Pharmacist Clinical Diabetic Patient Review

A thesis submitted in partial fulfilment of the requirements

for the award of Doctorate in Pharmacy

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To my parents and my fiancé Dylan

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Abstract

The accessibility of community pharmacists puts them in a strategic position to support and empower patients in managing and reducing risks associated with diabetes.

The aims of the research were to develop and validate a toolkit for community pharmacist-led diabetic patient review, implement the toolkit, and evaluate pharmacist interventions.

The methodology involved development of a community pharmacist-led diabetic patient review toolkit in English and Maltese. The toolkit was validated by an interprofessional panel consisting of six members. Sixty diabetic patients registered with a private community pharmacy and taking at least one antidiabetic medication were invited to participate in the study. At baseline (t0), chronic and non-prescription medications were compiled prior to the first session (t1) with the patient, and any pharmaceutical care issues were identified and documented as patient needs. During t1, the pharmacist assessed medications, diabetic knowledge, medication adherence, diabetic complications, lifestyle, laboratory investigations, and monitoring using the devised toolkit. An individualised pharmaceutical care plan was developed for each patient, and an intervention was proposed for each identified need. Follow-up was conducted after one month (t2) to assess patient improvement and actioning of the care plan by the patient.

Fifty-five patients attended at t1; male (n=29), mean age 61 (range 24-92) years, diabetes type 2 (n=41), mean number of medications per patient 5 (range 1-11), 2 of which were antidiabetic drugs (range 1-4). Metformin was the most common antidiabetic medication used in 36 patients. Mean duration for t1 was 15 minutes (range 10-25) and 3 minutes (range 2-7) for t2. A total of 160 needs were identified in 50 patients; education-related in all 50 patients and drug-related in 18 patients. Patients required education regarding medication

use, adherence, and storage (n=28), lifestyle modifications (n=26), and monitoring (n=23). Drug-related problems concerned inappropriate drug selection (n=10), inappropriate dose selection (n=9), followed by inappropriate medicine handling by the patient (n=6). Referral to a general practitioner was needed for 9 patients. Fifty-three patients attended the follow-up session (t2). At t2, 104 (65%) needs were found to have been addressed by the patient. Implementation rate of education-related interventions was highest (100%) for adherence to medication, appropriate use of glucagon, diet/nutrition, blood glucose and blood pressure self-monitoring, foot check-ups at home and regular blood tests. Implementation rate of drug-related interventions was highest with respect to appropriateness in dose selection (89%), followed by patient medication handling (83%).

A limitation of the study was patient self-reporting. Community pharmacist interventions were successful in improving patient awareness and led to behavioural changes. The devised toolkit is feasible, practical, strengthens pharmacist-patient relationship, and supports patient empowerment.

Keywords: *clinical pharmacy interventions, community pharmacy practice, diabetes mellitus, patient needs*

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List of Abbreviations

DM - Diabetes Mellitus

HbA1c - Glycated Haemoglobin

POYC - Pharmacy of Your Choice

T1DM - Type 1 Diabetes Mellitus

T2DM - Type 2 Diabetes Mellitus

WHO - World Health Organization

Chapter 1

Introduction

1.1 Diabetes mellitus and its complications

Diabetes mellitus (DM) is a metabolic disorder that results in abnormalities of insulin secretion, activity of insulin, or both, leading to hyperglycaemia (Teka and Baye, 2018; Manithottiyle et al, 2021; Khaleel et al, 2023). Hyperglycaemia manifests itself as a fasting blood glucose level greater than 7 mmol/L or glucose levels that exceed 11 mmol/L two hours following a meal.[1] Hyperglycaemia, hyperinsulinemia, insulin resistance, and metabolic dysfunction increase morbidity and mortality (Dalton and Byrne, 2017; Bukhsh et al, 2018a,b; Durrer et al, 2019; Glovaci et al, 2019; Thoele et al, 2020; Coutureau et al, 2022).

While there has been an increase in the use of antidiabetic drugs and an array of therapies in diabetic patients, the number of patients with uncontrolled DM still remains a persistent challenge on a global scale, and continues to increase daily (Wang, et al, 2016; Durrer et al, 2019; Leite, 2020; Manithottiyle, 2021), with more than 1 out of every 10 adults reported to suffer from DM (Khaleel et al, 2023). The World Health Organisation (WHO) stated that the number of patients suffering from DM worldwide has escalated from 108 million in the 1980s to 422 million in 2014[1] and will keep increasing to 642 million patients by 2040 (Ogurtsova et al, 2017). In 2017, there were 66 million diabetic patients in Europe, with a prevalence of 9.1%, and by 2045, there are expected to be 81 million patients with DM (Uusitupa et al, 2019). A 70% increase since the year 2000 has made DM one of the top ten global causes of

[1] World Health Organization. Diabetes Fact Sheet; 2021 [cited 2023 Mar 5]. Available from: https://www.who.int/news-room/fact-sheets/detail/diabetes.

mortality (Khaleel et al, 2023). DM caused 6.7 million deaths in 2021[2] and by 2030 it is expected to be the seventh most common cause of mortality worldwide (Li, 2019; Sciberras, 2020).

Factors contributing to the diabetic epidemic include obesity, increased age, sex (male), hypertension, genetics, lack of exercise, gestational diabetes, giving birth to a baby weighing more than 4 kg, ethnicity, decreased levels of high-density lipoprotein, increase in triglycerides, polycystic ovaries, depression, and smoking (Zheng, 2018, Ceriello & Prattichizzo, 2021; Khaleel et al, 2023). Hypertension and Type 2 DM (T2DM) frequently coexist, with hypertension observed in diabetic patients twice as frequently as in people without DM (Coutureau et al, 2022). Persistently elevated glucose levels cause microvascular and macrovascular complications (Inasu and Kumudavalli, 2020). Microvascular complications include retinopathy, nephropathy, and neuropathy, while macrovascular complications include heart disease and stroke (Cheema et al, 2018; Iqbal et al, 2019). Diabetic nephropathy is the primary cause of end-stage renal disease, diabetic retinopathy is the primary cause of blindness in developed countries, diabetic neuropathy is the primary cause of foot ulceration and amputation, and sexual dysfunction is disproportionately common in diabetic patients (Faselis et al, 2020). DM causes kidney failure and blindness in 1% of patients (Ayadurai et al, 2016). Between 15% and 25% of diabetic patients suffer from foot complications, with estimates reaching up to 34%, and foot infections are the most common reason for hospitalisation for people with DM (Soprovich et al, 2019). These

[2] International Diabetes Federation. IDF Diabetes Atlas, 7th Edition; 2022 [cited 2023 Mar 5]. Available from: http://www.diabetesatlas.org/.

complications worsen if left untreated, resulting in higher financial burden (Syarifuddin et al, 2019), and increased mortality and morbidity (Dalton and Byrne, 2017; Bukhsh et al, 2018a,b; Durrer et al, 2019; Glovaci et al, 2019; Thoele et al, 2020; Coutureau et al, 2022).

In addition to being a public health concern, DM has significant negative economic effects and will continue to have a substantial financial impact in the years to come, especially with an ageing population and increasing diabetic complications (Uusitupa et al, 2019). Medical costs are usually 2.3 times higher for diabetic patients than for non-diabetics (Meade et al, 2018). The overall burden of DM on society and associated complications accounts for 12% of the global health expenditure (Toi et al, 2020). About USD 966 billion was spent on DM worldwide in 2021, a 316% escalation from 2007[2] and is estimated to increase to USD 2.5 trillion by 2030 (Zelnik, 2022).

1.2 Diabetes mellitus in Malta

Malta faced a sustained cultural change in cuisine from a predominantly Mediterranean diet to a Westernised diet, which together with other factors such as ageing and population growth, and a more sedentary lifestyle, has led to insulin resistance, obesity, and an increase in the development of DM (Caruana & Patterson, 2016). The prevalence of DM in Malta is 11%, amounting to 38,000 cases per year.[2] Incidence has increased exponentially in the last 35 years (1981-2016), consistent with the current global epidemic (Cuschieri, 2020). In 2019, 8.3% of Maltese people between the ages of 20 and 79 had DM (Sammut, 2021). Deaths attributable to DM in Malta are the third highest in the European Union, with 51 per 100,000

deaths in the population.[3] Total annual expenditure for DM in Malta in 2017 was calculated to be around €107 million (€98-1,178 million). By 2045, mean DM expenditure is expected to be €4,206 per patient, with total expenditure estimated to be €244 million (Cuschieri, 2020).

1.3 Community pharmacist interventions in diabetic patient review

A community pharmacist is "the health professional most accessible to the public," according to the WHO.[1] Pharmacists' strategic place in the community puts them in a position to be one of the most reachable health care professionals (Valliant et al, 2022) for reasons that include convenience due to shorter waiting times and long opening hours, and no payment for advice (Cooney et al, 2022a). Together with accessibility (Valliant et al, 2022), community pharmacists are one of the most trusted health care professionals, hence, patients frequently approach them for advice (Meade, 2018; Brewster et al, 2020; Parnis, 2020). Despite ease of accessibility and trust, community pharmacists are viewed as underutilised health professionals (Risøy et al, 2021; Gawlik et al, 2023). The role of community pharmacists has evolved beyond dispensing medications to include more patient-centric tasks, which has opened prospects to reduce pressure on primary care services (Alhabib et al, 2016; Milosavljevic et al, 2018; Douglas et al, 2019; Kalra et al, 2020). Pharmacists have

[3] European Observatory on Health Systems and Policies, Malta: Country Health Profile 2021, State of Health in the EU, 2021 [Cited 2023 Mar 10]. Available from: https://eurohealthobservatory.who.int/publications/m/malta-country-health-profile-2021.

an enormous opportunity to reduce global health expenditures due to their expertise in identifying, resolving and preventing medication errors and other pharmaceutical care issues. Pharmacist interventions reduce the risk of possible adverse effects, ameliorating patient outcomes, and have a good cost:benefit ratio. A decrease in incorrectly prescribed drugs reduces the cost of the individual medicines and decreases the chances of adverse effects and interactions (Dalton and Byrne, 2017).

Community pharmacists are 'the first port of call' for diabetic patients (Iizuka et al, 2011; Brewster et al, 2020). The onset of DM symptoms frequently occurs before the condition is diagnosed; about 50% of diabetic patients are undiagnosed due to mild DM or lack of symptoms (Al-Lawati, 2017; Zheng et al, 2018; Khaleel et al, 2023). Community pharmacists are helpful in identifying and managing diabetic patients at an early stage, through routine screening, monitoring, assessment, health education, and referral (Venkatesan et al, 2012; Erku et al, 2017). Given that community pharmacists routinely interact with diabetic patients (Hamarneh et al, 2021), they are in a critical position to observe any red flags, including hypoglycaemia and foot problems (Brewster et al, 2020). According to a joint recommendation from the WHO and the International Pharmaceutical Federation, community pharmacists should provide patients with services including screening and point-of-care testing.[1,2]

Physicians have articulated in various instances that, due to workload and lack of time, they can only spare five minutes per patient during visits (Siaw et al, 2017). This gap can be filled by pharmacists (Dalton & Byrne, 2017; Siaw et al, 2017; Meade et al, 2018). Community

pharmacists are well-positioned to act as an intermediary between patients and physicians for visits for point-of-care testing, education, follow-up, referral, medication reconciliation, and to conduct pharmaceutical care interventions in primary healthcare as a result of frequent patient interactions (Valliant et al, 2022). Frequent communication between the patient and the pharmacist allows for the development of a trustworthy rapport (Milosavljevic et al, 2018; Valliant et al, 2022; Woodhams et al, 2023).

According to a study carried out by Tsuyuki et al in Canada, more than 80% of participants concurred that going to the pharmacist is simpler than going to their general practitioner (Tsuyuki et al, 2018). In Ireland, it was shown that patients visit community pharmacies up to ten times more frequently than their primary care physician (Cooney et al, 2022b), creating an opportunity for pharmacists to advise and educate patients (Erku et al, 2017). An adult patient visits the pharmacy about sixteen times per year (Brewster et al, 2020), and patients with DM visit the community pharmacist three to eight times more than other patients (Khunti et al, 2013; Brewster, 2020). This situation presents an opportunity for pharmacists to recognise any signs and symptoms such as hypoglycaemia, patient concerns, and medication problems, and to optimise DM management (Brewster, 2020; Valliant, 2022). Such continuous connections enable pharmacists to act as a "bridge" between patients and other healthcare providers (Woodhams, 2023), where continuity of care is crucial for diabetes control (Pousinho et al, 2016). Pharmacists have the responsibility to refer patients to other healthcare professionals when deemed necessary (Mitchell et al, 2011; Gerber et al, 2012; Teka and Bayer, 2018). This collaborative practice improves communication (Brewster, 2020) and facilitates DM education and management (Jahangard, 2015; Korcegez,

2017).

