have been peer reviewed which helps decrease the use of ineffective recommendations and has the ability to improve the quality of care provided to the patients (Guyatt et al, 2008).

Lack of confidence in literature evaluation and lack of resources are two main barriers to evidence-based DI access. In a study by McKenna et al, practitioners carrying out ward rounds without the presence of a pharmacist as part of the team, did not fully implement evidence-based information in the practice but only used their experience to suggest recommendations (McKenna et al, 2014). In a separate study that evaluated drug information use for Australian practitioners, the primary barrier identified was lack of time. Lack of time in general was cited as a barrier for searching literature, evaluating the literature and the DI sources and discussing the recommendations with the multidisciplinary team. The use of mobile technology and online resources has reduced several of these barriers.

Systematic reviews, clinical practice guidelines and electronic databases summarise the evidence available for practitioners and pharmacists by using quick references and therefore point-of-care use. A healthcare team may lack a pharmacist at bedside and may come across a problem in that there is no access to high-quality evidence-based DI available. As pharmacists and DI resources on a mobile computer or a personal digital assistant (PDA) at bedside are included in the healthcare team, this barrier to practice will be reduced (Haynes et al, 1999).

4.4 Challenges to the Decision Making on the Rational Use of drugs

Organisational and funding issues to provide rational drug use remain the responsibility of governments and health care systems. The responsibility in prescribing rational drug therapy depends on the individual prescribers. The use of polypharmacy has increased, resulting in an increase in drug expenditure (Hovstadius et al, 2010), the risk of adverse drug reactions, drug interactions and medication nonadherence (Hovstadius et al, 2013).

Many questions arise in clinical care. In 2015, Covell et al observed that physicians raised two questions for every three patients seen in an acute inpatient setting. In 70% of the cases, these questions were not answered when a pharmacist was not present during ward rounds (Covell et al, 2015). A more recent research has produced similar results, with little improvement since Covell's study was published. According to a systematic review, estimates ranged from 0.2 to 1.9 clinical questions per patient seen, with over 60% of questions not being answered when a pharmacist was not present at patient bedside.

Clinical pharmacists at Mater Dei Hospital are only available in 3 wards, these being paediatric, infectious diseases and rheumatology. The consultants who participated in the focus group have no pharmacist as part of their bedside team while doing ward rounds. They reported spending a mean of 20 to 30 minutes pursuing questions with their team that arise in clinical care, especially when such queries need to be forwarded to the DI centre. These consultants reported that a clinical pharmacist during ward round is the most ideal scenario since drug information queries at patient bedside are forwarded to them reducing the time to take a clinical decision, especially in complex

questions. According to Cook et al, the presence of clinical pharmacists during ward rounds reduced the time to take a clinical decision to 10 minutes (Cook et al, 2013).

Lack of time and the questions not being urgent or important for the patient's care are common barriers to pursuing a DI request at patient bedside. Complexity of patients' comorbidities and contexts, as well as constantly changing resources are limitations to pursue clinical questions.

Pharmacists providing DI, both at patient bedside and after hours as shift pharmacists have time constraints. The role of clinical pharmacists and shift pharmacists is not only limited to DI provision. As concluded in the focus group, shift pharmacists dispense medication to discharged patients, refill emergency trolleys and medicine reconstitution. Clinical pharmacists in Malta who are involved at patient bedside also form part of the DI centre since both entities are combined. Apart from DI queries which have been requested at patient bedside and have not been answered at patient bedside, these clinical pharmacists might also have DI requests forwarded to the DI centre. Due to the other roles these DI providers might have, not enough time might be provided to DI requests forwarded from patient bedside.

DI requests might need to be backed up with background information such as patient information which is also not always readily available not even at patient bedside since patient medical history and treatment chart is recorded mostly manually which may sometimes be lost or misplaced. The iSOFT programme is sometimes used to access this missing patient information but when the necessary patient data is not inputted, this might still be lacking. This was pointed out by a clinical pharmacist during the focus group: 'Not all of the required information is available there and then

and this might require the pharmacist needing to leave the ward round to research and then return at a later time. This leaves a time gap for DI access and for queries to be answered'

During the focus group it was concluded that 2 clinical pharmacists, 1 shift pharmacist and 2 DI pharmacists find lack of DI training as a limitation for DI access. Providers at MDH are given a 2-week training in DI before becoming DI providers but it might need to be made more effective to help in the improvement of DI access. DI pharmacists and clinical pharmacists in international hospitals are all trained before specialising in their area, with each hospital formulating a training dossier to be completed by all pharmacists taking a role in DI. At both hospitals in Chicago, all pharmacists initially spend six months as residents undertaking DI services as part of their Doctorate in Pharmacy degree and another six months training programme before becoming DI pharmacists or clinical pharmacists.

As the availability of drug information resources increases online, pharmacists' access to both scientific and information on diagnosis and treatment, along with other health issues increases. A number of scientific articles is published daily. Alper et al estimated estimated that to keep current in primary care by reading articles, health care professionals have to read 7287 articles monthly, spending a mean of 29 hours per weekday reading (Alper et al, 2004). Clinical guidelines and SPCs are intended to help healthcare professionals make the correct treatment decisions. As patients' multimorbidity and complexity of drug therapy increases, physicians are faced with many guidelines and literature none of which satisfy the need for information adapted to the specific clinical situation.

The situation with DI resources at Mater Dei Hospital is a limiting factor to the providers of DI, both at patient bedside and when shift pharmacists provide DI after hours. During the focus group, the pharmacists stated that only about 25 books and 10 online sources are available. The books available are not all updated to the latest version and in these cases, the pharmacists might need to acquire their own personal copy to have access to updated resources. The online sources available are also limited and the mostly used resource, Micromedex®, only has one access point. This means that if one pharmacist is using Micromedex®, no other pharmacist can use that same source at the same time. A shift pharmacist pointed out during the focus group that 'Another limitation not limited to after-hours only but also to pharmacists at patient bedside is that MDH has limited access to primary literature such as PubMed articles. Some pharmacists have access to these articles from their University of Malta accounts but when the pharmacists graduate this access is lost. MDH needs its own access to primary literature and must not rely on that provided indirectly by UOM indirectly'

When compared to other hospitals offering DI services, MDH has limited number of DI resources. The reason for the lack of access points and lack of updated resources at MDH might be the financial burdens and budget restraints.

Pharmacists carrying out ward rounds in hospitals visited at Chicago all have access to a bedside portable computer. This computer in turn has access to all the online DI resources available at the DI centre. 'Limited access to a bedside computer having all the necessary resources' was a limitation pointed out by clinical pharmacist who carry out ward rounds at patient bedside. This results in pharmacists 'using up their own personal internet access and portable tablets or phones to access the DI resources'. 'Slow IT access' is also an issue in the other sections where DI is provided.

During the 8-week observational study at the ITU, Wi-Fi access was not an issue since, though slightly slow, this was available throughout the ward. At this ward level, a bedside portable computer was not available. Other fixed computers were present in each section of the ward but most of the time it is not available for use since consultants, house officers, nurses or any other member of the healthcare team would be using it to check any patient test results or to carry out other tasks and therefore it would not be always readily accessible for the pharmacist. When it is available, the pharmacist needs time to log into the account, log into the DI resources and access the resource accordingly. This process has to be repeated for each computer used by the pharmacist.

