Pharmacist-Led Transition of Care in Diabetic Patients

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ABSTRACT

Pharmacist-led interventions have shown to decrease drug-related problems (DRPs) and improve clinical outcomes. This study aimed to develop and implement a pharmaceutical service at the outpatient setting for diabetic patients focusing on medicine reconciliation and effective Transition of Care. This prospective investigational study was conducted at Mater Dei Hospital diabetic clinic in the outpatient department where patients ≥18 years of age, taking at least one antidiabetic medication were eligible to participate in the study. A Transition of Care document, aimed at compiling the necessary medical information obtained during the medicine reconciliation undertaken during this study, was developed and disseminated to the patients' community pharmacist via electronic mail. Three questionnaires were developed, one was sent together with the Transition of Care document to the community pharmacist to assess the effectiveness of the document, a second questionnaire was completed by the patient to assess the pharmacist intervention, and the third questionnaire was disseminated to the diabetologists, diabetic specialists and the diabetic nurses working at the diabetic outpatient clinic.

Hundred patients were recruited in the study. One hundred ninety-four drug-related problems were identified during the medicine reconciliation and classified into six categories. The four most prevalent DRPs were "Lack or misinterpretation of information" (n=48), "Insufficient awareness of health and diseases" (n=47), "Inappropriate timing of administration and/or dosing interval" (n=36) and "Non-adherence to treatment" (n=27). Eighty-five patients required verbal intervention from the clinical pharmacist, nine patients required written advice and four patients required both written and verbal intervention.

The Transition of Care document was disseminated to 73 community pharmacists. Forty-one community pharmacists completed the questionnaire and unanimously agreed that there is a need for better communication between hospital pharmacist and the community. Patients (98%) reacted positively to the clinical service offered by the pharmacist at the diabetic clinic while all healthcare professionals (N=9) encouraged the addition of a clinical pharmacist to the diabetic team.

The implementation of the developed pharmacist-led Transition of Care service was shown to be relevant to the outpatient diabetic group, as demonstrated by the identified DRPs. The effectiveness of the Transition of Care document needs to be further evaluated.

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LIST OF ABBREVIATIONS

DEU	Diabetic Education Unit
DRPs	Drug Related Problems
GDPR	General Data Protection Regulation
GP	General Practitioner
HCP	Healthcare Professional
MDH	Mater Dei Hospital
MR	Medicine Reconciliation
NHS	National Health System
NPSG	National Patient Safety Goal
OTC	Over-the-Counter
PCNE	Pharmaceutic Care Network Europe
ToC	Transition of Care

CHAPTER 1 INTRODUCTION

1.1 Background

Medication errors are the leading causes of morbidity and mortality among patients (Abdulghani et al., 2018; Wheeler et al., 2018). More than half of these errors occur during the transition between different healthcare settings, residential homes, or different outpatient care facilities. The shift of patients is usually for the purpose of receiving medical care, in most instances, patients would require consultations with different healthcare providers.[1] Studies reveal that movement of patients within the healthcare system are considered 'high-risk scenarios' and predispose the patients to medication errors or loss of critical clinical data which in turn can jeopardise patient safety (Allende Bandrés et al., 2013; Brantley et al., 2018).

1.2 Seamless pharmaceutical care

The concept of seamless pharmaceutical care refers to the continuity of care across the spectrum of caregivers and healthcare settings without embracing discrepancies.
Transferring between different healthcare sectors are often accompanied by either new diagnosis, new treatment or a change of the current treatment. This issue of manoeuvring of patients has been gearing up importance globally for the past few years (Hume et al., 2012). This importance was mainly attributed to the readmissions of patients, mostly due to suboptimal care during this crucial period (Hertig et al., 2017).

[1] World Health Organization [Internet]. Apps.who.int. 2016 [cited 2018 December 6]. Available from: http://apps.who.int/iris/bitstream/handle/10665/252272/9789241511599-eng.pdf;sequence=1

One fundamental element at ensuring this continuity is by having the correct flow of information between healthcare professionals (van Hollebeke et al., 2016). Studies show that 15-87% of patients experience some medication errors during the transitioning, mainly due to the gaps which exist in this continuity of information (Gleason et al., 2004; Cornish et al., 2015; Lessard et al., 2016). This is not a new concept for health professionals. They are indeed aware that there are gaps in the system which needs to be overcome, thereby ensuring a smooth and seamless transition between these interfaces (Lessard et al., 2016). One way how these gaps can be overcome is by having harmonisation between different healthcare providers. This entails having direct communication between health sectors, their community pharmacist and their family doctor. All sectors should be informed of any changes in treatment. If this practice fails at any point, crucial data can be left unnoticed. In many instances, the community pharmacists are often not included in the chain of Transition of Care, despite many patients receiving their medications from community pharmacies while in the outpatient setting (van Hollebeke et al., 2016; Moreau et al., 2017).

Community pharmacists are ideally positioned at ensuring continuity of care. This is executed by optimising the utilisation of the patient's medications and improving patient education. The pharmacist can also enhance the communication of medical data between the hospital and the community pharmacist thus reducing medication errors and hospital readmissions (Bolas et al., 2004; Phatak et al., 2015; van Hollebeke et al., 2016). Unless the community pharmacists are supplied with a comprehensive and updated patient medication information, they cannot reconcile medications and prevent medication errors which predispose the patient at risk of obtaining incorrect medications.

If the pharmacist is not aware of any changes done to a patient's medication, the pharmacist will not be able to dispense the updated medication list and provide appropriate consultation (Bolas et al., 2004). The World Health Organisation (WHO) in 2016[1] issued a report to accentuate the need for improving the communication between healthcare professionals to increase the medication safety and reduce medication errors (Wheeler et al., 2017).

Feigenbaum et al., (2012), in one of his studies, suggests that 28% of readmissions were attributed to poor medication management during or immediately after hospital admission. Pharmacists have high education standards and specialised training and are therefore mostly equipped in managing these discrepancies by having the knowledge to identify, report and correct the inconsistencies encountered during the reconciliation by using a multidisciplinary approach. Lack of resources and time constraints are some of the main reasons why such a system has not been implemented.

1.3 Medicine reconciliation

Medicine reconciliation is an intervention that is effective and which can be implemented across the healthcare system regardless of their structure, size and funding (van Mil et al., 2004). It is a formal process of formulating the most accurate and detailed list of medications which is currently being taken by the patient. This list should include all the prescription and non-prescription drugs, including the drug name, dosage, route and frequency (Wheeler et al., 2018). This medication list should then be compared to a reference list, locally the Schedule V entitlement list. This list should then be revised periodically and appropriately transferred in the process of care, keeping in

mind that medications can be added or adjusted or non-prescription medications can be added to the medication lists (van Milet et al., 2000; Marinović et al., 2016). In the United States, the Joint Commission on Accreditation[2] in 2005, implicated medicine reconciliation as a National Patient Safety Goal (NPSG) and then later in 2006, the World Health Organisation (WHO) established the High 5s Project to reduce the issue related to patient safety. In this project, the WHO launched Standard Operating Procedures such as "Medicine Accuracy at Transition in Care"[3] to standardise the Transition of Care processes across countries. It was then followed by the WHO High 5s Protocol[4].

According to the Joint Commission, medicine reconciliation process should be performed using the following five-step approach[5]. The first step is the compiling of a comprehensive list including all current medications such as over-the-counter medications, non-prescription drugs, vitamins, and dietary supplements, along with their respective doses, frequency and route of administration. Adherence to treatment should also be taken into consideration.

The second step contributes to the compiling of a list of prescription drugs which were prescribed to manage both acute and chronic conditions. The patient's views and concerns on the previous treatment should be addressed and communicated in detail.

[2] Joint Commission. Sentinel Event Alert Using medication reconciliation to prevent errors. [Internet] Jointcommission.org. 2018 [cited 2018 November 29]. Available from https://www.jointcommission.org/sentinel_event_alert_issue_35_using_medication_reconciliation_to_prevent_errors/

[3] World Health Organization. High 5s Protocol on Medicine Reconciliation and Implementation Guide. [Internet]. [cited 2018 November 30]. Available from: http://www.who.int/patientsafety/implementation/solutions/high5s/h5s-guide.pdf?ua=1

[4] World Health Organization. High 5s: Standard operating procedures [Internet]. 2006 [cited 2018 November 30]. Available from: http://www.who.int/patientsafety/topics/high-5s/en/

[5] Ambulatory Health Care: 2015 National Patient Safety Goals. [Internet]. Jointcommission.org. 2015 [cited 2018 December 6]. Available from: https://www.jointcommission.org/assets/1/6/2018_AHC_NPSG_goals_final.pdf

Allergies should also be documented. The next step incorporates the comparison of the original list with the current and updated list. The fourth step is the actual hands-on medications, checking for drug-drug-interactions, and adverse effects. The appropriate use of medications should be considered. Extra care should be taken if the patient is taking high-risk medications which require close monitoring. The last step is patient education which will be addressed down the line (Johnson et al., 2015; Phatak et al., 2015).

1.4 Patient-centred approach

The patient needs to be the central focus of care, and hence the patient's input in the decision making has a significant role. The patient needs to accept and apprehend with the treatment plan, the goals to be achieved, and changes in lifestyle, which will ultimately affect the quality of life. It comes to no surprise that including the patient in decision making improves compliance, enhances the patient's wellbeing and reduces re-hospitalisations (Kristeller, 2014). This is even more significant when dealing with chronic patients, such as diabetic patients and elderly patients, as they are most likely to have more complex health profile and multiple prescribers. When dealing with chronic diseases, the patient has to deal with polypharmacy, which in many instances, is already a burden on the patient. Having a continuous change in treatment or change in dosage regimen can indeed be very confusing for the patients. One way how to drastically reduce medication errors is to ensure timely and accurate handover of data at all transition points of care (Wheeler et al., 2018).

Collaboration between the hospital pharmacist and the pharmacist in the community can assist in achieving the desired patient-centre approach.

1.4.1 Pharmacists in patient-centre approach and patient education

Hospital pharmacists play a leading role in the management of medication errors to ascertain seamless transitioning. For effective Transition of Care, one requires not only cooperation between clinicians and clinical pharmacist but also with the pharmacists in the community. The role of the community pharmacist has long started to shift from dispensing to actively participating in the patient's safety, counselling and education during the period of transition. The clinical pharmacist performs medicine reconciliation, identify patients with poor literacy so that more time is dedicated to patient education, especially on the correct administration of medications.

The pharmacist who leads the medicine reconciliation would investigate the appropriateness and effectiveness of each medication, determine adherence issues, possible consequences and monitoring plans (Cavanaugh et al.,2015). Patient-centred communication has been associated with increased patient satisfaction, better adherence to treatment and improved health outcomes. The community pharmacist must then ascertain that the patient is actively participating, and showing interest in the awareness of their condition and treatment. The patient should be encouraged to express concerns with regards to treatment, whether a change in treatment is essential, what to expect, and what actions to follow after experiencing adverse drug reactions (Ensing et al.,2018). Identifying the adherence barriers can be challenging, but by gaining the patient's confidence, and offering the patient a comfortable environment, it is more

likely that they share their experiences and concerns about use-associated problems. The evaluation of the patient's medication is necessary since the patients could resume old and incorrect medication routines, new problems may arise such as new drug-related problems, undesired effects or misunderstanding or misinterpreting the new drug regimen. One might be in a better position to assess the patients' perceptions of their use of medications in general but also making particular emphasis on the newly started medications. By listening to the patients' concerns, one would be able to address the problems which are relevant to the patient and also decreasing the risk of resistance and rejection of medications (Ensing et al.,2015).

The Joint Commission Centre for Transforming Healthcare in the United States emphasises the importance of improving the Transition of Care through better communication.[6] When patients attend multiple outpatient appointments, due to their chronic disease, the pharmacist is not aware of any changes made to the patient's list of medications. The patients are not always in a position to inform the pharmacist about the changes themselves. There could be various reasons for this, either due to illiteracy or due to some cognitive impairment or only due to negligence (Geurts et al.,2013).

Having a hospital pharmacist communicating directly with the community pharmacist provides continuity of care. Community pharmacist, on the other hand, can and should take a more active role in the management and counselling of patients (Ensing et al.,2018). The community pharmacist will be provided with a list of medication-related problems to follow-up, or concerns which would have cropped up during the medicine

[6] Joint Commission Centre for Transforming Healthcare. Improving transitions of care: hand-off communications. [Internet]. Centerfortransforminghealthcare.org. [cited 2018 December 6]. Available from: https://www.centerfortransforminghealthcare.org/assets/4/6/handoff_comm_storyboard.pdf

reconciliation. The community pharmacist can then follow up on these concerns, counsel patients when best to repeat blood test to follow-up on any underside effects which the medications can cause (Kristeller, 2014).

1.4.2 Barriers to medicine reconciliation

Human resources and time constraints are some of the barriers which limit the success of medicine reconciliation across the continuum of care (Manias et al., 2018). Another limitation would be having patients with limited health literacy, which might be overseen as a barrier to medication reconciliation. Prior studies have shown that patients with limited health literacy have a poorer understanding of prescription medication names, indications for use, and instructions (Dowse et al., 2003; Davis et al., 2006). Lack of electronic health records is another limiting factor. If information is not accessible across the continuum of care such as with the community pharmacist, ambulatory clinics and private hospitals can indeed disrupt the seamless transition of important information (Johnson et al., 2015).

1.5 Transition of Care

Transition of Care refers to the shifting of patients between healthcare settings and providers during which their condition and medical needs might change. This includes the transition between the home, hospital, residential care setting and consultation with different healthcare providers in the outpatient setting. This transition often involves

the patient, close family or caregiver, a nurse, a pharmacist and the physician.[7] The patient is the only constant factor during the transitioning, and should the communication fail to be transmitted between all healthcare providers successfully, relevant medical data can, and will get lost. This will inevitably lead to delay of care, inappropriate monitoring, additional primary care or emergency department visits, additional or duplicate tests, adverse effects, patient's overall confusion and increase re-hospitalisations (Johnson et al., 2015). This inadequate transitioning is said to account for 40% of all medication errors in the United States alone (Brantley et al., 2018). This is mostly due to inadequate medicine reconciliation and missed or overlooked follow-ups (Kristeller, 2014). There are several actions which are designed to ensure coordination and continuity of care. These include having a comprehensive care plan with well-trained practitioners and pharmacists who have current information about the patient's treatment goals, preferences, and health or clinical status. The plan should include logistical arrangements and education of patient and family, as well as coordination among the health professionals involved in the transition.[8]

Discrepancies can occur at any level of care such as between medications people take at home, what their family doctor assumes that they are having, the medications listed on the referral ticket or discharge letters to the medication lists which are collected from the Pharmacies (Naccarella et al., 2013). The following three phases encompass the ideal Transition of Care model: medication management, which we have addressed in

[7] National Transitions of Care Coalition. Improving transition of care: findings and consideration of the "Vision of the National transitions of Care Coalition". [Internet]. Ntocc.org. [cited 2018 December 6]. Available from: http://www.ntocc.org/Portals/0/PDF/Resources/NTOCCIssueBriefs.pdf

[8] The National Transitions of Care Coalition [Internet]. Ntocc.org. 2008 [cited 2018 December 7]. Available from: http://www.ntocc.org/Portals/0/PDF/Resources/TransitionsOfCare_Measures.pdf

detail in section 1.3, communication while actively involving the patient in the decision-making and patient education.

1.6 Bridging the gaps between tertiary care and the community

The need for better communication between different health systems has been cited as being crucial for the past 15years (Brackenborough et al., 1997).To ascertain continuity of care and that no medical data is lost in any level, there must be a clear understanding of the reasons for therapy and any changes involved including the names of the medications and dosages. All healthcare professionals involved in the management of medications need to be informed. Literature shows that supplying the pharmacist with a discharge letter, improved the unintended medication discrepancies drastically (Duggan et al., 1998). In many instances, even more so locally, the community pharmacists are not informed whether the patient has been hospitalised, attended outpatient appointments or whether there was a change in treatment, allergies or drug interactions. Community pharmacists have a significant role in counselling the patients and so by keeping the flow of information, they can follow-up the patient when transferred in the community setting.

Another critical area which calls for improvement is the increased focus on the needs of patients and their families and carers, improved communication with patients and between healthcare providers across settings, and the need for recognition of Transition of Care as an integral component of care coordination (van Mil et al., 2004; Geurts et al., 2013; Urban et al., 2013)

1.7 Diabetic patients as the study population and the elderly

Advances in medicine have led to an increase in the ageing population. Geriatric patients, together with diabetic patients, are more vulnerable to DRPs since they are more likely to be diagnosed with multiple diseases. Diabetic patients form a significant proportion worldwide. The International Diabetes Federation (IDF) reported that about 382million people had diabetes in 2013.[9] It is estimated that the incidence of diabetes will increase globally by 50% within the next 20 years (Shaw, Sicree, Zimmet, 2010).

The average HbA1c in this study was calculated to be 9%, which is very high, considering that a small sample of one hundred patients was studied. These findings necessitate the urgent intervention of the pharmacist as there is a positive correlation between adherence, patient education and disease control. During the pharmaceutical session, the research-pharmacist emphasized on drug adherence and education, especially when these findings were noted (Schectman et al., 2002; Myriam et al., 2017). Forgetfulness was one of the reasons why patients were not adherent to treatment, and thereby the reason why one of the most prevalent DRP observed in the study was "Insufficient awareness of health and disease".

[9] International Diabetes Federation - Home [Internet]. Idf.org. 2019 [cited 2018 September 8]. Available from: https://www.idf.org/

1.8 Adherence in diabetic patients

Some countries have implemented support-programmes, managed by a pharmacist to ensure that the patients were compliant with their treatment. These support-programmes includes not only the patient but also family members as the latter can assist the patient in the management of the disease. These pharmacist-led support groups also liaise with the physicians, should the need arises, for any change in treatment or the correct management of the disease (Kharjul et al., 2018).

Patients who have type 2 diabetes, which is a condition of growing interest, require the patients to administer the correct dosage of oral hypoglycaemic tablets regularly. A study conducted in the US by Herz et al., (2005) showed that 37% of the patients discontinued their medications. This low compliance has led to an estimated 1billion US dollar increase in the medical expenses due to the complication arising from the lack of medication adherence (Egede et al., 2002; Pladevall et al., 2004).

1.9 Diabetes and family

The International Diabetes Federation had the theme for the years 2018-2019 as being 'the Family and Diabetes'.[10] Some literature stresses the importance of family with regards to diabetes self-management education and diabetes self-management (Powers et al., 2015; Cheval et al., 2016). Managing diabetes can present several difficulties, not only lifestyle changes but also psychologically. Some patients might also suffer from various social issues, such as the need for injecting oneself while socialising in a restaurant, the phobias of using insulin, and the need to closely monitor the diet (Kovacs et al., 2013).