Community pharmacists implement pharmacological and non-pharmacological interventions to support patients in the management of DM as part of patient review (Abubakar and Atif, 2021). Pharmacist interventions include advice on diet and nutrition (Jordan and Harmon, 2015; Sebire et al, 2018; Tabassum et al, 2019), lifestyle changes, carbohydrate counting, blood glucose self-monitoring (Meade, 2018; Tabassum, 2019), medication review (Simpson et al, 2017), performing examinations of the feet and skin, and monitoring blood pressure and weight (Tabassum, 2019), advice on how to improve medication adherence and to reduce complications (Jahangard et al, 2015; Korcegez et al, 2017; Bukhsh et al, 2018b; Durrer et al, 2019; Durrer et al, 2021). Foundations for the implementation of pharmacist interventions are that diabetes education encourages patients to take a proactive role in the management of their condition and to improve their overall health (Farsaei et al, 2011; Mitchell et al, 2011; Nishita et al, 2013), increase patient knowledge and adherence to medication, decrease side-effects, improve self-testing, and have better involvement in patient care (Farsaei, 2011; Bukhsh, 2018b).

Diet and physical exercise management are an important part of a patient review in diabetic patients to improve outcomes in DM (Durrer, 2019). Treating obesity produces beneficial effects on cardiovascular health, insulin sensitivity, body composition, and quality of life (Iizuka et al, 2011; Folorunso & Oguntibeju, 2013; Tol et al, 2014; Delahanty et al, 2015; Kolb and Martin, 2017; Durrer, 2019). The Western diet, together with a sedentary lifestyle, are major causes of obesity and T2DM (Kolb, 2017). It has been shown that 2 to 3 hours of

walking per week can decrease the occurrence of DM by 34%, and 1 hour of walking is linked to a 50% decrease in coronary artery disease over 7 years (Glovaci et al, 2019). High-density lipoprotein and low-density lipoprotein are linked to cardiovascular disease, with diabetics seeing a notable variation in lipid plasma levels and a decreased heart rate, which increases the risk of cardiac disease and death (Ceriello and Prattichizzo, 2021).

Pharmacists can provide an eating plan, weight management tips, and discourage excessive alcohol consumption and smoking (Jordan and Harmon, 2015; Medhat et al, 2020). Pharmacists encourage patients to attend scheduled yearly eye and foot examinations (Venkatesan et al, 2012), regular blood tests, and regular general practitioner or specialist reviews (Presley et al, 2019). Patient self-monitoring is important, as it prevents the exacerbation of the disease and prevents microvascular and macrovascular complications (Khan et al, 2021). Patients whose self-monitoring is stricter have better HbA1c control (Polonsky et al, 2011; Knapp et al, 2016; Jamshed et al, 2018; Khan et al, 2021). When deemed necessary, pharmacists can refer patients to other health care professionals, such as dieticians (Mitchell et al, 2018).

A medication review is an organised assessment of a patient's medications with the goal of optimising medicine use and improving health outcomes (Schindler, 2020). Medication review performed with the patients provides an opportunity for patients to express any concerns they may have, which could assist in increasing patient satisfaction and medication adherence, reducing pharmaceutical waste, and enhancing health outcomes (Diggle, 2015). Adherence to medication is described as "the extent to which a person's behaviour in taking

medication, following a diet, and/or executing lifestyle changes corresponds with agreed-upon recommendations from a health provider". Lack of adherence to medication can result in inappropriate management of the condition (Presley et al, 2019; Al Assaf et al, 2022; Valliant et al, 2022). About 50% to 60% of patients with chronic diseases, including DM, do not adequately adhere to the medications they are prescribed (Valliant, 2022). Forgetting to take their medication, worrying about adverse effects, cost, low perceptions of medicine need, inadequate health literacy, and stigma associated with DM and chronic medication use are other factors that contribute to non-adherence (Witry, 2019, Al Assaf et al, 2022).

Studies show that diabetic patients who have received consultations from pharmacists demonstrate better blood glucose management, medication adherence, self-management, weight control, and decreased risk of cardiovascular risk factors (Hassali, 2015; Jahangard et al, 2015; Bukhsh et al, 2018a). Structured self-management education, such as one-on-one or group sessions, can be delivered by pharmacists to educate, guide, and empower diabetic patients in the management of DM to make day-to-day changes to their lifestyle to reduce the risks associated with inadequate control of blood glucose (Castejón et al, 2013), improving quality of life and clinical outcomes (Nishita et al, 2013; Bukhsh et al, 2018a; Meade et al, 2018). Motivation and support are cornerstones of patient lifestyle behaviour changes and goal setting (Sevire, 2018). The right interventions from pharmacists can help to prevent and decrease the progression of DM and its complications (Iqbal et al, 2021). Programmes should continually emphasise the importance of risk factors, prevention, medication adherence, and supporting patients in modifying behaviours (Tabassum et al, 2019).

Studies have emphasised the significance of patient reviews as a valuable tool in managing DM effectively, highlighting the positive impact of patient feedback on treatment adherence and self-care practices, and underscoring the importance of regular patient reviews in achieving optimal glycaemic control and reducing the risk of complications. The participation of community pharmacists in patient reviews delivering pharmacist interventions have been explored in studies that demonstrated significant improvement in health outcomes and quality of life in patients with DM. A meta-analysis conducted by Van Eikenhorst et al (2017), included twenty-four studies which unequivocally support the participation of community pharmacists in the management of diabetic patients through the provision of education in usual practice settings. Community pharmacists were associated with significant improvements in clinical outcomes, including improved HbA1c levels, a positive effect on blood pressure, body mass index, lipid profile, self-management skill development, and adherence to medication seen in the intervention group during the follow-up period in all the studies, providing evidence that pharmacist-directed interventions for diabetic patients can have a positive impact on clinical outcomes. Education about DM complications, medications, lifestyle changes, laboratory monitoring, and eye and foot clinic visits and teaching of self-management techniques were included as pharmacist-led self-management interventions. The intervention type and frequency varied across the studies included in the meta-analysis. There were variations in the number of visits required for face-to-face encounters. Fifteen studies offered a tailored plan for the patient's needs. The difference in the frequency of encounters ranged from once per week to once per year. Different modalities were used, which included face-to-face contact with pharmacists in some of the studies, and a combination of face-to-face and telephone interaction with pharmacists in other studies. In some of the studies, a patient education programme on DM

was employed as an intervention, which took the form of basic knowledge about the disease or information about immediate and long-term diabetic complications, instructions on lifestyle change, exercise needs, foot care, management of a good diet, and smoking cessation. Pharmacists provided patient education on medication with the goals of increasing patient adherence, lowering dosage-related issues, improving correct medicine use and storage (Van Eikenhorst et al, 2017).

The meta-analysis by Van Eikenhorst (2017) is supported by further research on pharmacist interventions and diabetic patient reviews. Pharmacists' involvement with diabetic patients led to improved management of the condition and its consequences, as well as an improvement in patient quality of life (Bukhsh et al, 2018a; Meade et al, 2018; Iqbal et al, 2019; Lau et al, 2020; Pousinho et al, 2020; David et al, 2021; Alabkal, 2022; Cahyaningsih, 2023). A more recent systemic review conducted by Al Assaf et al (2022) and a systemic review and meta-analysis conducted by Coutureau et al (2022) confirmed that pharmacist-led interventions in the primary care setting can improve glycaemic control for adults with T2DM. Patient education and counselling were the most common intervention methods, and these enhanced clinical outcomes and patient adherence to treatment (Al Assaf et al, 2022, Coutureau et al, 2022). An observational analysis by Iqbal et al (2019) and a meta-analysis by Bukhsh et al (2018b), which included twenty-five studies and forty-three studies respectively, indicated that pharmacist-led interventions in DM can significantly improve outcomes and reduce complications (Bukhsh et al, 2018b; Iqbal et al, 2019). Pharmacist-led care significantly improved glycaemic control in patients with uncontrolled T2DM (Milosavljevic et al, 2018; Presley et al, 2019; Syarifuddin et al, 2019; David et al, 2021;

Manithottiyle et al, 2021). The effectiveness of patient reviews indicates the pharmacist's expanding role in supporting patient care (Muscat, 2017; Van Eikenhorst et al, 2017). Long-term improvements in outcomes add more value to the contribution of pharmacists in health-care systems (Bukhsh et al, 2018b; Iqbal et al, 2019).

1.4 Barriers for pharmacist interventions

Pharmacists have a leading role in DM management and provide various interventions in community pharmacies (Muscat, 2017; Van Eikenhorst et al, 2017; Bukhsh et al, 2018a; Iqbal et al, 2019; Lau et al, 2020; Pousinho et al, 2020; David et al, 2021; Alabkal, 2022; Cahyaningsih, 2023). However, barriers such as lack of time (Teka and Baye, 2018; Presley et al, 2019; So et al, 2021) and issues with current workflows may result in pharmacists not involving themselves in patient-centric care (So et al, 2021) as well as poor counselling (Teka and Baye, 2018; Presley et al, 2019). Pharmacist practices that are more appropriate for dispensing than for patient-centered care may be a factor in the difficulties pharmacists are facing when implementing hypertension and DM treatment reviews (So et al, 2021). Duties in managing chronic diseases and health promotion have to be improved further to properly use pharmacists' priceless contribution to patient care (Erku et al, 2017; So et al, 2021).

It has been shown that pharmacist interventions in DM care are cost-saving (Dalton and Byrne, 2018). There is presently no reimbursement for offering patient review services (Cooney et al, 2022a), and to use this opportunity to its full potential, incentives should be provided to pharmacists (Valliant et al, 2022). Literature shows that pharmacist training and

compensation are driving forces for the implementation of pharmacist interventions (Bacci et al, 2019).

1.5 Use of toolkits for pharmacist interventions

Toolkits are a useful resource and aid in the assimilation of evidence-based interventions in a real-life scenario (Besemah et al, 2021; Sivapragasam et al, 2022). Toolkits may include a single document or a collection of documents created to support the implementation of clinical processes aimed at patients, community health workers, and healthcare practitioners (Newell, 2017; Sivapragasam et al, 2022). The implementation of evidence-based interventions in real-world scenarios is often skipped (Newell, 2017; Thoele et al, 2020). This gap can lead to an increase in mortality and morbidity. Addressing the gap involves identification of the barriers, readiness, and adaptability of the intervention. Toolkits serve this purpose by bridging the transition from research to practice, and help pharmacists and general practitioners during the intervention to aid in the adoption, implementation, and sustainability of interventions (Newell, 2017; Thoele et al, 2020). Finding the ideal tools and procedures for routine data collection in the clinic setting requires organisation and groundwork that will eventually assist pharmacists by providing them with reliable information for patients with DM (Nair and Kachan, 2017; Gonçalves et al, 2021). Education in patients with DM can be very time-consuming, especially with pharmacist time constraints, and evidence shows that incorporating toolkits is a very practical way to assist patient education and improve patient outcomes (Newell, 2017). Creating and using a toolkit tailored to a specific healthcare environment is one method to implement evidence-based

interventions (Sivapragasam et al, 2022). Adopting a toolkit in conjunction with a therapeutic intervention leads to better health outcomes, such as fewer falls, fewer hypoglycaemic episodes, and shorter hospital stays (Sivapragasam et al, 2022). Clinical interventions that are evidence-based provide better quality of care, reduce costs, and improve patient follow-ups and outcomes (Newell, 2017; Thoele et al, 2020).