4.5 Recommendations to Improved DI access

From the limitations and barriers as found from the study, the following recommendations can be brought forward to help improve the DI access at patient bedside on a local scenario:

a. Inclusion of a Clinical Pharmacist at Patient Bedside
b. DI services as standalone
c. Continual Professional and Service Development
d. Inclusion of Ask Watson as a Resource at Patient Bedside

Clinical pharmacy has spread out drastically in terms of its professional services throughout the past few years and it has been renowned as an important profession in the multidisciplinary setup of health care. Clinical pharmacists have the precise knowledge about therapeutics and regular interaction with prescribers therefore they are placed to bridge the gap between patients and physicians. Clinical pharmacists should therefore be included in all wards around Mater Dei Hospital. Apart from being standalone entities, international

hospitals including UIC and Northwestern Memorial Hospital in Chicago both have clinical pharmacists in all wards.

The addition of a pharmacist to the physician-led ward round has provided evidence of improved prescribing quality in other clinical settings. A pharmacist added to the physician-led rounding team has been shown to reduce preventable ADEs by 78% in a general medical unit and 66% in an intensive therapy unit. The presence of a pharmacist on a physician-led general medical ward round shortly after admission has also been shown to improve the accuracy of drug history documentation, reduce prescribing costs and decrease the potential risk to patients.

Recommendations regarding drug choice, dose and need for drug treatment were the most common interventions leading to optimization of treatment for individual patients. There is evidence that suggestions made by a pharmacist on a ward round are adopted; in two studies, the rate was 98% and 99% (Mulvogue et al, 2017).

The importance of the inclusion of a pharmacist at patient bedside and its role in accessing DI was given during the 8-week observational study at the ITU. Since the healthcare team at the ITU and even other wards changes weekly, having a fixed pharmacist may help in accessing DI and answering such requests in a shorter time. Since the multidisciplinary team at bedside changes, DI requests might be repeated by a different professional. Pharmacists may also intervene if any decision taken by the healthcare team is seen inappropriate. As given in Table 3.5 and Table 3.6, since the pharmacist was the only fixed healthcare professional throughout the ward rounds at ITU, having a pharmacist at patient bedside

improves patient care. Responses to DI queries, especially those which are repeated from one ward round to another is given in a short time. The pharmacist also intervened in any actions taken by the medical team which were not considered ideal by the pharmacist. Without the pharmacist intervention, there could have been medication errors or drug related problems. International hospitals including the UIC Hospital and NW Memorial Hospital have clinical pharmacists specifically based at bedside to provide DI services or any other clinically related role at ward level.

A shift pharmacist who provides DI after hours and who participated in the focus group suggested the presence of a dedicated DI pharmacist also at shift hours. *'The best scenario is to have a dedicated DI pharmacist who answers queries after-hours with all the necessary resources available. Such a pharmacist can also go up to the wards to answer DI queries which might not make it to the pharmacy. By having a pharmacist at ward level, the query can be answered better because all the necessary background information is available. This might be difficult due to budget restraints.'*

The DI service at patient bedside should also be made as a standalone service. Both DI services should be staffed by pharmacists trained effectively depending on the section. Both standalone sections should have the same types and amounts of resources, with bedside services mostly have online resources which are easily accessible via a portable bedside computer. The provision of tablets and improvement in WiFi access should be considered as a recommendation to improve DI access.

A recommendation brought up in the focus group is the collaboration between different DI centres around Europe, during which specific cases may be discussed.

An effective DI training programme was formulated by the American Society of Hospital Pharmacists[9]. The main goals needed to be achieved by the DI providers are to:

- Apply advanced literature analysis skills to evaluate and effectively communicate evidence-based information
- Search the proper literature and DI resources depending on the request forwarded
- Create pertinent, evidence-based medication information for health care professionals
- Provide effective information and education on medication-use issues to the public
- Manage the use of study drugs according to established protocols and the organisation's policies and procedures
- Utilise appropriate procedures in documenting DI requests and responses

This training programme should be implemented in the local scenario to help provide pharmacists with effective training and DI practice. At UIC, weekly journal clubs are held during which different journals related to different topics are presented and discussed. This should be implemented locally at MDH since it allows pharmacists, both ward-based and DI centre based, to continually develop knowledge related to DI which eventually helps them improve their access to DI.

[9] American Society of Hospital Pharmacists ASHP. Educational Outcomes, Goals, and Objectives for Postgraduate Year Two (PGY2) Pharmacy Residencies in Drug Information [Internet]. [cited 2018 October 10]. Available from: https://www.ashp.org/-/media/assets/professional-development/residencies/docs/pgy2-drug-information.ashx

The inclusion of Ask Watson™ when answering the bedside DI queries helped improve the time taken to get a response. As medical literature expands, clinicians' and pharmacists' responsibility to stay updated with the most recent information is important but difficult due to time constraints. Ask Watson™ applies artificial intelligence to help change how to approach and understand clinical information in a more facilitated way. Ask Watson™ improves times for DI access due to the AI-powered search technology directly from Micromedex®. Clinical concepts necessary at patient bedside are available in Ask Watson™ and users have more flexibility to ask questions in a natural and more conversational way, such as: "What's the dose of rivaroxaban for DVT?" or "Are there renal dosing adjustments?" Ask Watson™ answers many DI questions from specific content within Micromedex®, which is the source mostly used at patient bedside and is therefore a reliable source among clinical pharmacists. Being combined to Micromedex®, Ask Watson™ contains evidence-based content which helps support clinical decision.

4.6 Strengths of the Study

This study is innovative and it tackles two aspects simultaneously. It is the first study to consider and evaluate all local DI services, these being DI centre, DI at patient-bedside and DI at shift hours. Secondly, apart from the comparison carried out among the 3 sections, an innovative hands-on prospective study related to DI services was carried out in an acute setting. The ITU is the most acute ward within MDH and this clinical area was considered the most ideal for this study since treatment and patient interventions should be carried out in the least possible time. Timely access to DI is required an asset in this acute setting.

4.7 Limitations of the Study and Recommendations for Further Studies

i) Literature about DI services and DI access at patient bedside was limited especially that related to scenarios from different countries. In cases where literature was found, data was outdated since no recent articles within the past 5 years was available.

ii) The second part of the method consisted of a focus group which brought together users and providers of DI working only at MDH. Pharmacists from other local hospitals were invited but could not attend the focus group on the date chosen. Due to time constraints, the focus group had to be carried out without the presence of these pharmacists.

Future similar studies should be expanded by considering more pharmacists from different wards not only from within MDH but also from other non-governmental hospitals. This helps provide feedback on the different DI accessibility procedures and positive points from each scenario may be implemented in others resulting in a standard procedure.

iii) The 8-week prospective study was carried out in one ward. Different wards may have resulted in different types of queries. Similar studies to be carried out in the future may consider other wards to observe the DI access with the current resources in another scenario.

4.8 The Future of DI services

The role of DICs may change according to the needs of the users. Clinical decision support systems integrated in prescribers' software may cover patient-specific information needed such as pop up of alerts if 2 interacting drugs are combined. Such systems will never fully replace the need for DICs question and answer services because there are many possible drug-related questions. No other drug information source can take patient-specific data such as comorbidities, severity of disease,

organ function, age and use of other drugs into account as DICs do. Personal contact between enquirer and the DIC pharmacist can ensure an adapted response to a specific case.

The increasing use of bedside tablet computers and smartphones and the developments of apps for healthcare professionals mean that DICs are a part of the rapid development taking place in health information technology. The possibility of a two-way communication between enquirer and DICs through chat functions and telephone services must be promoted.

4.9 Conclusion

The main conclusions from this study are:

1. Ask Watson improved the time taken to answer drug information queries and should be included as one of the resources available at patient bedside.

2. Micromedex is the mostly used resources by pharmacists providing drug information services at Mater Dei. A one access point between all pharmacists within the hospital is a limitation and this should be increased to help improve DI access. Unlimited access to updated DI resources should be offered at bedside, ideally with the same resources found at the DI centre being found at patient bedside. This prevents the referral of DI queries to the DI centre resulting in queries being answered in a shorter time. A more effective clinical decision can therefore be taken directly at bedside resulting in decreased drug costs and a reduction in hospital stays.