Powers et al., (2015) in their study, accentuate the importance of including the family members. Close family members to diabetic patients are at a higher risk of developing diabetes since diabetes is a disease which is highly determinant on the lifestyle of the individual (Raghavan et al., 2015). The 'healthy' family members might be more motivated to modify the lifestyle in order to improve health, and this should be used to promote the prevention of diabetes.[11]

[10] International Diabetes Federation - World Diabetes Day 2018-19 [Internet]. Idf.org. 2018 [cited 2018 December 5]. Available from: https://www.idf.org/e-library/epidemiology-research/54-our-activities/455-world-diabetes-day-2018-19.html

[11] Kalra S, Saboo B, Cho N, Sadikot S, Hasnani D, Chandarana H et al. Strengthening the Family – the '5I' Approach [Internet]. Touch ENDOCRINOLOGY. 2018 [cited 2018 December 5]. Available from: https://www.touchendocrinology.com/articles/strengthening-family-5i-approach

1.10 Setting of the research

This study was conducted at the Diabetes Education Unit (DEU) and the Diabetic Outpatient clinic of Mater Dei Hospital (MDH). MDH is an acute general hospital which offers both inpatient and specialist outpatient services. DEU was established to develop a holistic approach for the care of all diabetic patients in Malta. Diabetes is a global affliction and is on the rise across the globe, as reported in this 8th edition of The International Diabetes Federation (IDF) Diabetes Atlas 2017. It is no longer considered as a health-crises but as a 'global societal catastrophe'.[11] The IDF estimates that the prevalence of diabetes in Malta in 2017 was of 13.2%. It is also estimated that about 42.3% of people aged between 20-79 years have diabetes. Fifteen per cent of adults aged 20-79 years are still undiagnosed.[12]

Currently, nearly half a billion people are living with diabetes, where 80% of this burden is shared between the low and middle-income countries. This is mostly due to the rapid urbanization, sedentary lifestyle and unhealthy diets. These factors have led to an increase number of obesity and diabetes. These figures, as depicted by the IDF are genuinely horrifying, but there is still hope for a brighter future if the knowledge and expertise are utilized to raise awareness on the importance of healthy diet and physical activity, especially among children and adolescents.

The DEU of Mater Dei Hospital aims at incorporating the expertise nurses who are trained specially to educate diabetic patients and their relatives. Currently, the unit has five nurses and is focusing on educating patients who are started on insulin treatment.

[12] International Diabetes Federation. IDF diabetes atlas - Home [Internet]. Diabetesatlas.org. 2018 [cited 2018 December 8]. Available from: http://www.diabetesatlas.org/

Education leaflets are given to the patients, demonstrating how to deal with hypo/hyperglycaemic episodes. Direct actions are emphasized on the measure which needs to be taken not to overcorrect. Diabetic patients are also invited to attend lectures which are organized by this unit. Lectures are also given to the general public, intended to increase the awareness of this disease.

1.11 Rationale of the research

Currently, patients are referred to the diabetic clinic at Mater Dei hospital by the general practitioner. A referral ticket is usually the only means of communication between the referring doctor and the hospital specialist. A prescription will be given directly to the patient following change in treatment, and the patient is reassessed in a follow-up appointment, usually after six months.

Patients who require further assistance in managing their diabetes are referred to as the Diabetes Education Unit. This unit offers a promising niche for pharmacist-led transition services such as medicine reconciliation and education both to the patient and to their close relatives or caregivers.

Locally, communication between healthcare providers is currently minimal. This is usually executed by providing a yellow treatment booklet where a change in treatment is usually noted. The patient then proceeds to their local health centres where the general practitioner (GP) issues a prescription for repeat medications. The last step calls for the patient to present the prescription to the community pharmacist of their choice, where the new or amended treatment will be dispensed for free.

Should the patient abstain to either visit a GP or unintentionally avails from presenting the prescription to the community pharmacist, incomplete or outdated treatment will be dispensed, leading to suboptimal treatment, medication errors or even worse hospitalisation. Suboptimal treatment, especially in diabetes where treatment can be quite complex, can easily lead to serious repercussions. This led to the idea of setting this research project at the diabetes education unit, where a pharmacist-led service would be provided to enhance both the pharmacist-patient contact where education can be the primary focus and also drastically increase the communication between hospital pharmacists and the pharmacists at the community.

This gave rise to the concept of developing a tailor-made Transition of Care document, which clearly outlines any changes in treatment which took place at the diabetic outpatient and DEU. This document, which was e-mailed directly to the community pharmacist, offers direct and quick communication between pharmacists, which is innovative for our National Health system.

1.12 Aim and objectives

This research aimed to increase the communication between hospital healthcare professionals and the community pharmacist who is handling chronic treatment by developing a pharmacist-led Transition of Care service.

The objectives of the research were to:

1. Perform medicine reconciliation in order to identify existing gaps or drug therapy problems when patients present at the Diabetes Clinic.
2. Develop transitional tools which can be easily shared across the different care settings.
3. Assess and evaluate the impact of the Transition of Care document by the end-users, namely the healthcare professionals at both settings of care.

CHAPTER 2 - METHODOLOGY

2.1 Study design

This study is a prospective, single-centre, convenience sampling study conducted at Mater Dei Hospital. Patients attending the diabetic outpatient clinic or the diabetic education unit (DEU) were eligible to participate in the study. The study was carried over four months, between September and January 2019. The study protocol and the templates of the consent forms, Transition of Care document, study information sheet, data collection sheet, pharmacist intervention sheet and questionnaires, were approved by the Faculty Research Ethics Committee (FREC) and by the University Research Ethics Committee (UREC reference FRECMDS_1718_045, dated 27/08/18) (Appendix 1).

The study was divided into five phases.

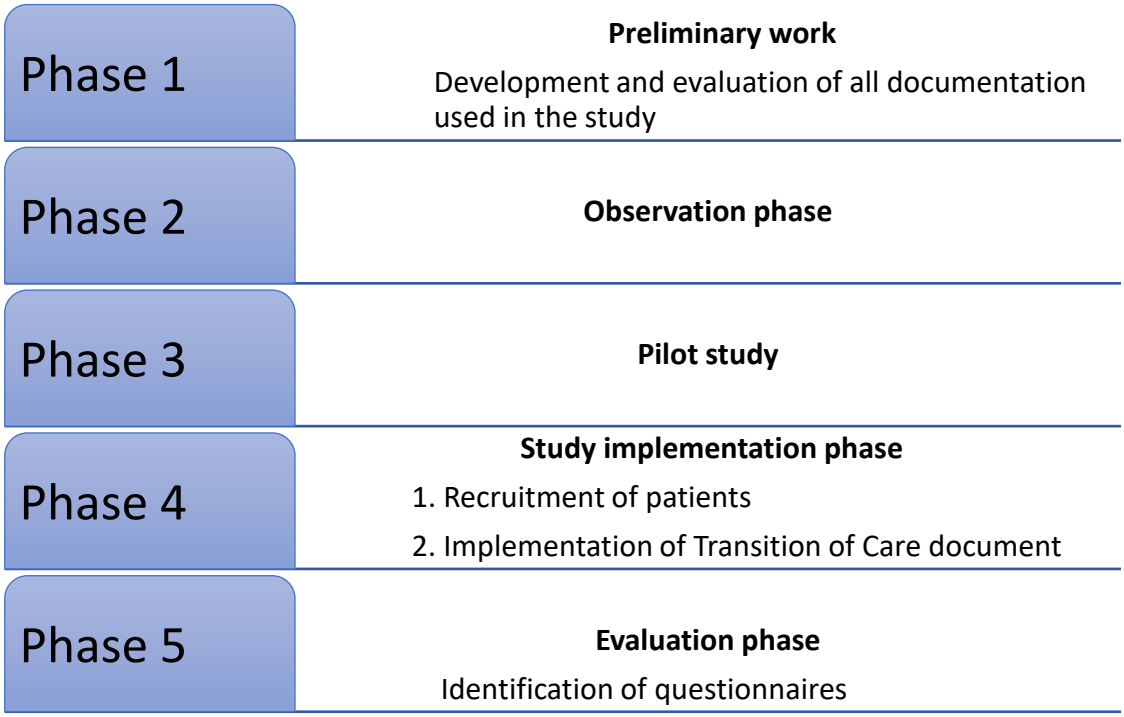

Figure 2.1 Work-flow design

2.2 Phase 1 – Preliminary work

Phase 1 of the study consisted of compiling the documentation required for the implementation phase of the study and acquiring the necessary approvals. The compilation and validation of the consent forms, data collection sheet, pharmacist intervention sheet, Transition of Care document, study information sheets for recruitment of patients and identification of questionnaires to be used within the study are described in this section.

2.2.1 Consent forms, study information sheet and data collection sheet

Consent forms (Appendix 2), the study information sheet (Appendix 3.1) and data collection sheet (Appendix 3.2) were prepared in both Maltese and English language. The study information sheet was used to inform the patient with the details of the study. The data collection sheet (Appendix 3.2) was developed to aid the researcher in the collection of the patient's information during the pharmacist-patient session. Clinical data such as age, gender, weight, family history, social status and health literacy were included in the data collection sheet. Other information such as medication adherence, allergies, HbA1c, living alone or with family, past medical history, family history of diabetes and admissions to hospital due to co-morbidities related to diabetes were also found in the data collection sheet.

Medication adherence was assessed by asking direct questions to the patient during the session. Adherence to treatment was highly significant to this study as part of the session included guidance on the importance of medication adherence. The data collection sheet consisted of a separate section where the researcher could list all the

medications, including non-prescription, herbal medicines and nutritional supplements which were currently administered by the patient. Questions asked during the pharmacist-patient session were close-ended and concise to facilitate the session. All documentation meant to be used in the study were validated using the same expert panel, which was made up of four pharmacists, one of whom has a particular interest in information technology, a pharmacist working in quality assurance, two pharmacists working in the community and two laypersons.

2.2.2 Transition of Care document

An innovative Transition of Care document (ToC) (Appendix 4), was developed following two meetings with the expert-panel. During the first meeting, ideas were pooled on the design of the document. A draft copy was developed and discussed during a second meeting where the document was then validated and finalised. During the meeting, it was concluded that two different documents were to be developed, to make it more specific and prevent misinterpretation by the community pharmacists. One ToC document denotes a change in treatment entitled "Transition of Care document requiring a change in treatment" (Appendix 4.1) and the other document denotes no change in treatment entitled "Transition of Care document NOT requiring a change in treatment" following the medicine reconciliation (Appendix 4.2). The advice given to the patient was documented in the ToC document, which could then be followed by the community pharmacist. The panel concluded that the ToC documents should contain all the patient's information to ensure the safe transfer of clinical information, but one has to take into consideration that the ToC document should be concise and easy to follow.

2.3 Phase 2- Observation phase.

A total of two, 30 minutes meetings were set up with the nurse in charge of the diabetic education unit. During these meetings, issues such as how the unit operates, whether there was a niche for a clinical pharmacist in the unit and other preliminary issues such as the need for the nurses to obtain verbal consent before introducing the patient to the researcher, and how the session would ideally proceed were discussed. At the diabetic education unit, the patients would have an appointment with the nurses to discuss issues such as hypo- or hyperglycaemia in both type 1 and type 2 diabetes. For the purpose of the study, the nurse approached the patient first, obtained verbal consent, carried out the nurse session as necessary, and referred the patient to the pharmacist researcher for the pharmacist session (Fig 2.2).

During the observation phase, the educational patient information leaflets routinely distributed to the patients attending this unit were reviewed.

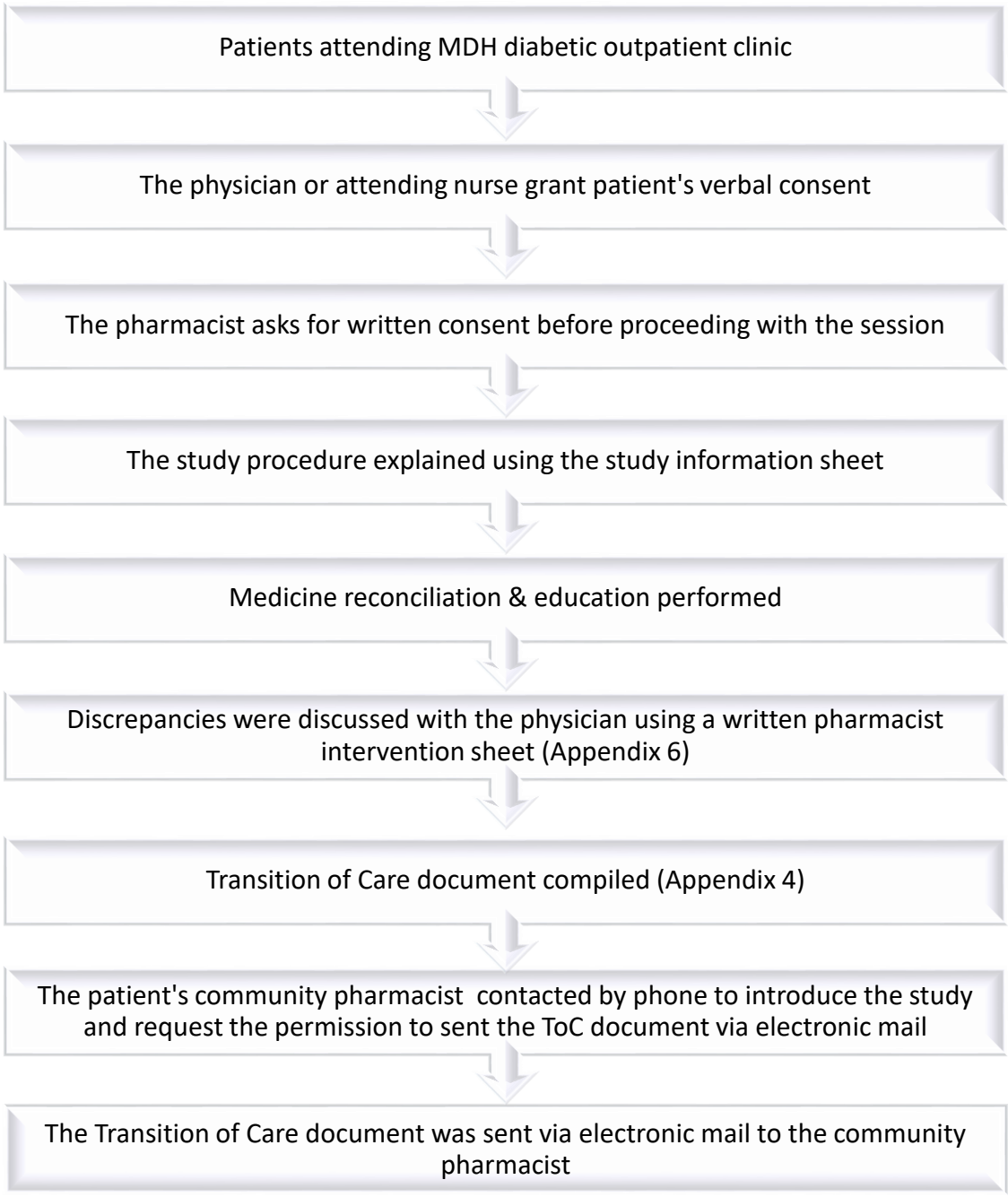

Figure 2.2 Study procedure

Patients attending the diabetic outpatient's clinic at Mater Dei Hospital, and satisfied the inclusion criteria, were eligible to participate in the study. Following verbal consent, the patient was introduced to the researcher. After signing a written informed consent, the study procedure was explained to the patients using a designated study information sheet. Medicine reconciliation was then performed, any concerns raised by the patient were discussed with the researcher. In the case where the clinician needed to be involved, the pharmacist intervention sheet was filled in (Appendix 6).

A Transition of Care document (Appendix 4) was then be compiled using data collected during the medicine reconciliation. The ToC document together with the questionnaire (Appendix 7.2) we sent via electronic mail.

2.4 Phase 3 – Pilot study

A pilot study was conducted on ten patients. Five patients were recruited from the diabetic outpatient and another five patients from the diabetic education unit. This pilot study phase played a crucial role in the development and refinement of the session and the sequence that the session had to follow. The same procedures that we meant to be used in the large-scale study were implemented during the pilot study. Another fundamental purpose of conducting the pilot study was to assess the feasibility of the recruitment of patients and the implementation of the medicine reconciliation. It was also a good opportunity to develop consistent practices such as good clinical practice and refinement of informed consent procedures, monitoring/oversight procedures such as the need to consider the HbA1c prior to the initiation of the session so that if the patient is not compliant with treatment, the session would be more focused on the importance of adherence.

Following the pilot study, the data collection sheet (Appendix 3) and the pharmacist's intervention sheets (Appendix 6) were slightly modified to facilitate the data collection. The study work-flow process was altered and implemented throughout the large-scale study.

2.5 Phase 4 – Clinical implementation

2.5.1 Study participants

All adult patients aged 18 years or older and diagnosed with diabetes attending Mater Dei Hospital outpatient or diabetes education unit (DEU) were eligible to participate in the study provided they satisfied the inclusion criteria.

The **inclusion** criteria

- Attending MDH diabetic outpatient
- Diabetic and currently on at least one antidiabetic treatment
- 18 $\geq$ years of age
- Able to understand Maltese or English
- Willing to participate in the study
- Informed consent

The **exclusion** criteria

- Diabetic patients controlled on diet and lifestyle changes only
- Cognitively impaired
- No documentation of medication treatment

The patients were asked to read and understand the written informed consent and then signed voluntarily by each patient. A study information sheet, designed for this study, entitled 'Study Information Sheet' (Appendix 3.2) was used to explain the study procedure.

2.5.2 Medicine reconciliation

The pharmacist-patient session commenced by asking the patient several direct questions such as; family history, age, weight, the date when the patient was first diagnosed, their social status and in general whether being diagnosed with diabetes changed their quality of life (Appendix 3). Other data included asking the patient's overall activity, whether they have a sedentary lifestyle and whether being diabetic encouraged the patient to engage in some sort of aerobic activities. An essential factor in the data collection was the patient's HbA1c. If this value was high, the session was focused more on patient compliance and other nutritional guidance. Each session was customised according to the patient's needs. Compliance with the current medications and other medication concerns or allergies were also taken into consideration during the session.

The patient was asked to present the Schedule V entitlement card, as this document shows all the medications that the patient is entitled to collect from our national health system (NHS) using the pharmacy of your choice (POYC) scheme. Maltese citizens and foreigners paying the national security are entitled to free medications but are only eligible for medications which are listed in the outpatient government formulary list.

