HARMONISATION OF A 24-HOUR

DRUG INFORMATION SERVICE

Submitted in partial fulfilment

of the requirements of the Degree of

Doctorate in Pharmacy

JEFFREY CASSAR

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L-Università ta' Malta

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Abstract

The Pharmacy Department at Mater Dei Hospital (MDH) operates a drug information service (DIS) during normal working hours through its Medicines Information Department (MID). The after-hours DIS is provided by shift pharmacists and follows a different model to that made available by the MID. The aim of this research was to achieve harmonisation between the DIS provided by the MID and shift pharmacists by addressing the needs of, and identifying improvements required by, the after-hours DIS. A three-week research observation placement was attended at the drug information centre at the University of Illinois in Chicago (UIC), USA, to detect the framework used. A gap-analysis comparing the DIS at MDH to that of UIC was performed. A nine-member focus group was set up to discuss improvements required in the after-hours DIS at MDH, based on the observational placement. An improvement framework with a timeline over four months for implementation was drafted and validated. Five categories of needs were identified from the improvement framework: communication, quality assurance, documentation, standardisation of workforce number and organisation of resources. A liaison pharmacist, introduced to enhance communication between the MID and after-hours, performed eighteen interventions. Eleven training sessions were held by the MID for the two pharmacists forming part of one shift complement. Seven and seventeen pharmacists attended the journal club and clinical-based discussion, respectively. An electronic documentation form was developed, validated and used to document seventy-one DI requests, nine of which were audited by three pharmacists. An on-call system to keep staff levels constant was implemented in thirteen and nine cases of vacation and sickness leave, respectively, for one shift complement. Twelve out of twenty-four printed after-hours reference resources were

outdated and were removed from circulation. Access information for four electronic subscription-based reference resources was assembled. The improvements identified from the gap analysis and the focus group led to the development and implementation of the improvement framework. The outcomes of the framework laid down a harmonised system leading to the supply of high quality DI at all hours. Features of the improvement framework were incorporated into standard work practice at MDH.

Keywords:

Drug information, after-hours, harmonisation, improvement framework, documentation

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List of Abbreviations

ASHP	American Society of Hospital Pharmacists
BNF	British National Formulary
CASP	Critical Appraisal Skills Programme
CPD	Continuous Professional Development
DI	Drug Information
DIC(s)	Drug Information Centre(s)
DIS	Drug Information Service
JIST	Journal Interpretation Summary Tool
MDH	Mater Dei Hospital
MID	Medicines Information Department
PDF	Portable Document Format
RPS	Royal Pharmaceutical Society
SOP(s)	Standard Operating Procedure(s)
UIC	University of Illinois in Chicago
UPS	Uninterruptible Power Supply

CHAPTER 1

INTRODUCTION

1.1 The Pharmacist and the Future of Drug Information

The American Society of Health-System Pharmacists (ASHP) describes the provision of drug information (DI) to healthcare professionals and patients as a core competency of all pharmacists (ASHP, 2013). This ensures the optimisation, safety and efficacy of medication therapy and the reduction of errors and prevention of adverse drug reactions (Entezari-Maleki et al, 2014; dos Santos et al, 2015). Such services are traditionally provided through a drug information centre (DIC) albeit this model is transforming in several countries especially in the USA where many formal DICs have closed in recent years because of increased accessibility to electronic DI resources, and changes in local practices, education and budgetary funds (Gabay, 2017).

Clinical pharmacy has led to DI requests being answered at the patient bed-side but DICs are still expected to remain relevant due to their role in the extraction, distribution and analysis of unbiased, accurate information received from pharmaceutical companies (Palaian et al, 2006; Lassanova et al, 2007; Samuel et al, 2014; Reppe et al, 2016a). Establishment and development of a drug information service (DIS) is still desired (Tumwikirize et al, 2011; Ashenef et al, 2018). Procedures may need to be introduced to ensure that DISs supplied by pharmacists are utilised to their full extent by users (Lua et al, 2011; Ali et al, 2013; Almazrou et al, 2017). Clinicians may have limited concerns on issues of information validity, bias and conflicts of interest, making an entity which supplies accurate and unbiased information all the more relevant (Formoso et al, 2016).

Present DICs have expanded their services leading to the evolution of the DI pharmacist into other areas of pharmacy practice like academia, managed care, medication policy, industry, patient safety, medical writing and informatics (Bernknopf et al, 2009; Gabay, 2017). Networking amongst DICs from different countries utilising numerous

information databases, such as the Scandinavian Regional Medicines Information Centres (*Regionale Legemiddelinformasjonssentre*, or RELIS network), has provided the added benefits of shared resources and access to a greater number of archived DI requests (Alván et al, 2013; Schjøtt, 2017). The network model aids in the answering of potentially complex questions (Schjøtt et al, 2012). Collaborations have also been proposed between poison control centres in Africa with the purpose of harmonising research and information between countries and obtaining a common network hub (Marks et al, 2016). Integration of the DIS within electronic health records is another future development in DI (Felkey & Fox, 2014). DICs can be used as referral services for specialities like orthopaedics and neurology and can provide specialised information on particular products like herbal drugs (Atavwoda & Gabriel, 2012; Behera et al, 2017). Partnerships with academic detailing programs and ventures into academia and pharmacy education represent other means of growth for DICs (Bhavsar et al, 2012; Wisniewski et al, 2014; Hoover et al, 2018). DICs can use the internet to provide patient-oriented information and advice through web-based platforms (Cheng et al, 2018). In the USA, the DI pharmacist has expanded into the role of submitting reconsiderations for local fee coverage determinations with claims rejected by the Centres for Medicare and Medicaid Services (Heindel et al, 2017).

1.2 Mater Dei Hospital and Foreign Scenario

Mater Dei Hospital (MDH) is an acute general teaching hospital in Malta comprising approximately 1,000 beds[1]. It is the only entity in the country that operates a 24-hour DIS run by pharmacists. The DIS also functions as an unofficial acute poison control

[1]Health Ministry. *Mater Dei Hospital* [home page]. c2008 [updated 2019; cited 2019 Jun 9]. Available from: https://deputyprimeminister.gov.mt/en/MDH/Pages/Home.aspx

centre and is provided by the Medicines Information Department (MID) during normal working hours. The MID comprises six pharmacists and operates between 07:30 and 15:00 during weekdays and between 07:30 and 13:15 on Saturdays, whilst being closed during the other hours and on Sundays and Public Holidays. The DIS is offered, at no fee, for MDH and other hospitals, primary care settings and patients, including the private sector. A systematic approach is followed by the MID when answering DI requests through its quality management system and internal standard operating procedures (SOPs).

After-hours hospital pharmacy services, also referred to as on-call services, refer to those activities rendered to users outside the normal working hours of the pharmacy department. Such services may not always be available in all global clinical scenarios, and differ in the way they are implemented across different hospitals and healthcare settings (Holder et al, 2013). In the case of the National Health Service of the United Kingdom, a significant proportion of these after-hours services involve pharmacists responding to DI requests put forward by nursing and medical staff unable to answer such queries from readily available sources (Dunn, 2018). The provision of DI by after-hours pharmacists in the USA has had a direct impact on patient safety, medication access and quality of care in specialised areas such as paediatrics (Condren et al, 2018). The extension of all pharmacy services across 24 hours in the USA has provided educational and financial advantages and a reduction in medication errors (McConeghy et al, 2012). Such services different from DI have been provided through telepharmacy involving remote review of medication orders by pharmacists (Schneider, 2013).

At MDH, after-hours services are provided by eight shift pharmacists and four pharmacy technicians operating on a “Day”, “Night”, and “Rest” and “Off” system with day and night shifts lasting twelve hours from 8 AM until 8 PM and vice-versa. Each

shift complement (referred to as Shifts A, B, C and D) comprises three personnel, with at least one pharmacist and one pharmacy technician present during each work period. Shift pharmacists manage other pharmaceutical services apart from the DIS including the dispensing of medication and oxygen cylinders to in and out-patients and the replenishment of emergency drawer medication. During after-hours, such services are provided from the dispensary section. The model of the DI pharmacist having other duties is adopted by other hospitals apart from MDH (Samuel et al, 2014).

The after-hours DIS follows a different system to that provided by the MID. Queries received by the MID are discussed between pharmacists before an answer is provided, whereas those submitted after-hours are sometimes answered by a single shift pharmacist. Shift pharmacists are part of the dispensary section and not the MID.

1.3 Local Studies

As part of a study undertaken at MDH in 2016 by Cassar & Azzopardi, a documentation tool was developed and validated for the purpose of recording DI requests received after-hours. The tool was used to document 224 after-hours DI requests received over 6 months and 65 twelve-hour shifts. It was determined that nursing staff were responsible for 72% of requests placed, with almost 45% of these being related to drug administration. In 92% of cases, information was conveyed to requesters over the telephone. Pharmacists used textbooks to answer requests in 38% of situations and provided answers within 30 minutes in over 99% of circumstances (Cassar & Azzopardi, 2016).

A 2015 study involving a focus group composed of MDH after-hours pharmacists, tested the after-hours DIS by comparing it with the latest standards published by the

ASHP and the Royal Pharmaceutical Society (RPS) (Cassar, 2015). The evaluation identified various needs of the after-hours DIS which would be required to be equivalent to the service provided by the MID during normal working hours namely quality assurance, documentation, workforce and resources issues (Table 1.1).

Table 1.1: Needs of after-hours DIS at MDH

Category	**After-Hours DIS Need**
Quality assurance	Improving weak training system
Documentation	Electronic and manual documentation of DI requests
Workforce	Keeping shift complement constant to three people in case of personnel absence due to vacation or sickness leave
Resources	Augmenting and organising electronic and manual references

Classification of MDH after-hours DIS needs into four categories: quality assurance, documentation, workforce and resources.[2]

1.3.1 Quality Assurance Issues and DI Training

All pharmacists should have the ability to attend education and training programs to enhance their competence and skill level (ASHP, 2013). Having pharmacists provide DI without any specialized training is considered a weakness in the service provided and an issue which needs to be addressed to comply with official guidelines and standards (Alamri et al, 2017). DI pharmacists are the ideal candidates to provide training for

[2] Cassar J. Evaluation of after-hours pharmaceutical services in a general hospital [MSc (Pharmacy) dissertation]. Msida: Department of Pharmacy, University of Malta; 2015

students and trainees, and for other pharmacists wishing to specialise in DI (Bernknopf et al, 2009).

DI training for after-hours pharmacists can take place in the form of workshops utilising peer-grading and peer-mentoring, as is used in the curricula for pharmacy students and residents (Davis, 2014; Rodis et al, 2014). PowerPoint presentations, training modules, digital badges, online support and educational boot camps are other means of providing pharmacist education and training (Mensink & Paterson, 2010; de Sousa et al, 2013; Ferguson & Timpe Behnen, 2015; Fajiculay et al, 2017; Wisniewski, 2018). Compulsory training ensures that all concerned pharmacists receive information on DI procedures and systems (Mensink & Paterson, 2010). Training programs can be evaluated by assessing satisfaction levels of trainees (Yamamoto et al, 2011).

Quality assurance also incorporates audits and reviews of DI responses; internal (pharmacists) or external (physicians) experts who validate individual queries can perform this. Co-signatures are another method of quality assurance which may be employed (Reppe et al, 2016b).

1.3.2 Documentation of After-Hours DI Requests

Documentation is part of the systematic approach to answering DI queries and apart from being related to progressing patient care, it also plays a role in highlighting accountability and the resolution of legal issues should these arise (Ghaibi et al, 2015). Quality assessment of written responses is rarely possible and commonly inaccurate without a documentation system (Reppe et al, 2017). Information databases are used to generate management reports and analyse DI requests pertaining to a particular specialisation such as management of poisoning, breastfeeding, complementary and

alternative medicine and psychopharmacology (Sawalha, 2008; Sawalha et al, 2012; Gregory et al, 2016; Schjøtt, 2016; Escalante-Saavedra et al, 2017; Jahnsen et al, 2018). Retrospective analysis of documented DI queries aids in the assessment of newly installed DICs (Ashenef et al, 2018).

A variety of means can perform documentation of DI, including by using software and applications intended for other utilisations like poison information documentation and Google Forms (Wisniewski et al, 2009; Gregory et al, 2016). Consistency in the documentation of requests received during normal working hours by the MID was observed; this uniformity was lost after-hours leading to a deficiency in the 24-hour DIS (Cassar, 2015).

1.3.3 Strengthening the Shift Workforce

Guidelines published by the RPS[3] recommend the establishment of corrective actions when there are imbalances in the complement of pharmacy staff to ensure sustainability of the system. Staffing levels are to be reviewed regularly to ensure the safe delivery of pharmacy services. Support personnel like pharmacy technicians and clerical staff should be employed to smooth the progress of such services (ASHP, 2013).

A previous study at MDH showed that the reduction of the number of after-hours personnel from three to two, in case of vacation or sickness leave, reduced the time allocated by pharmacists for the search of DI (Cassar, 2015). The literature search is one factor that determines how long a pharmacist spends answering a DI query; a

[3] Royal Pharmaceutical Society. Professional standards for hospital pharmacy. 2017. Available from: https://www.rpharms.com/resources/professional-standards/professional-standards-for-hospital-pharmacy [accessed 9 Jun 2019].

Scandinavian study has shown that reduction of this time frame may cause a decrease in the accuracy and completeness of the information supplied but increasing time consumption may not necessarily increase the quality of the DI answer (Reppe et al, 2010; Reppe et al, 2016b).

1.3.4 Electronic and Manual Information Resources

Pharmacists in different settings and DICs have access to different numbers and types of information resources to search for DI (Schjøtt et al, 2018). Access by pharmacists is crucial considering that other health care professionals may require further training in the selection process of DI references (Hughes et al, 2015). The adequacy of resources depends on the particular setting and area of practice with the desired outcome being that pharmacists have access to sufficient DI resources to answer information requests, although this is not always the case (Wong et al, 2009; Chang et al, 2016; Asmelashe Gelayee et al, 2017; Moorman et al, 2017). Pharmacists may show preference towards tertiary literature for the dissemination of information to requesters (Palaian et al, 2006; Hassali et al, 2010).

Age may be a factor determining the preference between electronic and manual resources, with the older generation being less comfortable using online databases; gender may also play a role (Hanrahan & Cole, 2014). Previous evaluations of the MDH after-hours DIS identified printed resources as the preferred method by pharmacists to access information (Cassar & Azzopardi, 2016). Printed DI sources have disadvantages and may commonly contain errors and outdated information (Paparella, 2010). Electronic resources are preferred for their regular and real-time updating but if maintained only in favour of manual references may hinder the performance of

pharmacists who prefer using the latter (Carvajal et al, 2013). Printed resources should supplement electronic ones and be available as a backup in case of equipment downtime or failure (ASHP, 2013). DI accessed from electronic public domains like Wikipedia and certain Smartphone applications is not updated as frequently as that found in subscription-based databases like Lexicomp and should be interpreted with caution (Boruff & Storie, 2014; Duncan et al, 2015; Koppen et al, 2015). Multiple electronic resources need to be available to pharmacists to ensure the entirety and accuracy of information since this is not standardised (Rambaran et al, 2018).

1.4 User Input

Surveys and questionnaires are a way of getting a representation of user satisfaction with a DIS as a means of evaluation; high satisfaction is the desired outcome amongst such tools (Bertsche et al, 2007; Fatelrahman et al, 2008; Saavedra et al, 2017). A previous evaluation of the after-hours DIS at MDH assessed the system from the provider point of view and did not take into consideration users of the service (Cassar, 2015).

1.5 Aim and Objectives

The aim of this research was to achieve harmonisation between the DIS provided during normal working hours and that delivered after-hours at MDH.

The objectives of the research were to:

i. Address the needs of, and identify improvements required by the current after-hours DIS, and;
ii. Implement and evaluate such improvements over a scheduled, validated timeline.

CHAPTER 2

METHODOLOGY

2.1 Study Design

The study consisted of three phases (Figure 2.1). Phase I included a gap analysis of the present DIS at MDH. Phase II involved the execution of a focus group session by recruiting an expert panel of DI providers and users within the institution. Phase III involved the development, validation, implementation and evaluation of an improvement framework to set up a 24-hour DIS.

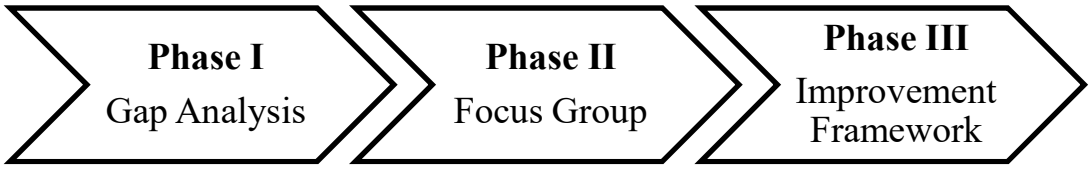

Figure 2.1: Phases of the study

The three phases of the study in order of implementation: gap analysis, focus group and improvement framework.