3. The availability of pharmacists at patient bedside improves patient outcomes. An effective way to access DI and give an answer to a query presented at bedside in the shortest time possible is the availability of efficiently trained pharmacists at wards with a standalone service offered at bedside.

References

Adibe M. Assessment of attitude and behaviour of health professionals towards provision of Drug Information Services in Enugu State. International Journal of Drug Development & Research. 2010;2(3).

Ajanandh M., Ramasamy C. Assessment of Drug Information Services in a South Indian Tertiary Care Hospital. International Journal of Pharmacy and Pharmaceutical Sciences. 2011;3(3):273276.

Alper BS., Hand JA., Elliott SG., How much effort is needed to keep up with literature relevant to primary care? J Med Libr Assoc. 2004; 92: 429-437.

American Society of Health-System Pharmacists. ASHP Statement on the Pharmacist's Role in Clinical Informatics. Am J Health-Syst Pharm. 2016; 73: 410-413.

Bahri P. Public pharmacovigilance communication: a process calling for evidence-based, objective-driven strategies. Drug Saf 2010; 33 (12): 1065-1079.

Beaird SL, Coley RMR, Crea KA. Current status of drug information centers. Am J Hosp Pharm. 1992;49(1):103-106.

Beena G, Padma GM Assessment and Evaluation of drug information services provided in a South Indian teaching hospital. Indian Journal of Pharmacology, 37(5), 2015, 315-319.

Bernknopf AC, Karpinski JP, McKeever AL et al. Drug information: from education to practice. *Pharmacotherapy* 2009; 29(3): 331-346.

Bond CA, Raehl CL. 2006 National clinical pharmacy services survey: clinical pharmacy services, collaborative drug management, medication errors, and pharmacy technology. *Pharmacotherapy*. 2008;28(1):1–13.

Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacist staffing, and drug costs in United States hospitals. *Pharmacotherapy*. 1999;19(12):1354–1362.

Cassar J, Azzopardi LM. Documentation and Analysis of After-Hours Drug Information requests in a general hospital. Journal of Euromed Pharmacy 2016.

Chhetri A, Palaian S, Mishra P. Drug information services in Nepal: The changing perspectives. Kathmandu University Medical Journal. 2008;6(1):117-121.

Cook DA., Sorenson KJ., Wilkonson JM., Berger RA., Barriers and decisions when answering clinical questions at the point of care: a grounded theory study. JAMA Internal Medicine 2013; 173: 1962-1969.

Covell DG, Uman GC, Manning PR. Information needs in office practice: are they being met? Ann Intern Med 2015; 103:596–599.

Dunn SP, Birtcher KK, Beavers CJ, Baker WL, Brouse SD, Page RL. The role of clinical pharmacist in the care of patients with cardiovascular disease. J Am Coll Cardiol 2015; 66: 2129-2139.

Fass JA, Carvajal M, Polen H et al Knowledge, use and decision-making considerations for drug information resources in community and hospital pharmacies. Poster presented at ASHP Midyear Clinical Meeting; December 2012; Las Vegas NV.

Fox BI., Thrower MR., Felkey BG. Building core competencies in pharmacy informatics. Washington DC: American Pharmacists Association; 2010.

Gabay M. The clinical practice of drug information. 1st ed. Jones & Bartlett Learning; 2015.

Gershman JA, Fass AD. Medication Safety and Pharmacovigilance Resources for the Ambulatory Care Setting: Enhancing Patient Safety. Hosp Pharm 2014 April; 49 (4): 363-368.

Ghaibi S., Ipema H., Gabay M. ASHP Reports - Pharmacist's role in providing drug information Am J Health-Syst Pharm 72; 575). 2016.

Guyatt G, Rennie D. Users' Guide to the Medical Literature: A manual for evidence-based clinical practice. Chicago, IL AMA Press: 2012.

Guyatt G, Oxman A, Vist GE et al GRADE: what is the quality of evidence and why is it important to clinicians? BMJ 2008; 336 (7651): 995-998.

Haynes B, Haines A. Challenges to using evidence-based medicine in daily clinical practice. Sem Med Pract 1999; 2(3): 21-24.

Hedegaard U, Damkier P. Problem-oriented drug information: physicians' expectations and impact on clinical practice Eur J Clini Pharmacol 2009; 65: 515-522.

Hovstadius B, Hovstadius K, Astrand B, Petersson G. Increasing polypharmacy – an individual based study of the Swedish population 2005-2008. BMC Clin Pharmacol. 2010; 10:16.

Hovstadius B, Petersson G. The impact of increasing polypharmacy on prescribed drug expenditure – a register-based study in Sweden 2005-2009. Health Policy. 2013; 109: 166-174.

Jacobi J. Clinical Pharmacists: Practitioners who are essential members of your clinical care team. Critical Care Clinical Pharmacist. 2016;27(5):571-577.

Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care, a systematic review Arch Intern Med 2006; 166: 955-964.

Kinky DE, Erush SC, Laskin MS, Gibson GA. Economic Impact of a Drug Information Service. *Annals of Pharmacotherapy*, 20099 *33*(1), 11–16.

Klopotowska JE, Kuiper R, van Kan H, de Pont AC, Dijkgraaf MG, Lie L. On ward participation of a hospital pharmacist in a Dutch intensive care unit reduces prescribing errors and related patient harm: an intervention study. Crit Care 2010. 14: 174.

Kopp BJ, Mrsan M, Erstad BL, Duby JJ. Cost implications of and potential adverse effects prevented by intervention of a critical care pharmacist. Am J Health-Syst Pharm 2017; 64: 2483-2487.

Kucukarslan SN, Peters M, Mlynarek M, Nafzige DA. Pharmacists on rounding teams reduce adverse drug events in hospital general medicine units. Arch Intern Med 2013; 163: 2014-2018.

Lyrvall H, Nordin C, Jonsson E, Alvan G. Potential savings of consulting a drug information centre. Ann Pharmacother 2013; 27: 1540.

Malone PM, Kier KL, Stanovich JE, Drug Information: a guide for pharmacists, 4th edition New York: Mc Graw-Hill; 2012.

Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

Maxwell S. Rational prescribing: the principles of drug selection. Clin Med (Lond) 2009 October; 9 (5): 481-485.

McKenna H, Ashton S, Keeney S. Barriers to evidence-based practice in primary care. J Adv Nurs 2014; 45(2): 178-189.

Mulvogue K., Roberts JA., Coombes I., Cottrell N. The effect of pharmacists on ward rounds measured by the STOPP/START tool in a specialized geriatric unit. Journal of Clinical Pharmacy and Therapeutics. April 2017; 42, 2: 178-184.

Närhi U, Pohjanoska-Mäntylä M, Karjalaienen A, Saari JK, Wahlroos H, Airaksinen MS et al The Darts tool for assessing online medicines information. Pharm World Sci. 2008 December; 30 (6): 898-906.

Rajanandh MG, Varghese R, Ramasamy C. Assessment of Drug Information Services in a South Indian Tertiary Care Hospital in Kanchipuram District. International Journal of Pharmacy and Pharmaceutical Sciences 3(3), 2011, 273-276.

Rosenberg JM, Martino FP, Kirschenbaum HL, Robbins J. Pharmacist-operated drug information centers in the United States—1986. Am J Hosp Pharm. 1987;44(2):337-244.

Sackett D, Rosenberg WM, Gray JA et al. Evidence-based medicine: what it is and what it isn't *BMJ* 1996; 312 (7023): 71-72.

Schnipper JL, Rothschild JM. Improving medication safety. Lancet 2012 April; 379 (9823): 1278-1280.