If the patient did not present this documentation, the researcher asked the patient's authorisation to access their Schedule V entitlement using the software Schedule V, which is available at Mater Dei Hospital (MDH). The researcher resumed the session by asking the patient to list the medications which the patient is currently taking verbally,

and these were verified with the schedule V card. The list of medication was documented using the Data Collection Sheet (Appendix 3).

Medications which were not listed on the schedule V, but form part of the current medications were also included in the list. These include herbal medicine, over- the-counter medications or supplements. Discrepancies were categorized into six drug-related problems (DRPs) using the Pharmaceutical Care Network Europe (PCNE) categorisation. Educational advice was given to the patients, mainly concerning oral medications and insulin administration. In the case of insulin, detailed instructions were given on how to correct a hypo/hyperglycaemia, including detailed instructions, especially if the patient routinely experienced high or low glucose episodes.

DRPs, such as "Treatment Not According to Guidelines", "Need for Additional Drug" or "Drug Interactions" were documented in the pharmacist intervention sheet (Appendix 6). This intervention sheet was compiled when the pharmacist needed to communicate with the patient's clinician. The pharmacist interventions were classified into four categories; Verbal advice, written advice, verbal and written advice and no advice.

Verbal advice was given to those patients who required minor changes to their medications, such as better timing of dosages, medication adherence and suggestion of OTC drugs.

The written advice was given to the patients who required a change in treatment, or the addition of a new drug. The verbal and written advice was given to those patients who required a change in treatment or the addition of a new drug, but the patient was also not compliant or was not administering the medications correctly.

Few patients required no advice at all since they were adequately managed. These interventions were recorded using a Microsoft® excel sheet.

Towards the end of the session, the researcher asked the patient whether they had any issues that they wanted to discuss. After the session, a 5 minute self-administered questionnaire was given to the patient by the nurse in order to avoid bias. This questionnaire, entitled 'Questionnaire for patients' was compiled on site.

Following the session, the researcher compiled the Transition of Care document (Appendix 4), listing all the medications, gathered during the medicine reconciliation, which the patient is currently taking not only through our NHS but also other medications that the patient is having, including over-the-counter and other prescription medications.

The researcher then contacted the patient's community pharmacist, briefly introduced the study and asked for the e-mail address so that the Transition of Care document could be sent. The questionnaire entitled 'Transition of Care questionnaire' was also sent via e-mail (Appendix 5). This questionnaire was designed to assess the effectiveness of the Transition of Care document. A reminder was sent a week after as the researcher was noticing a very poor response.

The third questionnaire was aimed at the healthcare professionals working within the diabetic outpatient and with whom the pharmacist worked closely during the course of the study. Five diabetic consultants, one diabetic specialist and five diabetic nurses were asked to participate in the study. The questionnaire was distributed as a hard copy in both Maltese and English, but all participants opted to use the English version. The semi-

structured questionnaire was left at the office of the respective healthcare professionals to avoid bias.

2.6 – Phase 5 Evaluation – Identification of questionnaires.

Three questionnaires were developed for this study, focusing on assessing the impact of the pharmacist interventions, the effectiveness of the Transition of Care document and the healthcare professionals' opinion regarding the innovative service being offered by the pharmacist.

2.6.1- Questionnaire for Patients

The first questionnaire, entitled 'Questionnaire for Patients' (Appendix 7.1.1), was compiled to evaluate the importance of the pharmacist's session with the patient, and to assess whether the patients regard similar sessions on a one-to-one basis as being beneficial. Three questions were asked in this questionnaire, the first question aimed at assessing whether the patients were more confident and aware of their condition following the session, whether the patient felt more confident on how to store their medications and whether they could identify the tablets by name and not by the colour or shape of the tablet. The second question was aimed at assessing the pharmacist's knowledge. This includes whether the session was informative and easy to follow and

whether the patient was satisfied with the response given by the pharmacist. The importance which was given to the patient was also taken into consideration such as, whether the patients were encouraged to actively participate in the session, whether they were encouraged to ask questions and bring forward any concerns regarding complaints, or bothersome adverse effects which the patient might have experienced while taking the medication. The third question was more focused on encouraging the patient to appreciate the importance of having such sessions and to assess the patient's knowledge (Appendix 7.1).

2.6.2 - Transition of Care questionnaire

The second questionnaire, entitled 'Transition of Care Questionnaire' (Appendix 7.2), was developed to assess the effectiveness of the Transition of Care document. This questionnaire, which took approximately 5 minutes to complete, was conducted using Google® forms and distributed to the respective community pharmacist via electronic mail together with the Transition of Care document. This questionnaire was divided into three sections. The first section was aimed at gathering information on the respondent, such as the age and experience working within the community. The second and third sections were aimed at assessing the effectiveness of the Transition of Care document. In the second section, a scenario was presented, and then the pharmacist was asked whether they were concerned that some important medical data could get lost while the patient is transitioning between different healthcare settings and whether they consider the need for better communication between different healthcare providers.

Another question was whether they feel more at ease in dispensing medication, knowing that medicine reconciliation was performed. The questions in the third section were direct questions about the ToC document. One of the questions asked the pharmacist whether they found the Toc document useful, time-consuming, easy to follow and whether they would use the document if it was made available.

2.6.3 Questionnaire for healthcare professionals

A third questionnaire entitled 'Questionnaire for Healthcare Professionals (Appendix 7.3) assessed the diabetic specialists and the DEU nurses at the diabetic outpatient clinic. This questionnaire aimed to assess their perception with regards to the impact of the pharmacist conducting the study. The questionnaire, estimated to take 4 minutes to complete, was given in person as a hardcopy only and consisted of just two questions. The reason for such a short questionnaire was to encourage healthcare professionals to participate since they are usually engaged in several activities. The first question aimed at evaluating the service provided by the pharmacist and the second question was more direct, aimed at assessing how they perceive having a pharmacist as part of the diabetic team to assist the patient with medicine reconciliation and education. All three questionnaires were validated by the same expert-panel

CHAPTER 3 - RESULTS

3.1 Phase 1 -Preliminary phase - Validation of documentation

All the documentation used throughout the study were validated using an expert panel. The expert panel consisted of four pharmacists and two other laypersons. One of the pharmacists has a particular interest in information technology. The same panel was used throughout the validation process of all documents. All the documentation were presented in two versions, Maltese and the English language (Table 3.1).

3.1.1 Amendments of documentation following the validation process

After the validation, several changes were made to some of the documentation sheets. These include the Data Collection Sheet (Appendix 3), the Transition of Care document (Appendix 4) and the questionnaire entitled 'Questionnaire for patients' (Appendix 7.1).

3.1.2 The data collection sheet

The patient's HbA1c, the nationality and health literacy were added to the data collection sheet as it was considered that such data would strengthen the patient's demographic information. Other changes included the addition of the name and e-mail address of the respective community pharmacist. The patient's height was removed as this was considered as unnecessary data for this study. An additional section was added, which included remarks from the researcher, such as whether the patient was

interested in the pharmaceutical session and willing to participate in other sessions in the future.

3.1.3 Changes to the Transition of Care document

The Transition of Care document was discussed in great detail during the validation process, as this was one of the primary outcomes of this study. The panel unanimously agreed that two different ToC documents were to be drafted, one denoting a change in treatment (Appendix 4.1) and the other denoting that the patient still went through the process of medicine reconciliation but required no change in treatment (Appendix 4.2). This decision was considered to avoid confusion and misinterpretation of data by the community pharmacist. The issue of the new General Data Protection Regulation 2016/679[13] (GDPR) was seriously considered when drafting and validating this document as it contained very personal and confidential data. It was concluded that a telephone call was to be made to the community pharmacist, whereby the researcher introduced herself and gave an over view of the study. The permission for the community pharmacist to provide the e-mail address was granted whereby the Transition of Care document was to be sent. The e-mail denoted that the contents provide confidential information (Appendix 5).

[13] European Commission. 2018 reform of EU data protection rules [Internet]. - European Commission. 2019 [cited 2019 June 9]. Available from: https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en

Table 3.1 Documentation used in the study implementation phase

Documentation – all presented in both Maltese and English versions	Validated by the expert panel (n=6)
Consent form	yes
Study information sheet	yes
The data collection sheet	yes
Pharmacist intervention sheet	yes
Transition of Care document – denoting change in treatment	yes
Transition of Care document – denoting NO change in treatment	yes
Questionnaire for patients	yes
Transition of Care Questionnaire	yes
Questionnaire for healthcare professionals	yes

3.2 Phase 2 - Observation phase

A total of 10 hours, two hours for five days were devoted to this phase (Table 3.2). The rationale behind the selection of the hours was that the morning hours are usually most frequented at MDH, and the timing was convenient for the researcher.

Table 3.2 Distribution of the hours dedicated to the observation phase

Day	Time
Monday	8.00am – 10.00am
Tuesday	9.00am – 11.00am
Wednesday	11.00am - 1.00pm
Thursday	1.00pm – 3.00pm
Friday	12.00am – 2.00pm

During the observation phase, the operational aspect of the diabetic education unit at the diabetic outpatient clinic was analysed by having the researcher attending the one-to-one discussion appointments routinely conducted in this clinic by the five attending diabetic nurse specialists. Patients who were either newly diagnosed or the clinician suggests that the patients should closely monitor their glucose levels, usually due to uncontrolled HbA1c or repeated hypo-/hyperglycaemic episodes, were invited to attend the one-to-one appointments with the diabetic nurse specialist. During these sessions, the nurse assists the patients, especially newly diagnosed patients, on correct insulin administration. Nutritional advice such as proper management of blood glucose, altering the insulin dose according to the carbohydrate counting, and advice on how to correct blood glucose levels in case of a hypo-/hyperglycaemic episode, are some of the services offered to the patients in the DEU.

During this observation phase, it was decided by the researcher and the nurse in-charge that the pharmacist intervention should ideally follow the nurse's session. The justification being that the nurse advises the patients with regards to insulin application, and then the pharmacist would then discuss the medications, and advice accordingly to substantiate further the advice given by the nurse.

3.2.1 Pilot study

A total of 10 hours, two hours for five days were devoted to this phase (Table 3.2).

A sample of ten patients was included in the pilot study and recruited over a period of five days. An equal number of patients were recruited from the diabetic outpatient and the diabetes education unit (DEU). During the pilot study, it was observed that patients attending the DEU were more interested in participating in the study and more willing to discuss their medications. All patients (n=10) participated in the pharmacist-patient sessions, and medicine reconciliation was performed. A comprehensive list of all current medications for each patient was compiled and sent to their respective community pharmacist via e-mail. The DRPs which were identified during this period (n=21) were documented. All documentation, meant to be used in the implementation phase of this study, was assessed by the researcher for any necessary amendments.

3.3 Study implementation phase

During the data collection period, specifically between September 2018 and January 2019, there were a total of 115 patients who were randomly selected to participate in the study. Out of the 115, fifteen patients did not satisfy the inclusion criteria, and consequently, they could not be recruited in the study. Out of these 15 patients, one patient refused to give the verbal informed consent, while the others were patients younger than 18 years of age (n=10) or diabetic patients who were controlled only by

diet (n=4). The inclusion criteria state that patients must currently take at least one antidiabetic drug. Since these patients did not have any medications, medicine reconciliation could not be performed and were therefore excluded from the study.

The patients who did not satisfy the inclusion criteria (n=14) were still advised on nutrition, and the younger patients were still given leaflets and advice on how to better manage hypo-/hyperglycaemic episodes. Thus, the final study population was that of 100 patients. A very small group of patients participated in the pilot study (n=10), and these were also included in the final study population. The mean age of the patients was 34 years (25–75years), having 68 female and 32 male participants. The majority of patients were Maltese (n=87) while 13% were foreigners. The mean weight of the patients was 77 kilos, while the mean HbA1c was 9%. The majority of patients claim that they are health literate (n=76). The vast majority of the patients declared that they have a family history of diabetes (n=91), sixty-four patients reported that being diagnosed with diabetes did not change their lifestyle. Less than half of the patients (n=43) said that they exercise at least for 30 minutes. Thirty-five patients live alone in their residential home and require no assistance, while the others (n=65) live with their family. Twenty-four of the recruited patients required hospitalisation due to hypoglycaemic episodes while only two patients were hospitalised for hyperglycaemia. Five patients were hospitalised for reasons related to co-morbidities, while only nine patients were hospitalised for reasons not related to diabetes (Table 3.3).

All data collected during the pharmacist-patient session was inserted and analysed using Microsoft® Excel Sheet.

Table 3.3 Patient demographics

Characteristics		Nº of participants N = 100
Age (years)		
	≥65	17
	46-64	67
	<45	16
Sex		
	females	68
	males	32
Nationality		
	Maltese	87
	Foreigners	13
Obesity		
	Mean weight (kg)	77
Mean HbA1c (%)		9
Frequent monitoring of blood glucose levels at home		
	yes	43
	no	57
Health literacy		
	yes	76
	no	24
Family history of diabetes		
	yes	91
	no	9
Diagnosis with diabetes changed lifestyle		
	yes	64
	no	36
Exercise regularly (walking 30 minutes daily at least)		
	yes	43
	no	57
Mean number of medications per patient		7
Residence		
	living alone	35
	living with family	65
Admission to hospital		
	emergency due to hypoglycaemia	24
	emergency due to hyperglycaemia	2
	for other co-morbidities related to diabetes	5
	other reasons	9

3.4 Medicine reconciliation process

All recruited patients (N=100) were provided with a medicine reconciliation (MR) service by the pharmacist conducting this study. MR is a formal process which involves sourcing and verifying a complete and accurate list of the patient's current medications. It also implies providing information on their current and new medication where applicable and informing the patients of any changes to their medication regimen. These include prescribed and non-prescribed medications, OTCs and other food supplements. A comprehensive list of medications was compiled, having a mean number of medications (n=7). The accurate determined list was then compared to the Schedule V entitlement card, which is the NHS entitlement card, to identify and resolve medication discrepancies such as patients not taking medications as prescribed by the consult (n=3).

During the session, other issues such as difficulties in swallowing the tablets due to their size or shape, and difficulties in administering the medication such as the opening of containers in case of the elderly patients living alone were also given priority. These issues were considered important as they could lead to non-adherence and sub-therapeutic doses. The pharmacist also identified those patients who seemed to be non-adherent (n=27) and those who needed further assistance with correct drug administration (n=36).

3.4.1 Identification of drug-related problems (DRPs)

During the medicine reconciliation process, a total of one hundred ninety-four DRPs were identified. These drug-related problems were classified into eight categories, according to the Pharmaceutical Care Network Europe (PCNE) classification.[14] The four most prevalent DRPs were "Lack or misinterpretation of information" (n=48), followed by "Insufficient awareness of health and disease" (n=47), "Inappropriate timing of drug administration and/or dosing intervals" (n=36) and "Non-adherence to treatment" (n=27). Patients who had "Insufficient awareness of health and disease" as one of the drug-related problems (n=47) also had other DRPs such as "Non-adherence to treatment" (n=27), "Inappropriate timing of administration and/or dosing intervals" (n=36) and "Treatment not according to guidelines" (n=9).[15]

[14] Europe P. PCNE DRP classification now 8.02 - Pharmaceutical Care Network Europe [Internet]. Pcne.org. 2019 [cited 2019 March 21]. Available from: https://www.pcne.org/news/68/pcne-drp-classification-now-802

[15] Joint British Diabetes Society for Inpatient care [Internet]. Diabetes UK. 2019 [cited 2019 March 21]. Available from: https://www.diabetes.org.uk/Professionals/Resources/shared-practice/Inpatient-and-hospital-care/Joint-British-Diabetes-Society-for-Inpatient-care

Table 3.4 Drug-related problems identified during the medicine reconciliation

DRP category	Number of DRPs N=194
Lack or misinterpretation of information	48
Insufficient awareness of health and disease	47
Inappropriate timing of administration and/or dosing intervals	36
Non-adherence to treatment	27
Suggested an add-on treatment	21
Treatment not according to guidelines[13]	9
Dose adjustment	3
Drug interactions / adverse reactions	3

As can be seen from Table 3.4, non-adherence was reported in twenty-seven patients while only three patients stopped treatment due to adverse drug reactions (ADRs). Various ADRs were reported, the most common being diarrhoea, gastrointestinal upsets and hypoglycaemia. Non-adherence due to ADRs were mostly encountered with metformin, especially when taken at high doses. This lack of patient compliance was mostly documented in patients with low health literacy. This was demonstrated when some patients claimed to be non-adherent due to forgetfulness.

Since patients suffering from chronic conditions are entitled to free medications through our NHS, the financial burden was ruled out as one of the precipitating factors leading to non-adherence.

"Inappropriate timing of administration and/or dosing intervals", the third most prevalent DRP, was commonly observed in patients taking metformin (n=16) followed by simvastatin (n=12), gliclazide (n=9), vildagliptin (n=5) and omeprazole (n=6) as can be seen from Table 3.5

Table 3.5 Drugs most commonly administered inappropriately

Drugs not administered correctly	Number of Patients (N=100)
Metformin 500mg	16
Simvastatin 20mg	12
Gliclazide 60mg	9
Vildagliptin 50mg	5
Omeprazole 20mg	6

3.5 Pharmacist intervention

Following the medicine reconciliation, several pharmacist interventions were recorded. The majority of patients, 85% required verbal intervention only. These interventions were predominately due to lack of medication adherence and improper drug administration. The importance of drug adherence was emphasised, and the risk of co-morbidities, if treatment is not adherent to, was also highlighted.

Out of these 100 patients, 4 required both verbal and written advice, while only 9% required written advice. Out of the nine patients, four required both written and verbal advice. When the researcher noticed that the patient either required a change in treatment or a change in dose, a pharmacist intervention was documented using a pharmacist intervention sheet (Appendix 6) and asked the patient to present it the clinician. Eight patients required no interventions as their HbA1c was within the limit and were being managed very well. All patients were encouraged to ask any questions and to discuss any concerns which they might have. At the end of the session, the patient was asked to complete a questionnaire so that the pharmacist's input in the pharmaceutical session could be assessed.

Table 3.6 Pharmacist interventions during medicine reconciliation

Pharmacist intervention	Number of pharmacist interventions (N=104)
Verbal intervention	83 (80%)
No intervention	8 (8%)
Written advice given to physician	9 (9%)
Required both verbal and written advice	4 (4%)

3.6 Transition of Care document

Seventy-three different community pharmacies served the 100 patients recruited in the study. During the validation of the Transition of Care document, it was agreed that two different ToC documents were to be drafted; one denoting a CHANGE in treatment (Appendix 4.1) whilst the other denoting NO CHANGE in treatment (Appendix 4.2).