2.2 Ethical Approval

Ethical approval was granted after submission to the University of Malta Research Ethics Committee on the 30th April 2018 with reference number FRECMDS_1718_046 (Appendix I).

2.3 Phase I – Gap Analysis of DIS

A three week research placement was attended during May 2018 at the DIC of the University of Illinois in Chicago (UIC), USA. Procedures and roles observed included DI procedures, resources, documentation and quality assurance systems used.

A gap analysis was performed by comparing the present DIS at MDH to that adopted by the DIC at UIC, whose procedures followed ASHP guidelines, and which was identified as the best practice (ASHP, 2013; Ghaibi et al, 2015). The purpose of the gap analysis was to identify areas in the DIS at MDH which required improvement, and supplement the findings of the study performed by Cassar in 2015 on the after-hours DIS (Cassar, 2015). Following comparison of the two systems, gaps in the MDH DIS were identified (Table 2.1) using a gap analysis tool developed by Golden and associates for use across health systems (Golden et al, 2017).

Table 2.1: Results of Gap Analysis

Feature	UIC Service	Gap at MDH
DIS procedures	Fee-for-service system operated by pharmacists and pharmacy residents using systematic approach to respond to DI requests. Poisoning queries referred to Illinois Poison Centre. DI provided to requester via email. DIS included prior authorisation services for drug approval.	No official link between MID and after-hours
	After-hours queries answered by pharmacy resident on-call. Handover provided to DIC following end of after-hours.	
	Further provision of DI queries by clinical pharmacist during ward rounds at the University of Illinois Hospital.	
Resources	Compartmentalisation of printed resources in library format.	After-hours printed resources not compartmentalised.
	Use of and access to numerous electronic databases. Homepage with links to all electronic resources available. Automatic log in to resources from all terminals without consistent need to input usernames and passwords.	No organisation system of after-hours electronic resources.
Documentation	Hybrid manual and electronic documentation system which allowed prioritisation of requests.	After-hours DI requests not documented.
Quality Assurance	Weekly journal club discussions by pharmacists which consisted of critical analysis of primary literature.	No journal club sessions or audit systems present.
	Weekly presentations and discussions of DI questions received by pharmacy residents.	
	One archived DI query audited by each pharmacist every month.	

The gap analysis identified five gaps in the DIS at MDH based on observations from the DIC at UIC.

Needs of the after-hours DIS (Table 1.1) and gaps of the DIS (Table 2.1) were combined into five topics for discussion during Phase II of the study. These were quality assurance, documentation, workforce, resources and communication (Table 2.2).

Table 2.2: Focus Group Discussion Points

Quality Assurance (Training, Journal Clubs & Audits)	**Documentation** (Need for after-hours documentation)	**Workforce** (Reduction of after-hours shift workforce)
Resources (Management of Electronic & Printed)	**Communication** (Increase between MID and after-hours)	

Focus group discussion points sorted into five categories according to needs of after-hours DIS and gap analysis.

2.4 Phase II – Focus Group

The qualitative method of a focus group session was conducted to discuss and address the deficiencies of, and identify improvements required, by the current after-hours DIS at MDH. It allowed selection of participants to achieve study objectives. The group comprised nine members, four of whom were part of the provision of the DIS at MDH, and five were end users of the service (Table 2.3). The focus group allowed the assembly of all the stakeholders of the DIS, including management, who would rarely convene together under usual circumstances. All members were employed at MDH except for the community pharmacist identified from private practice since the majority of DI requests originated from within MDH (Cassar, 2015). The community pharmacist was included in the focus group to account for requests for DI received from retail community pharmacies.

Table 2.3: Focus Group Members

Providers	Users
Head of Pharmacy Services 1 Clinical/DI Pharmacist 1 After-Hours Pharmacist 1 Quality Assurance Pharmacist	2 Staff Nurses 2 Medical Doctors 1 Community Pharmacist

The focus group was composed of a balanced number of DI providers and users, with most of the members being employed at MDH.

Providers were recruited through purposive sampling to include the Head of Pharmacy Services and one member from each of the following sections at MDH: MID, after-hours and quality assurance. These were departments and personnel directly associated with the provision of the DIS. The individual pharmacists from the three sections were selected randomly using the free-for-use Random Number Generator® Smartphone application developed by UX Apps. A random number was assigned to pharmacists of each department and the pharmacist whose number was selected by the application was selected for inclusion in the focus group. With the Head of Pharmacy Services, no such procedure was followed since this included a single pharmacist.

Random selection was also applied for the selection of users from electronically archived DI requests at the MID. Each number generated corresponded to the identification number of an archived query. The process was repeated until requests put forward by two medical doctors, two nurses and one community pharmacist were selected. The requesters were chosen to form part of the focus group. A greater number of doctors and nurses compared to community pharmacists were selected since the two former professions are responsible for a significantly larger number of after-hours DI

requests (Cassar & Azzopardi, 2016). Users of the DIS were included in the focus group since a previous study of the after-hours DIS only took into consideration the view of the service provider (Cassar, 2015).

The most favourable focus group size is usually considered to be between five and ten members; the larger the group size, the higher the occurrence of members who do not contribute to the discussion (Huston & Hobson, 2008). For this purpose, a group size of nine members was selected. All the members were familiar with each other professionally which allowed a more familiar and relaxed environment. This was beneficial towards the intensity of discussion.

The focus group lasted for 90 minutes, the average time taken for a focus group session, and took place at the boardroom of the Pharmacy Department at MDH in July 2018 (Huston & Hobson, 2008). The dialogue was held in English since all members of the focus group were healthcare professionals who studied in Malta where English is the language of tuition. The principal researcher acted as the focus group facilitator. The discussion was followed according to a previously designed interview guide (Appendix II) based on five topics of discussion (Table 2.2). The interview guide comprised a set of probing questions intended to broaden the discussion. All talking points that emerged after each question were fully explored before other topics were discussed during the focus group. The researcher ensured that all opinions were obtained on each topic by directly requesting them from those participants who had not yet voiced their view. Other methods followed by the facilitator to widen the discussion included asking participants whether they shared similar or different outlooks to those proposed by the other members of the focus group. The participants were encouraged to divulge relevant experiences during the discussion to support their views.

A recruitment email, together with an information sheet (Appendix II) containing the contact details of the researcher was sent to the participants inviting them to take part in the focus group. This explained the study purposes and provided information on confidentiality and possible withdrawal from the study. A reminder was sent via email one day before the focus group. On the day of the focus group, participants were provided with a consent form (Appendix II) and were asked to sign it as an agreement to take part in the research. All the participants contacted agreed to take part in the study.

The discussion was recorded using two audio recorders with one meant as a backup in case of equipment failure. A password-protected sound file was stored on the researcher's personal computer. The password was known only to the researcher who listened to the recording for data evaluation and analysis. The sound file was not replicated or copied, nor was it uploaded to any public server, cloud storage, website or any other media. Participants were informed that the audio recording would be immediately destroyed in case of withdrawal from the study. The recording was transcribed *ad verbatim* by the researcher onto a Microsoft Word document, following which it was deleted. Transcription took place in an environment that did not allow data to be overheard. The transcribed document was password protected with the password known only to the researcher. No personal information, except for the profession and department of employment of the participants, was recorded during transcription. To ensure confidentiality, the nine participants were assigned a unique letter from A to I used to refer to them throughout the transcript.

Microsoft Excel was used to organise the transcript into common themes. Portions of the transcript were provided with short descriptions to facilitate their grouping into

themes. The identified themes were needs of the DIS and were used as the basis for the development and implementation of the improvement framework.

2.5 Phase III – Development and Implementation of Improvement Framework

Following thematic analysis in Phase II, inferences in the form of improvements to the DIS and a time schedule for implementation were drafted. This was referred to as the improvement framework (Appendix III). Five themes were identified. These were quality assurance, documentation, communication, workforce and resources. Each theme involved multiple improvement proposals. A timeline for the implementation of each proposal was included for feedback.

The improvement framework was sent via email to the focus group members for validation. Participants were asked to validate the framework in terms of content and feasibility of the timelines proposed. The validation panel further included two pharmacists each chosen randomly from the MDH inpatient and outpatient sections since members of these departments did not feature in the focus group, albeit they were not connected to the provision of after-hours DI. One member of the public with a background in education was also included in the validation study to obtain the viewpoint of a third party outside the providers and users of the DIS.

The form for documenting after-hours DI requests used in the 2016 study by Cassar and Azzopardi (Appendix IV) was sent as an attachment with the improvement framework for validation before being converted to an online format (Cassar & Azzopardi, 2016). Validation comments and recommendations were sent by participants to the researcher via email.

An updated version of the improvement framework was drafted following the validation study. The validated framework was implemented at MDH according to the proposed time schedule between October 2018 and January 2019.

2.6 Validation of Improvement Framework

Recommendations made to the improvement framework following its validation included language amendments and various additions and updates to the agenda (Table 2.4 and Appendix III).

Table 2.4: Recommendations to the Improvement Framework following Validation

Recommendation	Content
Language	After-hours DIS "deficiencies" renamed as "needs".
	Training of after-hours pharmacists described as "consistent" to better describe the ongoing scenario.
Additions	Feedback of participants of journal clubs and clinical-based discussions obtained via specially designed forms.
	Documentation tool in Cassar (2015) study subjected to a one month pilot study following its transfer to an online format. Online tool to document all DI requests not just those received after-hours.
	To discuss staffing levels on Sundays and Public Holidays with management.
	Liaison pharmacist responsible for compiling, updating and reviewing after-hours printed and electronic resources index.
Updates	Audit procedure consisting of three pharmacists auditing DI requests every month, using an audit feedback form. Feedback sent to pharmacist handling the DI request via email by liaison pharmacist.
	Handover of queries that required follow-up performed using handover log sheet.

Suggestions made by the validation panel included additions and updates to the improvement framework and changes in its wording.

2.7 Implementation and Evaluation of Improvement Framework

Areas of the improvement framework to be implemented included an assessment of the ways to improve communication between the MID and after-hours and strengthen the after-hours workforce during a shortage of staff, the quality assurance system of the DIS, documented DI requests and the after-hours reference resources organisation system.

2.7.1 Improving Communication between MID and After-Hours

Following the recommendations of the focus group, the researcher took up the role of a liaison pharmacist to serve as a communication link between the MID and after-hours pharmacists. The interventions of the liaison pharmacist between the two entities were recorded over three months, starting from October 2018. The method used to convey such information, and the types of information delivered were recorded. The liaison pharmacist was assigned the duties of organising and implementing a journal club and clinical-based discussion, providing feedback to pharmacists following audits of documented DI requests and updating and monitoring the printed and electronic resources index lists.

2.7.2 Quality Assurance Needs of DIS

The quality assurance needs of the MDH DIS included training shift pharmacists in DI queries by the MID, setting up journal clubs and clinical-based discussions and auditing documented DI requests.

2.7.2.1 Training of After-Hours Pharmacists

During the first half of each "Day" shift occurring between Monday and Saturday, all eight after-hours pharmacists attended compulsory training sessions at the MID. No training sessions were held on Sundays and Public Holidays since the MID was closed. The two pharmacists from each shift alternated with each other for the training session, with the pharmacist not attending the training being placed at the dispensary section.

The number of training sessions held by the MID for one shift group (two pharmacists) were recorded for four months between October 2018 and January 2019. This included the subjects discussed during the training sessions. Data from one shift group out of four was recorded since duties amongst shifts were identical and sessions taken by one shift group represented those undergone by other factions. The shift group chosen was the one which the researcher, who was also a shift pharmacist, formed a part of.

2.7.2.2 Journal Club

A journal club was held in November 2018 to increase awareness of critical evaluation of primary literature, whilst aiding pharmacists to apply such knowledge to their local scenarios. This is a highly important DI skill for pharmacists. The article discussed during the journal club was a randomised controlled trial entitled "Andexanet alfa for the reversal of factor Xa inhibitor activity" published by Siegal and associates in the New England Journal of Medicine in 2015 (Siegal et al, 2015). The topic was selected after discussion with the MID. All pharmacists at MDH were invited to take part in the journal club via email. The article, along with the critical appraisal skills programme

(CASP) randomised controlled trial checklist[4], was sent to pharmacists two weeks preceding the journal club. Pharmacists used the CASP tool to evaluate the study and generate topics for discussion during the journal club. Pharmacists were asked to confirm attendance via email before joining the journal club.

An interactive presentation using Microsoft PowerPoint® was held during the session which lasted for one hour inside the MID at MDH (Appendix V). The journal club was held in English since all participants were pharmacists licensed in Malta. A DI pharmacist validated the presentation before its execution. Copies of the presentation and the concerned article were distributed during the journal club to the attending pharmacists. A summary of the research in the article was shown through a video clip before starting the session so as to engage the participants in discussion.

Following conclusion of the sitting, a feedback form (Appendix VI) was circulated amongst attendees – this evaluated the presentation, clarity, usefulness, learning level, strengths and suggested improvements of the journal club. The form was used to obtain demographic data of journal club participants, including department of employment and number of years' experience as a pharmacist. The form was validated by two pharmacists and no amendments were made to the original format. The feedback obtained was used to improve the delivery of successive journal clubs.

2.7.2.3 Clinical-Based Discussion

A clinical-based discussion was held in January 2019 which functioned as a continuous professional development (CPD) module with the scope of educating pharmacists on

[4] Critical Appraisal Skills Programme UK. *Critical Appraisal Skills Programme* [home page]. c2019 [updated 2019; cited 2019 Jun 9]. Available from: https://casp-uk.net/

novel drugs and their use at MDH. The drug chosen was palivizumab (Synagis®) used at MDH for the prevention of respiratory syncytial virus infection in high-risk individuals. The choice was made after discussion with the MID and paediatric clinical pharmacist who classified the topic as a niche for further discussion.

All pharmacists at MDH were invited to participate in the clinical-based discussion via email. Pharmacists were asked to confirm attendance via email prior to joining the discussion.

A Microsoft PowerPoint® presentation utilising images and video was held during the discussion (Appendix V). The presentation was validated by one paediatric clinical pharmacist and one DI pharmacist before implementation. Two sessions of the same presentation were held in order to allow pharmacists from the same department to attend at least one session, a suggestion previously made by the journal club attendees. Both sessions were held in English since all participants were pharmacists. Copies of the presentation were distributed during the clinical-based discussion to the attending pharmacists. The two sessions were evaluated using a feedback form (Appendix VI) similar to the one used for assessment of the journal club. The latter was validated by two pharmacists and no alterations were made following this process.

2.7.2.4 Retrospective Auditing of Archived DI Requests

Three archived DI requests were selected randomly from the archives using the Random Number Generator mobile application. These were forwarded via email to one pharmacist auditor from each of the following departments: MID, inpatients and outpatients. An audit feedback form (Appendix VI) based on the systematic approach to answering DI queries, was forwarded to each auditor (Ghaibi et al, 2015). The form was

validated by two pharmacists; no changes were made following validation. The liaison pharmacist certified that the chosen auditor was not the same pharmacist who logged the DI request, and that duplication of assessment did not occur by auditors. The compiled audit form was forwarded to the researcher for analysis following its completion by each pharmacist. Following analysis of the audit form, the compiler was contacted via email and provided with feedback, if any. Feedback on improvement of DI provision was provided by the liaison pharmacist if any of the features audited were marked "No" or "Somewhat", or if indicated so in the comments section by the auditor.

The audit procedure was repeated every month starting from November 2018, for a period of three months until January 2019.

2.7.3 Electronic Documentation of DI Requests

The form for documenting after-hours DI requests (Appendix IV) used in the study by Cassar and Azzopardi in 2016 was subjected to validation before conversion to an electronic format by the validation panel (Cassar & Azzopardi, 2016). Changes made during validation included format amendments, additions, deletions and updates of material (Table 2.5).

Table 2.5: Electronic Conversion of After-Hours DI Documentation Form

Changes	Content	Reason
Format	"Normal working hours" added to "Shift Type" field.	Record any DI request and not just those received after-hours
Additions	"Urgency of Request" field.	Determine urgency of DI request.
	"Type of Request" field.	Differentiate between patient-related and academic DI requests.
Deletions	"Medication Details" field.	Information logged elsewhere.
Updates	Update of Information sources.	Better depiction of present resources.
	"Time to Finalise DI Request" field changed to open field.	Allow pharmacist to record exact time taken to provide information.

Changes to the after-hours documentation form proposed by the validation panel before its conversion to an electronic format.