Sreekanth S, Sreekanth D. Need and Importance of Drug Information Centres in Indian Hospital System. International Journal of Medicine and Health Profession Research2. 2015;2(1):9-16.

Sridevi K, Subbaiah V, Surekha M, Harini J, Chandini S, Basher S et al. Clinical Pharmacist Role in Drug Information Services and Medication Errors Management at the Tertiary Care Hospital. Journal of Dental and Medical Sciences. 2017;16(6):16-23.

Strand LM, Morley PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: their structure and function. DICP Ann Pharmacother 1990; 23: 1093-1097.

Vaida AJ, Lamis RL, Smetzer JL, Kenward K, Choen MR, Assessing the state of safe medication practices using the ISMP Medication Safety Self-Assessment for Hospitals: 2000 and 2011. Joint Commission. J Qual Patient Saf. 2014 February; 40 (2): 51-67.

Wang F, Troutman WG, Seo T Drug Information education in doctor of pharmacy programs. Am J Pharm Educ 2006; 70 (3): 51.

Watanabe AS, McCart G, Shimomura S. Systematic Approach to drug information requests. Am J Hosp Pharm. 1975; 32: 1282-1285.

Wojas A, Graham A. Drug Information Services: The Answer to Your Drug Related Questions. American Family Physician. 2009;80(7):670-672.

Wright SG., LeCroy RL., Kendrach MG., A review of the three types of biomedical literature and the systematic approach to answer a drug information request *J Pharm Pract* 1998; 11 (3): 148-162.

Zhang C, Zhang L, Huang L, Luo R, Wen J. Clinical Pharmacists on medical care of paediatric inpatients: A single centre randomized controlled trial. PlosOne 2012; 7(1).

Appendix 1

Tremfya® New Drug Executive

Tremfya (Guselkumab; Janssen Pharmaceutica NV)
100mg/ml single dose prefilled syringe

Introduction

Tremfya (guselkumab) is an interleukin (IL)-23 blocker that was approved by the Food and Drug Administration (FDA) in July 2017.[1,2] Guselkumab is used to treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy of phototherapy. IL-23 is a cytokine involved in the normal inflammatory and immune responses. Guselkumab is a fully human monoclonal IgG1 antibody that selectively binds to the p19 subunit of the IL-23, inhibiting it from binding to the IL-23 receptor and preventing downstream release of the pro-inflammatory cytokines such as IL-17A and chemokines.

FDA-approved and off-label use(s)

Guselkumab is approved for treatment of moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. No off-label uses have been established yet.[3] Guselkumab is the first selective IL-23 blocker to become available in the US.[2]

Dosing, Administration and Availability

Guselkumab is available as a 100mg/mL single-dose, prefilled syringe. It is a clear and colorless to light yellow solution that may contain small translucent particles. Guselkumab is administered by subcutaneous injection and each prefilled syringe is for single-dose only.[4] The recommended dose in adults is 100mg at week 0, week 4 and every 8 weeks afterwards.[3,5]

Special Populations

Pregnancy and Lactation: No data is available on the use of guselkumab in pregnant women. Whether guselkumab is present in human breast milk is not known but human IgG antibodies cross the placenta and can be found in breast milk.[2]

Paediatric and Geriatric Use: The safety and efficacy in paediatric patients less than 18 years of age have not been established. No overall differences in safety and efficacy were observed in geriatrics but the number of subjects was not sufficient to have a confirmed conclusion.[4]

Clinical Efficacy

Three trials were carried out in patients with moderate to severe psoriasis. In the NAVIGATE trial ($p<0.001$), 871 patients received open-label treatment with the IL-12/23 antagonist ustekinumab at weeks 0 and 4. After 16 weeks, 268 patients whose psoriasis had not adequately responded to ustekinumab were randomized to receive guselkumab or continue ustekinumab every 4 weeks for another 24 weeks. Patients who had switched to guselkumab had clear or almost clear skin at more visits between weeks 28 and 40. 51.1% of patients on guselkumab achieved a ≥90% reduction in the Psoriasis Area and Severity Index score (PASI 90) at week 52, which is more when compared to the 24.1% of those who continued receiving ustekinumab and achieved a PASI 90. [6]

In a double-blind trial VOYAGE 1 ($p<0.001$), 837 patients were randomized to treatment with guselkumab, adalimumab or placebo. At week 16 more patients had achieved a PASI 90 response with guselkumab (73.3%) than with adalimumab (49.7%) or placebo (2.9%). Guselkumab patients were also significantly more likely to have clear or almost clear skin at week 16 (85.1%) than those who received adalimumab (65.9%) or placebo (6.9%).[7]

In an open-label extension trial VOYAGE 2 ($p<0.001$), 112 patients enrolled in VOYAGE 1 whose psoriasis had not responded to adalimumab by week 28 were switched to guselkumab. After 20 weeks, 66.1% of these patients had achieved a PASI 90 response.[8]

A double-blind 24-week trial conducted in Japan was also carried out to show effectiveness of guselkumab. Participants were patients with moderate to severe plaque psoriasis who did not respond adequately to conventional treatments. Patients were randomised 1:1 to receive a dose of guselkumab 200mg or matching placebo at weeks 0 and another dose at week 4. The primary efficacy end point was the change from baseline in the PASI total score at week 16. At week 16, the proportion of patients achieving PASI-50 was significantly higher in the guselkumab group (60%) vs placebo group (21%).[11]

Contraindications

Specific contraindications have not been reported.[3,4]

Warnings and Precautions

Guselkumab should not be used concomitantly with live vaccines.[3] Prior to initiating therapy with guselkumab, there needs to be consideration for the completion of all age appropriate immunizations according to the current immunization guidelines. No data is available on the response to live or inactive vaccines.[4]

Active TB or reactivation of latent TB may occur. Patients need to be evaluated for TB infection prior to initiating treatment with guselkumab.[3] In clinical studies, 105 subjects with latent TB who were concurrently treated with guselkumab and appropriate TB prophylaxis did not develop active TB (during the mean follow-up of 43 weeks). Patients need to be monitored for signs and symptoms of TB during and after treatment with guselkumab. Anti-TB therapy should be considered prior to initiating guselkumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Guselkumab is not administered in patients with active TB.[4]

Guselkumab may increase the risk of infection. In clinical trials, infections occurred in 23% of subjects in the guselkumab group through 16 weeks of treatment. Upper respiratory tract infections, gastroenteritis, tinea infections and herpes simplex infections occurred most commonly in the guselkumab group. Treatment with guselkumab should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Adverse Events[5]

Adverse events occurred in 49% of subjects in the guselkumab group compared to 47% of subjects in the placebo group. Serious adverse events occurred in 1.9% of the guselkumab group compared to 1.4% of the placebo group. The following observed adverse events occurred more frequently in guselkumab than in placebo: diarrheoa (1.6% vs 0.9%), headache (4.6% vs 3.3%) and arthralgia (2.7% vs 2.1%)

Infections occurred in 23% of the guselkumab group compared to 21% of the placebo group. The most common were upper respiratory infections (14.3 % vs 12.8%), gastroenteritis (1.3% vs 0.9%), tinea infections (1.1% vs 0%) and herpes simplex infections (1.1% vs 0.5%). All cases did not lead to discontinuation of guselkumab. Elevated liver enzymes were reported more frequently in guselkumab (2.6%) than in placebo (1.9%). From all these cases, all events except one were mild to moderate in severity but none led to the discontinuation of guselkumab.