1.6 Rationale for the study

In 2018, it was estimated that Malta had the highest number of practising pharmacists in the European Union, with 129 pharmacists for every 100,000 inhabitants.[4] Multiple studies have demonstrated the effectiveness of pharmacist interventions and patient reviews on patient health outcomes in the management of chronic conditions, including diabetes (Muscat, 2017; Van Eikenhorst et al, 2017; Bukhsh et al, 2018a; Lau et al, 2020; Montebello, 2021). Adoption of patient reviews for diabetic patients within the Maltese community practice has not been formally established. The development and implementation of a toolkit for clinical patient review aims to be practical and standardised to identify, document, and address diabetic patient needs in a community pharmacy setting.

[4] Eurostat. Pharmacists in the EU. 2020. [cited 2023 Mar 10]. Available from: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20200925-2.

1.7 Aim and objectives

The aims of the research were to develop and validate a toolkit for community pharmacist-led diabetic patient review, implement the toolkit, and evaluate pharmacist interventions.

The objectives were to:

- Review patients' medications, medication use, adherence and storage, lifestyle, and monitoring, identify patient needs and propose an intervention for each need
- Review if needs identified were met after one-month follow-up

Chapter 2

Methodology

2.1 Research design

This was a longitudinal, interventional cohort study. The methodology employed consisted of two phases. Phase 1 involved the development and validation of a 'Pharmacist Clinical Diabetic Patient Review Toolkit', and phase 2 involved implementation of the toolkit within a community pharmacy, including patient recruitment, medication review at baseline (t0), patient review during the first session (t1), and follow-up during the second session (t2).

2.2 Development and validation of diabetic patient review toolkit

A 'Pharmacist Clinical Diabetic Patient Review Toolkit' was developed in English and Maltese. To aid in the development of the toolkit, a literature search was performed from November 2021 to March 2022. Databases including Hy-Di, Science Direct, Elsevier, PubMed, MEDLINE, Cochrane, and Google Scholar were used to identify related articles. Boolean operators 'AND' and 'OR' were used. Keywords used were: 'Diabetes', 'Pharmacist', 'Toolkit', 'Pharmacist Intervention', 'Diabetes Management', 'Nutrition', 'Physical Activity', and 'Diabetes Complications'. Journals that served as significant reference sources included the *Journal of Diabetes Research, Journal of Managed Care & Specialty Pharmacy* and *Journal of Diabetes Mellitus.* Articles published between 2010 and 2023 were included. Recent guidelines, including from the American Diabetes Association, Pharmaceutical Care Network Europe (PCNE), Diabetes Clinical Practice Guidelines, British National Formulary, International Pharmaceutical Federation, and Royal Australian College of General Practitioners, related to DM were reviewed.

For ease of use in a community pharmacy setting, the toolkit was kept concise. Space was left for the pharmacist to annotate any interventions that needed to be conducted and counselling provided to the patient. The toolkit was reviewed for face and content validity by an interprofessional panel of experts chosen by convenience sampling and consisted of six members, including a consultant diabetologist and endocrinologist, a general practitioner, two pharmacists (a community pharmacist and a pharmacist in academia), and two laypersons. Remarks made during validation were assessed. Based on validation feedback, a five-point Likert scale was implemented for certain statements to better assess the level of agreement and facilitate documentation of patient response, where 1 represented the highest agreement and 5 indicated the lowest agreement. The validation panel agreed on the relevance of content, comprehensiveness, and presentation of the toolkit, and a final version was developed (Appendix 1). The validated toolkit consists of six sections (Table 2.1).

Table 2.1: Toolkit sections

Section	Description
Review of medicines	Review of medicines, including drug selection problems, dosage form problems, dose selection, dispensing errors, patient medication handling problems and plan of patient review session
Adherence and monitoring	Medication adherence and patient monitoring, including blood glucose and blood pressure self-monitoring
Lifestyle	Diet, nutrition, physical activity, alcohol consumption, smoking, sleep hygiene
Complications	Occurrence and monitoring of complications, including foot and eye complications
Laboratory investigations	Monitoring of laboratory investigations, including glycated haemoglobin, blood glucose, kidney function tests, liver function tests and lipid profile
GP/Specialist review	Referral to a general practitioner or specialist review if needed

2.3 Ethics Approval

Ethics approval from the University of Malta Faculty of Medicine and Surgery Research Ethics Committee (FREC) was granted (MED-2022-00173) (Appendix 2).

2.4 Study setting

Implementation of the toolkit was conducted in a private community pharmacy between November 2022 and January 2023. The pharmacist intervention sessions (t1 and t2) were conducted in the consultation room inside the pharmacy to ensure privacy.

2.5 Study population and patient recruitment

The intermediary managing pharmacist invited sixty diabetic patients registered with the community pharmacy who met the inclusion criteria to participate in the study. Adult patients, over 18 years of age, diagnosed with T1DM or T2DM by a physician, and taking at least one glucose-lowering medication were eligible for the study. Patients with gestational diabetes and paediatric patients were excluded.

Patients were identified either through the Pharmacy of Your Choice (POYC) scheme, which is the National Health Service scheme supporting free chronic medications from community pharmacies, or while dispensing private prescriptions. Patients were approached by the intermediary managing pharmacist who explained the scope of the study using a patient information sheet, and informed written consent was requested. For patients who consented, an appointment to meet with the researcher at the pharmacy was set at the patient's convenience.

2.6 Pilot Study

Six patients were recruited for the pilot study, representing 10% of the total study sample. The pilot study was undertaken to assess the feasibility and practicality of the methodology employed. During the pilot study, no alterations were required, and the toolkit was deemed clear and easy to follow.

2.7 Implementation of the toolkit

Figure 2.1 shows an overview of how implementation of the toolkit was performed.

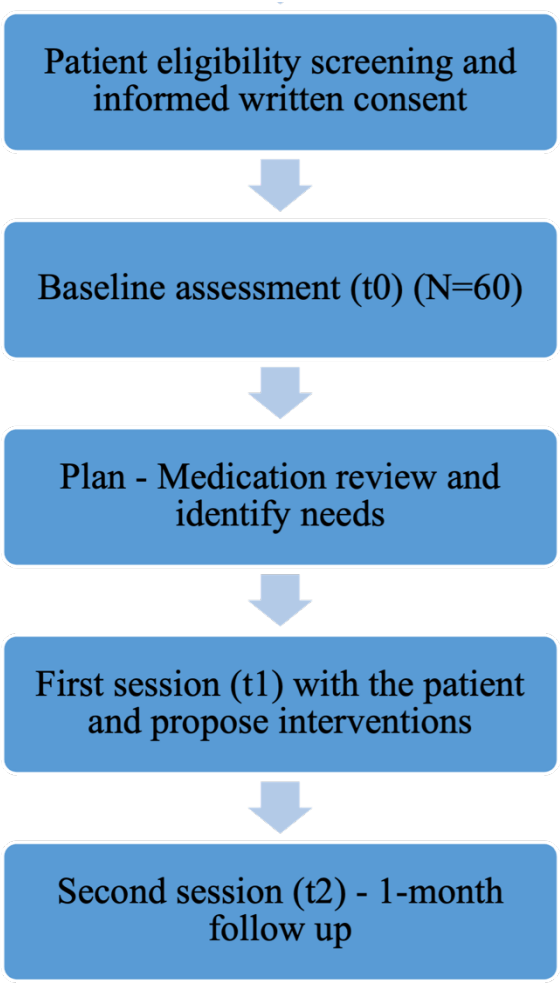

Figure 2.1: Toolkit Implementation

At baseline (t0), the researcher obtained the medication list of each patient. Drug therapy was analysed to identify patient needs prior to the first session (t1) with the patient. Any pharmaceutical care issues identified were documented as patient needs. An individualised

pharmaceutical care plan was developed for each patient and an intervention was proposed for each identified need during the first session (t1) using the toolkit which was applied via patient interview. The researcher obtained laboratory results from the patient if available, either through MyHealth or through printed results directly from the patient. Interventions proposed were documented in the toolkit and explained verbally to the patient. Towards the end of the session, patients had the opportunity to discuss any issues that they were having or any additional queries. A collaborative practice approach was adopted, and when necessary, patients were referred to other health care professionals. An appointment for follow-up was set up at the patient's convenience. A follow-up meeting was held after 1 month (t2) in the same pharmacy to review if the needs identified in the first session were met, identify any further interventions, review the patient's progress, and cover any patient queries.

2.8 Data analysis

Data collected was statistically analysed using IBM SPSS Statistics 24. Descriptive statistics were calculated for patient characteristics, medications used and to analyse needs identified in the baseline assessment (t0) and first session (t1) and needs met in the second session (t2). Pearson correlation coefficient was used to assess the relationship between patient needs and age and patient needs with number of medications. The Independent samples t-test was used to compare the mean number of patient needs with gender. A p-value less than 0.05 was considered statistically significant.

Chapter 3

Results

3.1 Practicality of the developed toolkit

The devised toolkit was helpful in identifying patient needs, such as need to increase physical activity, improve diet and nutrition, increase frequency of blood glucose and blood pressure self-monitoring, attend regular blood tests, eye and foot examinations. Gaps in diabetic patient care were identified and patient improvement following pharmacist intervention using the devised toolkit was determined. The mean time for the first session (t1) was 15 minutes (range 10-25) and the second session (t2) was 3 (range 2-7) minutes.

3.2 Patient characteristics

From the 60 patients invited, 55 accepted to participate in the study and attended at t1. Forty-one (75%) patients suffered from T2DM and 14 (25%) suffered from T1DM. Twenty-nine (52.7%) patients were male and 26 (47.3%) were female. Patients had a mean age of 61 (range 24-92) years. Age distribution from highest to lowest was: 66-75 years (n=18, 32.7%), 46-55 years (n=9, 16.4%), 56-65 years (n=9, 16.4%), 76-85 years (n=7, 12.7%), 26-35 years (n=7, 12.7%), 36-45 years (n=2, 3.4%), 86-95 years (n=2, 3.4%), 18-25 years (n=1, 1.8%).

Each patient took a mean of 5 different medications (range 1-11), 2 of which were diabetic medications (range 1-4). Metformin was the most common (n=36, 65.4%), followed by long-acting insulin (n=17, 30.9%), and gliclazide (n=17, 30.9%). Six patients had glucagon at home (Figure 3.1).

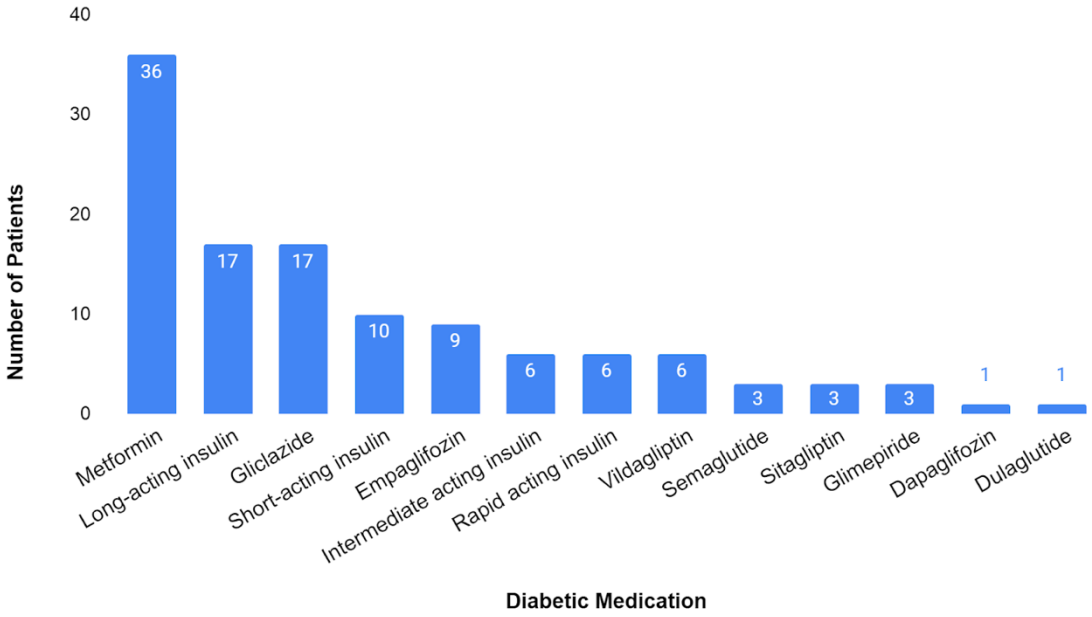

Figure 3.1: Diabetic medications (N=55)

Statins were the most common non-diabetic class (n=29, 52.7%) in this patient population, followed by angiotensin II receptor blockers (n=17, 30.9%) and calcium channel blockers (n=16, 29.7% (Table 3.1).