A Gmail account was created under the email address druginfodocumentation@gmail.com. The password of the account was known only to the researcher. The electronic form was constructed using Google Forms and stored on Google Drive (Appendix VII). Compilers of the form were not given amendment rights and they did not require a Google account prior to logging. An email notification was sent to the account to notify the researcher when a DI query was submitted using the form.

The use of a Google form allowed pharmacists to document DI requests remotely from all workstations and handheld devices with an Internet access, as opposed to other documentation software utilised by the MID.

Responses using the form were saved as portable document format (PDF) files from Google Drive and stored on a shared drive for access to all pharmacists. A summary of the response, including the drug name, was included in each PDF file name to facilitate searches.

A link to the form and instructions on its use were sent to all pharmacists working at MDH on their employment email. The pharmacists were informed that the form would undergo a pilot study for one month during October 2018, and to forward any recommendations to the researcher via email. Five pharmacists sent comments to the researcher, following which the form was updated (Appendix VII) (Table 2.6).

Table 2.6: Pilot Study of Electronic DI Documentation Form

Changes	**Content**	**Reason**
Additions	Further instructions in "Enquirer Background Information".	To log details of private practice, if relevant
	"Comments" field.	Allow pharmacist to enter comments to DI query
Deletions	"Shift Type" field.	Information could be deduced from time of receipt of the DI request
Updates	"Description of DI Request" field renamed "DI Question Requested".	To aid in generating a DI question when documenting request

Changes made to the electronic DI documentation form following the end of a one-month pilot study.

Google Forms is a service which is compliant to the General Data Protection Regulation. The pharmacists who used the Google Form were informed about it beforehand and the link sent to the form was not unexpected. The form did not request the email address of the person filling it out.

The form was used to document DI requests beginning from November 2018 for a period of three months until the end of January 2019, for the purposes of this study. Following conclusion of the three-month period, the form was adopted by the pharmacy department at MDH as an alternative documentation tool. The DI queries logged during the three month period were analysed quantitatively with regards to enquirer demographics, reference sources used to convey DI, classification of DI queries and method of delivery of DI. Pie charts were constructed to display the results.

2.7.4 Strengthening the Workforce during Shortage of Staff

Following a proposal by the principal researcher, an on-call system for pharmacy technicians was introduced to ensure that the shift complement was kept to three during periods of high workload. This would cover any vacation and sickness leave throughout "Day" shifts occurring on weekdays and Saturdays. As discussed during the focus group, the period of high workload was between 15:00 and 18:00 on weekdays and between 13:00 and 18:00 on Saturdays, during which patient discharges were frequent from MDH. This ensured that during periods of high workload, the shift complement consisted of either two pharmacists and one pharmacy technician, or one pharmacist and two pharmacy technicians. The on-call system was not adopted for "Night" shifts or for "Day" shifts occurring on Sundays and Public Holidays, as stipulated by management.

The number of times that the on-call system was enforced during day shifts of one shift group was recorded over a period of three months starting October 2018. Vacation and sickness leave taken by the personnel on day shifts falling on Sundays and Public Holidays, when the on-call system was not implemented, were recorded. The shift group chosen was the one which the researcher formed a part of.

2.7.5 Organisation of After-Hours Reference Resources

The organisation of after-hours reference resources by the liaison pharmacist involved printed and electronic references available at the pharmacy department at MDH.

2.7.5.1 After-Hours Printed Reference Resources

The four shelves at the dispensary section used to store the after-hours printed reference resources were assigned a location identifier as shown in Figure 2.2. Each shelf was labelled with its location identifier.

Top left A1	**Top Right B1**
Bottom Left A2	**Bottom Right B2**

Figure 2.2: Shelves housing the After-Hours Printed Resources

Location identifiers of the four shelves containing printed resources for use after-hours.

Each resource available was reviewed and classified into one of six categories: Toxicology, Drug Administration, Pregnancy and Lactation, Paediatrics, General and Miscellaneous. Each category was assigned a shelf location (A1, A2, B1 or B2) to facilitate retrieval of an information resource. Labels pertaining to each category were fixed on the respective shelves.

The resources were included in an index list which recorded the name of the resource and its author or editor, edition number, year of publication, classification and position in shelf (Appendix VIII). The list was used by pharmacists to establish the location of a resource and fasten retrieval of information after-hours. A statement was added on the front page of the index to remind pharmacists that printed resources were to be used only as a backup to and to supplement online information databases. The list was printed and stored in a plastic folder attached to the side of the shelves. The index list was uploaded onto a shared drive as a PDF file to enable its remote and electronic viewing by pharmacists. An email was sent out to all pharmacists at MDH explaining the re-organisation of the reference resources and the location of the index list. A pilot study of the index list was performed throughout October 2018. During this month, pharmacists were asked to evaluate the organisation system and provide recommendations to the liaison pharmacist via email. The index list was updated following the end of the pilot study and the re-uploaded onto the shared drive. The liaison pharmacist was assigned the duty of maintaining and updating the after-hours printed reference resources following conclusion of this research.

2.7.5.2 After-Hours Electronic Reference Resources

An electronic resources index list was compiled containing links and access information like user names and passwords to the four subscription-based electronic databases available at MDH (Appendix VIII). The list was sent via email to all pharmacists at MDH and uploaded onto a shared drive for remote access. A pilot study of the electronic list was carried out throughout October 2018. Pharmacists were asked to evaluate the list during this month and forward recommendations to the liaison pharmacist via email. The list was updated following cessation of the pilot study and re-uploaded onto a shared drive. The liaison pharmacist was assigned the duty of maintaining and updating the electronic reference resources following termination of this study.

CHAPTER 3

RESULTS

3.1 Results of the Improvement Framework

Results from the improvement framework included documentation of the liaison pharmacist interventions, number of training sessions for after-hours pharmacists, usage of the on-call system of pharmacy technicians to keep the shift workforce constant, assessment and evaluation of the journal club, clinical-based discussion and audit sessions, profiling of documented DI requests, and organisation of the printed and electronic after-hours reference resources.

3.2 Liaison Pharmacist Interventions

The liaison pharmacist made 18 interventions over four months (Figure 3.1). The largest group of interventions (22%) was that related to the establishment and update of the printed and electronic reference resources lists.

Seventeen out of eighteen interventions included the delivery of information via email. One intervention involved the use of a shared computer drive. Interventions concerning electronic documentation (17%) also included the use of Google Forms. Those related to the printed and electronic reference resources lists further employed the use of a shared computer drive to convey communicative information. The role of the liaison pharmacist was continued by the researcher beyond the timeline of this research.

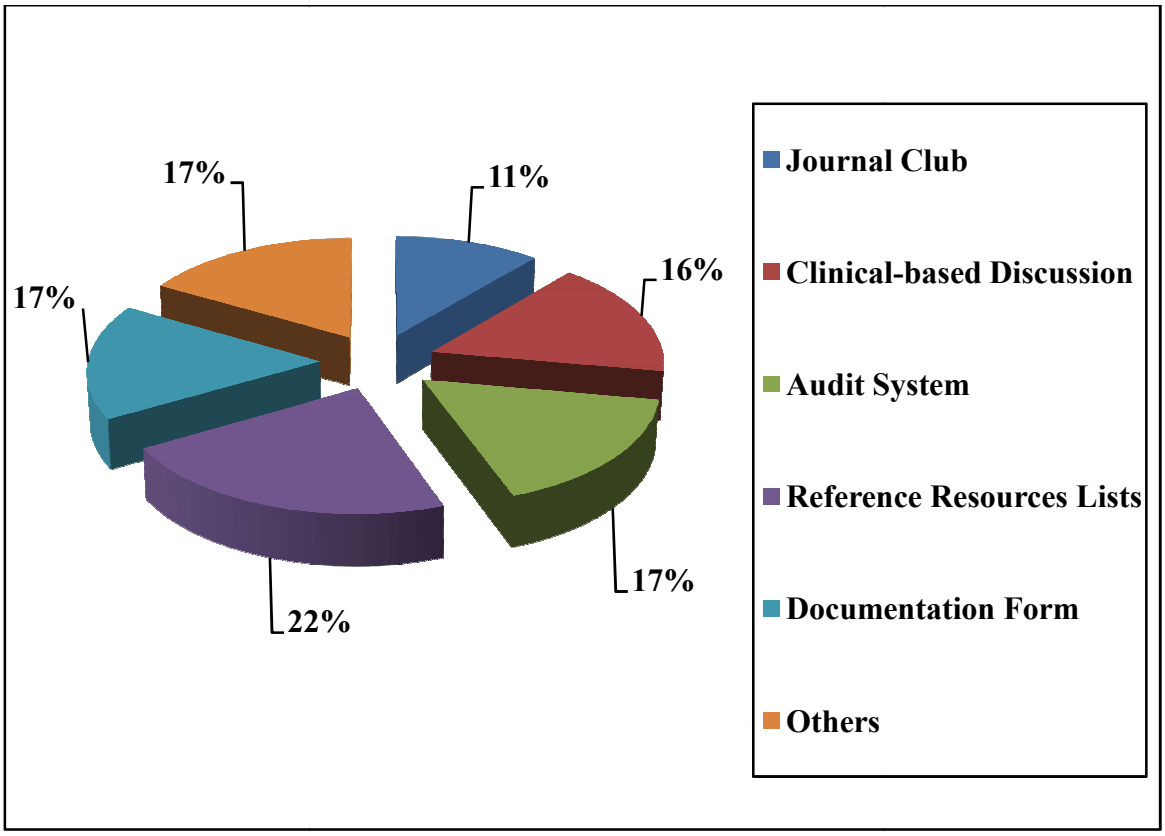

Figure 3.1: Liaison Pharmacist Interventions (n = 18)

Interventions listed as "Others" concerned transfer of information on common DI queries and electronic sources of information.

3.3 Training Sessions for After-Hours Pharmacists

Eleven training sessions were held by the MID for the two pharmacists forming part of shift D over four months (Table 3.1). Training varied between general topics such as the systematic approach to answering DI requests, to more specialised areas like antibiotic monitoring and management of poisoning. The continuous training sessions were retained for after-hours pharmacists following the end of the four month period.

Table 3.1: Shift D Training Sessions (n = 11)

Month	Pharmacist 1	Pharmacist 2	Training Topics
1	2	1	Systematic approach, vancomycin, gentamicin and amikacin monitoring, poisoning, drug administration and selection, posology, mock queries, therapy review
2	1	2	
3	2	1	
4	1	1	
Total:	**6**	**5**	

Training sessions were assigned between the two pharmacists forming part of Shift D.

3.4 Evaluation of Journal Club Session

Seven pharmacists from MDH attended the journal club (Table 3.2). All stated that the content of the journal club was presented at an appropriate learning level, the session segments were clear, and the facilitator was helpful in the implementation of the discussion. The size of the group was considered to be very or mostly adequate for its purpose. One pharmacist stated that they did not feel confident performing a critical appraisal of a research article following the journal club (Figure 3.2).

Strengths included the interactive and informal setup of the discussion and its adequate location, length and preparation time by the liaison pharmacist. It was suggested to send supplemental information in advance together with the journal article and CASP tool to ease analysis by pharmacists. In order to increase participation by other pharmacists, it was suggested to repeat the journal club session so as to allow pharmacists from the same department to attend one session each. This suggestion was implemented in the subsequent clinical-based discussion. Following the conclusion of the study, a journal club schedule was implemented at MDH which included a session every four months.

Table 3.2: Demographic Characteristics of Journal Club Pharmacists (n = 7)

Department	Number of years' experience	
	≤ 5 Years	> 5 Years
MID/Clinical Pharmacy	1	2
Compounding	1	0
Dispensing	1	1
Other	1	0
Total:	**4**	**3**

Attendees were from different MDH departments and with variable work experiences.

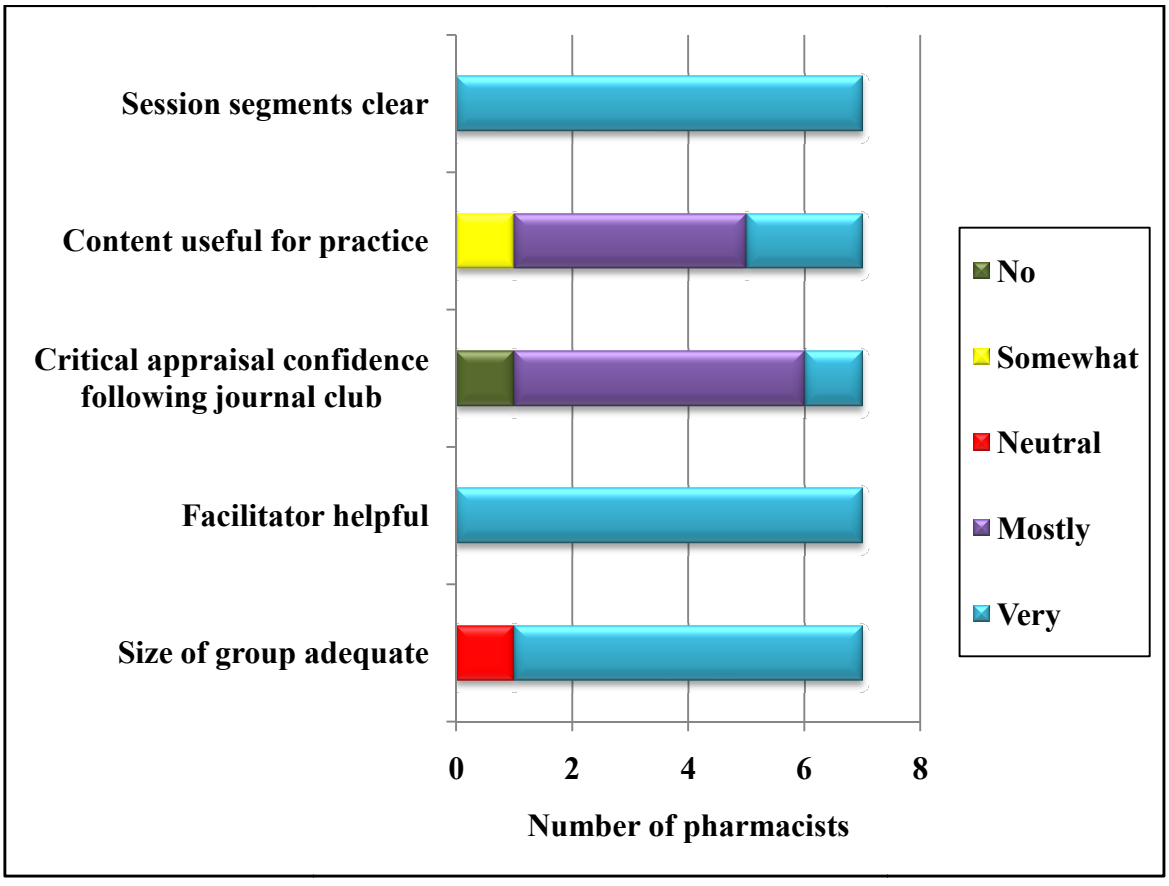

Figure 3.2: Journal Club Participant Feedback (n = 7)

Feedback for the journal club was largely positive for all segments tested.

3.5 Evaluation of Clinical-Based Discussion Session

Seventeen pharmacists from MDH attended the clinical-based discussion; 10 pharmacists attended Session 1 whereas 7 attended Session 2 (Table 3.3). Fourteen pharmacists stated that the content was presented at an appropriate learning level, two pharmacists answered that the content was greatly above learning level and one pharmacist responded that the content was somewhat below learning level. All pharmacists stated that the following were mostly or very adequately executed: clarity of presentation, usefulness for practice, helpfulness of liaison pharmacist and size of group. One pharmacist felt neutrally confident in the clinical subject after the discussion with the other sixteen pharmacists stating that they felt mostly or very confident (Figure 3.3).

Strengths of the clinical-based discussion identified by pharmacists included its clear presentation of relevant information through the use of multimedia such as video clips, and the promotion of discussion between pharmacists who rarely interact with each other since they are employed by different departments. The major recommendation by attendees was to hold similar clinical-based discussions more frequently. Following the conclusion of the study, a clinical-based discussion schedule was implemented at MDH which included a session every four months.

Table 3.3: Demographic Characteristics of Clinical-based Discussion Pharmacists

(n = 17)

Department	Session 1		Session 2	
	Number of years' experience			
	≤ 5 Years	> 5 Years	≤ 5 Years	> 5 Years
Quality Assurance	1	1	0	0
MID/Clinical Pharmacy	0	2	1	0
Compounding	1	0	1	0
Dispensing	3	2	2	2
Storage and Distribution	0	0	0	1
Total:	**5**	**5**	**4**	**3**

Attendees were from different MDH departments and with variable work experiences.