Drug Interactions

Since guselkumab blocks the IL-23, the formation of CYP isoenzymes and the metabolism of CYP substrates may be affected.[2] Monitoring for therapeutic effect or drug concentration should be considered upon initiation of guselkumab in patients receiving concomitant CYP450 substrates, especially those with a narrow therapeutic index. Patients being treated with guselkumab should not be given live vaccines.[4]

Biologic agents such as infliximab should not be given with guselkumab as this may result in increased immunosuppression and an increased risk of infection.[3]

Guidelines and Alternative Agents

Guidelines for management of plaque psoriasis are published by the American Academy of Dermatology (AAD)[9,10] and the National Psoriasis Foundation (NPF)[9,11].These guidelines do not include guselkumab as a therapeutic agent due to its recent approval and lack of published data on Phase III clinical trials.

Methotrexate, cyclosporine and acitretin are effective oral agents which control many cases of plaque psoriasis. Biologic agents include TNF inhibitors such as adalimumab, etanarcept and infliximab.[11]

Conclusion

Guselkumab appears to be effective and generally safe for treatment of moderate to severe plaque psoriasis. In one clinical trial, it was more effective than the TNF inhibitor adalimumab. In another trial in patients whose disease had not responded to ustekinumab, guselkumab was more effective than continuing ustekinumab. No results have been yet established as to how guselkumab compares to other drug for this indication.[2]

Uncertainties

The majority of patients included in the trials were white and below 65 years of age therefore the number of patients in other races and above 65 years of age was limited. Differences in response among races and between patients above and below 65 years of age could not be determined. Eligible patients for this study (aged ≥18 years, <65 years) had moderate to severe plaque psoriasis for at least 6 months and were candidates for other systemic therapy or phototherapy which was not effective. If patients received previous treatment with adalimumab, other anti-TNF-α or treatment targeting IL-12/23 within 3 months, were excluded from the study.

Formulary Recommendations

The Illinois Department of Healthcare and Family Services Preferred Drug List does not include a category for IL-23 inhibitors but other agents in other categories may be used for plaque psoriasis. This category is Analgesics - Anti-Inflammatory - Anti-TNF-alpha - Monoclonal Antibodies and include:

Preferred Agents

Humira

Non-Preferred Agents

Simponi

Targeting IL-23 and its associated immune cascade with guselkumab may be a safe and useful therapeutic option for treatment of plaque psoriasis. However, since guselkumab is a novel treatment and it has not been compared with many other treatments, use of guselkumab should require prior authorization.

1. Tremfya [Drug Information] CenterWatch; 2017
2. The Medical Letter. Guselkumab for Psoriasis; 2017
3. Guselkumab [Drug Information] www.micromedexsolutions.com/micromedex2/librarian/CS/C35330/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/A39E64/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932290&contentSetId=100&title=Guselkumab&servicesTitle=Guselkumab&brandName=Tremfya# website. Published August 2017. Updated January 2018. Accessed 10 May 2018
4. Tremfya [Full Prescribing Information] Janssen. Website http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf Published July 2017. Accessed May 19 2018
5. Medication Guide. Janssen. Website http://www.janssenlabels.com/package-insert/product-patient-information/TREMFYA-medication-guide.pdf Published July 2017. Accessed May 19 2018
6. RG Langley et al. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase III NAVIGATE trial. Br J Dermatol. 2018 Jan;178(1):114-123
7. A Blauvelt et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. J Am Acad Dermatol 2017; 76: 405.
8. K Reich et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. J Am Acad Dermatol 2017; 76: 418.
9. Psoriasis United States Guidelines www.dynamed.com/topics/dmp~AN~T116742/Psoriasis#Guidelines-and-Resources website Published June 2017. Updated December 2017. Accessed 9 May 2018
10. Menter A, Gottlieb A, Feldmen SR, Van Voorhees AS et al Guidelines of care for the management of psoriasis and psoriatic arthritis Journal of the American Academy of Dermatology, 2008-05-01, Volume 58, Issue 5
11. Hsu S, Alexander K, Lebwohl M et al. Consensus Guidelines for the Management of Plaque Psoriasis https://jamanetwork.com/journals/jamadermatology/fullarticle/1105195 *Arch Dermatol.* 2012; 148(1):95-102
12. Drug Trial Snapshots: Tremfya. Food and Drug Administration. Website https://www.fda.gov/Drugs/InformationOnDrugs/ucm568274.htm Published August 2017. Accessed 9 May 2018

Appendix 2

Email of Recruitment for Focus Group

Good morning,

Hope this email finds you well.

I, the undersigned, am currently in my second year of the post-graduate Doctorate in Pharmacy course and as part of my studies, I am carrying out a research study entitled *'Drug Information Access for Pharmacists' Bedside Decision Making'*.

As part of my study, I will be conducting a focus group consisting of users and providers of drug information. You are therefore invited for this focus group, the details of which are being attached. Kindly read the consultation letter attached as it contains all the necessary details and information to any queries you might have.

If you are interested in attending, kindly fill in the attached consent form and return by email

Do not hesitate to contact me if you have any other queries or if you require any further clarifications.

Best Regards,

Timothy Scicluna

E: timothy.scicluna.11@um.edu.mt
M: 79093577

Faculty Research Ethics Committee (FREC) Approval

L-Università ta' Malta

Faculty of
Medicine & Surgery

University of Malta
Msida MSD 2080, Malta

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

www.um.edu.mt/ms

Ref No: **FREC\MDS_1718_047**

Monday 30th April 2018

Mr Timothy Scicluna
Tamarisk
Triq Guzeppi Montebello
Tarxien TXN2405

Dear Mr Scicluna,

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

Drug Information Access for Pharmacists' Bedside Decision Making

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

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

Focus Group Consultation Invitation

Focus Group Consultation Invitation
Drug Information Access to Pharmacists' Bedside Decision Making

Dear Sir/Madam,

I, the undersigned, am currently in my second year of the post-graduate Doctorate in Pharmacy course and as part of my studies, I am carrying out a research study entitled *'Drug Information Access for Pharmacists' Bedside Decision Making'*.

What is the research about?

Hospitals, including those in the local scenario, have access to drug information (DI) through the drug information centres (DICs). Pharmacists at the patient bedside have different means to access drug information when this is required, with DICs being one of them. The first step of the dissertation is aimed at reviewing and assessing the DIC and access to DI at Mater Dei Hospital and other local hospitals and comparing the results to other foreign hospitals. The models found will then be presented, reviewed and assessed in a focus group.

Purpose of the focus group

The aim of the focus group is for users and providers of drug information to meet and discuss the strengths and weaknesses of current drug information practices, including any limitations and barriers encountered when presenting or answering a query. Ways on how to improve communication for the benefit of the patient's care are discussed. What is being done currently? What are the limitations and barriers met when answering/presenting a query? What can be done to improve communication and eventually improve patient care? These type of questions and other similar ones will be answered during the focus group with the intention to reach a consensus on the ideal practices to be implemented to improve access to drug information at the patient bedside.

Invit u Informazzjoni dwar il-Focus Group
Drug Information Access to Pharmacists' Bedside Decision Making

Għażiż/a,

Jien, hawn that iffirmat, bħalissa ninsab fit-tieni sena tad-Dottorat fil-Farmaċija u bħala parti minn dan il-kors, qiegħed nagħmel riċerka bl-isem *'Drug Information Access for Pharmacists' Bedside Decision Making'*

Fuq xhiex inhi r-riċerka?

Sptarijiet, inkluż dawk fix-xena lokali, għandhom aċċess għal informazzjoni fuq il-mediċina minn ċentri apposta li speċifikament jipprovdu din l-informazzjoni. Spiżjara li jkunu qed iduru fis-swali għandhom mezzi differenti ta' kif jistgħu jaċċessaw din l-informazzjoni meta din tiġi mitluba u dawn iċ-ċentri huma mezz minnhom. L-ewwel pass tar-riċerka għandu l-għan li jiġu mqabbla u evalwati mezzi differenti ta' kif sptarijiet bħall-isptar Mater Dei u oħrajn lokali jakkwistaw din l-informazzjoni u li dawn jiġu mqabbla ma' ta' sptarijiet oħra madwar id-dinja. Eventwalment dawn il-mudelli differenti jiġu diskussi waqt *focus group*.