Out of the hundred recruited patients, sixty-three did not require a change in treatment, although this does not mean that they did not require the pharmacist intervention. Actually, only 4% did not require any pharmacist intervention. The advice which was given to the patients was listed in the Transition of Care document in the second section; a note was written, that the patient went through the process of medicine reconciliation, but required no change in treatment, however, advice was given (Appendix 4). Having such information at hand, the community pharmacist could then continue to monitor and follow the patient, especially if the advice concerned

counselling on medication adherence or correct carbohydrate counting in type1 diabetic patients and diet management. Thirty-seven patients required a change in treatment. In most cases, the change is treatment was due to an alteration in the dosage or dosage regimen and only thirteen patients required change or add-on treatment.

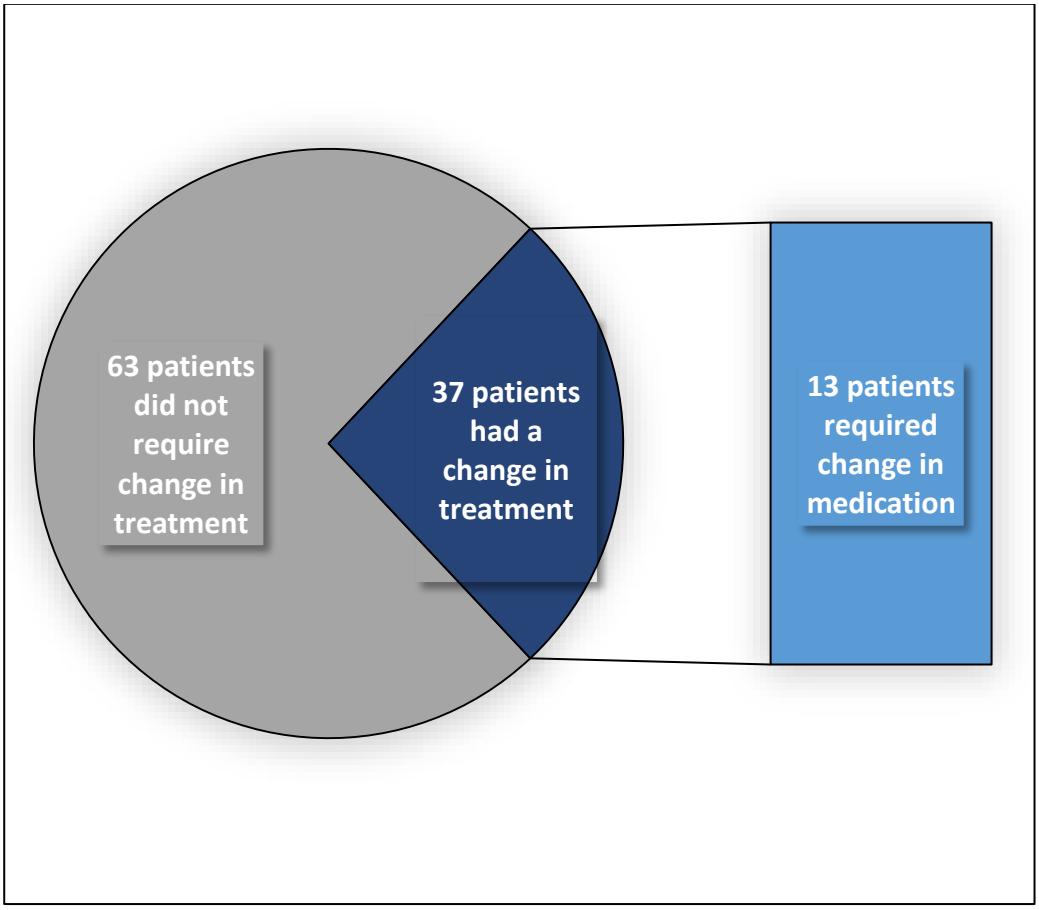

Figure 3.1 Patients requiring CHANGE or NO CHANGE in treatment

3.7 Assessing the effectiveness of the Transition of Care document

One hundred ToC documents were compiled and sent using electronic mail to the respective community pharmacist. A questionnaire entitled "Transition of Care questionnaire", was compiled using Google® forms. This questionnaire included thirteen questions, seven of which were answered using the Likert scale, two questions were direct questions whilst four questions were choose the correct answer. The questionnaire sent together with the Transition of Care document to the community pharmacist so that the effectiveness of the ToC document could be assessed. Some patients (n=27) frequented the same pharmacy, and so a total of 73 pharmacists were eligible to participate in the study since each pharmacy could partake the questionnaire only once.

Out of 73 questionnaires which were disseminated, only 41 completed the questionnaire. Two reminder e-mails were sent to the non-respondents. Out of the forty-one, 24 pharmacists were females while 13 pharmacists were males. The age ranges from 20-60+ years, having the majority of the respondents in the range between 40-50 years. The majority of the respondents had 10-25 years of experience working within the community. Thirty-seven pharmacists agreed with the statement that important medical data could get lost while the patients are transitioning between different healthcare settings. All pharmacist (N=41) agreed that there is a need for better communication between healthcare providers and that the pharmacist dispenses the medications more at ease knowing that medicine reconciliation was performed. Thirty-six pharmacists said that they would use the document if made available, whereas

four remained undecided. One pharmacist did not find this tool useful and would refuse to use it if made available. The reason for such decision was that from the time the pharmacist receives the ToC document to the time when the patient collects the medication, the pharmacist would have forgotten all about the new treatment. The pharmacist argued that a hard copy of the ToC document should be given to the patient.

Thirty-nine pharmacists found ToC document useful and easy to follow while two respondents were undecided. Thirty-nine respondents said that the document is not time-consuming and contains all the data that is required to follow-up patients in the community. One respondent said that the document is time-consuming, and another respondent argued that the document does not contain all the data required (Table 3.7).

Table 3.7 Effectiveness of the Transition of Care document as assessed by the community pharmacists (N=73)

Community pharmacist	Number of participants N=41
Age (years)	
20-30	5
31-40	10
41-50	15
51-60	8
60+	1
Gender	
female	24
male	13
Experience in the community pharmacy setting (years)	
0-5	7
6-10	7
11-25	15
25+	9
Concerned whether important medical data can get lost during the transitioning of patients from one setting to another	
yes	37
neutral	3
no	1
There is need for better communication between healthcare providers	
strongly agree	37
agree	4
Dispensing is done more at ease post medicine reconciliation	
strongly agree	37
agree	4
Would definitely use this document if made available	
yes	36
neutral	4
no	1
Transition of Care document is useful and easy to follow	
strongly agree	34
agree	5
neutral	2
Not time-consuming and contains all the data required	
yes	39
no	2

3.8 Patients' satisfaction questionnaire

Following the pharmaceutical sessions, the patients were asked to fill in a questionnaire, which was prepared in both Maltese and English and was available as a hardcopy only (Appendix 7.1). This questionnaire contained three questions; the first question aimed at assessing whether the patients were more knowledgeable about correct drug administration. The second question focused on assessing the pharmaceutical session, and the third question was aimed at assessing the patients' participation. All participants (N=100) completed the questionnaire, having the majority (n=95) assent that after the pharmaceutical sessions, they were more aware of the signs and symptoms of hyper/hypoglycaemic episodes, which was considered essential for diabetic patients. Very few patients (n=5) were uncertain whether the session did make a difference in their health literacy. The majority of patients (n=65) claimed that the pharmacist's involvement in the session helped the patient to feel more secure and knowledgeable, whilst thirty-five were uncertain and would appreciate further sessions and one-to-one assistance. Nearly all patients (n=90) debated that following the discussion with the researcher, they were more aware of the potential side effects caused by the medications. All patients (N=100) consented that subsequent to the pharmaceutical session, they felt more confident with correct drug administration which in turn will improve their medication adherence. Ninety patients declared that they have the knowledge to organise their medications better, in many instances using the weekly calendar containers.

The consensus was reached in the majority of patients (n=89) arguing that they are now more confident at approaching the pharmacist for queries related to their medications, while others (n=82) stated that they are more knowledgeable about the repercussions should the treatment is not taken as recommended by the pharmacist or clinicians. Patient education and literacy were stressed on many occasions during the pharmaceutical sessions. The majority of patients (n=74) declared they would be more patient compliant in the future as, during the session, the researcher explained and emphasised the complications which can arise if treatment is not adhered to.

The last section of the patient's questionnaire queries the patient on whether they were administering the medication the correct way. A minority of patients (n=15) consented that they were taking their medication incorrectly, while some others (n=9) were undecided or unwilling to commit.

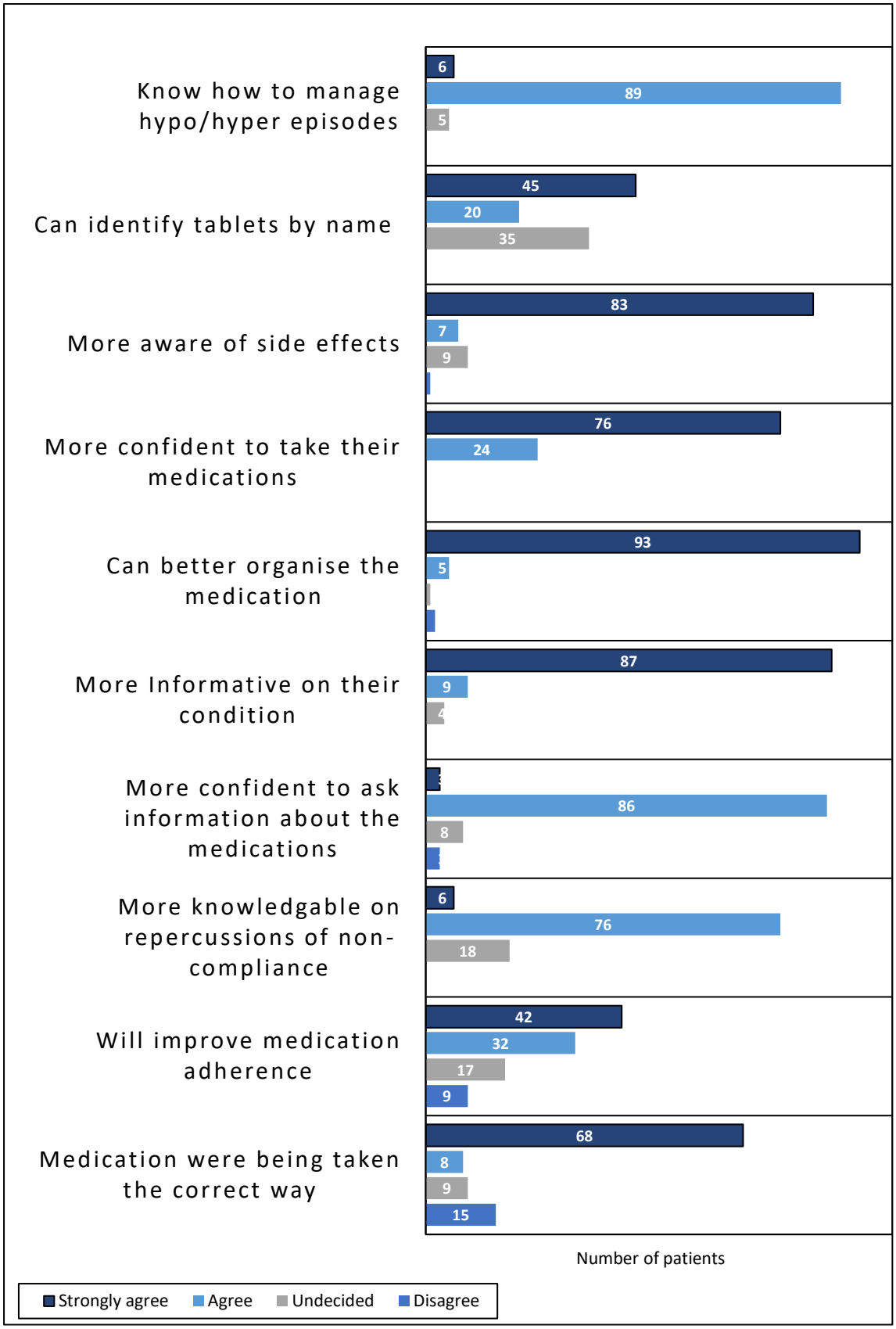

Figure 3.2 Patient's view of their knowledge following the pharmacist-patient session

3.9 Assessment of pharmacist intervention by the patient

The last section of the questionnaire was focused on the impact of the pharmacist. Ninety-five patients would like to have more one-to-one sessions with a pharmacist as they think that the medications and the adverse effects were very well explained. Five patients thought that having the appointment just with the clinician was enough. All patients thought that the session was very informative, that they could easily follow the pharmacist and that the pharmacist was knowledgeable on the subjects tackled. The pharmacist encouraged the patients to participate and that all the questions which were brought up during the session were all answered (Fig 3.2)

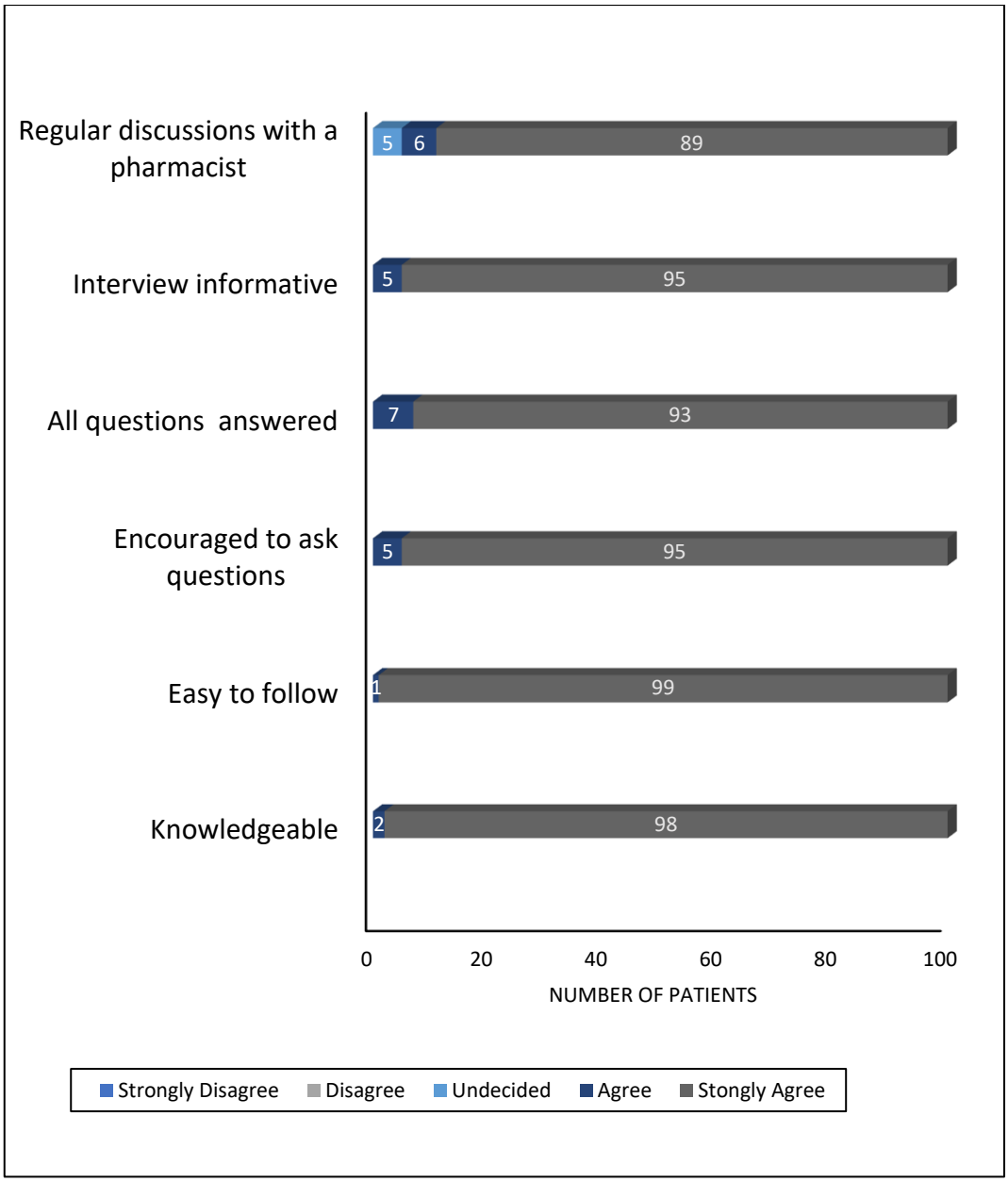

Figure 3.3 Assessment of pharmacist intervention by the patient

3.10 Assessment of pharmacist interventions by healthcare professionals.

Eleven healthcare professionals (HCP) working within the diabetic outpatient and the diabetic educational unit, were asked to participate in the qualitative study. These include five diabetic consultants, two diabetic specialist and five diabetic nurses.

Out of the eleven questionnaires which were distributed, nine were collected. The response was received from five consultants, one was a diabetic specialist, and three were diabetic nurses working within the diabetic education unit. Analysis from the qualitative study yielded several distinct themes. The first identified theme was an overall agreement amongst the HCP that pharmacist can prevent prescribing errors. Eight out of nine HCP recommend that a pharmacist should be part of the diabetic team and recommend that having a pharmacist as part of the multidisciplinary team can improve the patient's outcome. Seven HCPs were satisfied with the service offered at the diabetic outpatient, even though there were several limitations which need to be considered. While the majority of the HCP (n=8) agreed that pharmacists could audit prescriptions and that additional drug information can be given to the patients, some HCP (n=2) were undecided as to whether a pharmacist can identify and prevent side effects to the patients.

There was a consensus that (n=9) among the HCP participating in the study that medicine reconciliation is a requisite intervention which not only promotes the patient's safety but also improves the interdisciplinary communication and promotes continuity of care.

Table 3.8 Assessment of the pharmacist intervention by healthcare professionals (N=9)

	Strongly agree	Agree	Neutral
Recommend a pharmacist as part of the team	7	1	1
Satisfied with the pharmacist's service	4	3	2
The patient's outcome can be improved with the pharmacist interventions	6	2	1
Pharmacist can prevent prescribing errors	5	4	0
Pharmacists can audit prescriptions	4	4	1
Identify and prevent side-effects	4	3	2
Pharmacist provides additional drug information	5	3	1
Patients benefit from medicine reconciliation	5	4	0

Mater Dei diabetic outpatient clinic has no clinical pharmacist service within the diabetic firm. The majority of the healthcare professionals (n=7) agreed that they would welcome a clinical pharmacist in this unit.