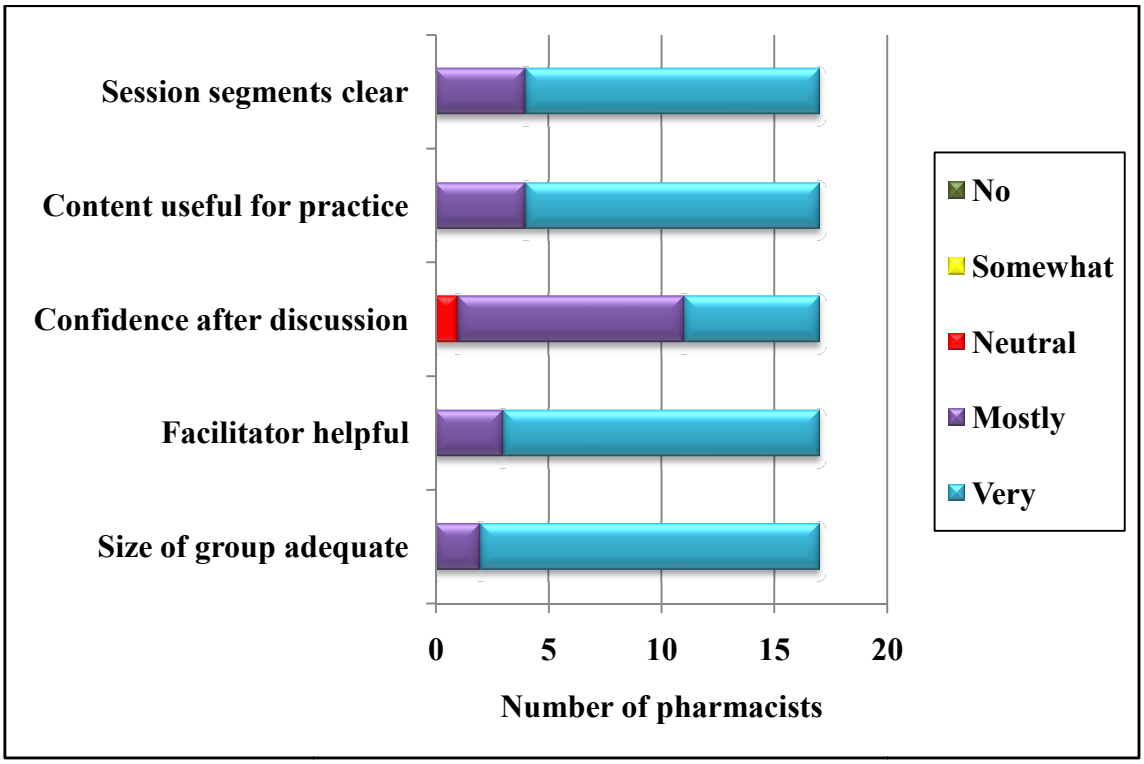

Figure 3.3: Clinical-based Discussion Participant Feedback (n = 17)

Feedback for the two discussions was largely positive for all segments tested.

3.6 Evaluation of DI Audits

Nine documented DI requests were audited by 3 pharmacists over 3 months, with each pharmacist auditing 3 queries each. In two audits, the background information of the enquirer was either absent or poorly recorded, and did not allow traceability should this have been required. The audit form was marked as "No" and "Somewhat" for the presence of traceability of these DI requests. In these two scenarios, the liaison pharmacist contacted the compiler via email and provided feedback so as to ensure traceability in future cases of documentation. Following the end of the study, the audit procedure was adopted by the pharmacy department. This consisted of 3 pharmacists auditing one DI request each every month.

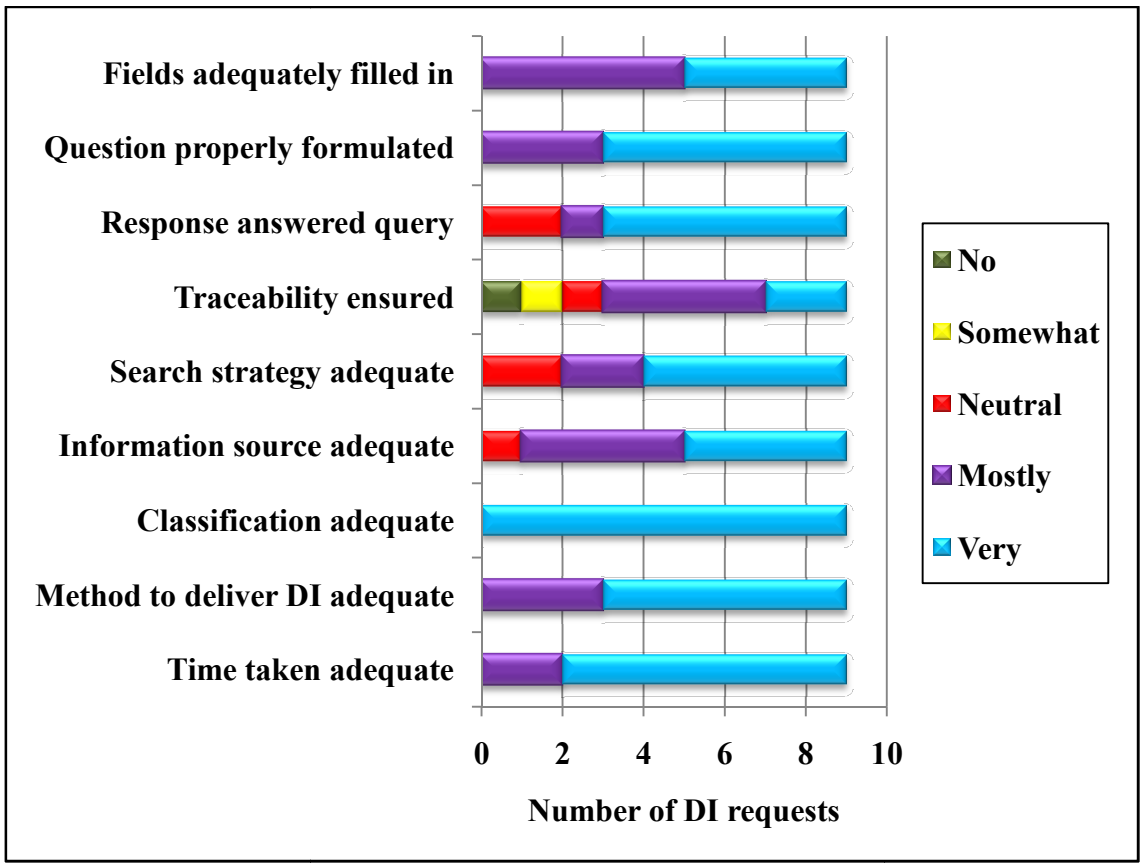

Figure 3.4: Auditing of DI Requests by Pharmacists (n = 9)

Feedback was positive for segments tested apart from the certification of traceability.

3.7 Profiling of Documented DI Requests

Seventy-one DI requests were documented over four months using the electronic Google Form. The liaison pharmacist saved each query as a PDF file and assigned it a title with keywords to facilitate retrieval by other pharmacists. Each title contained the generic name of the drug or product in question. The PDF files were uploaded onto a shared drive for access by all MDH pharmacists. The majority of DI requests received were patient-related (97.2%) and required information as soon as possible (95.8%). Pie charts were constructed to visualise requester profiles (Figure 3.5), DI classification (Figure 3.6), reference resources used to answer DI requests (Figure 3.7) and the method of delivery used to convey information (Figure 3.8). Following the end of the study, the electronic form was adopted by the Pharmacy Department as an alternative documentation tool.

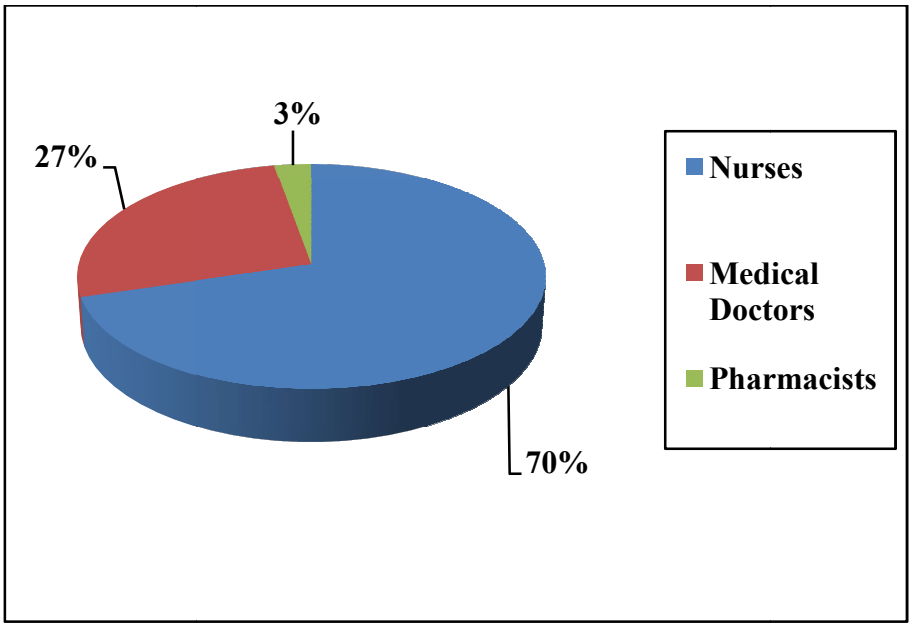

Figure 3.5: Requestors of DI Queries at MDH (n = 71)

The largest group of requestors were nursing staff followed by medical doctors and pharmacists

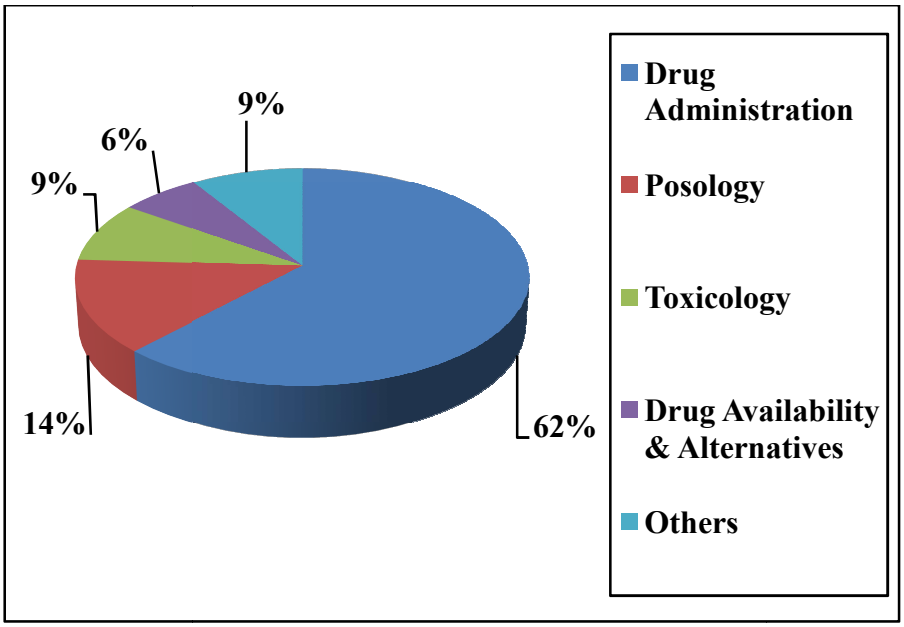

Figure 3.6: DI Requests according to Category (n = 79)

Eight from the 71 DI requests were classified into two categories resulting in a total of 79 classifications, of which drug administration was the largest group.

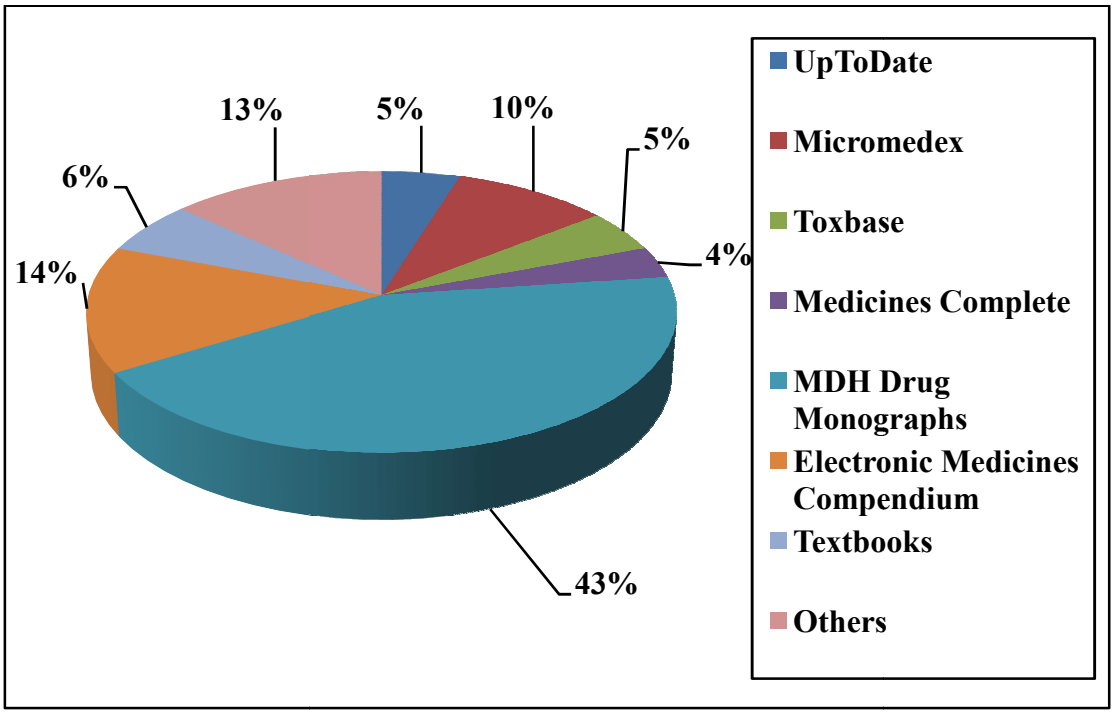

Figure 3.7: Reference Resources used to answer DI Queries (n = 83)

83 printed and electronic resources were used to answer 71 DI requests, with the most common being the electronic MDH drug monographs.

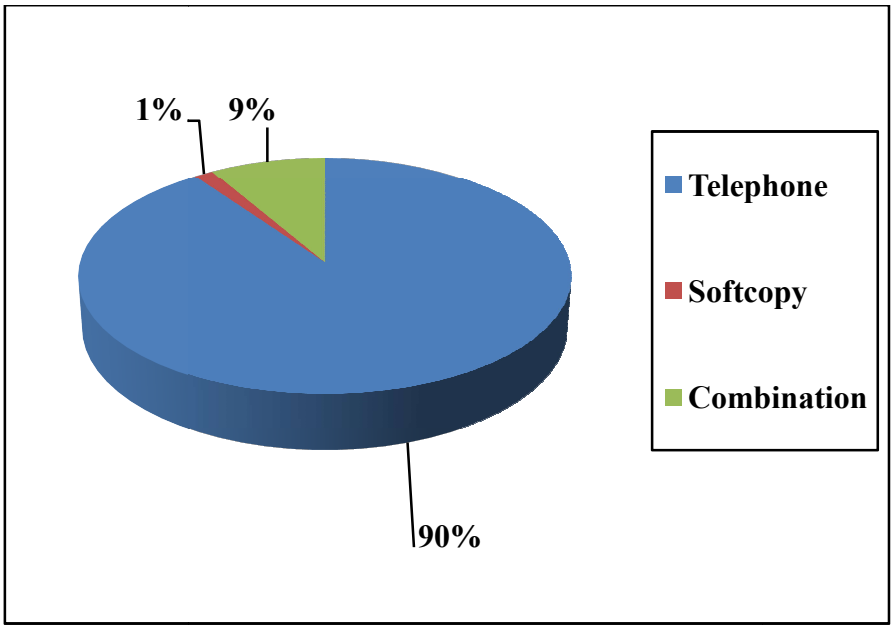

Figure 3.8: Method of Delivery of DI by Pharmacists (n = 71)

DI was conveyed to requesters largely via telephone and not in writing

3.8 Usage of On-call System and Strengthening of Workforce

The on-call system of pharmacy technicians was implemented in twenty-two from a possible twenty-five "Day" shift periods pertaining to shift group D (Table 3.4). There were two instances when the workforce required two replacements each and three instances when vacation or sickness leave was taken on a "Day" shift falling on a Sunday or Public Holiday, when the on-call system was not enforced. The on-call system continued to be enforced following conclusion of the study period. The workstations used by pharmacists to search for DI were updated and connected to an uninterruptible power supply (UPS).

Table 3.4: **Implementation of On-call System for Shift D**

Month	On-call Vacation Leave	On-call Sickness Leave	On-call required but not implemented
1	3	2	1
2	3	3	0
3	3	2	1
4	4	2	1
Total:	**13**	**9**	**3**

The on-call system was not used in the case of personnel absence during "Night" shifts or "Day" shifts occurring on Sundays and Public Holidays.