Għan tal-*focus group*

L-għan ewlieni tal-*focus group* hu li jlaqqa' l-utenti u l-fornituri tal-infomazzjoni fuq il-mediċina biex jiddiskutu u jilħqu kunsens dwar dak li jintuża lokalment, il-mudell ideali u x'jista' jiġi implimentat biex dan l-aċċess jissaħħaħ waqt li l-ispiżjara jkunu ħdejn il-pazjent fis-sala tal-isptar. X'qed isir bħalissa? X'inhuma l-limitazzjonijiet u l-ostakli li jaffaċċaw l-utenti u l-fornituri meta jistaqsu jew iwieġbu mistoqsija rigward medicina? X'jista' jsir biex titjieb din il-komunikazzjoni u eventwalment il-kura tal-pazjent? Mistoqsijiet bħal dawn u oħrajn fuq l-istess linji jiġu mwieġba waqt il-*focus group.*

Formation and tasks of the focus group

As part of my focus group I am recruiting healthcare professionals working at Mater Dei Hospital. These include clinical pharmacists, drug information pharmacists, pharmacists working on a shift basis, nurses and medical practitioners. The focus group will consist of around 12 to 15 members. It is expected to take place on the 22nd of June 2018 at around 3:30pm last around 2 hours. The meeting place is yet to be confirmed. The lead researcher will chair the discussion in the focus group and guide participants through each issue to be explored. There are no right or wrong answers in this discussion since the opinion of each member is all that the researcher is interested in.

What will happen with the results obtained?

The focus group discussion will be recorded by means of a voice recorder and transcribed by the researcher. The transcript will then be analysed qualitatively by looking for common input and recommendations given by the participants. By participating in this focus group, participants would be assisting in the improvement of drug information access while health care professionals are at the bedside of the patient. The results obtained from the focus group will lead to the implementation of a platform to improve access to DI while at the patient's bedside will be implemented. The intention of the researcher is to eventually publish the findings in a peer-reviewed academic journal.

Confidentiality

Please note that names and any identifying information shared will remain confidential. Every participant will be assigned a number at the start of the focus group and this will be used to refer to each individual throughout the focus group and data analysis. Responses will be summarized, compared to other responses and used collectively to help guide decision-making.

X'se jiġri waqt dan il-*focus group*?

Bħala parti mill-*focus group*, se nlaqqa' flimkien professjonisti tas-saħħa li jaħdmu l-isptar Mater Dei. Dawn jinkludu spiżjara kliniċi li jkunu fis-swali, spiżjara li jaħdmu fil-qasam tal-informazzjoni dwar il-mediċina, spizjara li jaħdmu bix-*shift*, infermiera u tobba. Dan il-*focus group* se jkun jikkonsisti f'madwar 12 sa 15-il membru u se jsir fit-22 ta' Ġunju 2018 f'xit-3:30pm. Hu mistenni li l-*focus group* idum madwar sagħtejn. Il-post ta' fejn ħa jsir il-focus group għad irid jiġi konfermat. Ir-riċerkatur ewlieni se jmexxi d-diskussjoni. Peress li din hi diskussjoni, tajjeb li joħorgu ideat differenti u għalhekk mhemmx risposti tajbin jew ħziena. L-għan ewlieni tar-riċerkatur hu li jixtarr l-opinjonijiet tal-parteċipanti fuq is-suġġetti differenti li jiġu diskussi.

X'se jiġri mir-riżultati miksuba?

Id-diskussjoni ta' waqt il-*focus group* se tiġi rrekordjata permezz ta' reġistratur u traskritta mir-riċerkatur. Wara dan, it-traskrizzjoni se tiġi evalwata b'mod kwalitattiv biex jinsiltu l-fatturi komuni li jkunu ntqalu mill-parteċipanti. Meta wieħed jieħu sehem f'dan il-*focus group,* se jkun qed jgħin għat-titjib tal-aċċess tal-informazzjoni waqt li jkun qed jiġi evalwat il-pazjent fis-sala. Il-konkluzjonijiet meħuda minn dan il-focus group iservu bħala spunt biex jigi mtejjeb l-aċċess għall-informazzjoni dwar il-mediċina. L-intenzjoni tar-riċerkatur hi li dawn ir-riżultati jiġu eventwalment ippubblikati f'ġurnal akkademiku.

Kunfidenzjalità

Nixtieq niġbidlek l-attenzjoni għal fatt li l-ismijiet u kull informazzjoni li tista' tindentifika lil parteċipanti, se jinżammu kunfidenzjali. Qabel ma jibda l-*focus* group, kull participant se jingħata numru li se jkun qed jintuża waqt id-diskussjoni u waqt l-analiżi tar-riżultati. Ir-risposti ta' kull partiċipant se jiġu mqassra u wżati kollettivament biex tittieħed deċizjoni. Kollox se jinzamm b'mod anonimu. Ħadd mhu se

No names or identifying information will be used when compiling the information. No one will be informed of who has taken part in the focus group, although there is a possibility that a member of the focus group might be recognized by another. The researcher might quote what is said during the focus group to highlight certain points, but these quotes will not reveal who the person is. All voice recordings will be destroyed once they are transcribed.

Consent

While participation in this focus group is highly appreciated, there is no obligation to participate therefore participation may be refused or withdrawn at any time by notifying the lead researcher. Kindly keep this information sheet for future reference.

No exact date and time have been established yet but when these are set, I will be giving more details about this.

I hope that your participation will be forthcoming and should there be any queries, do not hesitate to contact me.

Contact Details

Name and Surname: Timothy Scicluna
Identification Number: 74093M
Telephone Number: (+356) 21800497
Mobile Number: (+356) 79093577
Address: Tamarisk, Guzeppi Montebello Street, Tarxien TXN2405
Email: timothy.scicluna.11@um.edu.mt

Signature _____

jiġi nfurmat min ħa sehem f'dan il-*focus group*, għalkemm jista' jagħti l-każ li xi parteċipant ieħor jagħrfek. Ir-riċerkatur għandu mnejn jikkwota xi ħaġa li ntqal fil-*focus group* biex jenfasizza xi punt imma bl-ebda mod mhu dan se jikxef l-identità tal-parteċipanti. Kull ħaga li tiġi rrekordjata waqt id-diskussjoni se tiġi meqruda ladarba din tiġi traskritti.

Kunsens

Għalkemm il-parteċipazzjoni hi apprezata ferm, m'hemm l-ebda obbligazzjoni li wieħed jieħu sehem f'dan il-*focus group* u għalhekk hemm kull dritt ta' rifjut jew irtirar tal-parteċipazzjoni f'kull ħin wara li jiġi avżat ir-riċerkatur. Din l-informazzjoni għandha tinżamm għall-użu personali.

Għad m'hemmx indikazzjoni ta' data u ħin stabilliti ta' meta ħa jsir dan il-*focus group* imma kif dawn ikunu iffissati, kull participant se jiġi avżat mal-ewwel.