Table 3.1: Non-diabetic chronic medications (N=55)

Class	Number of patients
Statins	29
Angiotensin II receptor blocker	17
Calcium channel blocker	16
Diuretics	15
ACE inhibitors	12
Antiplatelets	12
Corticosteroids	9
Proton pump inhibitors	9
Short-acting β_2 adrenergic receptor agonists	7
Beta-blockers	6
Antipsychotics	5
Alpha blockers	4
Thyroid drugs	4
Anticonvulsants	4
Fibrates	3
Xanthine oxidase inhibitors	3
Serotonin and norepinephrine reuptake inhibitors	3
Nitrates	3
Antidepressants	2
Anticoagulants	2
Non-steroidal anti-inflammatory drugs	2
Other (5-alpha reductase inhibitors, fatty acid oxidation inhibitor, imidazoline/α-2 receptor agonist, carbonic anhydrase inhibitor, calcium channel blocker/angiotensin II receptor blocker, immunosuppressant, steroid/long-acting β_2 adrenergic receptor agonist)	7

3.3 Identification of patient needs

From the 55 patients reviewed, a total of 160 patient needs were identified; the majority were related to patient education (n=127, 79%). Referral to a specialist or a general practitioner was needed in 9 patients (Figure 3.2). Each patient had a mean of 2 needs (range 1-11).

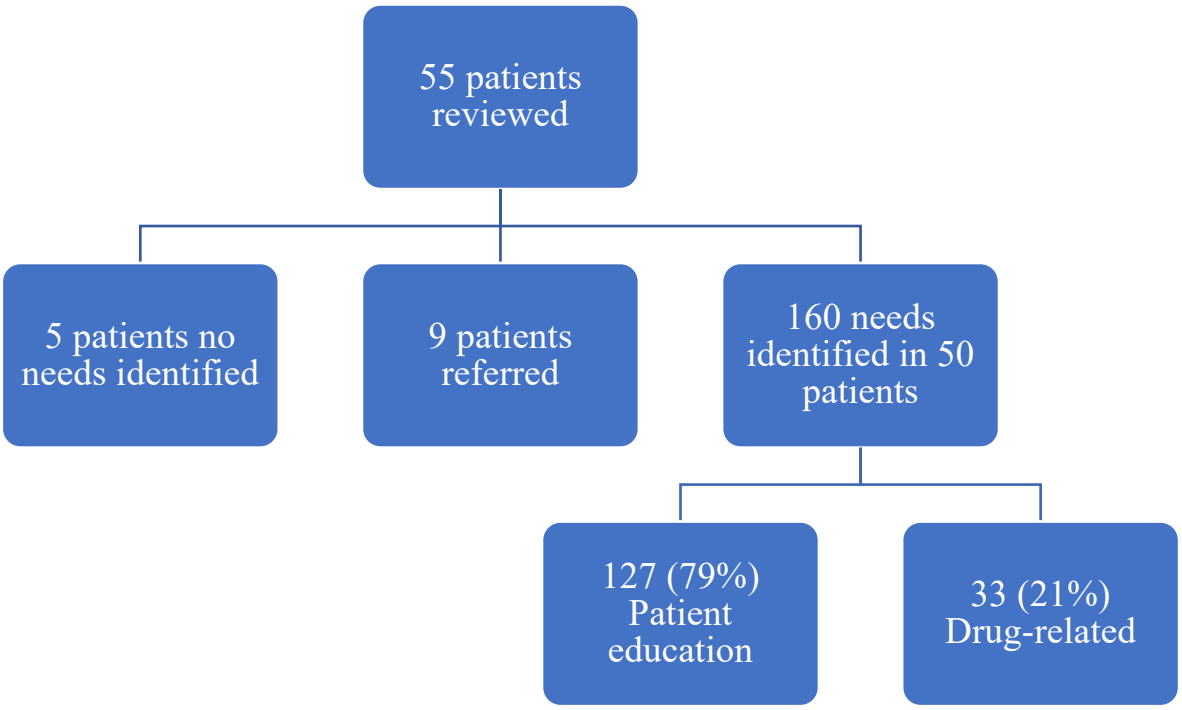

Figure 3.2: Patient review

3.4 Needs identified related to patient education

Needs related to patient education were identified in all patients (n=50). Patients required education regarding medication use, adherence, and storage (n=28, 56%), followed by lifestyle modifications (n=26, 52%) and patient monitoring (n=23, 46%), including self-monitoring. Patients identified with a need to improve adherence to medication were recommended to use a medication administration aid (n=9, 32.1%) (Table 3.2).

Table 3.2: Patient education relating to medication use, adherence and storage (n=28)

Patient need	Number of patients
Improved adherence to medication	9 (32.1%)
Appropriate use of glucagon	1 (3.6%)

Problems with non-adherence were identified. One patient decided to discontinue insulin without seeking medical advice, leading to toe amputation. This patient was advised to refer to the specialist, restart the medication, and have proper check-ups. One patient who had been started on insulin complained of suffering from profuse diarrhoea from the beginning of his treatment, hence this patient was referred. Another patient was referred due to very high blood glucose readings, including readings of 28 mmol/L. No problems were identified relating to inappropriate drug storage by patients. Additional information was requested by patients related to disease management and drug information, with patients seeking guidance

on how to properly control diabetes and any potential consequences, such as hypoglycaemia. The researcher provided instructions on how to use the devices appropriately and how to interpret results, including demonstration of how to use a blood glucose monitor (n=3) and blood pressure monitoring device (n=1). Additional information on medications being used was needed (n=12). Information on red flags (skin changes, increase thirst, urination and hunger, fatigue, vision changes and numbness) that warrant referral (n=7), and hypoglycaemia management (n=4) was needed.

The most common lifestyle modification needs identified were related to dietary advice (n=15, 57.7%), smoking cessation (n=12, 46.2%), followed by increase in physical activity (n=11, 42.3%) (Table 3.3).

Table 3.3: Patient education relating to lifestyle modifications (n=26)

Patient needs	Number of patients
Diet and Nutrition	15 (57.7%)
Reduce smoking	12 (46.2%)
Increase physical activity	11 (42.3%)
Improve sleep hygiene	4 (15.4%)
Reduce alcohol consumption	3 (11.5%)

The most common need related to patient monitoring was lack of yearly eye examinations (n=21, 91.3%). Lack of self-monitoring was an issue, including blood glucose self-monitoring (n=14, 17.4%) (Table 3.4).

Table 3.4: Patient education relating to patient monitoring (n=23)

Patient needs	Number of patients
Yearly eye examination	21 (91.3%)
Blood glucose self-monitoring	14 (60.9%)
Foot examination every 6 months at the podologist	13 (56.5%)
Foot check-ups at home	7 (30.4%)
Blood pressure self-monitoring	4 (17.4%)
Regular blood test	4 (17.4%)

3.5 Needs identified related to drug-related problems

Drug-related needs were identified in 18 patients, mostly drug selection problems (n=10) (Table 3.5), followed by dose selection problems (n=9) and patient medication handling problems (n=6). No patients had problems related to dispensing errors or drug forms. Potentially inappropriate drugs were identified in 4 patients, such as the concomitant use of simvastatin and amlodipine (n=2), omeprazole and clopidogrel (n=1) and lithium and quetiapine (n=1).

Table 3.5: Needs related to drug selection problems (n=10)

Patient needs	Number of patients
Duplicate drug	5 (50%)
No indication	5 (50%)
Inappropriate drug	4 (40%)
Contraindication	4 (40%)

The need for dosage timing instructions was identified in 6 patients (Table 3.6). No needs were identified related to dose too low or dose too high.

Table 3.6: Needs related to dose selection problems (n=9)

Patient needs	Number of patients
No dosage timing instructions	6 (66.7%)
Dosage regimen too frequent	2 (22.2%)
Dosage regimen to scarce	1 (11.1%)

Intentionally taking less doses of medication was identified in 3 patients (Table 3.7).

Table 3.7: Needs related to inappropriate medication handling by patient (n=6)

Patient needs	Number of patients
Takes less medication doses intentionally	3 (50%)
Unable to use drug as directed	2 (33.3%)
Takes more medication doses intentionally	1 (16.7%)

The relationship between patient needs with age, gender and number of medications was not statistically significant ($p>0.05$).

3.6 Acceptance of pharmacist interventions

Fifty-three of the 55 patients attended at t2. The implementation rate (%) was determined by dividing the number of needs met at t2 following pharmacist intervention by the number of needs identified at t1. After 1-month follow-up, 104 (65%) needs were addressed. Patient education needs were implemented at 64% and drug-related problems at 70%.

At follow-up, the implementation rate of educational related interventions was highest for adherence to medication (100%), appropriate use of glucagon (100%), diet and nutrition (100%), blood glucose self-monitoring (100%), foot check-ups at home (100%), blood pressure self-monitoring (100%), and regular blood tests (100%) (Table 3.8).

Dose selection and patient medication handling problems were implemented by 89% and 83% of patients, respectively, while drug selection problems were implemented by 56%, as most of these patients were recommended to visit the physician or specialist (Table 3.9).

Table 3.8: Implementation rate: Patient education interventions (n=53)

Patient needs	Implementation rate (%)
Adherence to medication	100%
Appropriate use of glucagon	100%
Diet and nutrition	100%
Blood glucose self-monitoring	100%
Foot check-ups at home	100%
Blood pressure self-monitoring	100%
Regular blood tests	100%
Increase physical activity	91%
Sleep hygiene	75%
Recommendation of using a medication administration aid	33%
Reduce alcohol consumption	33%
Foot examinations at the podologist every 6 months	31%
Yearly eye examinations	24%
Reduce smoking	8%

Implementation rate calculated: Number of needs met following pharmacist intervention in t2/ number of needs identified in t1

Table 3.9: Implementation rate: Interventions for drug-related problems (n=53)

Patient needs	Implementation rate (%)
Dose selection problems	89%
Inappropriate medication handling by patient	83%
Drug selection problems	56%

Implementation rate calculated: Number of needs met following pharmacist intervention in t2/ number of needs identified in t1

Chapter 4

Discussion

4.1 Evidence supporting diabetic patient reviews

Patient reviews include educational and behavioural interventions. In patient reviews, patients are encouraged to improve on medication adherence and to alter or adjust their behaviour to reach treatment goals. Patient reviews have a significant impact on chronic disease outcome measures such as HbA1c, fasting blood glucose, postprandial and random blood glucose. It has been shown that educational materials and training improve patient outcomes. The effectiveness of patient reviews demonstrates the pharmacist's expanding role in supporting patient care together with other healthcare providers (Muscat, 2017; Van Eikenhorst et al, 2017).

It is recommended that patients visit their general practitioner at least annually. Community pharmacists are the most accessible healthcare professionals and act as an intermediary between general practitioner or specialist visits for point-of-care testing, education, follow-ups, referrals, and medication reconciliation (Teka and Baye, 2018). Differently from the general practitioner, pharmacists are available for a longer duration without the need for an appointment (Ayadurai et al, 2018). As diabetic patients visit pharmacies frequently for various reasons, these visits provide an opportunity for patient education and counselling on topics such as weight management, exercise, diet, prevention and management of complications, and smoking cessation (Teka and Baye, 2018). Education is a key component of managing DM and is the most efficient method for reducing complications and is successfully performed by pharmacists as part of comprehensive patient care. Managing DM calls for patient participation to improve disease control. Counselling patients generally

contributes to lower medication inconsistencies and errors (Manithottiyle et al, 2021), increased medication adherence, and reduced risk of hospitalisations (Choudhry et al, 2018).

The relationship between the pharmacist and patient serves as a foundation to support DM self-management. Self-management of DM is optimised through support and structured DM education. Pharmacists provide services such as blood pressure monitoring, blood glucose monitoring, cholesterol testing, emergency contraception, and smoking cessation (Manithottiyle et al, 2021; Cooney et al, 2022a), creating the need to deliver consistent, quality care and a structured intervention (Ayadurai et al, 2018). The present study highlights the significance of the pharmacist's contribution in supporting diabetic patients in improving medication adherence, glucose control, and knowledge.