3.9 Organisation of Printed After-Hours Resources

The Printed After-Hours Resources Index List documented 24 printed references. During the pilot study, three pharmacists sent suggestions to the liaison pharmacist leading to two changes in the format of the index list (Appendix VIII). The statement on the front page was updated to remind pharmacists that the primary sources for information were the online subscriptions and databases; printed sources listed in the index list were meant only as backup. Older printed resources which were deemed outdated and superfluous were removed, shortening the list from 24 resources to 12 (Table 3.5). This included all printed versions of the British National Formulary (BNF), which was available electronically on all workstations at MDH. The 12 outdated resources were segregated and transferred to the MID for archiving. Although all paediatric resources were removed, the label for the paediatric classification was kept on the shelf in case of future reference expansion. A list of the removed printed resources was sent to all pharmacists via email. The index list was set to be updated and

monitored every three months, or when a new printed resource was added to the library, whichever came first. Each list was assigned a unique identifier number to distinguish between its different versions. The duties were continued by the liaison pharmacist following the end of the study.

Table 3.5: Printed After-Hours DI Resources removed from circulation

Printed Resource	Publication Information	Classification	Substitute
Psychotropic Drug Directory	S Bazire, 1st ed, 2003	Miscellaneous	Electronic database
The Sanford Guide to Antimicrobial Therapy	Gilbert et al, 33rd ed, 2003		
Poisoning and Drug Overdose	KR Olson, 3rd ed, 1998	Toxicology	Newer edition
BNF 40	British Medical Association (BMA) & RPS, 40th (2000), 54th (2007) & 65th (2013) eds	General	Electronic subscription
BNF 54			
BNF 65			
Chemist & Druggist Guide to OTC Medicines	C Gladwin, 21st ed, 2002		Electronic database
Middle East Medical Index	CCM Middle East, 21st ed, 1999		
Drugs in Pregnancy and Lactation	GG Briggs & RK Freeman, 6th ed, 2002	Pregnancy and Lactation	Newer edition
Medication and Mothers' Milk	T Hale Jr, 11th ed, 2004		Electronic database
BNF for Children	BMA & RPS, 1st (2006) & 6th (2010) eds	Paediatrics	Electronic subscription
BNF for Children			

All removed printed resources, except for two, were older than 10 years.

3.10 Organisation of Electronic After-Hours Resources

Four electronic subscription-based databases were identified and included in the electronic resources index list. During the pilot study, one pharmacist sent a suggestion to the liaison pharmacist concerning the electronic resources index list (Appendix VIII). The suggestion proposed was to include, in the index list, a reference to the latest version of the internal standard operating procedure MEIN 001 entitled "Procedure for answering a medicines information enquiry". The reason for inclusion of the SOP reference was because it contained a list of non-subscription based electronic resources used by pharmacists for DI purposes.

The electronic resources index list was set to be updated every three months, or when a new subscription-based electronic reference was purchased by the Pharmacy Department, whichever came first. As in the case of the printed reference list, versions of the electronic list were assigned a unique number to differentiate between them. The responsibility of updating the electronic list was assigned to the liaison pharmacist who continued such duties following the end of the study.

CHAPTER 4

DISCUSSION

4.1 Study Synopsis

This study continued on the results established from a previous research conducted in 2015, which identified deficiencies in the after-hours DIS at MDH which could hinder the quality of DI delivered by pharmacists (Cassar, 2015). An innovation of this study included a gap analysis which compared the DIS at MDH to that provided by a foreign institution (UIC) which followed DI guidelines published by the ASHP and was unique in its self-sustainability and services provided to several organisations (Ghaibi et al, 2015). After-hours deficiencies and gaps in the DIS were addressed via the development and execution of an improvement framework, which provided a detailed step-by-step approach, and a timeline for implementation over four months. Validation of the improvement framework was performed by a diverse group of individuals which included pharmacists, doctors, nurses and a member of the public. Some features of the improvement framework which were implemented were evaluated, including the planning and development of a journal club and clinical-based discussion. Features of the improvement framework were continuous and ongoing and continued beyond the four-month study period, resulting in their adoption as a work practice at MDH, and the establishment of a harmonised 24-hour DIS.

4.2 Features of the Improvement Framework

The role of the liaison pharmacist was the first of its kind at the Pharmacy Department at MDH whose scope was to enhance communication between different sectors. This role was essential in the execution of a harmonised 24-hour DIS. The liaison pharmacist utilised different methods of information delivery and this was carried out in the written format via email, Google Forms or a shared computer drive. This enabled pharmacists

to consult such information at a later stage should this be required, as opposed to the delivery of information solely via word of mouth. The vast majority (83%) of the pharmacist interventions were related to the improvement framework, including the setting up and monitoring of a journal club, clinical-based discussion and audit system. The remaining interventions (17%) involved day-to-day DI activities. This included dissemination of guidelines and electronic textbooks deemed useful for the supply of DI by pharmacists. Efforts can be made to increase those interventions independent of the improvement framework. This can be maintained by having a pharmacist solely responsible for the role of the liaison pharmacist since during the course of the study the researcher acted as the liaison pharmacist, whilst performing other duties as a shift pharmacist.

Training of shift pharmacists was conducted by the MID which was the specialised DI unit at MDH. Pharmacy standards dictate that all personnel should possess the relevant training to carry out their duties, as well as the possibility to participate in CPD curricula to enhance their abilities (ASHP, 2013). Specialised DI training for pharmacists has been suggested as one of the ways to improve a DIS (Alamri et al, 2017). A strong training system ensures that an institution achieves the highest level of pharmacy practice possible (Knoer et al, 2016). Topics discussed during the training sessions were various, and included clinical-oriented areas such as antibiotic drug monitoring of MDH inpatients. This further amplified the skill of shift pharmacists in DI. Training sessions were well distributed amongst the two pharmacists of one shift group, ensuring that both pharmacists from each shift received equal DI training. During the course of the study, dispensing duties at the inpatient section were given priority over DI training. This led to the omission of training sessions for one pharmacist when the other was absent because of sickness or vacation leave, and

explains the low number of training sessions held over the four-month period. The low number of training sessions corresponds with the high usage of the on-call pharmacy technician system. This factor increases the importance of assessment of the training sessions held to determine whether measures should be initiated to increase training of after-hours pharmacists.

The roles of journal clubs are threefold: (1) to enhance critical appraisal skills, (2) to provide knowledge and experience in literature evaluation, and (3) to augment discussions between pharmacists and other healthcare professionals, students, academics and management personnel (Generali, 2015). Critical appraisal skills are a prerequisite for DI pharmacists in the evaluation of primary literature leading to a significant relationship between journal clubs and a DIS. The article selected for the journal club was a randomised controlled trial leading to the use of a CASP validated checklist for such research studies (Ghaibi et al, 2015). The CASP tool was designed by the CASP network in Oxford specifically for the evaluation of research and the development of critical appraisal skills. A similar tool is the Journal Interpretation Summary Tool (JIST). The JIST provides guidelines and suggestions for the evaluation of research and aids journal club participants to apply the results of research to the local scenario (Kovacevic et al, 2018). The journal club consisted of pharmacists coming from different areas of expertise and with variable work experience. This led to a wider and more intense discussion during the session. Validated surveys are a way of getting feedback from participants on the setup and usefulness of a journal club (Boss et al, 2018). The reaction by pharmacists to the journal club session at MDH was largely positive and the setup used can be implemented in future sessions. Such sessions should have a comparable group size and operation format. Six out of seven pharmacists felt more confident in carrying out a critical appraisal of a study after the session. This

concurs with other studies which show that journal clubs are beneficial in pharmacy practice and can improve critical appraisal skills (Landi et al, 2015; Boss et al, 2018). Apart from traditional roundtable discussions, implementation of a journal club can utilise online platforms (Generali, 2015). This can include content shared on common drives and online surveys for the appraisal of presenters (Devabhakthuni et al, 2016). Online software is useful for holding journal clubs across multiple institutions and increase collaboration between entities (Miller Quidley et al, 2015). This applies to MDH since the DIS is national and is provided to all institutions across Malta. An online-based journal club centred on MDH will further increase access to information by pharmacists and other professionals who did not attend the journal club. Traditional journal clubs are limited to an in-depth discussion of just one or two articles. A specialised tool can screen journal periodicals and identify relevant articles to a particular specialisation. This method distributes workload amongst pharmacists and allows the presentation of numerous articles, keeping them updated on current affairs (Dickerson et al, 2017). Such a tool can be used at MDH when there are periods of high workload, which makes it less feasible to hold frequent journal clubs. Future journal club sessions should be held in duplicate so as to allow pharmacists from the same department to attend at least one session during work hours. This was recommended by participants and realised for the clinical-based discussion.

The clinical-based discussion functioned as a CPD programme for MDH pharmacists. CPD improves pharmacy practice, including the supply of DI (Schindel et al, 2012). The medication and condition chosen (palivizumab and respiratory syncytial virus infection, respectively) were discussed in view of both the local and foreign scenarios. Feedback was largely positive, as shown from the forms circulated to the attending pharmacists. Holding two sessions of the same discussion allowed more pharmacists to

attend, resulting in a higher turnout than the journal club. Pharmacist attitudes towards CPD are affected by a number of factors. Attitudes improve with motivation but lessen in the presence of barriers to accessibility, job availability and time (Saade et al, 2018).

Audits are a valuable tool used to evaluate pharmacy services, including the DIS. The audit feedback form was based on the ASHP guidelines for the systematic approach for answering DI queries, adopted by DISs across the USA (Ghaibi et al, 2015). This study incorporated the use of the liaison pharmacist into the DIS audit system to provide feedback to compilers of documented DI queries in the case of subpar replies identified by the auditor. An alternative audit method is to use a quality assessment checklist combined with a grading system, with the grade assigned to each DI query corresponding to the number of points allotted by the auditor (Himanshu et al, 2015). Although simpler and presents data in a numerical format, this system has disadvantages including the assignment of high grades for queries which lacked only one feature of the systematic approach. The involvement of the liaison pharmacist in the audit procedure ensured that feedback was delivered to pharmacists even if the DI response was substandard in only one feature. The results confirmed the lack of requester information and the absence of traceability in two audited DI requests. A grading system might have overlooked such deficiencies in the DI answering procedure. Acquiring the requester information is essential since this allows the response to be curtailed according to the requester's professional background and health literacy, and makes contact possible if future follow-up by the pharmacist is required (Nathan, 2013; Ghaibi et al, 2015). The appraisal of DIS can also occur via feedback forms, which can include user satisfaction questions (Bhavsar et al, 2012). Evaluation of a DIS can be expanded to include the identification of drug side effects and interactions (Entezari-Maleki et al, 2014).

Electronic documentation of DI requests determined that nursing staff at MDH formed the absolute majority of requesters, and that the largest group of requests were related to drug administration. This is a rational finding considering that drug administration is a typical nursing responsibility at MDH. Such findings are similar to those divulged by another study performed at MDH which analysed DI requests answered after-hours showing a prevalent use by nurses of the DIS at MDH at all hours (Cassar & Azzopardi, 2016). Nurses were also the largest group of requesters in an Indian proactive DI study of a rural hospital (Bhavsar et al, 2012). A high frequency of drug administration queries was also reported in studies from Saudi Arabia and Malaysia, although in these researches the largest requester groups vary between physicians and pharmacists (Ali et al, 2013; Alamri et al, 2017; Almazrou et al, 2017). In contrast to the Cassar and Azzopardi (2016) study, textbooks were an infrequent reference source of information for DI responses. This study showed a high use of electronic sources of information, with the MDH drug monographs being the most used, although such information was available to all MDH staff through cloud sharing. Management should employ measures to increase the use of such monographs by MDH healthcare professionals, especially nurses. Using electronic resources over printed ones is advantageous, and should be encouraged, although printed resources should still be present to supplement information and as a backup. Subscription-based databases were found to be the major source of DI used by pharmacists in a number of studies (Ali et al; 2013; Alamri et al, 2017; Almazrou et al, 2017; Ashenef et al, 2018). The study has confirmed that the DIS at MDH is telephone-based, with most requests being answered over the telephone and not in writing. This is similar to that found in the after-hours DI analysis, and augments the importance of the process of DI documentation by pharmacists (Cassar & Azzopardi, 2016).

Guidelines by the ASHP state that a plan should be available to address staff shortages that might affect patient needs (ASHP, 2013). This led to the establishment of an on-call pharmacy technician system that ensured at least three personnel during the peak hours of after-hours. Since the overtime system did not include "Night" shifts and "Day" shifts occurring on Sundays and Public Holidays vacation or sickness leave taken on such occasions still reduced the workforce number from three to two. Monitoring of the on-call pharmacy technician system showed a high frequency of usage amongst the shift workforce. In 88% of situations (22 out of 25), a replacement pharmacy technician was required during peak hours, showing frequent absences of personnel because of vacation and sickness leave, confirming one of the main concerns expressed by pharmacists in a focus group on the after-hours DIS at MDH performed in a previous study (Cassar, 2015). Such frequent absences previously reduced the shift workforce from three to two and reduced the time allocated by shift pharmacists for the provision of DI requests since the same professional duties were distributed amongst a smaller number of personnel. The on-call system was beneficial towards implementing a 24-hour DIS and its constant implementation is essential for a smooth running operation. Expansion of the system to include peak hours during "Day" shifts occurring on Sundays and Public Holidays will further distribute work responsibilities on such occasions and strengthen the premise of a 24-hour DIS. The pharmaceutical workload occurring during "Night" shifts at MDH should be investigated to determine whether the on-call pharmacy technician system needs to incorporate such shifts. At present, even with the pharmacy technician on-call roster, after-hours shift workforces may contain only a single pharmacist. This averts discussion of DI queries with other pharmacists and differs from the procedure followed by the MID. Expanding the system to include at least two pharmacists during peak hours may address this

deficiency. Management should consider certain unique characteristics before recruiting pharmacists for shift work. A study in Illinois, USA, determined that shift pharmacists were more likely to be those who have children and carried out dispensing duties as opposed to managerial and other tasks (Quiñones & Pullin, 2011). Physicians and clinical pharmacologists can also be considered for future recruitment in order to obtain a diverse DI team with clinical knowledge and expertise, as is found in the Scandinavian setting (Schjøtt & Spigset, 2019). The update of computer terminals to newer and faster workstations ensured timely retrieval of DI and addressed a concern stipulated by shift pharmacists (Cassar, 2015). Connection to a UPS resulted in an unremitting DIS even in the case of a power failure. Measures to strengthen the after-hours pharmacy workforce contributed towards the harmonisation of a 24-hour DIS. Such measures were significant after-hours since responsibilities during this period are various and not confined to the provision of DI.

The organisation of after-hours printed and electronic reference resources hastened the process of information retrieval by pharmacists. This was beneficial for shift pharmacists, who had other duties to attend to besides the provision of DI, and operated as part of a skeleton staff system during after-hours. Where possible, the liaison pharmacist ensured the access by pharmacists of up-to-date printed and electronic resources, a necessary aspect of any DIS (Ghaibi et al, 2015). The organisation of resources improved their familiarity and identification by pharmacists, ameliorating the information retrieval process and leading to more time dedicated to the analysis and dissemination of information (Ghaibi et al, 2015). The pilot study for the printed resources library showed that half of the textbooks being used for the supply of DI were outdated or superfluous to the electronic resources, and were removed from circulation by the liaison pharmacist. This included different editions of four reference sources,

which before their removal increased the risk of the supply of outdated or conflicting information by pharmacists. The printed and electronic resources lists led to the quick retrieval and access to information sources by pharmacists. The printed list facilitated the identification of older editions of textbooks so these could be removed from circulation by the liaison pharmacist. Electronic resources are quickly replacing traditional printed textbooks (Ghaibi et al, 2015) and quick and easy access to subscription-based databases is essential for any DIS. Inadequate access to information resources limits the retrieval of information and acts as a barrier towards the supply of complete and accurate DI, leading towards medication errors (Asmelashe Gelayee et al, 2017; Rambaran et al, 2018).

4.3 Limitations

Although available to all pharmacists at MDH, the electronic documentation form was not the sole method of documentation for DI requests during the course of the study. An internal documentation and database software continued to be used during the four-month study period. The DI requests documented in this study might not be representative of the whole DIS at MDH. DI queries documented using all methods should be combined into a common, easily accessible database to facilitate their access by pharmacists.