CHAPTER 4 - DISCUSSION

4.1 Outcome of the study

The pharmacist-led Transition of Care is an innovative clinical pharmacy service which was devised and implemented within the diabetic outpatient clinic, more specifically at the diabetic education unit at Mater Dei Hospital during the four months (September 2018–January 2019) of the study. The pharmacist leading this study provided customised one-to-one pharmaceutical sessions which were composed of medicine reconciliation, pharmaceutical interventions when necessary, communication between the patient's community pharmacist and the hospital pharmacist through the Transition of Care document and patient counselling. The research of this innovative service led to the design of a Transition of Care document, compiled using the data collected during the medicine reconciliation, which was then disseminated to all respective community pharmacist who provided the day-to-day care of the patients in the community.

In this study, one could easily observe a positive effect of the pharmacist-led patient-centred Transition of Care advice, where all patients who participated in the study (n=100) stated that they were very satisfied with the service provided by the researcher. The evaluation from the healthcare professionals and the patients themselves showed a high level of satisfaction with the pharmacist's contribution. This correlated very well with several studies, such as the one performed by Duedahl et al., (2017), wherein three hundred and thirteen poly-medicated patients, the majority of patients, showed very positive feedback.

4.2 Medicine reconciliation service at the diabetic outpatient clinic

Medicine reconciliation is a well-defined process, which is highly essential when patients are transferred between healthcare settings or different levels of care within the same setting, whereby ensuring smooth transitioning of medical data and ensuring continuity of care.[16] This is especially true in patients with multiple medications, such as diabetic patients, who require proper managing of medications. Such patients with complex health issues tend to have multiple outpatient appointments, during which their health needs and care change.[17] Suboptimal treatment, either through omission of treatment or due to unintentional discrepancies, often led to morbidity and in many instances, hospitalisation (Graabaeket et al., 2013).

In this study, throughout the four months, a total of 194 DRPs were detected. The relatively high DRPs demonstrates that patients will indeed benefit from the pharmaceutical service of MR provided during this study. These findings relate well with a study conducted by Duedahl et al., (2017) where 83% of the patients who participated in the study had at least one identified the drug-related problem.

A study performed by Tam et al., (2005) revealed that discrepancies in the patient's medications, were in many instances, unintentional. This relates to the current study, as the majority of the DRPs detected were unintentional (n=131). In many instances, these

[16] Behavioral Health Care Accreditation Program National Patient Safety Goals Effective January 2018 [Internet]. Jointcommission.org. 2019 [cited 2019 March 13]. Available from: https://www.jointcommission.org/assets/1/6/NPSG_Chapter_BHC_Jan2018.pdf

[17] How-to Guide: Prevent Adverse Drug Events (Medication Reconciliation) [Internet]. Ihi.org. 2019 [cited 2019 March 19]. Available from: http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventAdverseDrugEvents.aspx

DRPs were mainly due to carelessness and health illiteracy. This study also corresponds well with another study conducted by Kjeldsen et al., (2014) in a Danish hospital. In this Danish study, it was observed that the most prevalent DRPs were "Inappropriate dosing regimen", "untreated indications", "Dose" and "Non-adherence to guidelines". The current study also revealed that "Non-Adherence" (n=27) was also one of the four most prevalent DRPs together with "Inappropriate Drug Administration" (n=36), and "Insufficient Awareness of health and disease" (n=47). During the medicine reconciliation performed in this study, a list of the current medications was compiled and compared to a standard reference, the Schedule V entitlement card and/or the discharge letter. (The Schedule V card is an entitlement card, issued by the NHS personnel, and the patients can collect their entitled medications, by using the Schedule V card to collect the medication from the community pharmacy for free through our NHS system). In many instances, the schedule V entitlement card is the only document which the patient routinely presents to the community pharmacist. The prescription, which is also a prerequisite, needs to be presented to the community pharmacist while collecting the medications. Consequently, to ensure proper communication between healthcare professionals, this Schedule V entitlement card should be updated every time the patient presents to a new appointment whilst notifying the community pharmacist with any changes.

Discrepancies and DRPs were resolved verbally by giving advice to the patients or written advice when clinicians had to be informed. If these DRPs were not detected and resolved, the patients would continue to neglect treatment or administer incorrect dosages.

In Mater Dei diabetic outpatient clinic, there is currently no clinical pharmacy service, and therefore, the pharmacist is not there to support the physicians in identifying and resolving DRPs. The results of this study demonstrate that providing the service will significantly improve the patient's outcome and inevitably increase the safety of the patients and ensures continuity of care, as could be demonstrated by the COACH (Continuity Of Appropriate Pharmacotherapy patient counselling and information transfer in Healthcare) study conducted by Karapinar-Carkeit et al., (2010). In this study, which correlates well with the current study conducted at MDH, Karapinar-Carkeit argues that medication errors are the most common medical errors which jeopardise patient's safety, and commonly occur at points of transition. In Karapinar-Carkeit's study, the three most prevalent issues which can give rise medication errors were incomplete and inappropriate medication list, insufficient patient information and insufficient communication with other healthcare professionals. The same medications errors were observed in the current study. The interventions performed by the Karapinar-Carkeit et al., were analogous with this study as they included patient counselling, medicine reconciliation and patient education. The same study design was employed in this study, but an added intervention was included in this study, the ToC document aimed at increasing the communication between the hospital pharmacist and the pharmacist in the community through the Transition of Care document.

Borgsteede et al., (2011) conducted a study in St Lucas Andreas Hospital, pharmaceutical interventions through semi-structured interviews. The findings of this study correspond with this study, as most patients were interested in receiving basic information about their current or new medications. Borgsteede argues that the patients who participated

in these sessions appreciated the information which was given to them by the pharmacist. Similar findings were observed in this study, where the majority of the participants rated the sessions very informative (n=96) and will attend future sessions.

The Joint Commission also recognizes that the process of transitioning predisposes the patient to a higher risk of medication errors. It also recognizes that there are challenges which need to be addressed so that one can ascertain smooth transitioning of the patients.[12] The Joint Commission argues that it can be laborious and somewhat difficult to obtain the complete list for every individual and hence the Commission issued some standards, National Patient Safety Goal (NPSG), which were specifically designed to assist organisations with reducing the negative outcomes associated with medication discrepancies. These standards include coordinating information during transitions both within and outside an organisation, education of the individual on safe medication use and communications with other providers. Having such sessions at the Transition of Care can indeed result to be difficult to achieve due to several reasons, but mainly due to time constraints. This issue was also observed in this study, where each session took at least 30-45 minutes to diligently go through all the medications and explaining in detail certain issues which arises.

4.3 Implementation of interventions

The descriptive analysis of this study in the DRPs and the actions documented yield several findings and interventions were provided on every identified DRP (n=194).

The most common intervention recorded in this study was "Lack or Misinterpretation of information" (n=48). This observation could be due to several factors, such as health literacy. Twenty-four patients stated that they were health illiterate, and since there are no clinical pharmacists within the diabetic outpatient who can provide pharmaceutical advice, such patients remain at higher risk of experiencing medication errors. The DRP "Lack or misinterpretation of information" included those patients who were not aware that it is essential to administer the correct dose of medications regularly and as instructed. These patients did not comprehend the rationale behind the correct administration of prescribed medications and their adverse effects.

"Insufficient awareness of health and disease" was the second most common reported DRP. Sixty-four patients stated that being diabetic did not change their lifestyle, and the majority of patients (n=57) stated that 30minute sports activity per day was not part of their daily schedule. This also means that they were not aware of the serious consequences of uncontrolled diabetes. Diabetic patients should be vigilant on their carbohydrate and glucose intake, and they should regularly monitor their blood glucose levels while keeping a daily food record. Consequently, most of the pharmacist interventions, which were carried out during the pharmaceutical sessions, were verbal advice. During the session, the patients were advised how to perform carbohydrate

counting in type 1 diabetic patients, and how to manage symptoms of hyper/hypoglycaemia episodes.

The third most prevalent DRP observed in this study was "Inappropriate timing of administration and /or drug intervals" (n= 36). The patients were advised on the proper administration of medications to ensure that the patients administer the recommended treatment without interruptions, especially following discharge from the hospital or post outpatient appointments. During this period, patients can get confused or misunderstand the instruction given to them by the clinicians. Throughout this study, the patients were provided with correct adherence instructions which were thoroughly explained without using technical language by the researcher. The rationale behind specific timing for some medications was also explained. The pharmacist verbally advised most patients on how to improve the drug administration. Two of the most common drugs which were not appropriately administered were metformin (n=16) and the statins (n=12) although gliclazide (n=9), vildagliptin (n=5) and omeprazole (n=6) were also among the drugs which frequently required advice on proper administration.

During the session, the pharmacist went through the medication list, having a mean number of medications for each patient equivalent to seven, and explained how they should be administered. A brief explanation was given to encourage patients to understand more the rationale of correct drug administration. In many instances, the pharmacist first questioned how the patient administered the drug, and then correct the inaccuracies and explain to proper procedure.

This study correlates very well with another study where a community pharmacist-led service was offered to patients to facilitate the Transition of Care and reduce

hospitalisations. In his study, Feldman et al., (2018) observed that non-adherence, not related to cost, was identified as one of the main problems encountered during the study. Twenty-seven patients were recorded to be non-adherent to treatment in this study, mainly not due to financial problems, but due to lack of awareness. There are several other issues where this study correlated with Feldman's study. A common DRP in this study was "Insufficient awareness of health and disease" where patients stated that they are forgetful, or they misinterpret the clinician's instructions. Feldman's study also observed this trend, and he argues that this is a challenge for the community pharmacist to try and educate the patient on the proper administration of medications.

4.4 Transition of Care

During the transitioning between different healthcare settings, such as from outpatient appointments to the community, medicine reconciliation is of utmost importance for hospital-initiated medication changes to be maintained. Medications which were usually taken by the patients in the community and which were, in many instances, prescribed by their general practitioner are often changed following either outpatient appointments or hospital admission (McNab et al., 2017). The transition can pose a hazard to the patient's safety mainly due to lack of communication between different healthcare providers leading to loss of crucial medical data. Inaccurate communication practices have been studied and blamed for many unfortunate events. For this reason, the Joint Commission on Accreditation of Healthcare Organisation added standardised

communication as the new risk factor leading to adverse effects.[18] [19] When performing MR, the process should ideally follow a multidisciplinary and multidimensional health process for it to be successful, as it requires the collaboration of various healthcare providers, such as clinicians, nurses, carers at various care levels. It should, therefore, be integrated with a multi-component bundle specifically designed to improve the patient outcome. Consequently, it is inappropriate to consider MR as a stand-alone, in isolation of other activities. This was observed in this study that although the effectiveness of the Transition of Care document cannot be clearly assessed due to the low contributions from the community pharmacist, but from all those who participated (n=41), they were unanimously in agreement that more communication is needed between healthcare professionals and that the pharmacist will dispense the medication more at ease knowing that medicine reconciliation was performed. Consequently, a well-developed MR process requires the role of the pharmacist, including the community pharmacist, where they are encouraged to define their own MR processes and adopt MR within their routine workflow.

In a study conducted by Hammad et al., (2017), it was observed that the continuity of care was improved by MR pharmacist, who intercepted and clarified medication discrepancies. In this study, the pharmacist had to intervene and in many instances, to

[18] The Joint Commission on Accreditation of Health Organisation. Healthcare at the crossroads: strategies for improving the medical liability system. [Internet]. Jointcommission.org. 2019 [cited 2019 March 19]. Available from: https://www.jointcommission.org/assets/1/18/health_care_at_the_crossroads.pdf

[19] The Joint Commission on Accreditation of Health Organization. National Patient Safety Goals. [Internet]. Jointcommission.org. 2019 [cited 2019 March 19]. Available from: https://www.jointcommission.org/standards_information/npsgs.aspx

correct and clarify certain doses and dosage regimen, especially when the patients were not health literate or clearly confused.

4.5 Community pharmacist involvement in the Transition of Care

Fewer than expected participated in this study (n=41), and this could have been attributed to the limited time available for the community pharmacist to read their e-mails and participate in studies. The results of this study illustrate some core points with regards to the perception of the community pharmacist and their concern with medication errors during this crucial period of transitioning of patients. This study also shed light on the community pharmacist perception of involvement in Transition of Care. The pharmacist in the community often reports that there is a lack of communication received from hospitals during the transitioning of patients to primary care. This was also observed in this study, where the majority of the community pharmacist (n=41) stated more communication is needed between different healthcare providers. Locally, the only means of communication between the hospital and the community pharmacist is through prescriptions or discharge letters, which are given directly to the patient. The pharmacist has no access to medical information. There are several studies which try to address this gap in communication deficit, but interventions which include the community pharmacist are very limited (Kennelty et al., 2015).

Out of all the pharmacists who were contacted and asked to participate in the study (N=73), a very unsatisfactory response was received, even after sending two reminder e-mails.

From this study, it was observed that only a small number of pharmacist (n=41) participated or were willing to get involved in the team of the Transition of Care study. It was observed that all those who participated in answering the 5 minute questionnaire (n=41), were concerned that crucial medical data could get lost during the transitioning of the patients. One can also observe that community pharmacists are less confident as they have very limited information at hand to effectively advice patients or perform medicine reconciliation. This study addressed this issue of lack of communication between different healthcare professional, namely the outpatient hospital setting and the community by sending the Transition of Care document to the community pharmacist, which document contains all the medical data required to follow-up patients

Positive results were observed (n=37) in the majority of the participant pharmacists when asked whether they are concerned that significant medical data can get lost during the transition. The majority of pharmacist (n=37) stated that they would dispense the medications more at ease knowing that medicine reconciliation was performed and that they will use the Transition of Care document which was purposely designed for this study. This correlated very well with a study performed by Graham et al.,(2019) wherein the study it was concluded that the pharmacist does not have access to adequate information regarding their patients and that they do not feel confident counselling patients.

The World Health Organisation has stated that the community pharmacists are the most easily accessed health specialists to implement several duties such as counselling of patients.[20]

4.5.1 Barriers for the community pharmacist

Workload and time constraints are some of the barriers which the community pharmacists need to overcome. This is especially true locally, where the pharmacist's workload needs to shift from dispensing to patient counselling, to allow time for patient care services. The inability to independently charge a patient for the services provided by the community pharmacist hinders the pharmacist from providing the patient with the care in full capacity (Nguyen E, Holmes J, 2019).

4.6 Enhancing the communication between pharmacists

Effective communication between healthcare providers has a crucial role in providing essential hand-over information with regards to changes in medications while the patient is transitioning. Medication errors occurring during this transitioning, account

[20] The Role of the Pharmacist in the Healthcare System [Internet]. Apps.who.int. 1994 [cited 2019 March 13]. Available from: http://apps.who.int/medicinedocs/en/d/Jh2995e/

for almost half of all errors, many of which are attributed to ineffective communication between different healthcare providers (Ensing et al., 2015).

This trend was also observed in this study, where all the pharmacists (n=41) consented for better communication between healthcare providers. Our results support the concept that the transmission of inpatient information to community pharmacist can indeed contribute at providing quality of care, through our designated Transition of Care document, where the majority of the pharmacist (n=36) stated that they would use the Transition of Care document.

Community pharmacist tends to not always actively participate in transition initiatives, especially when patients shift from hospital to the community. This lack in communication is particularly problematic, and although there are several studies which have identified the potential role of the community pharmacist in these circumstances, the level of engagement and follow-ups still tend to be uncertain (Rodrigues et al. 2017). It is essential for a pharmacist to be prepared with the right information and to feel warranted to be part of the team which aims at improving the quality of care for the patients. There are only a few studies which examine the pharmacist perception and attitudes with regards to community pharmacist as part of the multidisciplinary team, especially in the ToC process (Zeleznikar et al., 2017).

Using the local scenario, we do not have an elaborate IT system where-by the pharmacist, and the clinician can communicate directly. In the UK, according to a study conducted by Nazar et al., (2016) they evaluated their electronic patient referral system from one UK hospital to the community pharmacist, and it was concluded that this system inevitable filled the gap of lack of communication. Their findings indicate that a

solution to the risk of medical data being lost is using an electronic platform, where data can be accessed by all healthcare providers, including hospital pharmacist and pharmacist in the community. By using today's technology, one can facilitate the transfer of information, very quickly between all healthcare providers concerned. This will inevitably improve the coordination of care as patients are transferred from one healthcare setting to another.

The role of the pharmacist has slowly evolved from the product-oriented form of dispensing to more patient-oriented services, namely clinical pharmacy and pharmaceutical care, which includes prevention and identification of drug-related problems (Butt et al., 2016). Studies have shown that interventions made by pharmacists showed an increase in medication adherence, increase in patient compliance, increase in knowledge and awareness and hence improved glycaemic control (Sullivan et al., 2016). Other studies suggest that patients find difficulties in understanding how to administer their treatment. It is also known that the physician-patient communications can sometimes be ineffective and so the patient leaves the physician's office with unclear information and questions which the patients refrain from asking the specialist, mainly due to time constraints (Lafata et al., 2013, Dutton et al., 2014). Adding to these challenges of physician-patient communication is literacy skills. Since illiterate patients encounter more difficulties in understanding medical instructions and medicine labels, they have a higher probability of rehospitalisation or showing at the emergency department. If the transition of medical information from the hospital or clinic to the community is ineffective due to inappropriate handovers, this can seriously jeopardise the safety and the quality of the patient's care. Such lack of

handovers can lead to co-morbidities or unanticipated hospitalisations, which could very well be prevented (Heselink et al., 2012).

This research aims at overlapping the gap which exists at the Transition of Care while diabetic patients move from the specialised Diabetes Clinic at Mater Dei Hospital to the community setting by developing a Transition of Care tool which is shared with the healthcare professionals in the community.

4.7 Gaps in Transition of Care in diabetic patients

Diabetic patients often have multiple outpatient appointments such as diabetic consultations at least twice a year, annual retinal eye check, foot testing, annual influenza immunisation, blood lipid profile, to name a few. Some patients, especially those who are not health literate, in this study (n= 24), often encounter difficulties to keep track of all appointments and consultation visits (American Diabetes Association, 2018). Following visits to different outpatient consultants and other health professionals can easily result in a change in treatment. There is evidence that shows that patients with low health literacy have poor health outcomes (Berkman et al., 2011). This could also be observed from this study, as the majority of patients who required additional professional advice were those who claim that they were health illiterate.

Thus, this study aimed at providing extra educational advice, which will increase the ability of the patient to at least read and interpret simple instructions. Patients with low health literacy have less understanding of their medications, and this has significant

implications on the patient's ability to understand instructions which are usually written on the prescription or the discharge note. Improving health literacy will, in turn, also ameliorate the adherence to treatment (Marvanova et al.,2011).