4.2 Patient review prioritisation

It would be unreasonable to advocate for pharmacists to play a bigger role in treating chronic conditions without mentioning the challenges. The implementation of community pharmacist-led services is hampered by aspects including lack of time, financial incentives, training, interprofessional collaboration, and public knowledge of available services (Milosavljevic et al, 2018; Gawlik et al, 2023). To-date, there has been no standardisation of community pharmacist-led patient review services for the management of DM.

Pharmacists often lack the time and resources necessary to successfully perform patient reviews on every diabetic patient and to address every patient need. It is challenging for

pharmacists to effectively target patients with the most complications, who may gain the most benefit from patient review services (Mullan et al, 2020). In the current study, a stepwise approach was adopted to prioritise and address the most severe issues, as some patients had numerous needs. The researcher used clinical judgement to determine which concerns merited priority in the clinical evaluation. Applying multiple variables at once is generally not advisable on scientific grounds, as this may result in the patient receiving many changes at once. Further modifications may be made over time to optimise the patient's treatment, and regular patient reviews are crucial (Fourbert et al, 2020). Adopting patient prioritisation is one option for achieving just treatment for patients. The dynamic comparison of patients' priorities based on the health status and the potential benefits of the services they are awaiting is one of the challenges related to patient prioritisation. As a result, determining a patient's priority tends to vary depending on the assessor. Accessibility to healthcare may be impacted by the absence of formal, standardised procedures for patient prioritisation. For instance, if the condition is deemed less urgent than others, "low priority" patients, such as those with chronic diseases, do not obtain publicly accessible healthcare treatments in a timely way (Déry et al, 2019). Prioritisation can be based on the patient setting, patient priorities in accordance with the clinical condition and capacity for change. High-risk patients should receive special attention since they use a disproportionate amount of time, energy and may benefit the most from pharmacist reviews. Compared to patients at lower risk, patients with a high risk of serious consequences typically have a better short-term return on investment. On the other hand, younger, average-risk individuals could have more time to experience severe diabetes-related problems and to develop them. Risk prioritisation is impractical if patients with moderate risk are ignored. In comparison to the smaller percentage of high-risk individuals, the majority of cardiovascular events occur in patients

with moderate risk. Moderate-risk patients can become high-risk patients who use more resources. Because of the complexity of caring for patients with DM and comorbidities, it may not be possible to create a DM care guideline that applies to all patients. Patients should be questioned about expectations from the treatment and the level of interest in collaborative decision-making (Laiteerapong et al, 2011).

Medication review as part of patient reviews should be conducted on patients with polypharmacy.[5] Reviews should be prioritised on patients who are experiencing new complications such as foot problems or hypoglycaemia, commencement of new therapy newly diagnosed DM, experiencing side effects, lack of DM control, prescription of new medicine, new cardiovascular disease or chronic kidney disease diagnosis, absent data or overdue review more than 18 to 24 months (Holman, 2020; Mullan et al, 2020; Stewart, 2020). Health priorities listed included maintaining independence, remaining alive, reducing or eliminating pain, and reducing or eliminating other symptoms, and by a discussion of the goals and preferences for treating DM such as avoiding hypoglycaemia, reducing polypharmacy, avoiding insulin therapy, and improving quality of life (Fried et al, 2011). A follow up should normally be conducted 12 months after the first meeting unless otherwise decided by the pharmacist to conduct a review sooner.[5] It is recommended that diabetic patients receive a review every 6 months when they are not stable and every year for patients who are stable (Mullan et al, 2020). Patient prioritisation tools are created to assist in the decision-making process that results in patient prioritisation in a clear, open, and equitable

[5] NHS. Structured medication reviews and medicines optimisation: guidance. 2021. [cited 2023 May 19]. Available from: https://www.england.nhs.uk/wp-content/uploads/2021/03/B0431-network-contract-des-smr-and-mo-guidance-21-22.pdf

way. When demand is high and resources are scarce, such tools or systems are set up to assist in choosing which patients should be treated first (Déry et al, 2020).

4.3 Outcomes of the study

Reviews during this research helped to identify patient needs, provided patients with an individualised plan, led to proposal of interventions, provided time to discuss with the pharmacist-researcher any queries and led to provision of education. Most patients during the patient review had at least one need that was documented, with lifestyle and monitoring goals being the most prevalent. When given the option to choose how to manage chronic conditions, patients are more likely to concentrate on the aspects of self-management that are most important or are relevant to them, as evidenced by the greater willingness to set lifestyle goals. Personal investment and the perception of control that an individual feels s/he has over an event are key components of successfully achieving goals. Changes in lifestyle may be seen as more personally controlled in the context of the current investigation than adjustments to drug schedules. This suggests that pharmacists may offer efficient self-management interventions to encourage lifestyle modifications to ameliorate glycaemic control and lower the risk of complications. The degree to which the goals were met further shows that patients gained the desire, expertise, and abilities needed to support behaviour change techniques during the review as evidence by Mitchell et al (2011) and Saisho, (2018).

The current research showed that the majority of patient needs identified were related to patient education, with eye examinations, diet and nutrition and blood glucose self-

monitoring being the most common patient needs identified and interventions discussed with the patients. Self-reported changes were observed in the patients, mainly in diet and nutrition, blood glucose and blood pressure self-monitoring, and physical activity. Interventions that involved adherence to medication, appropriate use of glucagon, diet and nutrition, blood glucose and blood pressure self-monitoring, foot check-ups at home and regular blood tests had the highest implementation rates. Pharmacist interventions, such as improving medication adherence and checking feet at home, were fully executed, which was in contrast to other pharmacist interventions that involve making appointments with the general practitioner or with the government health centre, such as foot appointments and eye test appointments, which have a substantially lower success rate when put into practice. Of the 55 patients, two were recommended to start carbohydrate counting, which they did following pharmacist recommendation. Findings indicate that some pharmacist interventions were not fully implemented after one month follow-up. These included non-pharmacological interventions such as smoking cessation and reducing alcohol consumption. It is possible that some patients neglected to discuss the advice with the general practitioner since they did not think it was sufficiently relevant or important.

The most frequent drug-related problems were related to drug selection and dose selection. This is in line with other studies, which show that drug selection and drug dosage were the most frequently detected drug-related problems (Mitchell et al, 2011; Saisho, 2018). These patients were encouraged to visit the general practitioner or specialist on a regular basis to conduct check-ups, inform them through a note of what had been discovered during the review, and resolve the drug-related problem. Another drug-related problem was the

detection of an inappropriate dosage regimen. Appropriate dosage regimens are important for patient adherence and to minimise side effects. To increase patient adherence, the daily drug dosage should be as low as possible. This can be seen in earlier studies, which confirm that less frequent dosing regimens are associated with better patient adherence to medications (Claxton et al, 2001; Aslani and Krass, 2009).

The most frequent interventions employed by pharmacists to improve medication adherence are education and consultations. Education is thought to be the key to enhancing medication adherence by including the patient and the healthcare provider (Presley et al, 2019). The combined educational-behavioural strategy sought to improve patient knowledge of DM (aetiology, short- and long-term complications of DM, risk factors) and the ability to manage the condition (treatment target monitoring, behaviour changes to improve one's lifestyle, timing of medication, monitoring of side effects, and medication adherence). Both strategies work well to increase medication adherence and glycaemic targets (Presley et al, 2019).

The study's findings aid in the development of a framework for community pharmacy services tailored specifically to diabetic patient requirements. The developed toolkit serves as a guide for the development of similar tools for other populations and patient needs. The study uses the integration of the POYC system. The study could be applied to any healthcare scenario by using the medication list that the patient provides. The integration of the POYC scheme has provided opportunities for pharmacists to follow up with patients who are registered with them. The integration of dispensing histories for medications in the POYC scheme is a positive move; such a system may be further utilised to link the community

pharmacy with more patient health data, such as laboratory results, which until now were only available through the myHealth online service for the patient, general practitioner, or specialist. Refill rates are low, and as a result, the patient's adherence to chronic medicine is restricted since the dispensing history for purchased prescriptions cannot be shared across pharmacies or in the same pharmacy.

The inadequate and even non-existent communication between hospitals and community pharmacies is a significant challenge that is evident in daily practice. To support a smooth transition of care, the community pharmacist needs access to updated clinical data and discharge letters. With access to this clinical data, pharmacists would be better able to contribute to medication optimisation. Sharing of clinical data facilitates patient reviews. DM management requires close cooperation between the patient and the multidisciplinary team, where pharmacists may contribute by offering pharmaceutical care programmes. A system that would allow patients to be registered with a general practitioner in both private and public organisations may be the key to ensuring a more harmonious approach. A primary healthcare system that is more organised and personalised may be possible if patients are only registered with one general practitioner. Currently in Malta, patients register with a community pharmacy of their choice allowing for regular review and patient follow-up. Patients access general practitioner services funded through the national health service scheme through the healthcare centres where different medical practitioners are available, hence leading to fragmentation of care. Unquestionably, such a setup would make it easier for the pharmacist and general practitioner to work together, improve patient review services, and encourage crucial medical follow-ups. The lack of follow-up may mean that the patient

did not disregard the pharmacist's advice, but it could be possible that the patient did not access physician services during the two-month period.

In an earlier study conducted by Thoopputra et al. in Australia and Thailand, interventions were classified into patient-oriented and professional interventions, including medication review and referral, and it was found that more than half (53%) of interventions were patient-oriented, focusing on patient education, counselling, monitoring, and risk screening. In the community pharmacy environment, educational interventions are simple to execute, relatively inexpensive, and successful with various participant groups (Thoopputra et al, 2016). They can increase patient knowledge and satisfaction because patients often want more information about the treatments (Milosavljevic et al, 2018). When comparing in this study, the two patient sessions conducted over a one-month period, the duration of the sessions in the two stages appears to be positively correlated; the longer the first session, the longer the second session. This is reasonable given that the majority of the issues raised during the first session needed to be assessed and evaluated during the second session. It was discovered that the follow-up interview was much shorter in duration than the first session but was more intense and direct. Additionally, it was demonstrated that the one-month follow-up exhibited less fluctuation in terms of duration than the first interview. One might conclude that the majority of pharmacist interventions were performed after one month based on the implementation rate of 64% for all implemented interventions. Barriers to adherence to medication can range from patient challenges to financial difficulties and requirement of additional medical assistance (Fukunaga and Tan, 2020). Pharmacists offered suggestions for improving drug adherence, such as streamlining a patient's schedule and promoting the use

of a medication administration aid. Forgetfulness is one of the major reasons for non-adherence (Adisa et al, 2011; Gelaw et al, 2014; Meinema et al, 2015; Ipingbemi et al, 2021). Partially achieved interventions at follow-up visits imply that behavioural changes take time, which further emphasises the significance of reviewing and monitoring goals to encourage behaviour changes in patients. In particular, lifestyle choices like quitting or reducing smoking, decreasing alcohol consumption are difficult to make in a short amount of time. To increase the possibility that they will improve behaviour, ongoing assistance and affirmation from healthcare professionals are essential.

Most of the interventions in the included studies referred to DM self-management education (Bukhsh et al, 2018a; Meade et al, 2018; Van Eikenhorst et al, 2017; Iqbal et al, 2019; Lau et al, 2020; Alabkal, 2022; Cahyaningsih, 2023). DM self-management education is defined as information given by all medical professionals to patients to enhance knowledge and ability to manage the condition (Coutureau et al, 2022). Diabetic patients are open to participating in patient reviews and perceive pharmacists to be qualified to lead these sessions. Pharmacists should continue to educate patients on the benefits of education to improve patient participation in these services (Moore et al, 2022). General information about the disease or information about immediate or long-term risks and complications of DM were covered in DM education. This advice was given to increase the adherence of patients, limit side effects, improve storage conditions, and limit improper use of medications. Education relating to lifestyle measures included physical activity, eye and foot care, smoking cessation, and a proper diet (Iqbal et al, 2019). In the present study, counselling on weight management, exercise, and nutrition was applied the most.