The study analysed the number of training sessions and implementation of the on-call pharmacy technician system for only one shift group, which the researcher formed a part of. This was due to an inconsistent monitoring of such services by other shift groups, leading to their incoherent recording. Only the services provided for one shift group could be certified to be in completion and could be analysed for the purpose of

this study. Although each shift group is representative of the others due to identical work responsibilities and duties, variations between the different shift groups, if any, could not be identified. Future monitoring of training sessions and on-call systems should be performed in completion to identify possible variations between shift groups.

4.4 Future of the MDH DIS

A 24-hour system allows options for DIS expansion to be explored, including the provision of fee-for-services contracts to clients belonging to external and foreign institutions. The evolving role of the DI pharmacist into other areas of pharmacy practice should be applied to the local scenario and analysed accordingly (Bernknopf et al, 2009; Gabay, 2017). Revenue obtained from such ventures may allow the MID to become self-sustainable and independent from the Pharmacy Department at MDH. This will initiate a cascading effect of DI diversification as the MID searches for newer revenue areas in its attempt to remain self-sustainable.

Ongoing aspects of the improvement framework require continuous development and assessment of their structure and contents, with revisions made when required, as is characteristic of a DIS (Alván et al, 2013). Measures should be in place to ensure that this occurs.

4.5 Recommendations for Further Research

The short study time-frame prevented the evaluation of the training received by after-hours pharmacists and the pharmacy technician on-call system concerned with the standardisation of the shift workforce. It is recommended that future research focuses on

the evaluation of these two after-hours systems. Training can be evaluated by a variety of means such as by the use of scores from standardised knowledge tests, similar to what is used in the USA to assess resident training (Thompson et al, 2016). The results of such assessment will indicate whether to increase or keep constant the training sessions attended per pharmacist. The impact of a pharmacist dedicated solely to the enhancement of communication between the MID and other departments within the Pharmacy Department at MDH should be investigated. Future journal clubs at MDH can assess the impact on critical appraisal skills by comparing surveys taken by pharmacists before and after a journal club, similar to those used in academic settings for pharmacy students (Landi et al, 2015). Such journal clubs at MDH can alternate between the CASP and JIST tools as methods of research evaluation. Pharmacist attitudes towards clinical-based discussions should continue to be assessed in order to determine what revisions, if any, are required in the future. The DIS at MDH can form the basis from which accredited CPD programmes are instigated. Such programmes can be developed for different types of healthcare professionals and providers, similar to what is achieved by the Accreditation Council for Pharmacy Education in Chicago, Illinois (Travlos et al, 2017). Future quality assessments of the DIS at MDH can look into the prevention of adverse patient events through the supply of high quality DI.

4.6 Conclusion

This study has led to the development and implementation of an improvement framework which resulted in the construction of a harmonised 24-hour DIS. Needs of the after-hours DIS identified in an earlier study were addressed and rectified, as were gaps identified after comparison to a US-based DIS which was both self-sustainable and

offered a wide perspective of services (Cassar, 2015). The system developed through this study has contributed to the provision of high quality DI by the Pharmacy Department at MDH, irrelevant of the time that a request was received.

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APPENDIX I

ETHICAL 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: **FRECMDS_1718_046**

Monday 30th April 2018

Mr Jeffrey Cassar
31, Twilight
Triq il-Kmand
Zurrieq ZRQ4113

Dear Mr Cassar,

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

Setting up a 24-hour drug information service

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

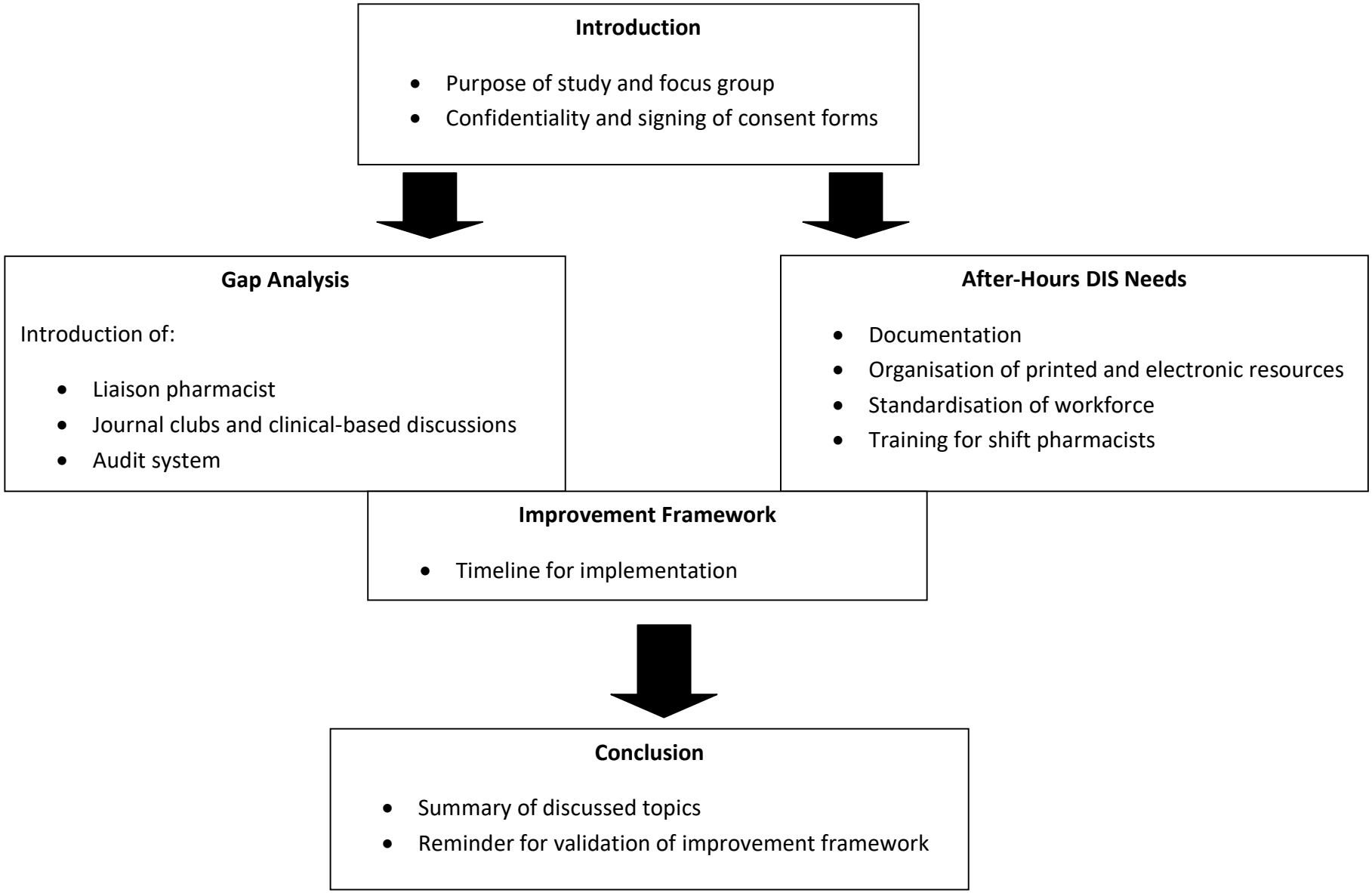
Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

APPENDIX II

FOCUS GROUP DOCUMENTATION

FOCUS GROUP INTERVIEW GUIDE



INFORMATION SHEET FOR PARTICIPANTS

Dear Sir/Madam,

I would like to invite you to participate in this focus group as part of a dissertation entitled "Setting up a 24-hours drug information service." Please be aware that participation is voluntary and refusal to participate will not disadvantage you in any way.

What is the research about?
Mater Dei Hospital (MDH) operates a 24-hour drug information service (DIS) by means of its Pharmacy Department. The DIS is provided by the Medicines Information section during normal working hours and by shift pharmacists after-hours. An evaluation of the after-hours DIS revealed several weaknesses. The aim of this focus group is to discuss these weaknesses, present suggestions to overcome them, and set up an improvement framework over which such amendments can be performed. You will be asked to validate this improvement framework at a later date and not on the day of the focus group.

The research will be carried out in fulfilment of a Doctorate in Pharmacy at the University of Malta.

What will happen during the focus group?
The focus group will consist of 9 members and will last for approximately 2 hours. The lead researcher will lead the discussion in the focus group and guide you through each issue to be explored. There are no right or wrong answers in this discussion; your opinion is all that the researcher is interested in.

What will happen to the results?
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 factors in what the participants have said. The intention of the researcher is to publish the findings in a peer-reviewed academic journal.

What about confidentiality?
You will not be identified in any way in the recordings but instead will be assigned a number at the start of the focus group. This number will be used to refer to you throughout the focus group and data analysis. No one will be informed that you have taken part in the focus group, although there is a possibility that another member of the focus group might recognize you. The researcher might quote what you say during the focus group to highlight certain points, but these quotes will not reveal who you are. All voice recordings will be destroyed once they are transcribed.

What if I want to withdraw from the study?
If you agree to take part in this study, you can withdraw at any moment by notifying the lead researcher on any of the contact details mentioned below.

What if I have further questions?
Should you have any questions about the research, please contact the lead researcher through any of the means mentioned below. You can keep this information sheet for your reference.

Contact Details of Lead Researcher

Name and Surname:	Jeffrey Cassar
Identification Number:	1587M
Telephone Number:	(+356) 21680809
Mobile Number:	(+356) 99836225
Address:	31, Twilight, Triq il-Kmand, Zurrieq, ZRQ 4113
Email:	jeffrey.cassar.04@um.edu.mt

CONSENT FORM FOR PARTICIPANTS

Please complete this form after you have read the Information Sheet and listened to an explanation about the research.

Title of Research: Setting up a 24-hour drug information service

	Please tick
I understand that if I decide to withdraw from the project I can do so immediately by notifying the lead researcher and without giving any reason.	
I consent to the processing of my personal information for the purposes explained to me. I consent for my participation to be voice-recorded.	
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.	

Participant's Statement:

I _____
confirm that the research named above has been explained to me to my full satisfaction and agree to take part in the study. I have read both this Consent Form and the accompanying Information Sheet and fully understand what this research involves.

Signature of Participant **Date**

_____ _____

Lead Researcher's Statement:

I _____
confirm that I have carefully explained the nature and demands of this research to the participant.

Signature of Lead Researcher **Date**

_____ _____

Signature of Supervisor **Date**

_____ _____

APPENDIX III

IMPROVEMENT FRAMEWORK

Improvement Framework – Pre-validation

After-hours drug information service deficiency	Improvement proposed during focus group	Timeline
Quality Assurance Issues	Training of after-hours pharmacists on frequently encountered drug information topics via rotation at Medicines Information Department (MID) during first half of DAY shift	Ongoing and continuous
	Setting up of regular journal clubs and/or clinical-based discussions between MID and after-hours pharmacists	Commencing October 2018 and held every 2 months
	Auditing of documented after-hours drug information requests via discussion between MID and after-hours pharmacists	Commencing November 2018 and held every 2 months
Lack of Documentation	Documentation of after-hours drug information requests using tool in Attachment A	Commencing November 2018
	Transfer of documentation tool in Attachment A to online format	Concluded by end of October 2018

Lack of communication and follow-up between MID and after-hours pharmacists	Liaison pharmacist to act as a reference point between MID and after-hours pharmacists	Commencing October 2018
	Handover by after-hours pharmacists of queries that require follow-up to MID via email or handover file on P drive	
Workforce shortage	Increase shift complement from 2 to 3 during peak hours of DAY shift in the case of vacation and/or sickness leave taken by after-hours personnel	Ongoing and continuous
	Dedicated computer station to hasten the answering of after-hours DI queries	To be discussed with management
Disorganisation and lack of manual and online DI resources	Organisation of after-hours manual resources [books] in library format to be used only as backup to online resources	Concluded by end of December 2018
	Compilation of online document on P drive with links to online resources and passwords for easy access	

Improvement Framework – Post-validation

After-hours drug information (DI) service needs	Improvement proposed during focus group	Timeline
Improve the quality of communication and follow-up between Medicines Information Department (MID) and after-hours pharmacists	Liaison pharmacist to act as a reference point between MID and after-hours pharmacists.	Commencing October 2018
	Handover by after-hours pharmacists of queries that require follow-up to MID via handover log sheet.	
Quality Assurance of DI service	Consistent training of after-hours pharmacists on frequently encountered drug information topics via rotation at MID during first half of DAY shift.	Ongoing and continuous
	Setting up of regular journal clubs and/or clinical-based discussions between MID and after-hours pharmacists. Feedback of participants obtained via dedicated forms.	Commencing October 2018 and held every 2 months
	Auditing of 3 documented DI requests per month using feedback forms; liaison pharmacist responsible for sending feedback to pharmacist answering DI request.	Commencing November 2018 and held every 2 months

Improve Documentation of DI requests	Transfer of documentation tool in Attachment A to online format following its validation. Online tool subjected to one month pilot study before full implementation.	Concluded by end of October 2018
	Documentation of any DI request using aforementioned online tool.	Commencing November 2018
Strengthening Workforce	Increase shift complement from 2 to 3 during peak hours of DAY shift in the case of vacation and/or sickness leave taken by after-hours personnel including Sundays and Public Holidays.	Ongoing shift complement increase during weekdays and Saturdays; Sundays and Public Holidays shift increase to be discussed with management
	Dedicated smooth running computer station with UPS to hasten the answering of after-hours DI queries.	To be discussed with management
Augment and organise online and manual document library used for DI	Organisation of after-hours backup manual resources in library and index format; liaison pharmacist responsible for compiling, updating and reviewing said index.	Concluded by end of December 2018
	Compilation of online document on P drive with links to online resources and passwords for easy access; liaison pharmacist responsible for compiling, updating and reviewing document.	

APPENDIX IV

AFTER-HOURS DRUG INFORMATION DOCUMENTATION FORM

AFTER-HOURS DRUG INFORMATION (DI)

DOCUMENTATION FORM

DATE:	*(Record as dd/mm/yyyy)*

SHIFT TYPE:	☐ Day	☐ Night

TIME OF RECEIPT OF DI REQUEST:	*(Record as hh/mm)*

ENQUIRER BACKGROUND:

☐ Medical doctor	☐ General public/Patient
☐ Nurse	☐ Other
☐ Pharmacist	_____

ENQUIRER INFORMATION:	*(Include contact information of enquirer including name, grade, location, telephone number, pager number etc.)*

MEDICATION DETAILS:

DRUG NAME	**DOSE**	**FORMULATION**	**CLASSIFICATION/INDICATION**

DESCRIPTION OF DI REQUEST:

(Record information requested. Also include a description and history of the event that led to the request for information, and patient details, if available and/or applicable)

INFORMATION PROVIDED:

(Record information provided as per DI request)

INFORMATION SOURCE:

- ☐ Micromedex® online database
- ☐ TOXBASE® online database
- ☐ British National Formulary (BNF)
- ☐ Electronic medicines compendium (eMC)
- ☐ Internet search including URL

  _____
- ☐ Medicines Authority Website
- ☐ Patient Information Leaflet (PIL)
- ☐ Medical Textbook including name, date of publication and edition number

  _____
- ☐ Previous DI record
- ☐ Personal experience
- ☐ Other _____

CLASSIFICATION OF DI REQUEST:

- ☐ Drug Administration
- ☐ Posology
- ☐ Toxicology and Adverse Reactions
- ☐ Drug Availability and Alternatives
- ☐ Indications and Contraindications
- ☐ Drug Monitoring
- ☐ Drug Identification
- ☐ Other _____

METHOD OF DELIVERY OF DI:

- ☐ Telephone
- ☐ Hardcopy (*)
- ☐ Softcopy
- ☐ Other _____

(include information provided as hardcopy as an attachment with this form)*

TIME TO FINALISE DI REQUEST:

- ☐ Immediately (within 10 minutes)
- ☐ Within 30 minutes
- ☐ Between 30 minutes to 1 hour
- ☐ More than 1 hour
- ☐ Other _____

OTHER RELEVANT INFORMATION:

(Include other information such as follow up and disease progression, trade name of medication, impact on patient care, improvement in medication use, requester satisfaction)

_____

_____

_____

_____

_____

ATTACHMENTS:

NAME OF ATTACHMENT(S)	NUMBER OF PAGES

STATUS OF DI REQUEST:

- ☐ Closed
- ☐ Pending
- ☐ Referred to _____
- ☐ Other _____

NAME OF PHARMACIST, REGISTRATION NUMBER & SIGNATURE:	

APPENDIX V

JOURNAL CLUB AND CLINICAL-BASED DISCUSSION PRESENTATIONS

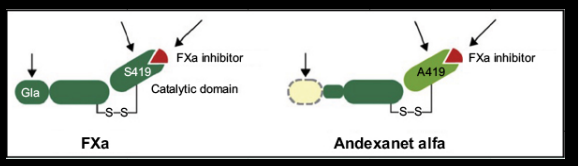
Andexanet alfa for the reversal of Factor Xa Inhibitor Activity (Siegal et al, 2015)