Grazzi tal-attenzjoni u nispera li nirċievi risposta għal attendenza waqt dan il-*focus group.* F'każ ta' diffikultà jew bżonn ta' xi kjarifika, ninkoraġġixxi kuntatt mieghi

Dettalji fejn nista' niġi kkuntatjat

Isem u Kunjom: Timothy Scicluna
Numru tal-Identità: 74093M
Numru tat-Telefon: (+356) 21800497
Numru tal-Mowbajl: (+356) 79093577
Indirizz: Tamarisk, Triq Ġuzeppi Montebello, Ħal Tarxien TXN2405
Email: timothy.scicluna.11@um.edu.mt

Firma: _____

Consent Form in English and Maltese distributed to Focus Group Participants

CONSENT FORM FOR PARTICIPANTS
FORMOLA TA' KUNSENS GĦAL PARTEĊIPANTI

Title of Research: Drug Information Access for Pharmacists' Bedside Decision Making
Titlu tar-Riċerka*: Drug Information Access for Pharmacists' Bedside Decision Making*

Please complete this form after you have read the Information Sheet and after having clarified the aim of the study with the researcher.
Jekk jogħġbok imla din il-formola wara li tkun qrajt il-karta dwar l-Informazzjoni fuq il-Focus Group u wara li tkun iċċarajt l-għan tal-istudju mar-riċerkatur.

	Initials *Inizjali*
I have understood the aim of the research and any requests for clarification were answered in a satisfactory manner by the lead researcher. *Jien fhimt l-għan ta' dan l-istudju u talbiet għal xi kjarifikazzjonijiet ġew imwieġba b'mod sodisfaċenti mir-riċerkatur.*	
I understand that the findings of the study will be published as part of a dissertation and in a peer-reviewed academic journal. Such publications are to be made available to me by the lead researcher should I ask for them. *Jien nifhem li r-riżultati li joħorgu minn dan l-istudju ħa jiġu ppubblikati bħala parti minn riċerka u eventwalment f'ġurnal akkademiku. Dawn il-pubblikazzjonijiet jistgħu jkun miksuba minghand ir-riċerkatur ladarba jien nistaqsi għalihom.*	
I understand that the results obtained from the focus group will be used exclusively for the purposes of this study and I, therefore, intend to give my honest opinion on the issues being discussed. *Jien nifhem li r-riżultati miksuba mill-focus group ħa jintużaw esklussivament għal għanijiet akkademiċi u għal dan l-istudju u għalhekk ħa nagħti l-opinjoni onesta tiegħi fuq il-kwistjonijiet li jkunu qed jiġu diskussi.*	
I consent for my participation to be voice-recorded. *Nagħti l-kunsens biex din id-diskussjoni tiġi rrekordjata.*	
I consent to the processing of my personal information for the purposes explained to me. *Nagħti l-kunsens biex jiġu pproċessati d-dettalji personali tiegħi għar-raġunijiet spjegati lili mir-riċerkatur.*	
I understand that if I decide to withdraw from the study I can do so with immediate effect and without giving any reason, by notifying the lead researcher. *Jien nifhem li jekk niddeċidi li nirtira minn dan l-istudju, nista' nagħmel dan b'effett immedjat minghajr ma naghti ebda raguni billi navża lir-riċerkatur*	

I,_____
____ confirm that the above mentioned study has been explained to me to my full satisfaction and I **agree/disagree** to be part of the focus group. I have read both this Consent Form and the accompanying Information Sheet and I fully understand what this research involves. I am informed about my right to access, rectify and where applicable erase data concerning me.

Jien,

_____

*nikkonferma li l-istudju msemmi hawn fuq ġie spjegat b'mod ċar u b'mod sodisfaċenti u **naċċetta/ma naċċettax** li nieħu sehem f'dan il-focus group. Nikkonferma li qrajt kemm din il-formola ta' kunsen kif ukoll il-karta bl-informazzjoni relatata mehmuża ma' din. Nifhem kompletament x'tinvolvi din ir-riċerka. Nifhem li għandi d-dritt naċċessa, inbiddel jew inħassar informazzjoni li tikkonċerna lili.*

_____ _____

Signature Date
Firma *Data*

Lead Researcher's Statement:

I, **Timothy Scicluna ID: 74093M** confirm that I have carefully explained the aims and requirements of this research to the participant. No information has been deliberately left out.
Email: timothy.scicluna.11@gov.mt
Mobile: 79093577

Stqarrija mir-Riċerkatur:

*Jien, **Timothy Scicluna ID: 74093M** nikkonferma li spjegajt b'mod ċar l-għanijiet ta' dan l-istudju lill-parteċipant. L-ebda informazzjoni ma tħalliet barra apposta.*
E: timothy.scicluna.11@um.edu.mt
M: 79093577

_____ _____

Signature Date
Firma *Data*

Appendix 3

Focus Group Questions

Drug Information Access for Pharmacists' Bedside Decision Making

Focus Group
22nd June 2018

Drug Information Providers

1. What information resources do you have access to and what types of resources do you use when responding to a DI query?
2. Types of queries received?
3. Average number of queries daily?
4. Average time taken to answer queries?
5. Who uses the services most?
6. What is the approach to answering a DI query?
7. How are requests from clinical pharmacists handled?

Drug Information Users

1. Who do you ask first when such a query arises?
2. How many queries, on average, do you usually have?
3. What topics do you usually ask about?
4. Since no clinical pharmacist is available in your area of specialisation, what is the procedure followed when a DI query arises?

Clinical Pharmacists

1. What queries do you usually encounter at patient bedside?
2. What sources of information do you use at patient bedside?
3. Do you always find the required information when asked? If no, what barriers do you meet which prevent from obtaining this information?
4. What procedure is followed when DI response not found in the available resources?
5. When there is referral to DIC:
a. What is used to ask query?
b. What procedure is followed?
c. How long do you wait for a response?
6. What can be improved? What other sources can be included?

Conclusion Questions

1. What can be improved? What other sources of information do you suggest?
2. Suggestions about a DI framework to help increase DI access at patient bedside.

Questionnaire distributed to experts not available for Focus Group

Drug Information Access to Pharmacists' Bedside Decision Making

I am currently in my second year of the post-graduate Doctorate in Pharmacy course and as part of my studies, I am carrying out a research study entitled 'Drug Information Access for Pharmacists' Bedside Decision Making'. The aim of the questionnaire is for users and providers of drug information to put their thoughts forward and discuss the strengths and weaknesses of current drug information practices, including any limitations and barriers encountered when presenting or answering a query. Ways on how to improve communication for the benefit of the patient's care are to be determined. No names or identifying information will be used when compiling the information. Thank you for your help.

* Required

1. Area of Profession*

After Hours Pharmacist
Clinical Pharmacist
Drug Information Pharmacist
Nurse
Medical Practitioner

2. How often do you receive a drug information query? *

Never
1
2
3
4
5
More than 5 times a day

3. What type of queries do you usually receive? *

Your answer

4. From whom do you get the most queries? *

Pharmacists
Nurses
Medical Practitioners
Other:

5. What resources do you have access to when answering a DI query? *

Your answer

6. How long does it usually take to respond to a DI query? *

Immediately
<10 minutes
10 - 20 minutes
>20 minutes
Other:

7. What is the approach to answering a DI query? *

Your answer

8. How often do you receive requests from clinical pharmacists who are at patient bedside? *

Never
1
2
3
4
5
>5 requests

9. Is the same approach mentioned above used when answering requests from clinical pharmacists?

Your answer

10. What are the main limitations encountered when answering a DI query? *

Your answer

11. What do you suggest should be done to improve DI access? *

Your answer

SUBMIT

Appendix 4

Questionnaire distributed to shift pharmacists

Drug Information Access to Pharmacists' Bedside Decision Making

I am Timothy Scicluna and as part of my Doctorate in Pharmacy dissertation, I am required to gather data from pharmacists working on shift bases in order to compile results regarding drug information given to wards and how this is accessed.

Thank you for your help.