Compared to patients with low diabetic health literacy, those with high DM literacy are more likely to achieve the desired glycaemic control. Nearly all these patients are expected to be knowledgeable about the disease, its management, and self-care for diabetics. Good glycaemic control was significantly associated with having better diabetic health literacy. This is in line with the results of the T1DM cohort study by Tefera et al. (2020) in Ethiopia and Kasper et al. (2022) in America, which found that to achieve desired glycaemic control, knowledge significantly influences medication adherence and self-care practices. These findings highlight the need for ongoing DM education to address problems with diabetic health literacy and medication adherence, both of which are the most practical strategies for managing DM (Tefera et al, 2020; Kasper et al, 2022).

Similar results were noted in two French studies, where community pharmacists' counselling improved participants' knowledge of DM and hypertension (Delage et al, 2021; Malik et al, 2022). Unexpectedly, and less frequently than expected, diabetic medication was addressed. Adherence to medicine is possibly easier to achieve than healthy diet and exercise objectives, which can be difficult and call for altering lifetime habits (Nishita et al, 2013).

4.4 Strengths of the study

The study’s applicability to a real-world scenario is one of its main advantages. The study included diabetic patients who visited a community pharmacy. Patient sessions allowed the pharmacist to identify patient needs and carry out individualised interventions for each

patient. The study demonstrated that pharmacist interventions led to improvements in patient self-care behaviours.

Patients prefer short duration consultations (Presley et al, 2019); hence, in the present study, patient reviews were relatively short (15 minutes, range 10-25). Reviews usually take a considerable amount of time; this was overcome by compiling the medications before actually meeting the patient through the POYC system. If the patient did not take the medication through the POYC scheme, the medications were compiled by the researcher through patient interview. The complexity of the advice given and needed by each patient may differ; hence, the length of each consultation varied.

Pharmacists are easily accessible, although some days are busier than others, making walk-in visits more challenging to tackle. In such cases, an appointment would be preferred. This is time-saving, as the patient does not need to wait in queues, the patient would receive complete attention from the pharmacist, which may not be possible during walk-ins, and always received continuity of care from the same pharmacist who is aware of the patient and history. Patients may feel more comfortable contacting the same pharmacist if they have any additional problems regarding medication or health; the researcher's contact details were given to the patient to encourage contact if required. To decrease the probability of dropouts, an appointment was set up for the follow-up session during the first session. During the duration of the study, consultation with the pharmacist led to a stronger bond between the patient and the pharmacist, increased patient confidence in managing their health, and

improved patient adherence to medications. Private counselling areas helped overcome barriers to safeguarding patients' privacy and confidentiality.

4.5 Limitations of the study

Community pharmacies in Malta do not typically gather information on laboratory results or a patient's diagnosis, including the severity and duration of the patient's condition. The lack of availability of laboratory data is a barrier to providing care in the community, compared with hospital pharmacists. The lack of a patient's medication history was a limiting factor, as this was based solely on the knowledge and memory recall of each patient with the restricted assistance of the POYC system, which does not necessarily reflect all the medication the patient is taking. Community pharmacists cannot give specific information on these concerns in depth. The availability of electronic health records for the community pharmacist would have facilitated pharmacist access to medications and laboratory results. Furthermore, we hypothesised that patients who took an antidiabetic drug and disclosed to the pharmacist that they suffer from DM were truly suffering from the condition.

During the data collection phase, the Hawthorne effect could have had an effect (Korcegez et al, 2017). The participants' responses may have been affected by the researcher's presence. This limitation may have led some patients to behave differently since they were aware they were participating in a study or since they wanted to impress the researcher. This type of study depends on honesty and truthfulness. The methods used to gather the data in the study were self-reporting, which might have resulted in some inherent bias, including memory bias,

where patients may over- or underreport some of the information provided. As the responses relied on the participants' knowledge and memory, there was a chance of self-reporting bias.

Similarly, to the study conducted by Feldman (2017) in Sweden, the limitations of this study were that nutrition, reduction in alcohol consumption, reduction of smoking, and exercise were all self-reported. All patients stated that they tried to follow the guidelines suggested by the researcher. Physical activity was increased in 10 patients. Alcohol consumption was reduced in 1 patient who stated that he was trying to drink alcohol only on weekends. The last risk factor for which a change was found was reducing smoking; 1 patient reduced daily cigarette intake by 5 cigarettes per day. Two patients stated during follow-up that they were still awaiting a specialist appointment. One patient stated in the follow-up that regular self-monitoring of blood glucose aided in decreasing the occurrence of hypoglycaemic attacks. Another patient stated that self-monitoring helped to control blood glucose through food intake management. Self-reporting of diet, alcohol, smoking, physical activity, and medication adherence may not be accurate as this depends on the patient's perspective.

4.6 Recommendations for further study

Another longitudinal study can be conducted, similarly to the present study, with a larger sample cohort, a longer time period, and with a control group. The research setting was limited to a single pharmacy chosen by convenience sampling and did not adequately reflect Malta's many districts. The study's findings would be more generally applicable if several pharmacies and pharmacists are included. One month was not sufficient to implement some

interventions, such as smoking cessation, which may take longer to implement. Other interventions, such as advising patient to try alternative non-pharmacological methods, could be implemented. These methods could take longer for the patient to adopt and/or see the impact. A higher implementation rate may be seen if the study is conducted over a longer period of time, for example, by having a second follow-up 8 weeks after the first session, as most patients would be able to conduct the second session when collecting their POYC medications.

It may be advisable to consider parameters such as HbA1C, blood pressure, blood glucose readings, and BMI to assess the toolkit's impact on patient outcomes. Additional research is required to determine how these pharmacy interventions affect clinical outcomes, including microvascular complications and macrovascular complications (Coutureau et al, 2022).

The financial cost of managing uncontrolled DM exceeds the cost of implementing this type of review into a healthcare system (Langran et al, 2017). The study highlights the need for a comparable analysis to be conducted to determine the service's sustainability and decide if pharmacist interventions are cost-effective. A pharmacoeconomic evaluation and cost-effectiveness study may shed information on the viability of comparable programmes targeted at reaching a broader segment of the population. To help policymakers create healthcare models in which pharmacists take the initiative to promote patients' wellbeing, further research analysing the human-centred and financial results of pharmacist interventions are recommended to be conducted (Pousinho et al, 2020). Delivery of this type of service, both in the community and in hospitals, will lead to pharmacists being seen as

care providers rather than just dispensers of medications. The funding of these pharmacy services can be provided through government or user fees, and models are needed for the implementation (Hughes et al, 2017).

Future research should assess the study's long-term impact, including patient satisfaction, and assess whether patients would be willing to pay for this type of service (Hassali et al, 2015; Shindler et al, 2020). A study in Nigeria noted that some patients were willing to pay for healthcare treatments at a reasonable price (Jackson et al, 2023). To use this opportunity to its full potential, pharmacists' thoughts should be evaluated on providing advanced care to diabetic patients, including perspectives on how to provide this service to diabetic patients and any emphasis on the remuneration or incentives that should be provided. As highlighted in a study carried out in Ireland, remuneration may be an incentive for pharmacists to perform more reviews (Cooney et al, 2022a). Lack of reimbursement, whether from government financing, patients, or private health funds, is a global issue and a significant impediment to service delivery, such as pharmacist-led services (Woodhams et al, 2023).

One may consider using telemedicine to further reach patients who may be either too busy to attend the pharmacy, homebound, live in rural areas, or in particularly difficult situations such as during the COVID-19 pandemic or other crises (Iqbal et al, 2019). Communication with other healthcare professionals may prove difficult, especially for those with poor communication skills and/or minimal medical literacy. A conversation with the general practitioner for the pharmacist to outline evidence-based suggestions to address these difficulties would be preferable to resolve issues. A meeting between a general practitioner

and a pharmacist is ideal, but it is occasionally improbable that this will take place since some patients may want to consult with a different general practitioner or specialist who does not practice within the pharmacy. Pharmacist involvement is not intended to replace physician-directed care or formal DM education, but to support and enhance patient care (Inasu and Kumudavalli, 2020). An increased level of interdisciplinary collaboration and communication is required for the service to be implemented in pharmacies (Valliant et al, 2022).

4.7 Conclusion

The study contributes a patient review toolkit which can assist community pharmacists in the identification of diabetic patient needs and implementation of pharmacist interventions in diabetic patients in the context of collaborative care. The toolkit for community pharmacist-led diabetic patient review represents an innovative contribution to community pharmacy practice to improve the quality, efficiency, and effectiveness of patient review services. The toolkit provides pharmacists with a comprehensive tool to conduct thorough and personalised diabetic patient reviews to improve the quality of care delivered to diabetic patients, ultimately leading to improved patient outcomes. The devised toolkit has been shown to be practical and feasible to be implemented into routine practice and has the potential to strengthen pharmacist-patient relationships, while supporting patient empowerment and acting as an integrated patient management tool.

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Appendices

Appendix 1

Pharmacist Clinical Diabetic Patient Review Toolkit

Patient Code _____

Gender: Male ☐ Female ☐ Other ☐

Age: 18-25 ☐ 26-35 ☐ 36-45 ☐ 46-55 ☐ 56-65 ☐ 66-75 ☐ 76-85 ☐ 86-95 ☐

How to use this Toolkit

Step-by-step process:

1) Invitation: Patients are invited for review (Adult patients over 18 years of age, diagnosed with Type 1 or Type 2 diabetes mellitus by a physician and taking at least one glucose lowering medication. Patients with gestational diabetes and paediatric patients are excluded).
2) Consent form: Written informed consent obtained from the patient.
3) Set an appointment with the patient at his/her convenience.
4) Baseline:
    a) Data Collection: compile a list of all medications including POYC (Pharmacy Of Your Choice) and private medications.
    b) Review medications and plan patient session.
5) First Session: Consultation with the patient using the toolkit:
    a) Review the patient level of understanding.
    b) Review medicines management and adherence.

c) Organisation of follow up visit after one (1) month to assess symptoms and patient improvement.

d) Suggest changes and inform patient accordingly. Communication with or refer patient to the prescriber or health care professional about these suggested changes.

e) Second Session: Identify if needs were met.

Review of Medicines and Plan of Patient Session			
Pharmaceutical Care Issue Classification			
	Primary Domain	**Code**	**Sub-Class**
1.	Drug Selection problem	1.1	Inappropriate drug - Inappropriate drug being used to treat a certain medical condition
		1.2	Duplicate drug - Two or more drugs from the same pharmacological class being used to treat a certain medical condition
		1.3	Contraindication - Medication may be harmful to the patient due to a medical condition
		1.4	No indication - No apparent indication for use of the drug
2.	Drug Form	2.1	Inappropriate drug form - Drug form being used is inappropriate for intended use or patient needs
3.	Dose Selection	3.1	Dose too low - Dose too low to control patient condition
		3.2	Dose too high - Dose exceeds required dosage to treat condition or patient parameter
		3.3	Dosage regimen scarce - frequency of drug taking is too little to treat patient's condition
		3.4	Dosage regimen too frequent - frequency of drug taking is too much to treat patient's condition
		3.5	No dosage timing instructions given to patient
4.	Dispensing Error	4.1	Wrong drug dispensed to patient
		4.2	Wrong dosage dispensed to patient

5.	Patient-Related	5.1	Patient intentionally takes less drug than prescribed
		5.2	Patient intentionally takes more drug than prescribed
		5.3	Patient stores drug inappropriately
		5.4	Patient unable to use drug as directed due to physical or mental disability or any other reason

Diabetic Medication Checklist		
Drug Name	**Maximum Dose and Frequency**	**Pharmaceutical Care Issue Classification Comments**
Sulphonylureas		
Glibenclamide	2.5 - 5mg 1-2 doses	
Gliclazide modified-release	40 - 320 mg 1-3 doses	
Gliclazide immediate-release	30 - 120 mg 1 dose	
Glimepiride	1 - 6mg 1-3 doses	
Biguanides		
Metformin immediate-release	500 - 2000mg 1 - 3 doses	

Metformin slow-release	500 - 2000mg 1 dose	
Sodium glucose co-transporter-2 inhibitors		
Canagliflozin	100 - 300mg 1 dose	
Dapagliflozin	5 - 10mg 1 dose	
Empagliflozin	10 - 25mg 1 dose	
Meglitinides		
Repaglinide	1.5 - 16mg 1 dose	
Dipeptidylpeptidase-4-inhibitor (Gliptins)		
Linagliptin	5mg 1 dose	
Sitagliptin	100mg	