Journal Club 1

November 2018

Summary of Trial

Mechanism of Action



- Approved 2018 by FDA in USA
- Recombinant modified version of human activated factor Xa – Factor Xa inhibitors bind to andexanet alfa with same affinity as natural Factor Xa

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

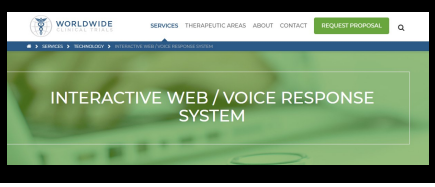
- Factor Xa inhibitors:
  - Limited by lack of antidote to reverse their anticoagulation effects
  - Associated with increased risk for bleeding if emergency surgery is required
- Need for antidote to reverse effects of Factor Xa inhibitors in patients who are bleeding or require emergency surgery

1. Did the trial address a clearly focused issue?

- 2 parallel trials (ANNEXA-A [apixaban] & ANNEXA-R [rivaroxaban])
- Outcomes: Efficacy and Safety of andexanet alfa for reversal of anticoagulation with apixaban or rivaroxaban
- Population studied: Older, Healthy volunteers (50-75 years)
  - Older patients more similar to those who receive Factor Xa inhibitors in the community

2. Was the assignment of patients to treatments randomised?

- Both trials randomised
  - Randomisation using interactive Web-response system to receive andexanet or placebo
  - Interactive system = allocation concealed from researchers and patients



3. Were all of the patients who entered the trial properly accounted for at its conclusion?

- Supplement with study includes details of patient accountability:
  - ANNEXA-A
    - 1 exclusion (inadequate IV access)
    - 1 withdrawal (mild hives)
  - ANNEXA-R
    - 1 lost to follow-up
    - 1 withdrawal (no reason provided)

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

- Intention-to-treat (ITT) analysis
  - Participants who withdrew or were lost to follow-up included in safety and efficacy studies

4. Were patients, health workers and study personnel "blind" to treatment?

- Double-blind and placebo-controlled study reduces bias from patients and researchers
- Triple-blind strengthens the study
- Study sponsored by multiple pharmaceutical companies

5. Were the groups similar at the start of the trial?

- Treatment groups balanced with respect to baseline characteristics
- Treatment groups matched with placebo groups
  - Placebo administered at same administration rate as andexanet alfa

5. Were the groups similar at the start of the trial?

	Apixaban				Rivaroxaban			
	Part 1 bolus only		Part 2 bolus + infusion		Part 1 bolus only		Part 2 bolus + infusion	
	Andexanet	Placebo	Andexanet	Placebo	Andexanet	Placebo	Andexanet	Placebo
N	24	9	24	8	27	14	26	13
Age - Yr								
Median	60.0	58.0	56.0	58.5	56.0	53.5	56.0	57.0
Female sex, N (%)	11 (45.8)	3 (33.3)	7 (29.2)	3 (37.5)	9 (33.3)	6 (42.9)	11 (42.3)	6 (46.2)
BMI, Mean (SD)	26.7 (2.5)	27.4 (2.5)	27.5 (2.1)	27.8 (2.4)	27.0 (3.4)	25.9 (3.4)	27.8 (3.0)	27.6 (2.6)
Creatinine, Mean (SD) (mg/dL)	0.8 (0.2)	0.8 (0.1)	0.9 (0.2)	0.9 (0.2)	0.9 (0.2)	0.8 (0.2)	0.9 (0.2)	0.9 (0.2)
Race, N (%) White	24 (100)	9 (100)	21 (87.5)	8 (100)	22 (81.5)	10 (71.4)	20 (76.9)	8 (61.5)
Ethnicity, N (%) Hispanic or Latino	10 (41.7)	4 (44.4)	11 (45.8)	2 (25)	9 (33.3)	4 (28.6)	4 (30.8)	10 (38.5)

Table S1: Clinical characteristics of the subjects

6. Aside from the experimental intervention, were the groups treated equally?

- Dose of andexanet alfa to reverse 20mg rivaroxaban > than that of 5mg apixaban – PK factors
  - Higher $Conc_{max}$ of rivaroxaban
  - Larger V_d of rivaroxaban

Section B: What are the results?

7. How large was the treatment effect?

- 1ª outcome
  - % change in anti-factor Xa activity
- 2ª outcomes
  - No of participants ≥ 80% reduction in anti-factor Xa acitivity
  - Change in unbound inhibitor plasma conc [1]
  - Change in thrombin generation
  - Occurrence of endogenous thrombin > lower limit of baseline-derived range

[1] Only unbound is pharmacologically active

7. How large was the treatment effect?

Outcome(s)	Result (compared to placebo)
Primary	Anti-factor Xa activity greatly reduced (> 90%) and persisted for 2 hours in both studies
Secondary	All patients except 1 had ≥ 80% reversal of anti-factor Xa activity
	Unbound anti-factor Xa greatly reduced
	Thrombin generation fully restored in 96% of participants

7. How large was the treatment effect?

- 1[a] outcome
  - 99% powered to detect change
  - Power of study not related to 2[a] outcomes
  - 145 participants sufficient to detect change in anti-factor Xa activity from baseline

7. How large was the treatment effect?

Trial Arm	Change in Anti-Xa Activity (1a outcome)
ANNEXA-A, Part 1	94 vs. 21% ($p < 0.001$)
ANNEXA-A, Part 2	92 vs. 33% ($p < 0.001$)
ANNEXA-R, Part 1	92 vs. 18% ($p < 0.001$)
ANNEXA-R, Part 2	97 vs. 45% ($p < 0.001$)

7. How large was the treatment effect?

- No data on urgent reversal of factor Xa inhibitor due to emergency surgery or bleeding
  - Setting too well-controlled to produce detailed PK and PD data
  - Difficult to determine whether complications of bleeding are due to treatment reversal or underlying medical illness

8. How precise was the estimate of the treatment effect?

- N (145) powered with modified ITT population
  - Assumption: differences relative to placebo observed in previous studies represent true differences
- Wilcoxon rank-sum test to compare end points

8. How precise was the estimate of the treatment effect?

- 95% CI for both 1[a] and 2[a] outcomes
- $\alpha = 0.05$
  - P-value (two-sided) ≤ 0.05 = statistically significant
- High precision

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

- Sample Population:
  - Mean age: 57.9 years
  - 61% Male, 39% Female
  - Normal renal function
  - Overweight patients (mean BMI: 25-28)
  - Predominantly Caucasian
    - Hispanic/Latino ethnicity mentioned exclusively

9. Can the results be applied to the local population, or in your context?

- Results cannot be applied for patients with renal failure
- Older, Overweight patients – high prevalence
- Details lacking in race/ethnicity information
- No indication of other treatment – healthy, older patients in trial may not be necessarily target population of Factor Xa inhibitors

9. Can the results be applied to the local population, or in your context?

- Not tested in bleeding patients or as emergency treatment before surgery
- Andexanet alfa not yet available
  - Availability of antidote may increase use of Factor-Xa inhibitors

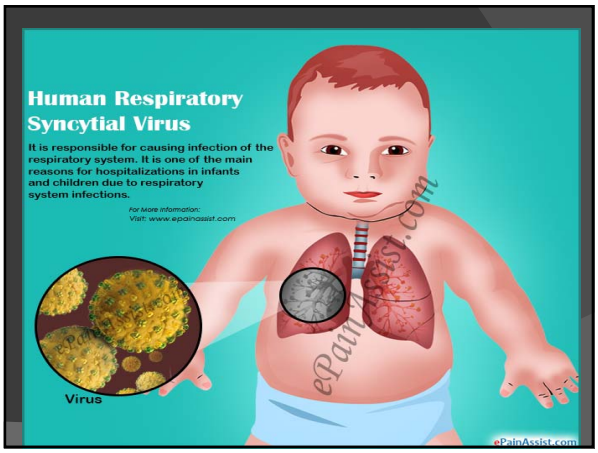
10. Were all clinically important outcomes considered?

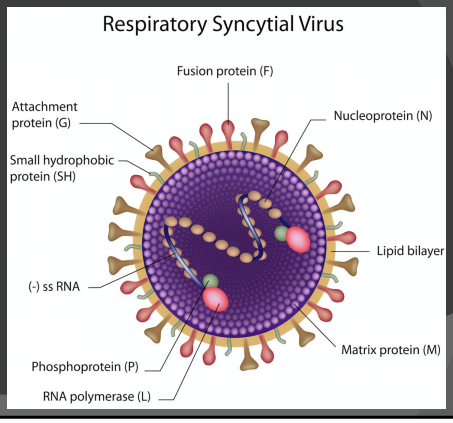
- Safety and Efficacy both considered
- Larger study required – ANNEXA-4 ongoing (andexanet alfa in patients with acute major bleed receiving Factor-Xa inhibitors)
- Andexanet alfa has greatest use in emergency surgery and bleeding

11. Are the benefits worth the harms and costs?

- Adverse events non-serious and mild
  - No thrombotic events
  - No infusion-related reactions
- Andexanet alfa has little immunogenicity after single dose exposure
- Cost – very high ($58,000 per reversal)
  - What do YOU think? Is there a need for andexanet alfa to be introduced in the MDH formulary?

PALIVIZUMAB FOR PREVENTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTION





Respiratory Syncytial Virus (RSV)

- Patients of all ages affected
- < 4 yrs highest risk of complications
- Severe in infants at risk of acute lower RTI
  - Chronic lung disease
  - Congenital heart disease
  - Immunodeficiency

Respiratory Syncytial Virus (RSV)

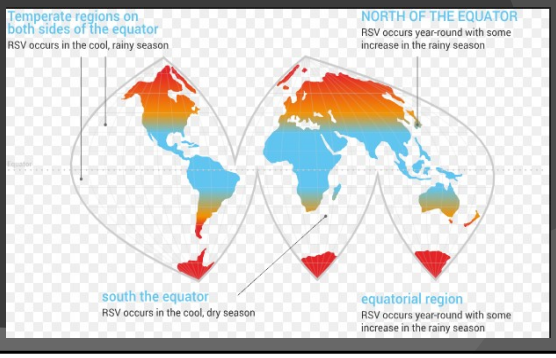
- Infects bronchial, alveolar, dendritic cells
- 50% of children with RSV exhibit re-infection during one winter
- Transmission via aerosol, direct contact
- 2-8 days incubation time
- Hospitalisation rate 3-10%
- Peak season: November (week 44) till March

Respiratory Syncytial Virus (RSV)

Symptoms	Risk factors*	Complications
URTI	Male gender	Apnoeas
Acute otitis media	Age < 6 months	Encephalitis
Croup	Birth during first half of RSV season	Encephalopathy
Bronchiolitis	Crowding & Presence of siblings	
Pneumonia	Day-care exposure	

* Risk factors do not signify indication for palivizumab

Epidemiology of RSV



Symptomatic Treatment of RSV

- Hydration (oral/IV)
- Oxygen
- Ventilation (acute respiratory failure)
- Nebulised bronchodilators
  - Unclear benefit – single trial if wheezing
  - Side effects problematic

Symptomatic Treatment of RSV

- 3% hypertonic saline
  - Can reduce hospital stay and improve clinical severity scores
  - Used according to patient (prolonged stays)

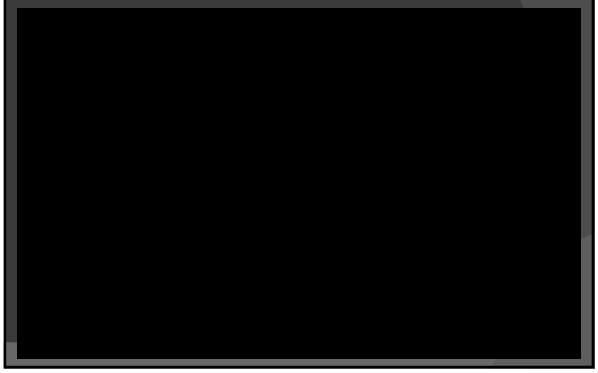
Symptomatic Treatment of RSV

- Inhaled/systemic corticosteroids – lack of benefit
- Ribavirin
  - Only antiviral approved by FDA for RSV in children (off-license in Malta)
  - Controversial – used only in life-threatening situations and immunocompromised patients
  - Syrup used in 1 case at MDH

Preventive Strategies

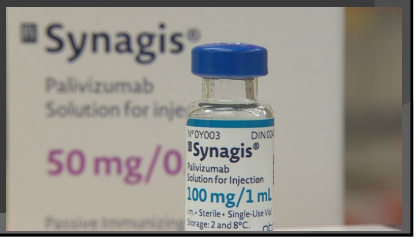
- Vaccine development ongoing
- PALIVIZUMAB (Synagis® - AbbVie Ltd)
  - 10 year development period (MedImmune Inc)
  - First humanised Mab shown to be effective against an infectious disease
  - Reduces hospitalisation rates & complications among high-risk infants

Palivizumab Mode of Action



Synagis®

- 50mg/0.5mL and 100mg/mL
- Stored refrigerated (2 – 8 ºC)
- POM



Administration of Synagis®

- Monthly IM injection (anterolateral aspect of thigh)
- Ready-to-use formulation
- Dose 15 mg/kg over RSV season once a month for 5 months (1st dose – Week 44)
  - No data showing benefit beyond 5 doses
  - Volume (mL) = patient weight (kg) X 0.15
- Volumes > 1mL given as divided doses

Side Effects of Synagis®

- Common
  - Rash
  - Pyrexia
  - Injection site reactions
  - Apnoea
- Uncommon
  - Thrombocytopenia
  - Convulsions
  - Urticaria
  - Anaphylaxis (< 1 per 100,000)

Cautions of Synagis®

- Cautions
  - Moderate-severe thrombocytopenia
  - Coagulation disorders
- No interference by active immunisations e.g. Influenza vaccine
- Mild URTI or fever not usually reason to defer administration

Contraindications of Synagis®

- Hypersensitivity
  - Palivizumab
  - Excipients
  - Other MABs

Cost

- High – limits access by some countries and reduction of global burden of RSV disease
  - 50mg ~ 500-600 EUR per vial
  - 100mg ~ 1,000-1,100 EUR per vial

Cost

- Cost-effectiveness – palivizumab used in high-risk infants for first RSV season
  - Bronchopulmonary Dysplasia (chronic lung disease)
  - Congenital Heart Disease
  - Severe Combined Immunodeficiency Syndrome (SCID)

Cost

- Palivizumab also considered for children < 2 yrs:
  - On long-term ventilation with co-pathology (heart/lung disease)
  - Have abnormalities of lungs or neuromuscular disease that compromise handling of respiratory secretions
  - Requiring treatment for bronchopulmonary dysplasia within last 6 months

Procedure at MDH

- Palivizumab Approval Committee (MDH)
  - Includes clinical pharmacist (paediatrics)
- Palivizumab Register
  - Patient details (P-drive)

Procedure at MDH

Submission

- **Exceptional Medicinal Treatment Request Form**
- Approval by Committee

Patient Registration

- Patient details in palivizumab register
- Appointment at PDCU
- Dose calculation
- Calculate cumulative dose estimating patient's weight using growth chart

Procedure at MDH

Administration

- Paediatrician cover (HST or higher)
- Consent by parents/guardians
- Confirmation of dose (re-weighing of patient)
- Compile **Paediatric Anaphylaxis Medication Chart** for each patient for each dose
- Baseline parameters at administration and every 30 minutes thereafter

Discharge

- Compilation of Immunisation Sheet
- Give date of next appointment
- Warn patients of late response anaphylaxis

Inpatient Procedure

- List of patients eligible for palivizumab
- Patient marked following dispensing
- Order placed for following month based on child's weight (ensures availability of stock)

Future of RSV Treatment

- Vaccine still unavailable
- Antiviral treatment limited
- Palivizumab is only tool available in preventing RSV infection in high-risk individuals
- Motavizumab-YTE – long-lasting Mab with similar safety profile to palivizumab except skin events
  - Unlikely to replace palivizumab

References

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Olchanski N, Hansen RN, Pope E, D'Cruz B, Fergie J, Goldstein M, et al. Palivizumab prophylaxis for respiratory syncytial virus: examining the evidence around value. Open Forum Infect Dis. 2018;5(3):ofy031.

References

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National Health Service. Green book Chapter 27a – Respiratory syncytial virus version 2.0. 2015

Sammut P, Cassar Flores AM. Guideline for the use of palivizumab (Synagis). Mater Dei Hospital. 2016.