In this study, since the sessions were one-to-one, the communication and the education needed by the patients was tailored according to the patient's level of literacy. Throughout the study, medication management was one of the main focus in the discussions, having the pharmacist performing the medication review and then including potential adverse effects, drug interaction and ongoing monitoring requirements. The researcher also recommended alternative formulations when swallowing was an issue for the patient, and reviewing the timing of the medication to optimise adherence to get the full benefit of the treatment.

4.8 Pharmacist-patient pharmaceutical sessions

The sessions aimed to gain insight in the pharmacotherapy of the patient. Data on medication use, medication adherence, difficulties in administering the medications, medication knowledge and health literacy were some of the information gathered during this session. Additional questions not related directly to medications were also gathered such as allergies, lifestyle, living status such as living alone or with family or in an elderly residential home, the functional status, recent hospitalisations and fall incidents. Subsequently, the pharmacist performed the pharmacotherapeutic analysis to identify any DRPs, with particular focus on medication use and adherence and adverse drug reactions. During the medication review, besides asking the current

chronic medications list of both the prescribed and the non-prescribed medications, other information such as the name of the medication and dosage regimen were also registered, and remarks were taken and recorded in the Data Collection Sheet (Appendix 3.2). The pharmacist then went through the medication list, analysing the treatment for any DRPs, and then went through the entire list with the patient, checking that the patient comprehends all that is said and discussed. Adherence outcomes were analysed both objectively as well as subjectively using the patient's questionnaire.

4.9 Healthcare professional perception

Evaluation of satisfaction measures reveals a high degree of contentment with the service and interventions provided by the pharmacist. This was evident from the 5-minute write-up questionnaire that was distributed to eleven healthcare professionals. The pharmacist-led medicine reconciliation was classified as one of the most rated and evaluated activity by healthcare professionals. This also corresponds well with another two studies conducted by Duedahl et al., (2017) and Karapinar-Carkit et al., (2010), where they observed high acceptance rate, ranging from 39-100% which confirms the high clinical relevance of the pharmaceutical input. This sustains the importance of the clinical pharmacist contribution to ensure the safe administration of medications.

4.10 Patients' perception of the pharmacist service offered

It is clearly defined that teamwork and effective communication throughout the healthcare setting is essential for providing patients with an efficient and quality of care. The healthcare system is highly complex and dependent on several different healthcare professionals. This attenuates the need for better communication not only between healthcare providers but also with the patient and the carers. All those patients who participated in the study (n=100) stated that they were more informed about their medications following the session. All patients who participated in this study (N=100) appreciated the extra quality assessment, which was provided by the pharmacist when compiling the medication list and giving advice.

4.11 Improving the pharmacist-led service

The communication between the hospital and the community can be increased by having a hospital-based community liaison pharmacist, which can then assist in the transfer of data from the secondary to the primary care (Bolas et al., 2004). Bolas, in his study, concluded that having a pharmacist who can perform several duties can significantly improve the patient's outcome.

The pharmacist took the responsibility of conducting MR, prepared the discharge letter and explained the medication changes to the patients and offered patient education and counselling. A complete current medication list was compiled together with a letter for the general practitioner (GP) and the local pharmacy having copies of the discharge

prescription and an assessment of the patient's medications before discharge. In the Irish study, nearly half of all GPs and the majority of the local pharmacies were in favour of this service. This also correlated very well with this study, as the majority of the healthcare professionals (n=7) recommend that a pharmacist should be part of the team assisting the clinicians, while most others (n=6) are in favour that a pharmacist, can improve the patient's outcome.

4.12 Limitations of the study

The study concerns a mono centre study, while the pharmacist-led service offered covered only a small population, namely diabetic outpatient attending MDH diabetic outpatient. This may have limited generalisability and a degree of selection bias since the patients were only selected from the diabetic outpatient. This bias might have been introduced as the patients participating in the study all attended the MDH diabetic outpatient. Patients who attend such appointments tend to exhibit higher interest in their health in general, and this might not represent the Maltese population.

The evaluation of the healthcare professionals would have been strengthened if the service included other areas such as regional diabetic polyclinics and then evaluated by an even larger number of healthcare professionals. This would give a better insight into the pharmacist's interventions.

Since the study was implemented on four months, the patients could not be followed and reassessed to gather the feedback and to assess whether the pharmacist

interventions did improve the patient's outcome. Although there is no control group, the study provides a detail description of the drug-related problems and the interventions which were executed by the pharmacist.

The Transition of Care document, which was purposely designed for this study, was evaluated by a limited number of community pharmacists (n=41), and hence requires further assessment to assess the effectiveness of this document.

4.13 Recommendations for further studies

The pharmacist-led service, which was provided at the diabetic outpatient, can be spread to other areas such as regional diabetic clinics in different districts in Malta.

The patients would then be followed throughout their inpatient stay, and then counselled before the transition to the community. Inter-professional education is essential to incorporate the community pharmacist with advising the patient in the primary care setting and hence following the patient and counselling on any changes in treatment or other issues which the patient requires. Medicine reconciliation should a process which is continually updated throughout the entire patient journey from admission to discharge to outpatient appointments. This process should be embedded in a multidisciplinary plan, where the pharmacist can lead this process.

Further studies should include a second appointment to follow up the patient to assess the pharmacist interventions and to analyse whether actions were taken to optimise the recommended treatment.

This study revealed that the average HbA1c was that of 9%. This is rather high and indicates the need for more educational programs which include a strong focus from pharmacists.

4.14 Conclusion

A clinical pharmacist contributes to ascertain a smooth transitioning of patients between one healthcare setting to another by providing MR service to all patients and also improves communication between different healthcare providers such as by compiling a Transition of Care document directed to community pharmacists

This study demonstrates that a pharmacist providing direct patient services at the diabetic clinic and acting as liaison with the multidisciplinary team of healthcare professionals, including the community pharmacist, supports patients in identifying drug-related problems.

By having this innovative service, which was offered in this study, the pharmacist not only identified and resolved adverse drug reactions, but other important aspects were also taken into consideration. This included patient education and health literacy, medication management, including medicine reconciliation and communication with the healthcare team and with the patients and their families or carers.

REFERENCES

Abdulghani K, Aseeri M, Mahmoud A, Abulezz R. The impact of pharmacist-led medication reconciliation during admission at tertiary care hospital. International Journal of Clinical Pharmacy. 2017;40(1):196-201.

Allende Bandrés M, Arenere Mendoza M, Gutiérrez Nicolás F, Calleja Hernández M, Ruiz La Iglesia F. Pharmacist-led medication reconciliation to reduce discrepancies in transitions of care American Diabetes Association. Standards of medical care in Diabetes Care.2018;41:S13-S27

Argyle M, Newman C. An assessment of pharmacy discharge procedures and hospital communications with general practitioners. Pharm J. 1996;256(6898):903–905

Aronson J. Medication errors: what they are, how they happen, and how to avoid them. QJM. 2009;102(8):513-521.

Berkman N, Sheridan S, Donahue K, Halpern D, Crotty K. Low Health Literacy and Health Outcomes: An Updated Systematic Review. Annals of Internal Medicine. 2011;155(2):97.

Bolas H, Brookes K, Scott M, McElnay J. Evaluation of a hospital-based community liaison pharmacy service in Northern Ireland. Pharmacy World & Science. 2004;26(2):114-120.

Borgsteede S, Karapinar-Çarkit F, Hoffmann E, Zoer J, van den Bemt P. Information needs about medication according to patients discharged from a general hospital. Patient Education and Counseling. 2011;83(1):22-28.

Brackenborough S. Views of patients, general practitioners and community pharmacists on medication related discharge information. Pharm J. 1997;259:1020–1023

Brantley A, Rossi D, Barnes-Warren S, Francisco J, Schatten I, Dave V. Bridging gaps in care: Implementation of a pharmacist-led transitions-of-care program. American Journal of Health-System Pharmacy. 2018;75(5 Supplement 1):S1-S5.

Brown J, Brown D. Pharmaceutical care at the primary-secondary care interface in Portsmouth and South East Hampshire. Pharm J. 1997;258:280–4.

Cavanaugh J, Lindsey K, Shilliday B, Ratner S. Pharmacist-Coordinated Multidisciplinary Hospital Follow-up Visits Improve Patient Outcomes. Journal of Managed Care & Specialty Pharmacy. 2015;21(3):256-260.

Chau S, Jansen A, van de Ven P, Hoogland P, Elders P, Hugtenburg J. Clinical medication reviews in elderly patients with polypharmacy: a cross-sectional study on drug-related problems in the Netherlands. International Journal of Clinical Pharmacy. 2015;38(1):46-53.

Cheval CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control. Patient Educ Couns. 2016;99:926–943.

Cornish PL, Knowles SR, Marchesano R, Tam V, Shadowitz S, Juurlink DN, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med. 2005;165:424-9.

Davis TC, Wolf MS, Bass PF, Tilson H, Neuberger M, Parker RM. Literacy and misunderstanding of prescription drug labels. Ann Intern Med. 2006;145:887–94.

Dowse R, Ehlers MS. The influence of education on the interpretation of pharmaceutical pictograms for communicating medicine instructions. Int J Pharm Pract. 2003;11:11–8.

Duedahl T, Hansen W, Kjeldsen L, Graabæk T. Pharmacist-led interventions improve quality of medicine-related healthcare service at hospital discharge. European Journal of Hospital Pharmacy. 2017;25(e1):e40-e45.

Duggan C, Feldman R, Hough J, Bates I. Reducing adverse prescribing discrepancies following hospital discharge. Int J Pharm Pract. 1998;6:77–82.

Egede L, Gebregziabher M, Dismuke C, Lynch C, Axon R, Zhao Y et al. Medication Nonadherence in Diabetes: Longitudinal effects on costs and potential cost savings from improvement. Diabetes Care. 2012;35(12):2533-2539.

Ensing H, Stuijt C, van den Bemt B, van Dooren A, Karapinar-Çarkit F, Koster E et al. Identifying the Optimal Role for Pharmacists in Care Transitions: A Systematic Review. Journal of Managed Care & Specialty Pharmacy. 2015;21(8):614-636.

Ensing H, Vervloet M, van Dooren A, Bouvy M, Koster E. Patient-pharmacist communication during a post-discharge pharmacist home visit. International Journal of Clinical Pharmacy. 2018;40(3):712-720.

Feigenbaum P, Neuwirth E, Trowbridge L, Teplitsky S, Barnes C, Fireman E et al. Factors Contributing to All-cause 30-day Readmissions. Medical Care. 2012;50(7):599-605.

Feldman J, Otting R, Otting C, Witry M. A community pharmacist–led service to facilitate care transitions and reduce hospital readmissions. Journal of the American Pharmacists Association. 2018;58(1):36-43.

Frydenberg K, Brekke M. Poor communication on patients' medication across healthcare levels leads to potentially harmful medication errors. Scandinavian Journal of Primary Healthcare. 2012;30(4):234-240.

Geurts M, van der Flier M, de Vries-Bots A, Brink-van der Wal T, de Gier J. Medication reconciliation to solve discrepancies in discharge documents after discharge from the hospital. International Journal of Clinical Pharmacy. 2013;35(4):600-607.

Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. AmJ Health Syst Pharm. 2004;61:1689–95.

Graabaek T, Kjeldsen L. Medication Reviews by Clinical Pharmacists at Hospitals Lead to Improved Patient Outcomes: A Systematic Review. Basic & Clinical Pharmacology & Toxicology. 2013;112(6):359-373.

Graham J, Tusing L, Gregor C, Wright E. Community Pharmacists' Perceptions of Care Following the Implementation of a Transitions-of-Care Program. Journal of Pharmacy Practice. 2019;089719001882481.

Grech M, Chaney D. Screening for type 2 diabetes and pre-diabetes in general practice: A descriptive study of Maltese practices. Primary Care Diabetes. 2014;8(3):224-230.

Hammad E, Bale A, Wright D, Bhattacharya D. Pharmacy led medicine reconciliation at hospital: A systematic review of effects and costs. Research in Social and Administrative Pharmacy. 2017;13(2):300-312.

Hawes E, Lambert E, Reid A, Tong G, Gwynne M. Implementation and evaluation of a pharmacist-led electronic visit program for diabetes and anticoagulation care in a patient-centred medical home. American Journal of Health-System Pharmacy. 2018;75(12):901-910.

Hertig R, Ackerman R, Zagar B, Tart S. Pharmacy student involvement in a transition of care program. Currents in Pharmacy Teaching and Learning. 2017;9(5):841-847.

Hertz R, Unger A, Lustik M. Adherence with pharmacotherapy for type 2 diabetes: a retrospective cohort study of adults with employer-sponsored health insurance. Clinical Therapeutics. 2005;27(7):1064-1073.

Hume A, Kirwin J, Bieber H, Couchenour R, Hall D, Kennedy A et al. Improving Care Transitions: Current Practice and Future Opportunities for Pharmacists. The Journal of Human Pharmacology and Drug Therapy. 2012;32(11):326-337.

Improving care transitions: Optimizing medication reconciliation. Journal of the American Pharmacists Association. 2012;52(4):e43-e52. International Diabetes Federation, IDF The Diabetes Atlas, 6th ed., Atlas, Brussels, 2013.

Jaam M, Ibrahim M, Kheir N, Awaisu A. Factors associated with medication adherence among patients with diabetes in the Middle East and North Africa region: A systematic mixed studies review. Diabetes Research and Clinical Practice. 2017;129:1-15.

Johnson A, Guirguis E, Grace Y. Preventing medication errors in transitions of care: A patient case approach. Pharmacy Today. 2015;21(3):79-90.

Karapinar-Çarkıt F, Borgsteede S, Zoer J, Siegert C, van Tulder M, Egberts A et al. The effect of the COACH program (Continuity Of Appropriate pharmacotherapy, patient Counselling and information transfer in Healthcare) on readmission rates in a multicultural population of internal medicine patients. BMC Health Services Research. 2010;10(1).

Kennelty K, Chewning B, Wise M, Kind A, Roberts T, Kreling D. Barriers and facilitators of medication reconciliation processes for recently discharged patients from community pharmacists' perspectives. Research in Social and Administrative Pharmacy. 2015;11(4):517-530.

Kharjul M, Braund R, Green J. The influence of pharmacist-led adherence support on glycaemic control in people with type 2 diabetes. International Journal of Clinical Pharmacy. 2018;40(2):354-359.

Kjeldsen L, Birkholm T, Fischer H, Graabæk T, Kibsdal K, Ravn-Nielsen L et al. Characterization of drug-related problems identified by clinical pharmacy staff at Danish hospitals. International Journal of Clinical Pharmacy. 2014;36(4):734-741.

Kjeldsen L, Olesem C, Truelshoj T, Nielsen L. Quality assurance of medical treatment- an approach by Danish clinical pharmacist. EJHP Pract.2011;17:31-4.

Kovacs Burns K, Nicolucci A, Holt RI, et al.; DAWN2 Study Group. Diabetes attitudes, wishes and needs second study (DAWN2™): Cross-national benchmarking indicators for family members living with people with diabetes. Diabet Med. 2013;30:778–88.

Kristeller J. Transition of Care: Pharmacist Help Needed. Hospital Pharmacy. 2014;49(3):215-216.

Lessard S, DeYoung J, Vazzana N. Medication discrepancies affecting senior patients at hospital admission. Am J Health Syst Pharm. 2006;63:740–743

Manias E, Hughes C. Challenges of managing medications for older people at transition points of care. Research in Social and Administrative Pharmacy. 2015;11(3):442-447.

Marinović I, Marušić S, Mucalo I, Mesarić J, Bačić Vrca V. Clinical pharmacist-led program on medication reconciliation implementation at hospital admission: experience of a single university hospital in Croatia. Croatian Medical Journal. 2016;57(6):572-581.

Marvanova M, Roumie C, Eden S, Cawthon C, Schnipper J, Kripalani S. Health literacy and medication understanding among hospitalized adults. Journal of Hospital Medicine. 2011;6(9):488-493.

McNab D, Bowie P, Ross A, MacWalter G, Ryan M, Morrison J. Systematic review and meta-analysis of the effectiveness of pharmacist-led medication reconciliation in the community after hospital discharge. BMJ Quality & Safety. 2017;27(4):308-320.

Mekonnen A, McLachlan A, Brien J. Pharmacy-led medication reconciliation programmes at hospital transitions: a systematic review and meta-analysis. Journal of Clinical Pharmacy and Therapeutics. 2016;41(2):128-144.

Moreau C, Sando K, Zambrano D. Assessing the Effect of Pharmacist Care on Diabetes-Related Outcomes in a Rural Outpatient Clinic: A Retrospective Case-Control Study. Ann. Pharmacother.2017;51(6):473-478.

Naccarella L, Pirotta M. Communication at the interface between hospitals and primary care: A general practice audit of hospital discharge summaries. Australian Family Physician.2013;42(12):886-890.

Nazar H, Brice S, Akhter N, Kasim A, Gunning A, Slight S et al. New transfer of care initiative of electronic referral from hospital to community pharmacy in England: a formative service evaluation. BMJ Open. 2016;6(10):e012532.

Nguyen E, Holmes J. Pharmacist-provided services: Barriers to demonstrating value. Journal of the American Pharmacists Association. 2019;59(1):117-120.

Phatak A, Prusi R, Ward B, Hansen L, Williams M, Vetter E et al. Impact of pharmacist involvement in the transitional care of high-risk patients through medication reconciliation, medication education, and postdischarge call-backs (IPITCH Study). Journal of Hospital Medicine. 2015;11(1):39-44.

Pladevall M, Williams L, Potts L, Divine G, Xi H, Elston Lafata J. Clinical Outcomes and Adherence to Medications Measured by Claims Data in Patients With Diabetes. Diabetes Care. 2004;27(12):2800-2805.

Pourrat X, Roux C, Bouzige B, Garnier V, Develay A, Allenet B et al. Impact of drug reconciliation at discharge and communication between hospital and community pharmacists on drug-related problems: study protocol for a randomized controlled trial. Trials. 2014;15(1):260.

Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care. 2015;38:1–11.

Raghavan S, Porneala B, McKeown N, et al. Metabolic factors and genetic risk mediate familial type 2 diabetes risk in the Framingham Heart Study. Diabetologia. 2015;58:988–96.

Rodrigues C, Harrington A, Murdock N, Holmes J, Borzadek E, Calabro K et al. Effect of Pharmacy-Supported Transition-of-Care Interventions on 30-Day Readmissions: A Systematic Review and Meta-analysis. Annals of Pharmacotherapy. 2017;51(10):866-889.

Schectman J, Nadkarni M, Voss J. The Association Between Diabetes Metabolic Control and Drug Adherence in an Indigent Population. Diabetes Care. 2002;25(6):1015-1021.