* Required

1. How many Drug Information (DI) queries from wards do you receive during your shift? *

< 5 queries
5 - 10 queries
10 - 15 queries
> 15 queries

2. What type of queries do you mostly receive? Tick all applicable responses *

Evidence Based Recommendations
Product Availability
Contraindication
ADR/Drug Interaction
Product Identification
Drug Comparison
Drug Administration
Pharmacotherapy
Foreign Drug Identification
Calculation
Pharmacokinetics
Other:

3. Who requests the most DI queries from wards? *

Consultants
House Officers
Nurses
Other:

4. What is the average time taken for a DI query to be responded and finalised? *

< 5 minutes
5 - 10 minutes
> 15 minutes
Other:

5. How are resources mostly accessed? *

Online
Hard Copy
Other:

6. What resources are mostly used? *

Micromedex
SPC
Up To Date
BNF
Other:

7. From which wards are most DI queries forwarded? *

Your answer

8. What are the limitations to DI access after-hours? *

Your answer

9. What recommendations would you suggest? *

Your answer

SUBMIT

Appendix 5

List of Publications

78th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Glasgow
September 2018

Title: Drug Information Access to Pharmacists' Bedside Decision Making
Topic Area: Health and medicines information

Background Information

Providing drug information (DI) is a pharmacist professional responsibility. Medication therapy management services have placed pharmacists in complex patient-care roles and in higher levels of competence to meet DI needs.

Purpose

To improve DI access for pharmacists at the patients' bedside.

Method

Literature relating to different DI models globally is reviewed and compared. Taking the positive points from these DI services, an ideal model to respond to a DI query is identified. This is presented to a focus group of users and providers of DI whose feedback is adopted to improve and set up a DI framework. A pilot study is carried out to review its feasibility. This provides pharmacists an easy access to the necessary data to assist in bedside decision-making.

Results

Countries to be analysed include UK and other EU countries, USA, Scandinavia and Saudi Arabia, all having their own DIC. In EU countries, health authorities provide DI resources like the SPC, prescribing rules, data on correct use of medicines and EMA documents to a centralised DIC. Countries like UK and Germany show an advanced framework of evidence-based information since the hospital-based DICs also answer queries to the general public[1]. In the US, only 25% of the DICs provide direct patient care at bedside[2]. The decrease in DICs may be due to the widespread availability of electronic media which serve as a substitute to answer DI queries. Pharmacists at the patient bedside are also receiving better training to handle DI requests.

Conclusion

A pharmacist at the patient bedside promotes patient care by interacting with prescribers and acts as a bridge between patients and physicians. This provides a base for quality assured patient-care.

1 Formoso G., Font-Pous M., Wolf-Dieter L., Phizackerley D., Bijl D., Erviti J., Pospisilova B. et al Drug Information by public health and regulatory institutions: Results of an 8-country survey; Health Policy 121 257-264; June 2017
2 Rosenberg J., Schilt S., Nathan J.P., Zerilli T., McGuire H., Update on the status of 89 drug information centers in the United States; Am J Health-Syst Pharm 66 1718-1721; 2009

X Malta Medical School Conference
December 2018

Introduction

Providing drug information (DI) is a pharmacist professional responsibility. Medication therapy management services have placed pharmacists in complex patient-care roles and in higher levels of competence to meet DI needs. The aim of the study is to evaluate nature, extent and request of DI from clinical in-patient hospital settings and frameworks that improve DI access for pharmacists at the patients' bedside.

Methodology

1. A 3 week observation study was undertaken at the Chicago Hospital at the University of Illinois, USA. Literature on other DI centres is searched.
2. A focus group that consisted of providers and users of DI at Mater Dei Hospital was undertaken to identify a framework that are relevant for the local setting to improve DI access for pharmacists at the patients' bedside.
3. An 8-week pilot study is carried out at ITU at MDH out to review the framework's feasibility.

Results

DICs and clinical pharmacy services are separate entities in Chicago since pharmacists at patient bedside respond to DI queries using a portable bedside computer having all resources as the DIC. At MDH, challenges faced when responding to drug information queries included lack of time, questions not being urgent or important for patient's care, complexity of patients' comorbidities and context and resources changing constantly.

Conclusion

Recommendations include the availability of a bedside tablet with all available resources to all clinical pharmacists and clinical experientials so as to understand better the clinical context of certain queries.

79th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Abu Dhabi
September 2019

Evaluation of Pharmacists' Drug Information Access at Patient Bedside in the Intensive Care Unit

Pharmaceutical practice
Health and medicines information

Background: The provision of Drug Information (DI) is a routine component of the daily practice of a pharmacist and the presence of a pharmacist at the patient bedside has been associated with decreased drug cost and reduction in hospital stays.

Purpose: To evaluate and assess the access of DI by pharmacists at the patient bedside

Methods: A focus group was set up during which users and providers of DI at Mater Dei Hospital (MDH), Malta discussed limitations for DI access at bedside. An 8-week prospective study at the Intensive Therapy Unit (ITU) at MDH was carried out to identify challenges to offer a DI bedside service.

Results: Challenges to DI bedside access as identified from the focus group are WiFi access at ward level and lack of online and updated resources. During the period at ITU, 140 bedside queries were forwarded to the pharmacist. Most were inquired by medical officers (43%), medical consultants (32%) and nurses (16%). Medical officers and consultants queried about Pharmacotherapy such as ADRs and Drug Interactions while queries from nurses included Drug Administration and Dosing. Eight percent (8%) of DI queries were forwarded and completed by pharmacists while reviewing drug treatment charts. Fifty-nine percent (59%) of the queries were answered in less than 5 minutes. Queries which required an in-depth search about a specific topic (14%) were forwarded to respective entities. Micromedex was used to answer 60% of the queries while UpToDate had an answer to 36% of the queries

Conclusion: The presence of a pharmacist at patient bedside improves the time taken to answer DI queries at ward level. DI requests could be tackled by the pharmacist at bedside within 5 to 10 minutes using Micromedex and UptoDate.

European Society of Clinical Pharmacists 2019 Symposium, Ljubljana Slovenia
October 2019

Pharmacist Drug Information Access at Patient Bedside: Using Ask Watson

T. Scicluna, L. Grech, L. M. Azzopardi, M. Buttigieg

Background and Objective: The artificial intelligence (AI) Ask Watson is a new feature within Micromedex intended to improve Drug Information (DI) access. Micromedex combines the AI of IBM Watson with the evidence-based clinical decision support of Micromedex. Ask Watson answers drug questions from specific content within Micromedex. The aim of the study was to evaluate the use of Ask Watson platform when used at the patient bedside.

Design: An 8-week observational study was carried out at the Intensive Care Unit at Mater Dei Hospital (MDH), Malta. During this period, DI requests forwarded by the healthcare team and answers provided by the pharmacist at patient bedside were reviewed. These queries were first answered using online drug information sources including Micromedex and Up to Date, while noting the time taken to access these resources and provide an answer. The same queries were then re-answered using Ask Watson. The time taken to access and answer using this DI platform was noted and compared to the time taken to access and answer using conventional DI resources.

Results: A total of 140 DI queries were presented at patient bedside. Fifty-nine percent (59%, n=83) of the queries were answered in less than 5 minutes using the conventional DI resources. Fourteen percent (14%, n=20) of the bedside queries had to be referred to different sections according to the query specialisation, 7% of which were referred to the DI centre (DIC) at MDH since they were queries about dosing calculations or Total Parenteral Nutrition (TPN) doses. When the Ask Watson platform was adopted to respond to the 140 queries, 78% of the queries (n=110) could be answered at the bedside. Using Ask Watson, 87% (n= 95) were answered in less than 5 minutes and 9% (n=10) had to be forwarded to the respective entities.

Conclusion: Ask Watson improved the time taken for a DI response to be given since it accelerates access to information by bypassing the keyword-based research process. Ask Watson platform is a resource that improves DI response at patient bedside by pharmacists.