APPENDIX VI

FEEDBACK FORMS

Journal Club Feedback Form

1. **Pharmacy Section.**

_____

2. **Number of years' experience as a pharmacist.**

_____

3. **Descriptions of the session segments were clear.**

Not clear at all	Somewhat clear	Neutral	Mostly clear	Very clear

4. **The presented content was useful for your practice.**

Not useful at all	Somewhat useful	Neutral	Mostly useful	Very useful

5. **Please rate your confidence as a pharmacist in performing critical appraisal of a study after completion of this journal club.**

Not confident	Somewhat confident	Neutral	Mostly confident	Very confident

6. **The content was presented at an appropriate learning level.**

Greatly below learning level	Somewhat below learning level	At appropriate learning level	Slightly above learning level	Greatly above learning level

7. **Was the facilitator helpful in promoting understanding of the session material?**

Not helpful	Somewhat helpful	Neutral	Mostly helpful	Very helpful

8. **The size of the group was adequate for the purposes of the journal club.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

9. **Please enter comments on the strengths of this journal club.**

_____

_____

_____

_____

_____

10. **Please enter comments on the areas of suggested improvement of this journal club.**

_____

_____

_____

_____

_____

Thank you!

Clinical-based Discussion Feedback Form

1. **Pharmacy Section.**

_____

2. **Number of years' experience as a pharmacist.**

_____

3. **Descriptions of the session segments were clear.**

Not clear at all	Somewhat clear	Neutral	Mostly clear	Very clear

4. **The presented content was useful for your practice.**

Not useful at all	Somewhat useful	Neutral	Mostly useful	Very useful

5. **Please rate your confidence as a pharmacist in the clinical subject after completion of this discussion.**

Not confident	Somewhat confident	Neutral	Mostly confident	Very confident

6. **The content was presented at an appropriate learning level.**

Greatly below learning level	Somewhat below learning level	At appropriate learning level	Slightly above learning level	Greatly above learning level

7. **Was the facilitator helpful in promoting understanding of the session material?**

Not helpful	Somewhat helpful	Neutral	Mostly helpful	Very helpful

8. **The size of the group was adequate for the purposes of the clinical-based discussion.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

9. **Please enter comments on the strengths of this clinical-based discussion.**

_____

_____

_____

_____

_____

10. **Please enter comments on the areas of suggested improvement of this clinical-based discussion.**

_____

_____

_____

_____

_____

Thank you!

Drug Information Audit Form

The following is a retrospective audit of an online documented drug information (DI) query. The attached DI query was chosen randomly from archived documents using an online random number generator. As an auditor, you are being asked to evaluate the query, with respect to both its content and presentation, by answering the questions below.

1. **The fields in the documentation form were adequately filled in by the pharmacist.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

2. **The question asked by the requestor was properly formulated by the pharmacist.**

Not proper	Somewhat proper	Neutral	Mostly proper	Very proper

3. **The response provided by the pharmacist answered the query adequately.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

4. **The background information of the enquirer recorded was sufficient to allow traceability should this be required.**

Not sufficient	Somewhat sufficient	Neutral	Mostly sufficient	Very sufficient

5. **The search strategy followed by the pharmacist was adequate.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

6. **The information source consulted by the pharmacist to answer the question was adequate.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

7. **The DI request was classified appropriately.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

8. **The method used by the pharmacist to deliver DI was adequate.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

9. **The time taken by the pharmacist to answer the question was adequate.**

Not adequate	Somewhat adequate	Neutral	Mostly adequate	Very adequate

10. **Please indicate any comments you might have below.**

_____

_____

_____

_____

_____

APPENDIX VII

ELECTRONIC DI DOCUMENTATION FORM

Electronic Drug Information Documentation Form

Pre-Pilot Study

Drug Information (DI) Documentation Form

* Required

1. **Date** *

   Example: December 15, 2012

2. **Name of Pharmacist** *

3. **Time of Receipt** *

   Example: 8:30 AM

4. **Shift Type** *

   Mark only one oval.

   - Normal Working Hours
   - Day Shift
   - Night Shift

5. **Urgency of Request** *

   Mark only one oval.

   - ASAP
   - < 24 Hours
   - > 24 Hours

6. **Type of Request** *

   Mark only one oval.

   - Patient-related
   - Academic
   - Other:

7. **Enquirer Background** *

   Mark only one oval.

   - Medical Doctor
   - Nurse
   - Pharmacist
   - Patient
   - Other:

8. **Enquirer Background Information (include name, grade, location, telephone number etc)** *

9. **Information Source (check all that apply)** *
Check all that apply.

- [ ] UpToDate
- [ ] Micromedex
- [ ] Toxbase
- [ ] Medicines Complete
- [ ] MDH Drug Monographs
- [ ] British National Formulary (BNF)
- [ ] Electronic Medicines Compendium (eMC)
- [ ] Textbook (include name and edition number in "Other")
- [ ] Other:

10. **Classification of DI Request (check all that apply)** *
Check all that apply.

- [ ] Drug Administration
- [ ] Posology
- [ ] Toxicology, Adverse Reactions and Drug Interactions
- [ ] Drug Availability and Alternatives
- [ ] Drug Monitoring
- [ ] Drug Identification
- [ ] Indications and Contraindications
- [ ] Other:

11. **Method of Delivery of DI** *
Mark only one oval.

- ◯ Telephone
- ◯ Hardcopy
- ◯ Softcopy
- ◯ Combination of the above

12. **Description of DI Request** *

13. **Information Provided** *

14. **Time to Finalise DI Request** *

15. **Other Relevant Information**

16. **Status of DI Request** *
Check all that apply.

- [ ] Closed
- [ ] Referred to Medicines Information Department Pharmacist (include details in "Other")
- [ ] Other: _____

Electronic Drug Information Documentation Form

Post-Pilot Study

Drug Information (DI) Documentation Form

* Required

1. *

   Example: December 15, 2012

2. **Name of Pharmacist** *

3. **Time of Drug Info Receipt** *

   Example: 8:30 AM

4. **Urgency of Request** *

   Mark only one oval.

   - ASAP
   - < 24 Hours
   - > 24 Hours

5. **Type of Request** *

   Mark only one oval.

   - Patient-related
   - Academic
   - Other:

6. **Enquirer Background** *

   Mark only one oval.

   - Medical Doctor
   - Nurse
   - Pharmacist
   - Patient
   - Other:

7. **Enquirer Background Information (include name, grade, location, telephone number, details of private practice etc)** *

8. **Information Source (check all that apply)** *
Check all that apply.

- [ ] UpToDate
- [ ] Micromedex
- [ ] Toxbase
- [ ] Medicines Complete
- [ ] MDH Drug Monographs
- [ ] British National Formulary (BNF)
- [ ] Electronic Medicines Compendium (eMC)
- [ ] Textbook (include name and edition number in "Other")
- [ ] Other: _____

9. **Classification of DI Request (check all that apply)** *
Check all that apply.

- [ ] Drug Administration
- [ ] Posology
- [ ] Toxicology, Adverse Reactions and Drug Interactions
- [ ] Drug Availability and Alternatives
- [ ] Drug Monitoring
- [ ] Drug Identification
- [ ] Indications and Contraindications
- [ ] Other: _____

10. **Method of Delivery of DI** *
Mark only one oval.

- ◯ Telephone
- ◯ Hardcopy
- ◯ Softcopy
- ◯ Combination of the above

11. **DI Question Requested** *

_____

_____

_____

_____

_____

12. **Information Provided** *

_____

_____

_____

_____

_____

13. **Time to Finalise DI Request** *

14. **Other Relevant Information**

15. **Comments**

16. **Status of DI Request** *

Check all that apply.

- [ ] Closed
- [ ] Referred to Medicines Information Department Pharmacist (include details in "Other")
- [ ] Other: _____

APPENDIX VIII

AFTER-HOURS RESOURCES INDEX LISTS

Printed Reference Resources Index List

Pre-Pilot Study

AFTER-HOURS

MANUAL RESOURCES INDEX

(MANUAL RESOURCES TO BE USED **ONLY** AS A BACK UP TO AND/OR TO SUPPLEMENT ONLINE RESOURCES)

After-hours Manual Resources Index

Name of Manual Resource	Author/ Editor	Edition Number	Year of Publication	Classification	Position in Shelf
Guidelines for the Prescription and Use of Domiciliary Oxygen	Oxygen Guidelines Working Team	1st	2007	Miscellaneous	A1
CINV Pocket Guide	Hospital Pharmacy Europe	1st	2015	Miscellaneous	A1
Phosphate Binders Pocket Guide	Hospital Pharmacy Europe	1st	2016	Miscellaneous	A1
Psychotropic Drug Directory 2003/04	Bazire S	1st	2003	Miscellaneous	A1
The Sanford Guide to Antimicrobial Therapy 2003	Gilbert et al	33rd	2003	Miscellaneous	A1
Poisoning and Drug Overdose	Olson KR	3rd	1998	Toxicology	A1
Poisoning and Drug Overdose	Olson KR	6th	2011	Toxicology	A1
BNF 40	BMA, RPS	40th	2000	General	A2
BNF 54	BMA, RPS	54th	2007	General	A2
BNF 65	BMA, RPS	65th	2013	General	A2

Chemist & Druggist guide to OTC medicines	Gladwin C	21st	2002	General	A2
Maltese Medicines Handbook – an addendum to the BNF 2016	Scicluna T	4th	2016	General	A2
Martindale The Complete Drug Reference	Sweetman SC	34th	2005	General	A2
Middle East Medical Index July 1999 – June 2000	CCM Middle East	21st	1999	General	A2
The Merck Manual of Diagnosis and Therapy	Merck Research Laboratories	18th	2006	General	A2
Handbook of Drug Administration via Enteral Feeding Tubes	White R, Bradnam V	1st	2007	Drug Administration	B1
Handbook on Injectable Drugs	Trissel L	16th	2010	Drug Administration	B1
The Renal Drug Handbook	Ashley C, Currie A	3rd	2009	Drug Administration	B1
Drugs during Pregnancy and Lactation	Schaefer C, Peters PWJ, Miller RK	2nd	2007	Pregnancy and Lactation	B1
Drugs in Pregnancy and Lactation	Briggs GG, Freeman RK	6th	2002	Pregnancy and Lactation	B1
Drugs in Pregnancy and Lactation	Briggs GG, Freeman RK	7th	2005	Pregnancy and Lactation	B1

Medications and Mothers' Milk	Hale T Jr.	11th	2004	Pregnancy and Lactation	B1
BNF for Children	BMA, RPS	1st	2006	Paediatrics	B2
BNF for Children	BMA, RPS	6th	2010	Paediatrics	B2

Written By:	JEFFREY CASSAR
Stamp and Signature:	
Position:	Pharmacist
Date:	28th September 2018
Date of Next Revision:	31st October 2018

Printed Reference Resources Index List

Post-Pilot Study

AFTER-HOURS

MANUAL RESOURCES INDEX

(THE PRIMARY SOURCES ARE THE AVAILABLE ONLINE SUBSCRIPTIONS AND DATABASES. MANUAL SOURCES LISTED HEREUNDER ARE ONLY MEANT AS **BACKUP**)

After-hours Manual Resources Index

Name of Manual Resource	Author/ Editor	Edition Number	Year of Publication	Classification	Position in Shelf
Guidelines for the Prescription and Use of Domiciliary Oxygen	Oxygen Guidelines Working Team	1st	2007	Miscellaneous	A1
CINV Pocket Guide	Hospital Pharmacy Europe	1st	2015	Miscellaneous	A1
Phosphate Binders Pocket Guide	Hospital Pharmacy Europe	1st	2016	Miscellaneous	A1
Poisoning and Drug Overdose	Olson KR	6th	2011	Toxicology	A1
Maltese Medicines Handbook – an addendum to the BNF 2016	Scicluna T	4th	2016	General	A2
Martindale The Complete Drug Reference	Sweetman SC	34th	2005	General	A2
The Merck Manual of Diagnosis and Therapy	Merch Research Laboratories	18th	2006	General	A2

Handbook of Drug Administration via Enteral Feeding Tubes	White R, Bradnam V	1st	2007	Drug Administration	B1
Handbook on Injectable Drugs	Trissel L	16th	2010	Drug Administration	B1
The Renal Drug Handbook	Ashley C, Currie A	3rd	2009	Drug Administration	B1
Drugs during Pregnancy and Lactation	Schaefer C, Peters PWJ, Miller RK	2nd	2007	Pregnancy and Lactation	B1
Drugs in Pregnancy and Lactation	Briggs GG, Freeman RK	7th	2005	Pregnancy and Lactation	B1

Written By:	JEFFREY CASSAR
Stamp and Signature:	
Position:	Pharmacist
Date:	22nd November 2018
Date of Next Revision:	28th February 2019

Electronic Reference Resources Index List

Pre-Pilot Study

Electronic Subscription-based Resources

Database	URL	Username	Password
Medicines Complete	https://about.medicinescomplete.com/	ruth.agius@gov.mt	Agius123
Medusa	http://medusa.wales.nhs.uk/logon.asp	qehuser	angel9
Micromedex	https://www.micromedexsolutions.com/home/dispatch	MLTA293	M138163A
Toxbase	https://www.toxbase.org/	H5731	MAN66L

NB: All usernames and passwords are case-sensitive.

Electronic Reference Resources Index List

Post-Pilot Study

Electronic Subscription-based Resources

Database	URL	Username	Password
Medicines Complete	https://about.medicinescomplete.com/	ruth.agius@gov.mt	Agius123
Medusa	http://medusa.wales.nhs.uk/logon.asp	qehuser	angel9
Micromedex	https://www.micromedexsolutions.com/home/dispatch	MLTA293	M138163A
Toxbase	https://www.toxbase.org/	H5731	MAN66L

NB: All usernames and passwords are case-sensitive.

Refer to the latest version of **SOP # MEIN 001** *(Procedure for answering a medicines information enquiry)* for a list of non-subscription based electronic resources.

APPENDIX IX

ABSTRACT SUBMISSIONS

Submission to 2018 Malta Medical School Conference

Setting up a 24-hour drug information service

Jeffrey Cassar[+], Louise Grech[+], Lilian M. Azzopardi[+]

[+]Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Introduction

The Pharmacy Department at Mater Dei Hospital (MDH) operates a 24-hour drug information service (DIS) via its Medicines Information section during normal working hours and through shift pharmacists after-hours. This study aimed to identify deficiencies of the after-hours DIS and propose improvements required.

Methods

A thee-week research observation placement was attended at the drug information centre at the University of Illinois in Chicago, USA, to detect the framework used. Subsequently, a focus group consisting of nine members was set up to discuss improvements identified based on the observational framework and which are required in the after-hours DIS at MDH. The participants of the focus group included the Head of Pharmacy Services at MDH, one pharmacist from each of the following sections: Medicines Information, Quality Assurance and after-hours shift pharmacists; two staff nurses, two hospital doctors and one community pharmacist.

Results

Proposed improvements from the focus group and the three-week observation placement include introducing a pharmacist to serve as a liaison between the Medicines Information section and after-hours pharmacists, increasing training for after-hours pharmacists, organising online and physical after-hours information resources, setting up journal clubs and clinical-based discussions for after-hours pharmacists, introducing an audit system and documentation of clinically relevant requests.

Conclusion

Eliminating weaknesses in the after-hours DIS ensures the constant delivery of high quality drug information to users of the system, thereby improving patient care and allowing for a 24-hour seamless DIS.

Disclosure and Funding Sources

Nil of note.

Submission to 2019 FIP Congress

Harmonisation of a 24-hour drug information service

Jeffrey Cassar[+], Lilian M. Azzopardi[+], Louise Grech[+], Jennifer Pham*

[+]Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

***Department of Pharmacy, University of Illinois in Chicago, Chicago, IL, USA**

Background: Mater Dei Hospital (MDH) in Malta operates a drug information service (DIS) through two separate sections: the Medicines Information Section (MID) during normal working hours and the shift pharmacy service during after-hours.

Purpose: To achieve harmonisation between the DIS provided by the MID and shift pharmacists by addressing the needs and improvements required by, the after-hours DIS.

Methods: A three-week observation study was performed at the drug information centre at the University of Illinois in Chicago (UIC), USA, and a gap-analysis comparing the DIS at MDH to that of UIC was performed. A 9-member focus group was set up to discuss improvements required by the after-hours DIS at MDH. An improvement framework with a timeline over four months for implementation was drafted and validated.

Results: Five categories of needs were identified from the improvement framework: communication, quality assurance, documentation, standardisation of workforce number and organisation of resources. A liaison pharmacist was introduced to enhance communication between the MID and after-hours. 11 training sessions were held by the MID for two after-hours pharmacists. An electronic documentation form was developed, validated and documented 71 DI requests, 9 of which were audited by 3 pharmacists. An on-call system to keep staff levels constant was implemented in 22 instances. 12 out of 24 printed after-hours reference resources were outdated and removed. Access information for 4 electronic subscription-based reference resources was assembled.

Conclusion: The improvement framework laid down a harmonised system providing high quality drug information at all hours, and entered normal work practice at MDH.