Shaw J, Sicree R, Zimmet P. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Research and Clinical Practice. 2010;87(1):4-14.

Strand L, Morley P, Cipolle R, Ramsey R, Lamsam G. Drug-Related Problems: Their Structure and Function. DICP. 1990;24(11):1093-1097.

Tam V, Knowles S, Cornish P, Fine N, Marchesano R, Etchekks E. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. Canadian Medical Association Journal. 2005;173(5):510-515.

Urban R, Paloumpi E, Rana N, Morgan J. Communicating medication changes to community pharmacy post-discharge: the good, the bad, and the improvements. International Journal of Clinical Pharmacy. 2013;35(5):813-820.

van Hollebeke M, Talavera-Pons S, Mulliez A, Sautou V, Bommelaer G, Abergel A et al. Impact of medication reconciliation at discharge on continuity of patient care in France. International Journal of Clinical Pharmacy. 2016;38(5):1149-1156.

van Mil J, Westerlund L, Hersberger K, Schaefer M. Drug-Related Problem Classification Systems. Annals of Pharmacotherapy. 2004;38(5):859-867.

Wheeler A, Scahill S, Hopcroft D, Stapleton H. Reducing medication errors at transitions of care is everyone's business. Australian Prescriber. 2018;41(3):73-77.

Zeleznikar E, Kroehl M, Perica K, Thompson A, Trinkley K. Integration of Community Pharmacists in Transition of Care (TOC) Services: Current Trends and Pharmacist Perceptions. Journal of Pharmacy Practice. 2017;32(1):28-35.

APPENDIX

Appendix 1 Ethics Approval

1.0 UREC Approval

L-Università ta' Malta

Faculty of Medicine & Surgery
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Msida MSD 2080, Malta

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

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Ref No: **FRECMDS_1718_045**

Monday 27th August 2018

Ms. Charlene Camilleri
Orchid Mansions 6A,
Mejjiesa Street
Manikata

Dear Ms. Camilleri,

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

Pharmacist-Led Transition Care for Diabetic Patients

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

Yours sincerely,

Professor Pierre Mallia
Chairman
Research Ethics Committee

APPENDIX 2

CONSENT FORMS

2.1 Formola tal-kunsens

Jien, is-sottofirmat, niċċertifika li jiena Cittadin Malti u li għandi il-fuq minn tmintax –il sena (18) gejt mistoqsi biex nipparteċipa fir-riċerka ntitolata l-isem 'Kura ta' Tranżizzjoni Mmexxija mill-Ispiżjar għal Pazjenti Dijabetiċi'

L-għan u d-dettaliji tar-riċerka spjegathomli Charlene Camilleri, li wkoll iċċaratli xi mistoqsijiet li għamilt.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal-din ir-riċerka biex tagħmel l-osservazjonijiet ili hemm bżonn.

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

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

Jiena ġejt infurmat li għandi bżonn nimla kwestjonarju li jieħu madwar 5 minuti.

Jiena nista, meta irrid, ma nkompliex nieħu sehem fir-riċerka mingħajr ma' nagħti raġuni.

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

Jiena ġejt infurmat li għandi d-dritt għall-aċċess, nirettifika u fejn applikabbli nħassar id-data li tikkonċerna lili.

Jekk ikolli xi diffikulta nista' nikkuntatja lil Charlene Camilleri fuq 99467371 jew bil-posta eletronika fuq charlene.camilleri.98@um.edu.mt

Firma tal-parteċipant _____

Isem tal-parteċipiant _____

Isem tal-persuna responsabbli għal din ir-riċerka _____

Data _____

2.2 Consent Form

I, the undersigned certify that I am a Maltese citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled 'Pharmacist-led Transition Care in Diabetic Patients'

The purpose and details of the research have been explained to me by Charlene Camilleri and any difficulties which I raided have been adequately clarified.

I give my consent to the Investigator to make the appropriate observations.

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

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

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

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

I was informed that I have the right to access, rectify and where applicable erase the data which concerns me.

For any further details or queries, I may contact Charlene Camilleri on 99467371 or via email at charlene.camilleri.98@um.edu.mt

Signature of participant _____

Name of participant _____

Name of researcher _____

Date _____

APPENDIX 3

INFORMATION SHEET & DATA COLLECTION SHEET

3.1.1 Karta ta' Informazzjoni

Jien, Charlene Camilleri, spiżjar li qed nagħmel id-dottorat fl-University ta'Malta, jixtieq nistiednek biex tipparteċipa f'din ir-riċerka.

Huwa importanti li tkun taf li inti għandek tipparteċipa biss jekk trid; l-għażla li ma tipparteċipax mhux ser tiżvantaġġjak bl-ebda mod.

Qabel ma tiddeċiedi jekk tridx tieħu sehem, huwa importanti li tifhem għalfejn qed issir ir-riċerka u x'se tinvolvi l-parteċipazzjoni tiegħek.

Jekk jogħġbok ħu ftit ħin biex taqra b'attenzjoni l-informazzjoni li ġejja. Nitieq li tħossok liberu biex tiddiskuti xi kwistjonijiet miegħi bhal ezempju jekk hemm xi ħaġa li mhix ċara jew jekk tixtieq aktar informazzjoni.

L-għan ta' din ir-riċerka huwa li tiżdied il-komunikazzjoni bejn il-professjonisti tas-saħħa fl-isptar u l-ispiżjar tal-għażla tiegħek (POYC) li qed tieħu ħsieb il mediċini tiegħek.

Int, bħala l-parteċipant, ser tintalab biex:

I. Tippreżenta l-mediċini kollha li qed tieħu bħalissa, inklużi kwalunkwe OTC u vitamini fil-klinika dijabetika meta tigi ghal-intervista ma' l-ispizjar.
II. Wara li taqra din il-pagna ta 'informazzjoni, inti tkun mitlub tiffirma l-formola tal-kunsens.
III. Imbagħad tkun mistoqsi numru ta' mistoqsijiet dwar is-saħħa tiegħek, il-mediċini tiegħek anka fuq il-kondizzjoni tad-dijabete.
IV. Il-mediċini ser jigu analizati mil-ispizjar biex naraw jekk hemmx xi problemi jew zbaliji ta' mediċini li jistaw jitrangaw.
V. Ser jsir document, li hija għodda tranżitorja, fejn turi l-mediċini kollha li l-pazjenti qed jieħdu bħalissa,u b'hekk tista' faċilment titqasam ma' l-ispiżja tal- POYC.
VI. Wara l-intervista int mitlub timla kwestjonarju qasir, sabiex l-impatt tal-ispiżjar kif ukoll biex naraw jekk il-pacjent hux iktar infurmat wara l-intervista.
VII. Kwalunkwe informazzjoni li tipprovdi ser tiġi ttrattata skont l-Att dwar il-Protezzjoni tad-Dejta. Id-dejta tiegħek ser tinżamm kunfidenzjali, u ir-riċerkatur biss ser ikollu aċċess għaliha. Wara jitlesta tal-istudju, id-dejta kollha tintrema b'mod xieraq.

3.1.2 Study Information Sheet

I, Charlene Camilleri, senior pharmacist and 2nd year doctorate in pharmacy student at the University of Malta, would like to invite you to participate in this research project. It is important to know that you should only participate if you want to; choosing not to take part will not disadvantage you in any way.

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

Please take time to read the following information carefully. Feel free to discuss any issues with me if there is anything that is not clear or if you would like more information.

The aim of this research is to increase the communication between hospital healthcare professionals and the Pharmacist of your choice (POYC) community pharmacist who is handling the chronic treatment.

You, as the participant, will be asked to:

i. Present all the current medications including any OTC and vitamins to the diabetic outpatient clinic.
ii. After reading this information sheet, you will be asked to sign the consent form.
iii. You will then be asked a number of questions with regards to your health, knowledge on the medications and your condition.
iv. Medicine reconciliation will be preformed, identifying any already existing gaps or drug therapy problems
v. A transitional tool, which consists of a clearly defined document highlighting all the medications that the patients are currently taking. This tool can then be easily shared among the POYC pharmacist.
vi. After the session, you will be asked to fill in a short questionnaire which will last approx 5 minutes. The aim of this questionnaire is to access whether you, as a patient is more aware and informed with regards to your medications.
vii. Any data you provide will be treated in accordance to the Data protection Act. Your data will be held confidentially, with access only to me, the researcher, and the POYC pharmacist. After the completion of the study, all data will be discarded in a proper way.

3.2.1 Paga ta gbir ta’ informazzjoni

Skeda ta' ġbir ta’ informazzjoni tal-pazjent - Għandha timtela mill-investigatur

Numru ta' referenza ___ / ___ / ___ / Data ta' l-Intervista ___ / ___ / ___ /

Taqsima 1 - Informazzjoni dwar il-pazjent .

Raġel ☐ Mara ☐

Età __ / __ / Piż ___ / ___ / ___ / Kg

HbA1c _____ Toqhghod wahdek jew mal-familja

_____

Nazzjonalita’_____

Taqsima 2 - Informazzjoni Medika

Għandek dijabete fil-familja? IVA ☐ LE ☐

Int tpejjep Kuljum ☐ Kultant ☐ Qatt ☐ Waqqaft ☐

Inti tikkonsma l-alkoħol fuq bażi ta 'kuljum? IVA ☐ LE ☐

Sena ta 'l-ewwel dijanjosi bid-dijabete? Sena _____ Età_____

Qabel ma ġiet iddijanjostikata bid-dijabete, IVA ☐ LE ☐

Kont tiehu xi testijiet tad-demm regolari? Ez kul sena? IVA ☐ LE ☐

Qatt kont tiehu insulina? IVA ☐ LE ☐

Ticcekja iz-zokkor regulari d-dar? IVA ☐ LE ☐

Taqsima 3 - Għarfien tal-Pazjent dwar id-dijabete u kumplikazzjonijiet relatati

Tista' tidentifika l-mediċini kollha tiegħek bl-isem IVA ☐ LE ☐

Taf meta għandhom jittieħdu l-mediċini? IVA ☐ LE ☐

Taf għandhomx jittieħdu qabel jew wara l-ikliet? IVA ☐ LE ☐

Il-mediċina ghandha tittieħed anke jekk l-ikla tħassar? IVA ☐ LE ☐

Qatt kont infurmat dwar kif għandek tieħu l-mediċina tiegħek IVA ☐ LE ☐

Meta tkun infurmat dwar kif għandek taġġusta d-dieta tiegħek IVA ☐ LE ☐

Int tiċċekkja iz-zokkor fid-demm tiegħek b'mod regolari fid-dar IVA ☐ LE ☐

Inti eżerċita regolarment? IVA ☐ LE ☐

X'tip ta' eżerċizzju tagħmel? _____

Int taf li jekk id-dijabete, jekk ma tkunx ikkontrollata tajjeb wassal għal kumplikazzjonijiet serji? IVA ☐ LE ☐

Il-fatt li ghandek iz-zokkor, bidlitlek hajtek? IVA ☐ LE ☐

Int qatt inatajt informazzjoni jew gejt mistiedna biex tingħaqad f'grupp ghal lezzjonijiet dwar il-mediċini tiegħek? IVA ☐ LE ☐

Qatt dhalt l-isptar bħala pazjent? IVA ☐ LE ☐

Jekk iva, int inatajt istruzzjonijiet mil-ispiżjar IVA ☐ LE ☐

Jekk LE, tixtieq tingħata istruzzjonijiet dwar kif tieħu Il- mediċini tiegħek minn spiżjar IVA ☐ LE ☐

Taqsima 4 - Din it-taqsima għandha timtela mir-riċerkatur

Il-pazjent kellu bżonn aktar assistenza mill-ispiżjar? IVA ☐ LE ☐

Jekk iva, liema tip?

_____

Kien il-pazjent ħerqan li jisma 'l-parir tiegħek? IVA ☐ LE ☐

Il- pazjent laqgħet il-parir tiegħek? IVA ☐ LE ☐

3.2.2 Patient's Data Collection Sheet - To be filled by the investigator

Reference number ___/___/___/ Date of Session ___/___/___/

Section 1 – Patient information

Male ☐ Female ☐

Age __/__/ Weight ___/___/___/ Kg

HbA1c_____ Living alone or with family _____

Nationality _____

Section 2 – Medical information

Do you have a family history of diabetes? YES ☐ NO ☐

Are you a smoker? Daily☐ Occasionally☐ Never☐ Stopped☐

Do you consume alcohol on a daily basis? YES ☐ NO ☐

Year of first diagnoses with diabetes? Year _____ Age_____

Prior to being diagnosed with diabetes, YES ☐ NO ☐

did you have blood tests annually?

Do you check your blood glucose level regularly at home YES ☐ NO ☐

<u>The patient's anti-diabetic treatment include</u>

Medication _____ Dosage _____

Initiation of treatment ___/___/___/

Medication _____ Dosage _____

Initiation of treatment ___/___/___/

Medication _____ Dosage _____

Initiation of treatment ___/___/___/

Medication _____ Dosage _____

Initiation of treatment ___/___/___/

Section 3 – Patient's Knowledge on diabetes and related complications

Can you identify all your medications by name? YES ☐ NO ☐

Can you identify when the medications are to be taken? YES ☐ NO ☐

Are they to be taken before or after meals? YES ☐ NO ☐

Should the medication be taken even if meals

are skipped? YES ☐ NO ☐

Were you ever informed on how to take your

medications? YES ☐ NO ☐

Were you informed on how to adjust your diet YES ☐ NO ☐

after being diagnosed with diabetes?

Do you check your blood glucose regularly at home? YES ☐ NO ☐

Do you exercise regularly? YES ☐ NO ☐

If yes, what kind of exercise do you do? _____

Are you aware that if the diabetes is not controlled, YES ☐ NO ☐

it can lead to serious complications?

Does being a diabetic patient interfere with the way of life? YES ☐ NO ☐

How concerned are you that diabetes, if not controlled YES ☐ NO ☐

can lead to serious complications?

Were you ever given information or asked to join YES ☐ NO ☐

lecture with regards to your medications?

Were you ever an inpatient? YES ☐ NO ☐

If yes, were you given instructions by the YES ☐ NO ☐

clinical pharmacist?

If NO, would you like to be given instructions YES ☐ NO ☐

on how to take your medications by a pharmacist

prior to leaving the clinic?

Section 4. This section is to be filled in by the researcher .

Did the patient require further assistance by the pharmacist? YES ☐ NO ☐

If yes, what kind?

_____

Was the patient eager to listen to your advice? YES ☐ NO ☐

Did the patient welcome your advice? YES ☐ NO ☐

APPENDIX 4

TRANSITION OF CARE DOCUMENT

4.1 Transition of Care document denoting CHANGE in treatment

Transition of Care Document			
Ref Number:		ID Number:	
Date of Compilation:		Name:	
POYC Pharmacy:		Surname:	

	CHANGE in treatment

Description of Treatment	**Replaced by (if applicable)**

	Details of patient's treatment

Description of Treatment	**Strength**	**Regimen**	**POYC**

Pharmacist conducting the medicine reconciliation:	**Camilleri Charlene** BPharm (Hons) MPharm (Melit)
	Pharmacist contacts details: Charlene Camilleri. **E-mail**: charlene.camilleri.98@um.edu.mt; M**obile:** 99467371 Developed as partial fulfilment of the requirement for the degree of Doctor of Pharmacy

4.2 Transition of Care document denoting NO CHANGE in treatment

Transition of Care document

Ref Number:		ID Number:	
Date of Compilation:		Name:	
POYC Pharmacy:		Surname:	

Medicine reconciliation was performed but patient requires **NO CHANGE** in treatment

Advice given to patient

Details of patient's treatment

Description of Treatment	Strength	Regimen	POYC

Pharmacist conducting the medicine reconciliation: **Camilleri Charlene** BPharm (Hons)(Melit) MPharm (Melit)

Pharmacist contacts details: Charlene Camilleri. **E-mail**: charlene.camilleri.98@um.edu.mt; M**obile:** 99467371

Developed as partial fulfilment of the requirement for the degree of Doctorate of Pharmacy

APPENDIX 5

E-MAIL SENT TO COMMUNITY PHARMACIST

Dear Pharmacist,

Attached please find a Transition of Care Document which contains information regarding one of your POYC patients.

I am currently reading Pharm D course at the University of Malta and as part of my doctorate degree, I produced a Transition of Care document whereby MDH pharmacist can communicate directly with the pharmacist in the community

A *Transition of Care Document, attached, is being filled in by the hospital pharmacist* and consists of the following sections:

1. Section A - ANY change in treatment will be written in **BOLD**.
2. Section B - is a list of all the medications currently being taken by the patient.

Kindly note that I have the patient's consent to disseminate this information, which should be kept confidential at all times.

After using the Transition of Care document, may I ask you to please fill in the questionnaire which will assess the impact of this tool. (The questionnaire takes approx. 5 minutes))

Kindly access the questionnaire from this **LINK.**

https://goo.gl/forms/ag8m1Yye0d7i4TYK2

APPENDIX 6

PHARMACIST INTERVENTION SHEET

6.0 Pharmacist Intervention Sheet

SPTAR MATER DEI	Ref. Number: _____ Date of Compilation: _____ ID Card Number: _____
Name: _____ Surname: _____	
Suggestions for reconciliation:	

1. Description of Treatment	**Strength**	**Regimen**
Possible Issue:		
Suggestion:		
2. Description of Treatment	**Strength**	**Regimen**
Possible Issue:		
Suggestion:		
3. Description of Treatment	**Strength**	**Regimen**
Possible issue:		
Suggestion:		
4. Description of Treatment	**Strength**	**Regimen**
Possible Issue:		
Suggestion:		
Further Notes:		
Pharmacist Signature:		

APPENDIX 7

QUESTIONNAIRES

7.1.1 Kwestjonarju bil-Malti ghal pazjenti

Għażiż Pazjent,

Grazzi għall-parteċipazzjoni tiegħek f'dan l-istudju. L-għan ta' dan il-kwestjonarju huwa li jevalwa jekk kienx hemm xi bidliet fl-għarfien tal-pazjenti u wkoll biex jiġi evalwat il-livell ta' sodisfazzjon tal-pazjent mis-servizz offrut mill-ispiżjar fil-klinika tad-dijabete outpatient.