	1 dose	
Vildagliptin	50mg 2 doses	
Glucagon-like peptide-1 receptor agonist		
Dulaglutide	1.5mg SC 1 weekly	
Liraglutide	3mg 1 dose	
Semaglutide	0.25 - 1mg once weekly	
Rapid-acting Insulins		
Neutral/Soluble Insulin	According to requirements	
Rapid-acting Insulins Analogues		
Insulin Aspart	According to requirements	

Insulin Glulisine	According to requirements	
Insulin Lispro	According to requirements	
Intermediate-acting Insulins		
Insulin Biphasic Isophane	According to requirements	
Insulin Isophane	According to requirements	
Long-acting insulins		
Insulin Glargine	According to requirements	
Long-acting Insulin Analogue		
Insulin Degludec	According to requirements	

Baseline Medication Review and Assessment					
Other Medication					
Medicine (Non-proprietary name)	**Brand name**	**Formulation**	**Dose**	**Frequency**	**POYC/Privately bought**

Food Supplements and Herbal Medications					
Medicine (Non-proprietary name)	**Brand Name**	**Formulation**	**Dose**	**Frequency**	**POYC/Privately bought**

Prioritisation of Issues:

1. _____
2. _____
3. _____

First Session

Date _____

Patient Problems/Needs	**Required Intervention**
Perceived Level of Knowledge: **How do you rate level of understanding of:**	
Diabetes? • Very good _____ • Good _____ • Fair _____ • Poor • Very poor _____ Diabetic medicines you are using? • Very good _____ • Good _____ • Fair _____ • Poor _____ • Very poor _____ Low blood sugar (hypoglycaemic) attacks? • Very good _____ • Good _____ • Fair _____ • Poor _____ • Very poor _____ Medication storage? • Very good _____ • Good _____ • Fair _____ • Poor _____	

• Very poor _____	
Medication Adherence	
Circle the answer that best describes the patient's behaviour or attitude towards their medication during the past week. • On a scale of 1-5 (5 being the best and 1 being the worst), are you adherent to the dosing schedule? 1 2 3 4 5 • What is the cause of non-adherence? (If 1, 2 or 3 are marked)? _____ _____ _____ _____ • On a scale of 1-5 (5 being the best and 1 being the worst), would using a pillbox improve your adherence to medication intake? 1 2 3 4 5	
Patient Self-Monitoring	
• On a scale of 1-5 (5 being the best and 1 being the worst), do you understand the role of glucose self-monitoring? 1 2 3 4 5 • On a scale of 1-5 (5 being the best and 1 being the worst), are you capable of self-monitoring?	

1 2 3 4 5
• How frequently do you self-monitor?
  • Blood Glucose
  o Everyday _____
  o Twice weekly _____
  o On alternate days _____
  o Once weekly _____
  o Once monthly _____
  o Once yearly _____
  • Blood Pressure
  o Everyday _____
  o Twice weekly _____
  o On alternate days _____
  o Once weekly _____
  o Once monthly _____
  o Once yearly _____
• Are you aware of red flags that would require medical consultations? Yes/No
  o If yes – which? _____	

Lifestyle	
Diet/Nutrition	
• On a scale of 1-5 (5 being the best and 1 being the worst), does the food you choose to eat make it easy	

to achieve optimal blood sugar levels? 1 2 3 4 5 • On a scale of 1-5 (5 being the best and 1 being the worst), do you choose to eat food that is low in sodium? 1 2 3 4 5 • On a scale of 1-5 (5 being the best and 1 being the worst), are you following a healthy diet? 1 2 3 4 5 • On a scale of 1-5 (5 being the best and 1 being the worst), do you strictly follow the dietary recommendations given by your doctor or diabetes specialist (e.g. Carb counting)? 1 2 3 4 5	
Physical Activity	
Recommended: 30 mins walking, 5 or more days/week (total >150 min/week) During the past 7 days, how many times on average did you carry out any form of physical activity for more than 15 minutes during your free time? _____	Intervention: _____ _____ _____ _____ _____ _____
Alcohol Intake	
Alcohol intake ≤2 standard drinks per day (adult) (e.g. 1 beer can, 100ml of wine, 30ml of spirit)	

Smoking	

Mark with an X
• Never Smoked _____
• Past Smoker _____
• Current Smoker _____
  o How many cigarettes?
  _____	

Sleep	
Any sleeping problems? Yes/No	
Complications of Diabetes	
Foot Complications	
• Do you have a foot assessment every six months? Yes/No o Last visit _____ • On a scale of 1-5 (5 being the best and 1 being the worst), do you take care of and check your feet at home? 1 2 3 4 5 **Outcome** • Low Risk • Intermediate Risk • High Risk	
Eye Complications	
• Do you have an annual eye assessment? Yes/No • Last visit _____	
Biomedical	

Blood Tests	
Last visit _____ • Glycated haemoglobin (hba1c) _____ _____ _____ Last visit _____ • Blood Glucose _____ _____ _____ Last visit _____ • Kidney Function Test _____ _____ _____ Last visit _____ • Liver function test _____ _____ _____ _____ Last visit _____ • Lipid Profile _____ _____	

_____	
GP/Specialist Review	
• Last visit _____ • On a scale of 1-5 (5 being the best and 1 being the worst), do you keep all doctors' appointments as advised? 1 2 3 4 5 • On a scale of 1-5 (5 being the best and 1 being the worst), do you tend to avoid diabetes-related doctor's appointments? 1 2 3 4 5	

Outcome of Patient Review			
No.	**Primary Domain**	**Code**	**Sub-Classes**
1.	At Patient level	1.1 1.2 1.3 1.4	No issues Patient counselling needed Needs monitoring Lifestyle measure needed
2.	At prescriber level	2.1	Prescriber Referral

Notes for referral:

Second Session

Date _____

Pharmaceutical Care Issue from Session 1	**Intervention/Need Meet**

Intervention			
1.	Intervention Acceptance	1.1 1.2	Accepted Not Accepted
2.	Patient status	2.1 2.2 2.3	Patient improved Patient still needs more care Patient needs referral

Notes for referral:

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***Toolkit* għall-Monitoraġġ tad-Dijabete biex tintuża mill-Ispiżjar**

Kodiċi tal-pazjent _____

Ġeneru: Raġel □ Mara □ Oħrajn □

Eta' 18-25 □ 26-35 □ 36-45 □ 46-55 □ 56-65 □ 66-75 □ 76-85 □ 86-95 □

Kif tuża dan it-*Toolkit*

Proċess

1) Stedina: Il-pazjent/a j/tiġi mistieden/na għal-laqgħa mal-ispiżjar (adulti ta' 18 il-sena jew aktar, diagnostikati b' diabete ta' tip 1 jew 2 mingħand it-tabib u jieħdu minn tal-inqas mediċina waħda li tnizzel iz-zokkor. Pażjenti b' diabete assoċjata mat-tqala jew pazjenti pedjatriċi ġew eskluži)
2) Ittra ta' kunsens: Kunsens mill-pazjent/a.
3) Agħmel appuntament mal-pazjent/a meta huwa/hija komdu/komda.
4) Qabel l-ewwel konsultazzjoni:
    a) Iġbor il-mediċini kollha li j/tieħu il-pazjent/a kemm tal-POYC (Pharmacy Of Your Choice) u anke dawk li j/tixtri mill-privat.
    b) Reviżjoni tal-mediċini li j/tieħu l-pazjent/a u ipprepara l-intervent.
5) L-ewwel laqgħa mal-pazjent: Konsultazzjoni mal-pazjent bl-użu tat-*toolkit*:
    a) Ara kemm fehem il-pazjent.
    b) Reviżjoni tal-aderenza tal-mediċini.
    c) Organizza t-tieni laqgħa wara xahar (1) biex tara is-sintomi u t-titjib tal-pazjent.

d) Issuġġerixxi xi tibdil jekk hemm bżonn. Ikkomunika jew irreferi mat-tabib jew konsulent dwar xi tibdil li għandu jsir.

e) It-tieni laqgħa mal-pazjent: identifika jekk il-bżonnijiet intlaħqux.

Reviżjoni tal-Mediċini u Pjan tas-Sessjoni mal-Pazjent			
Kwistjonijiet Farmaċewtiċi			
Nru.	**Dominju primarju**	**Kodiċi**	**Klassifikazzjoni**
1.	Problema relatata mal-għażla tal-mediċina	1.1 1.2 1.3 1.4	Mediċina mhux adattata - Mediċina mhux adattata biex tikura ċertu kundizzjonijiet mediċi Mediċina duplikata - żewg jew aktar mediċini mill-istess klassi qegħdin jintuzaw biex jikuraw kundizzjoni medika Kontraindikazzjoni - Il-mediċina tista' tkun ta' ħsara minħabba kundizzjoni medika Ebda indikazzjoni - L-ebda indikazzjoni għall-uzu tal-mediċina
2.	Forma tal-mediċina	2.1	Forma tal-mediċina mhux adattata - Il-forma tal-mediċina uzata mhux adattata għall-pazjent
3.	L-Għażla tad-doża	3.1 3.2 3.3 3.4 3.5	Doża baxxa wisq - Doża baxxa wisq biex tikontrolla l-kundizzjoni tal-pazjent Doża għolja wisq - Doża għolja wisq biex tikontrolla l-kundizzjoni jew il-bżonn tal-pazjent Doża inqas frekwenti milli suppost - Doża inqas frekwenti milli suppost biex tikontrolla l-kundizzjoni tal-pazjent Doża frekwenti wisq - Doża frekwenti wisq biex tikontrolla l-kundizzjoni tal-pazjent Ebda struzzjonijiet dwar il-ħin ta' teħid tal-mediċina

4.	Tqassim ta’ mediċina	4.1 4.2	Tqassim ta’ mediċina ħazina mill-ispiżjar Tqassim ta’ doża ħażina mill-ispiżjar
5.	Problemi relatati mal-pazjent/a	5.1 5.2 5.3 5.4	Il-pazjent/a j/tieħu intenzjonalment inqas mediċina minn dik preskritta lilu/ha Il-pazjent/a j/tieħu intenzjonalment iktar mediċina minn dik preskritta lilu/ha Il-pazjent/a ma j/terfax il-mediċina b’mod tajjeb Il-pazjent/a ma’ fehemx/fhemitx il-mediċina /mhuwiex/mhijiex kapaċi j/tuża l-mediċina kif suppost

Reviżjoni tal-Mediċini għad-Dijabete		
<u>Isem tal-mediċina</u>	**<u>Doża u</u> <u>Frekwenza</u>**	**Kwistjonijiet Farmaċewtiċi**
Sulphonylureas		
Glibenclamide	2.5 - 20mg 1-2 dożi	
Gliclazide b'rilaxx modifikat	40 - 320 mg 1-3 dożi	
Gliclazide b'rilaxx immediat	30 - 120 mg Doża waħda (1)	
Glimepiride	1 - 4 mg Doża waħda (1)	
Biguanides		
Metformin b'rilaxx immediat	500 - 2000mg 1 - 3 dożi	

Metformin b'rilaxx modifikat	500 - 2000mg Doża waħda (1)	
Sodium glucose co-transporter-2 inhibitors		
Canagliflozin	100 - 300mg Doża waħda (1)	
Dapagliflozin	5 - 10mg Doża waħda (1)	
Empagliflozin	10 - 25mg Doża waħda (1)	
Meglitinides		
Repaglinide	1.5 - 16mg 3 dożi	
Dipeptidylpeptidase-4-inhibitor (Gliptins)		
Linagliptin	5mg Doża waħda (1)	

Sitagliptin	100mg Doża waħda (1)	
Vildagliptin	50mg 2 dożi	
Glucagon-like peptide-1 receptor agonist		
Dulaglutide	1.5mg SC 1 fil-ġimgħa	
Liraglutide	3mg Doża waħda (1)	
Semaglutide	0.25 - 1mg darba fil-ġimgħa	
Insulina effettiva fuq bażi ripetuta u fit-tul (Rapid-acting Insulins)		
Neutral/Soluble Insulin	Skond ir-rekwiżit	
Analogu tal-Insulina effettiva fuq bażi ripetuta u fit-tul (Rapid-acting Insulins Analogues)		
Insulin Aspart	Skond ir-rekwiżit	