1. Fir-rigward ta' l-intervista mwettqa mill-investigatur:	**Ma Taqbilx**	**Taqbel**	**Indeciz**	**Nqabel**	**Naqbel hafna**
a) Tikkunsidra lilek innifsek aktar konxju tal-kundizzjoni kronika tiegħek?	0	1	2	3	4
b) Thossok ikomdu bil-mod li għandek bżonn u torganizza l-pilloli tiegħek?	0	1	2	3	4
c) Thossok iktar kunfidenti dwar kif għandek taħżen il-mediċini tiegħek	0	1	2	3	4
d) Aktar infurmat fir-rigward ta 'effetti sekondarji possibbli	0	1	2	3	4
e) Tista' issa tidentifika l-pilloli tiegħek b'isimhom	0	1	2	3	4

2. . Fir-rigward ta' l-ispiżjar li iltqajt miegħu illum	Mhux Sodisfatt Hafna	Mhux Sodisfatt	Neutrali	Sodisfatt	Sodisfatt Hafna
a) Taħseb li kienet infurmata tajjeb dwar is-suġġett	0	1	2	3	4
b) Tkellmet b'mod facli u l-affarijiet gew spjegati b'mod li kien faċli għalik biex tifhimhom?	0	1	2	3	4
c) L--investigatur laqa' l-mistoqsijiet u wieġeb għalihom b'mod ċar?	0	1	2	3	4
d) Wieġebet għall-mistoqsijiet tiegħek dwar il-mediċini tiegħek?	0	1	2	3	4
e) Qed tħossok iktar confidenti meta tistaqsi il – mistoqsijiet fuq il-mediċini tiegħek?	0	1	2	3	4
f) Tirrakkomanda lill-ħbieb tiegħek jew lill-membri tal-familja biex isegwu dan l-eżerċizzju	0	1	2	3	4
g) Sibt din l-intervista informattiva?	0	1	2	3	4

3. Minn dak li ddiskutejna illum	Ma Naqbel Xejn	Ma tantx Naqbel	Neutrali	Naqbel	Naqbel Hafna
a) Kont qed tieħu l-mediċini b'mod korrett?	0	1	2	3	4
b) Tħossok aktar kunfidenti fil-parteċipazzjoni f'deċiżjonijiet dwar is-saħħa tiegħek	0	1	2	3	4
c) Se tieħu l-mediċini skont l-istruzzjonijiet li ingħatajt?	0	1	2	3	4
d) Taf issa li jekk ma tieħux il-mediċċina kif suppost, jista' jkollok konsegwenzi koroh bhal jinzillek jew jitla' iz-zokkor kif ukoll kumplikazzjonijiet ohrajt?	0	1	2	3	4
e) Meta tixtri mediċini mingħajr riċetta, bħal vitamini, jew mediċċini ta' l-irjiħatint, tħossok iktar kunfidenti biex titlob il-parir ta' l-ispiżjar tiegħek	0	1	2	3	4
f) Jekk tiġi mistieden għal laqgħa mill-ispiżjar, inti tattendi?	0	1	2	3	4

7.1.2 Questionnaire for patients in English

Dear Patient,

Thank you for your participating in this study. The aim of this questionnaire is to assess whether there were any changes in the patients' awareness and knowledge and also to evaluate the patient's level of satisfaction and perceived benefits from the service offered by the p**h**armacist at the diabetic outpatient clinic.

1. With regards to the interview conducted by the investigator:	Strongly disagree	disagree	Undecided	Agree	Strongly Agree
a) Would you consider yourself more aware of your chronic condition?	0	1	2	3	4
b) More at ease with the way you need to organise your tablets?	0	1	2	3	4
c) More confident on how you should store your medications?	0	1	2	3	4
d) More informed with regards to possible side effects?	0	1	2	3	4
e) Can you now identify your tablets by their name?	0	1	2	3	4

2. With regards to your pharmacist:	Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
a) How knowledgeable was she about the subject?	0	1	2	3	4
b) Where things explained in a way that was easy for you to understand.	0	1	2	3	4
c) Did the investigator welcomed the questions and answered to them clearly and appropriately?	0	1	2	3	4
d) Listened and answered to all your questions about your medications?	0	1	2	3	4
e) Did you feel at ease at asking questions?	0	1	2	3	4
f) Would you recommend your friends or family members to go through this exercise	0	1	2	3	4
g) Did you find this interview informative	0	1	2	3	4

3. From what we discussed today	Strongly disagree	Disagree	Undecided	Agree	Strongly Agree
a) Were the medications being taken in the correct way?	0	1	2	3	4
b) Would you feel more confident in participating in decisions regarding your health?	0	1	2	3	4
c) Will you be taking the medications as instructed?	0	1	2	3	4
d) Are you more aware that not taking the medication or taking them not as they should could result in either hypoglycaemia or hyperglycaemia; with the respective co-morbidities as a result to such lack of medication adherence?	0	1	2	3	4
e) When you buy non-prescription drugs, such as OTC and vitamins, are you more confident to ask your pharmacist to check for any drug interactions	0	1	2	3	4
f) If you were invited for a talk given by the pharmacist, would you attend?	0	1	2	3	4

7.2.1 Transition of Care questionnaire

Transition of Care Document

Dear Pharmacist,

As part of my doctorate dissertation, a transition of care document was designed as a tool to increase the communication between hospital pharmacist and the pharmacist in the community. Studies have show that during the transition between different settings, such as the outpatient clinics and the community, important medication information can get lost.

This questionnaire aims at assessing the impact of the transition of care document. The questionnaire takes approx 5 minutes to complete.

*Required

1. **Age** *
   Mark only one oval.
   - ◯ 23 - 30
   - ◯ 30 - 40
   - ◯ 40 - 50
   - ◯ 50 - 60
   - ◯ 60+

2. **Gender**
   Mark only one oval.
   - ◯ Female
   - ◯ Male

3. **For how long have you been practicing as a community pharmacist?** *
   Mark only one oval.
   - ◯ 0-5 years
   - ◯ 5-10 years
   - ◯ 10-25 years
   - ◯ 25+ years

IF we had to use the following scenario

A patient attending diabetic outpatient clinic. The patient already has a new set of prescriptions which were previously done at the local polyclinic. At the outpatient clinic, the physician decided to increase the dose of metformin from 4 to 6 tablets. If the patient fails to update the prescriptions, the OLD dose will be dispensed, and the pharmacist advice will reflect the prescription which was presented by the patient.

4. **Important drug information can get lost while patients attend various outpatient appointments and fail to present the prescription which shows a change in treatment to the community pharmacist** *
   Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

5. **Would you agree that there is a need for better communication between the hospital pharmacist and the pharmacist in the community?** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

6. **I would feel more at ease dispensing the medications knowing that medicine reconciliation was performed and hence the risk of having drug related problems would be markedly decreased** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

Considering the Transition of Care Document which was used in this study

How would you rate this tool

7. **I would definitely use this tool as it clearly lists what the patient is taking including the OTCs and vitamins** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

8. **I found this tool useful as I would know that the patient is attending follow-up appointments and I would know upfront that the patient had a change in treatment** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

9. **This tool was clear and easy to follow** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

10. **Would you say that this tool was time consuming?** *
Tick all that apply.

- ☐ YES
- ☐ NO

11. **This tool contains all the data required** *
Mark only one oval.

	1	2	3	4	5	
Totally Disagree	◯	◯	◯	◯	◯	Totally Agree

12. **Do you recommend any other additional data which can be added to this tool?**

13. **What improvements can be made to this tool?**

7.3.1 Kwestjonarju għal-professjonisti tal-kura tas-saħħa bil-Malti

Jiena, Charlene Camilleri, spiżjar f'MDH u studenta tal-Pharm,D,-3 sena fl-Università ta 'Malta, bħala parti mid-dissertazzjoni tad-dottorat tiegħi li jgib l-isem ta ' Kura ta tranzazzjoni f'pazjenti dijabetiċi 'kont qed nintervista u nagħti pariri lill-pazjenti għall-aħħar 4 xhur. Matul dan il-perjodu, ġiet iddisinjata għodda ta 'transizzjoni tal-kura u twettqet rikonċiljazzjoni tal-mediċina għall-pazjenti kollha li jipparteċipaw fl-istudju. Ingħataw pariri lill-pazjenti kollha u ġew diskussi xi tħassib jew mistoqsijiet dwar il-mediċina. It-transizzjoni tal-għodda tal-kura kienet maħsuba biex iżżid il-komunikazzjoni bejn l-ispiżjar tal-isptar u l-ispiżjar fil-komunità.

L-iskop ta 'dan il-kwestjonarju huwa li jivvaluta s-sodisfazzjon tal-professjonist fil-kura tas-saħħa u l-benefiċċji perċepiti li jkollok spiżjar kliniku fl-outpatient dijabetiku bħala parti mit-tim interdixxiplinarju.

X'inhi l-professjoni tiegħek?

Konsulent dijabetologu ☐

Speċjalista dijabetiku ☐

Tabib ☐

Infermier ☐

1. Kemm taqbel li l-preżenza ta 'spiżjar fil-outpatient dijabetiku, il-pazjenti se jibbenefikaw minn:	Ma naqbel Xejn	Ma Naqbilx	Newtrali	Naqbel	Naqbel Ħafna
a) Konsulenza dwar il-mediċini	0	1	2	3	4
b) Tipprovdi tagħrif dwar id-droga bħalma huma l-kompatibilità, l-istabbiltà, il-ħażna, id-disponibbiltà, id-doża	0	1	2	3	4
c) Analizza t-trattament tal-pazjent u jissuġġerixxi tibdil fit-terapija meta jkun meħtieġ	0	1	2	3	4
d) Il-prevenzjoni, l-identifikazzjoni u l-immaniġġjar ta 'effetti sekondarji	0	1	2	3	4
e) Il-prevenzjoni, l-iskoperta u r-riżoluzzjoni ta 'interazzjonijiet tad-droga	0	1	2	3	4

f)	Verifika tal-korrettezza tal-preskrizzjonijiet (pazjent id-dritt, droga dritt, ħin id-dritt, doża tajba u rotta t-tajba)	0	1	2	3	4
g)	Prevenzjoni ta 'żbalji ta' preskrizzjoni.	0	1	2	3	4
h)	Titjib tar-riżultat tal-pazjent / tal-kwalità tal-kura tal-pazjent	0	1	2	3	4
i)	Prevenzjoni ta 'żbalji ta' preskrizzjoni.	0	1	2	3	4
j)	Titjib tar-riżultat / kwalità tal-pazjent tal-kura tal-pazjent	0	1	2	3	4

2	Il-pazjenti li pparteċipaw f'dan l-istudju kollha kellhom ir-rikonċiljazzjoni tal-mediċina mwettqa:	Mhux sodisfatt ħafna	Mhux sodisfatt	Newtrali	Sodisfatt	Sodisfatt ħafna
a)	Kif tikklassifika dan l-eżerċizzju? (li l-pazjent ikollu lista ta 'mediċini fil-idejn)	0	1	2	3	4
b)	Jekk jogħġbok indika l-livell ta 'sodisfazzjoni tiegħek mas-servizz ġenerali pprovdut mill-Ispiżjar fl-outpatient dijabetiku	0	1	2	3	4
c)	Trid tirrakkomanda li spiżjar kliniku jifforma parti mit-tim outpatient tad-dijabete?	0	1	2	3	4
d)	Wara li l-pazjent ipparteċipa fl-istudju, tgħid li l-pazjent kien aktar konxju ta 'liema mediċini hu / hi qed jieħu?	0	1	2	3	4

7.3.2 Questionnaire for Healthcare Professionals

I, Charlene Camilleri, senior pharmacist at MDH and 3rd-year Pharm D student at the University of Malta, as part of my doctorate dissertation entitled 'Pharmacist-Led Transition Care in Diabetic Patients' was interviewing and advising patients for the past four months.

During this period, a Transition of Care tool was designed, and medicine reconciliation was performed to all patients participating in the study. Advice was given to all patients, and any medical concerns or queries were discussed. The Transition of Care tool, meant to increase the communication between the hospital pharmacist and the pharmacist at the community.

The purpose of this questionnaire is to assess the health-care professional's satisfaction and perceived benefits of having a clinical pharmacist at the diabetic outpatient as part of the interdisciplinary team.

What is your profession?

Consultant diabetologist ☐

Diabetic specialist ☐

Clinician ☐

Nurse ☐

Kindly indicate your preference

How far do you agree that the presence of a pharmacist at the diabetic outpatient, the patients will benefit from:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a) Medication counselling	0	1	2	3	4
b) Providing drug information such as compatibility, stability, storage, availability, doses	0	1	2	3	4
c) Analysing patient treatment and suggesting changes in therapy when necessary	0	1	2	3	4
d) Preventing, identifying and managing side effects	0	1	2	3	4
e) Preventing, detecting and resolving drug interactions	0	1	2	3	4
f) Checking the correctness of prescriptions (right patient, right drug, right time, right dose and right route)	0	1	2	3	4

g) Preventing prescribing errors.	0	1	2	3	4
h) Improving over-all patient outcome/quality of patient care	0	1	2	3	4

1. 100 patients participated in this study, and had medicine reconciliation preformed together with nutritional advice	Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
a) How would you rate the need of having medicine reconciliation performed on the diabetic patients? (Keeping in mind that they usually have at least 4 different medications)	0	1	2	3	4

b)	Kindly indicate your level of satisfaction with the overall service provided by the Pharmacist at the diabetic outpatient/ diabetic education unit	0	1	2	3	4
c)	Would you recommend that a clinical pharmacist form part of the diabetic interdisciplinary team?	YES □		NO □		

APPENDIX 8

DISSEMINATION OF FINDINGS

8.1 Abstract for Medical Conference 2018

Title

Development of a tool used for Pharmacist-led Transitional of Care service

Charlene Camilleri, Louise Grech, Lilian M. Azzopardi

Introduction

Pharmacist-led interventions have shown to improve both clinical outcomes and communication between different healthcare providers. The aim of this study was to develop a tool required to run a pharmacist-led transitional care service for diabetic patients attending the Diabetic Clinic at Mater Dei Hospital.

Method

A *Transition of Care Document* aimed at compiling all the necessary information drawn at the Diabetic Clinic that is relevant to the community pharmacist, to ascertain a smooth transition between different healthcare settings was developed.

Results

The Transition of Care Document encompasses three sections.

The first section includes the patient's medical history and drug history, where all the medications are listed, including non-prescription drugs. The tool is intended to be used by the pharmacist during medicine reconciliation at the Diabetic Clinic, and any drug changes identified or activated at the Clinic will be listed in the second section. The last section of the document lists the newly revised medication list.

Conclusion

The Transition of Care Document is innovative to our healthcare system and should be helpful at bridging the gap which currently exists at the Transition of Care. This document will be piloted at the diabetic outpatient clinic and its impact assessed through questionnaires aimed at the service users, namely the patient and the healthcare professionals at both the hospital and primary care setting.

8.2 Abstract for EAHP 2019

Title

Pharmacist-Led Transition of Care in diabetic patients

Charlene Camilleri, Louise Grech, Lilian M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background

Pharmacist-led interventions have shown to decrease drug-related problems (DRPs) and improve clinical outcomes. Patients with multiple-drug therapy are often at higher risk of having DRPs especially when patients are transitioning between different healthcare settings.

Purpose

This study aims at addressing DRPs in patients attending the Diabetic Outpatient Clinic and Diabetic Education Unit. This was achieved by having medicine reconciliation being conducted by a pharmacist while giving sessions to the patients and then a tool was developed, which enables better communication between hospital and community pharmacist.

Method

This is an ongoing prospective investigational study which is being conducted at the Diabetic outpatient and Diabetic Education Unit. Adults >18 years age or older and having at least one antidiabetic medication are eligible to participate in the study after giving their informed consent. A Transition of Care Document, which compiles all the

necessary medical information obtained during the medicine reconciliation, was developed disseminated to the patient's community pharmacist.

Results

Thirty-five patients have been recruited in this study. Fifty-six discrepancies were identified and classified into five different categories. Eighty-three per cent of the DRPs pertained to 'Lack or Misinterpretation of information' followed by 'Treatment not According to Joint British Diabetes Societies (JBDS) guidelines' 63%,' Requiring Additional Drug' 52% and 'Inappropriate Timing of Drug Administration and/or dosing intervals' 37%.

Metformin and the statins were the two most common drugs requiring pharmacist's interventions. The pharmacist provided recommendations for the identified DRPs, either verbally, in case of educational interventions or written in all other instances. About 95% of the pharmacist's interventions were accepted by the physicians.

Conclusion

In this study, 'Lack or Misinterpretation of information' was the most prevalent DRPs. This result shows that, in many instances, patients misinterpret what the physicians prescribe, leading to a higher risk of morbidities and mortalities. The input of clinical pharmacists can indeed assist in reducing such DRPs. These can be achieved not only through medicine reconciliation but also by increasing the communication between healthcare professionals. The Transition of Care Document, which was purposely designed to be used in this study, is innovative to our healthcare system and should aid at bridging the gap which currently exists at the Transition of Care.

8.3 Abstract for ESCP 2019

Title

Facilitation of Transition of Care between Outpatient Diabetic Clinic and Community Pharmacies

Charlene Camilleri, Louise Grech, Lilian M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background

Pharmacist-led interventions have shown to decrease drug-related problems (DRPs) and improve clinical outcomes. The aim of the study was to develop and implement a pharmaceutical service at the outpatient setting for diabetic patients focusing on medicine reconciliation and effective Transition of Care.

Setting and Design

A prospective investigational study conducted at Mater Dei outpatient diabetic clinic. Patients ≥18 years of age, having at least one antidiabetic medication were eligible to participate in the study. A Transition of Care Document, aimed at compiling all the necessary medical information obtained during the medicine reconciliation undertaken during this study, was compiled and disseminated to the patient's community pharmacist via e-mail. A questionnaire was sent together with the Transition of Care document (ToC) to assess the effectiveness of the ToC document by the community pharmacist.

Main Outcome Measures

DRPs were classified into six categories using the Pharmaceutical Care Network Europe classification (PCNE) while the Transition of Care document was assessed using a questionnaire.

Results

One hundred ninety-four DRPs were identified during the medicine reconciliation (N=100). 'Lack or misinterpretation of information' (n=48), 'Insufficient awareness of health and diseases' (n=47), 'Inappropriate timing of administration and/or dosing interval' (n=36) and 'Non-adherence to treatment' (n=27) were the four most prevalent DRPs were. Eighty-five patients required verbal intervention from the clinical pharmacist, nine patients required written advice and four patients required both written and verbal intervention (N=100).

Forty-one pharmacists (N=73) completed the questionnaire, which was sent together with the ToC document. All pharmacists (n=41) participating in the study agreed that there is the need to enhance the communication between healthcare professionals while the majority (n=36) found the ToC document informative and useful. The preference in the questionnaires was assessed using the Likert scale.

Conclusion

The implementation of this developed pharmacist-led Transition of Care service was shown to be relevant to the outpatient diabetic group, as demonstrated by the identified DRPs, which is a service totally innovative to our healthcare system.