Insulin Glulisine	Skond ir-rekwiżit	
Insulin Lispro	Skond ir-rekwiżit	
Insulina effettiva intermedju (Intermediate-acting Insulins)		
Insulin Biphasic Isophane (Isophane + Neutral)	Skond ir-rekwiżit	
Insulin Isophane	Skond ir-rekwiżit	
Insulina li taġixxi fit-tul (Long-acting insulins)		
Insulin Glargine	Skond ir-rekwiżit	
Analogu tal-insulina li taġixxi fit-tul (Long-acting Insulins Analogue)		
Insulin Degludec	Skond ir-rekwiżit	

Reviżjoni u Valutazzjoni tal-Mediċini					
Mediċini oħra					
Mediċini (Isem mhux propjetarju)	**Isem tal-prodott**	**Formulazzjoni**	**Doża**	**Frekwenza**	**POYC/ Tal-privat**

Mediċini oħra inkluż Mediċini Naturali					
Mediċini (Isem mhux propjetarju)	**Isem tal-prodott**	**Formulazjoni**	**Doża**	**Frekwenza**	**POYC/ Tal-privat**

Priorità tal-kwistjonijiet:

1. _____
2. _____
3. _____

L-Ewwel Laqgħa mal-Pazjent

Data _____

Problemi/bżonnijiet tal-pazjent	**Intervent meħtieġ**
Livell ta' litteriżmu: Kif inhu l-livell ta' fehim tiegħek:	
Fid-dijabete? • Tajjeb ħafna _____ • Tajjeb _____ • Mhux ħażin _____ • Ħażin _____ • Ħażin ħafna _____ Tal-mediċina tad-dijabete li qiegħed/qegħda tuża? • Tajjeb ħafna _____ • Tajjeb _____ • Mhux ħażin _____ • Ħażin _____ • Ħażin ħafna _____ Meta jinżillek iz-zokkor? • Tajjeb ħafna _____ • Tajjeb _____ • Mhux ħażin _____ • Ħażin _____ • Ħażin ħafna _____ Ta' kif terfa' l-mediċini? • Tajjeb ħafna _____ • Tajjeb _____ • Mhux ħażin _____ • Ħażin _____ • Ħażin ħafna _____	

Aderenza għall-mediċini

Agħmel ċirku madwar l-attitudni u l-imġieba tal-pazjent rigward il-mediċini.

- Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm tieħu l-mediċina kif suppost?

1 2 3 4 5

- X'inhi/x'inhuma r-raġuni/jiet għaliex ma tieħux il-mediċini kif suppost?

_____
_____
_____

- Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), l-użu ta' kaxxetta tal-pilloli (pillbox) kieku tgħinek biex tieħu l-mediċini b' mod aħjar?

1 2 3 4 5

Awto-monitoraġġ taz-Zokkor

- Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm tifhem l-importanza li tiċċekkja z-zokkor id-dar?

1 2 3 4 5

- Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm kapaċi tiċċekkja z-zokkor waħdek?

1 2 3 4 5

- Kemm-il darba tiċċekkja?
  - Zokkor fid-demm
    - Kuljum _____
    - Darbtejn f'ġimgħa _____
    - Darba iva u darba le_____
    - Darba fil-ġimgħa_____

○ Darba fix-xahar _____ ○ Darba fis-sena _____ • Pressjoni fid-demm ○ Kuljum _____ ○ Darbtejn f'ġimgħa _____ ○ Darba iva u darba le_____ ○ Darba fil-ġimgħa_____ ○ Darba fix-xahar _____ ○ Darba fis-sena _____ • Il-pazjent jaf x'inhuma l-kwistjonijiet li dwarhom għandhom bżonn konsultazzjoni? Iva/Le • Jekk iva – x'inhuma? _____	
Stil ta' ħajja	
Dieta u Nutrizzjoni	
• Minn skala 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), l-ikel li tagħżel jgħinek iżżomm il-livell taz-zokkor ikkontrollat? 1 2 3 4 5 • Minn skala 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), tagħżel ikel li fih inqas melħ? 1 2 3 4 5 • Minn skala 1-5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm qiegħed issegwi dieta bilanċjata? 1 2 3 4 5 • Minn skala 1-5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm timxi mad-dieta rakkomandata lilek mit-tabib jew l-ispeċjalista? 1 2 3 4 5	
Attività fiżika	

Rakkomandat: 30 minuta mixi, 5 darbiet jew aktar fil-ġimgħa (totali >150 min/ġimgħa) F'din l-aħħar ġimgħa, kemm-il darba għamilt xi tip ta' attività fiżika ta' madwar 15 il-minuta fil-ħin liberu tiegħek? _____	Intervent: _____ _____ _____ _____ _____ ___
Ammont ta' alkoħol li wieħed jista' jieħu	
• Ammont ta' alkoħol ≤2 fil-ġurnata (adult) (Pinta birra, tazza nbid jew grokk alkoħol)	
Tipjip	
• Qatt ma pejjipt _____ • Kont tpejjep _____ • Tpejjep _____ • Waqfien tat-tipjip	
Irqad	
• Problemi relatati mal-irqad? Iva/Le	
Kumplikazzjonijiet tad-Dijabete	
Kumplikazzjonijiet fis-Saqajn	
• Test tas-saqajn kull sitt xhur? Iva/Le • L-aħħar vista _____ • Minn skala 1-5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), il-pazjent/a għandu/a għarfien biżejjed dwar il-kura tas-saqajn u kif j/tiċċekjahom? 1 2 3 4 5 Rizultat	

• Riskju baxx • Riskju intermedju • Riskju għoli	
Kumplizzjonijiet fl-għajnejn	
• Test tal-għajnejn annwali? Iva/Le • L-aħħar vista _____	
Biokimika	
Testijiet tad-demm	
L-aħħar vista _____ • Glycated hemoglobin (hba1c) _____ _____ _____ L-aħħar vista _____ • Test taz-zokkor _____ _____ _____ L-aħħar vista _____ • Test tal-kliewi _____ _____ _____ L-aħħar vista _____ • Test tal-fwied _____ _____ _____ _____	

L-aħħar vista _____ • Test tax-xaħmijiet fid-demm _____ _____ _____	
Tabib/Speċjalista	
• L-aħħar vista _____ • Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm iżżomm mal-appuntamenti tat-tabib? 1 2 3 4 5 • Minn skala ta' 1 sa 5 (fejn l-5 huwa l-ikbar u l-1 huwa l-izgħar), kemm taqbeż appuntamenti tad-dijabete? 1 2 3 4 5	

Kwistjonijiet ta' kura farmaċewtika			
N.	**Dominju Primarju**	**Kodiċi**	**Klassifikazzjoni**
1.	Pazjent/a	1.1 1.2 1.3 1.4	Il-pazjent/a ma kellu/ha bżonn l-ebda intervent Il-pazjent/a għandu/a bżonn parir mediku Il-pazjent/a għandu/a bżonn monitoraġġ Miżura/i tal-istil tal-ħajja
2.	Preskrivent	2.1	Riferiment għall-preskrivent

Noti għar-referenza:

<u>It-Tieni Laqgħa mal-Pazjent</u>

Data _____

Kwistjonijiet farmaċewtiċi mill-ewwel laqgħa	**Intervent/Bżonn li ntlaħaq**

Intervent			
1.	Intervent aċċettat	1.1 1.2	Intervent aċċettat Intervent mhux aċċettat
2.	Status tal-pazjent/a	2.1 2.2 2.3	Il-pazjent/a j/tinsab aħjar Il-pazjent/a għandu/ha bżonn aktar kura Il-pazjent għandu bżonn referenza

Noti għar-referenza:

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Appendix 2

L-Università ta' Malta

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Ref No: MED-2022-00173

1 November 2022

Ms Justine Borg
8 RED ROSE
TRIQ IL-MUSKATELL
ATTARD
ATD2732

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Pharmacist Clinical Diabetic Patient Review

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee

Appendix 3

Abstract accepted for poster presentation at the 81st FIP World Congress of Pharmacy and Pharmaceutical Sciences, Brisbane, September 2023

Development of a toolkit for community pharmacist-led diabetic patient clinical review

Justine Borg, Francesca Wirth, Lilian M. Azzopardi

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

Background: Community pharmacists are strategically positioned to support and empower diabetic patients to manage their condition and reduce long-term risks. Toolkits are useful to aid in the assimilation of evidence-based interventions in a practical scenario.

Purpose: To develop, validate and test the feasibility of a toolkit for community pharmacist-led diabetic patient review.

Method: A toolkit for community pharmacist-led diabetic patient review was developed in English and Maltese. The toolkit is intended to be completed by the community-based pharmacist via patient interview. The developed toolkit was validated for content relevance, comprehensiveness and presentation by an expert panel consisting of six members, including a consultant diabetologist and endocrinologist, a general practitioner, a community pharmacist, a pharmacist in academia and two laypersons. Feasibility testing of the toolkit was conducted in a community pharmacy on 6 patients selected by convenience sampling.

Results: The validated toolkit consists of six sections: 1) assessment of patient current medications at baseline and plan of patient review session, 2) medication adherence and patient self-monitoring, 3) lifestyle including diet, nutrition, physical activity, smoking, alcohol consumption, sleep hygiene, 4) occurrence and monitoring of complications, such as eye and foot complications, 5) monitoring of laboratory investigations, and 6) referral for

general practitioner or specialist review as necessary. During the feasibility testing, the first section of the toolkit was compiled through the electronic patient profile and any pharmaceutical care issues were identified. During the patient review session (t1), sections 2 to 6 of the toolkit were completed. A pharmaceutical care plan was developed for each patient to address issues, and interventions were proposed. A follow-up session (t2) was conducted after one month to assess actioning of the care plan. Mean duration (t1) was 14 minutes (range 11-18) and mean duration (t2) was 4 minutes (range 2-8).

Conclusion: The devised toolkit is feasible and has potential to strengthen pharmacist-patient relationship, support patient empowerment for them to have an active role in their health, and act as a tool for integrated patient management.

Topic area: Community Pharmacy

Abstract accepted for poster presentation at the ESCP Symposium, Aberdeen, October 2023

Community Pharmacist-Led Clinical Review for Diabetic Patients

Justine Borg, Francesca Wirth, Lilian M. Azzopardi

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

Background and Objective: Community pharmacists have a strategic position to conduct pharmaceutical care interventions and contribute to patient management in diabetic patients. The aims were to develop and implement a diabetic patient review toolkit and evaluate pharmacist interventions in community pharmacy.

Setting and Method: A toolkit was developed and validated. Patients (N=60) registered with a private community pharmacy, taking at least one antidiabetic medication were invited to the study. At baseline (t0), medications were compiled through the electronic patient profile prior to the first session (t1) with the patient, and any pharmaceutical care issues identified were documented. At t1, the pharmacist reviewed medications and assessed patient diabetic knowledge, medication adherence, diabetic complications, lifestyle, laboratory investigations and monitoring using the devised toolkit. An individualised pharmaceutical care plan was developed for each patient to address issues, and interventions were proposed. Follow-up after one month (t2) was conducted to assess actioning of the care plan.

Main outcome measures: Pharmacist intervention in diabetic patient review

Results: Fifty-five patients completed the study; male (n=29), mean age 61 (range 24-92) years, diabetes type 2 (n=41), mean number of medications per patient 5 (range 1-11). Mean

duration of the review was 15 minutes (range 10-25) for t1 and 3 minutes (range 2-7) for t2. Metformin was the most common antidiabetic medication (n=34), followed by insulin glargine (n=17). A total of 160 pharmaceutical care issues were identified in 50 patients; patient education-related (n=127) or drug-related (n=33). Patients required education regarding medication usage, adherence, and storage (n=28), lifestyle modifications (n=26), and self-monitoring (n=23). Drug-related issues were inappropriateness of drug selection (n=18), dose selection (n=9) or use by patient (n=6). General practitioner/specialist referral was needed for 9 patients. At t2, 104 interventions were addressed. Implementation rate of interventions was highest for dose selection (89%), followed by patient medication handling (83%), medication use (68%), lifestyle (67%), self-monitoring (60%) and drug selection (55%).

Conclusion: The devised toolkit is practical, strengthens pharmacist-patient relationship and supports patient empowerment. Interventions improved patient awareness and led to behavioural changes. A limitation of the study is patient self-reporting.