Point of Care Testing in Community Pharmacy Practice

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

REBECCA ZAMMIT

Department of Pharmacy

University of Malta

2021

University of Malta Library – Electronic Thesis & Dissertations (ETD) Repository

Dedicated to my late grandparents

Acknowledgements

A number of people have shown never-ending support throughout these three fruitful years. I would like to thank my supervisor Dr Francesca Wirth and co-supervisor Professor Lilian M. Azzopardi, Head of the Department of Pharmacy for her continuous guidance throughout the PharmD course. Heartfelt thanks go to all the academic and administrative staff at the Department of Pharmacy.

My sincere gratitude goes to all the management and colleagues from Browns Pharma Ltd. as without them this would surely not be possible. My appreciation goes to all the panel of experts and all the patients who have taken their time to participate in this study.

I am forever grateful to Professor Liberato Camilleri for helping me with the statistical analysis.

On a personal note, my backbone throughout this journey, my family and Gabriel. I thank you for all the support and for sharing this journey with me.

Abstract

Community pharmacists are accessible health professionals who play a key role in the prevention and management of non-communicable diseases (NCDs). Point-of-care testing (POCT) service provision by community pharmacists has the potential to facilitate pharmacist intervention with respect to NCDs.

The aim of this research was to assess the feasibility and impact of POCT offered in community pharmacies for NCDs. The objective was to develop a framework for a collaborative care model to ensure consistency and standardisation in the provision of POCT services by community pharmacists.

A POCT service covering blood glucose, total cholesterol and triglycerides, blood pressure and body composition measurement was planned. A framework was developed and validated. A document was prepared and used to ensure standardisation and consistency by community pharmacists in offering the POCT service, and reliability, practicality, and feasibility in compiling the data collection sheet and of the testing process were established. The POCT service was implemented on 80 patients identified by convenience sampling from 4 community pharmacies. Test results were interpreted and an action plan for each patient was developed (t1). The action plan reflecting test results consisted of: lifestyle advice, referral to general practitioner (GP), referral to emergency department, and retesting at three (t3) and six (t6) months.

Of the 80 patients, 43 were female, mean age was 60 years (range 19-85 years) and patients were taking a mean of 2 medications daily (range 1-6 medications daily). At t1, all patients were offered lifestyle advice, patients were referred to a GP due to out-of-range blood pressure (n=17), out-of-range blood pressure and fasting blood glucose

(n=4) or due to elevated fasting blood glucose levels (n=2). Of the latter, 2 patients were started on antidiabetic treatment by the GP. Of the 80 patients, 56 patients were asked to retest at t3 and 24 patients at t6. At t3, 23 patients were tested and a statistically significant improvement (p<0.05) was observed through reduction in the level of systolic blood pressure (n=11), total cholesterol (n=9) and fasting blood glucose (n=6). At t6, 10 patients were tested, maintaining all parameters within range.

The outcome of this study was the development of a framework to ensure standardisation and consistency in the provision of POCT services by community pharmacists. The results indicate that provision of blood pressure, blood glucose and lipid profile POCT in community pharmacies is feasible and effective since improvement in test parameters at follow-up was observed.

Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

BMI	Body Mass Index
CVD	Cardiovascular Disease
DRP	Drug Related Problem
EAS	European Atherosclerosis Society
ESC	European Society of Cardiology
ESH	European Society of Hypertension
GP	General Practitioner
HbA1c	Haemoglobin A1c
HIV	Human Immunodeficiency Virus
INR	International Normalised Ratio
LDL	Low-Density Lipoprotein
NCD	Non-communicable Disease
NICE	National Institute for Health and Care Excellence
POC	Point-of-care
POCT	Point-of-care testing
WHO	World Health Organisation

Chapter 1

Introduction

1.1   Point-of-Care Testing

Point-of-care testing (POCT) involves the rapid testing for biomarkers within a direct patient service that facilitates disease diagnosis, monitoring and management (Vashist, 2017). POCT is efficient, accurate and non-invasive, and implementation of POCT services has led to positive outcomes in a number of healthcare sectors (Luppa et al., 2011; Wang and Kricka, 2018; Lingervelder et al., 2019), including in community pharmacies (Roszak and Ferreri, 2020). The benefit of result rapidity allows healthcare professionals to instantaneously offer patient care and interventions (Rajendran and Rayman, 2014; Wang and Kricka, 2018). The shorter time required to initiate treatment in certain patients can be crucial for a positive patient medical outcome (Rajendran and Rayman, 2014).

POCT involves the analysis of patient specimens outside a centralised laboratory by healthcare professionals and includes patient self-monitoring (Florkowski et al., 2017). The shift from utilising large complex equipment to simple devices being used outside the hospital care setting has been introduced over the years (Luppa et al., 2011; and Musaad, 2021). Advancement in technology has improved testing to become more available and portable (Rooney and Schilling, 2014; Wang and Kricka, 2018), providing patients with immediate access to healthcare when it is required (Francis and Martin 2010; Herd and Musaad, 2021). The World Health Organisation (WHO) states that the key characteristics that POCT should offer follow the acronym 'ASSURED', namely 'Affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and delivered' (Buss et al., 2019).

With the introduction of POCT services, barriers have been reduced with regards to time constraints in obtaining results and to make a clinical decision, and the need for specialised laboratory personnel (Hardy et al., 2016), resulting in an overall improvement in healthcare being observed (Saleem, 2018; Price and St John, 2019). Devices, namely blood glucose and blood pressure monitors, have been available for decades (Tanyanyiwa et al., 2015). Newer POCT devices, such as for testing of infectious diseases including human immunodeficiency virus (HIV) and testing for international normalised ratio (INR), have become available over the years (Saleem, 2018; Park, 2021). By incorporating POCT programmes within community pharmacy practice, the intervention of the pharmacist is strengthened together with the aim to further support public health (Hohmeier et al., 2017). A pharmacist can contribute greatly to the healthcare system by providing health screening services to prevent illness, monitor health and aid in medication therapy management (Hohmeier et al., 2017; Rodis et al., 2017).

Due to an increase in the number of older persons, a higher burden on healthcare systems is being observed (Steltenpohl et al., 2018). According to the WHO, the number of persons aged 60 or older in 2019 was 1 billion and it is forecasted to increase to 1.4 billion by 2030 and 2.1 billion by 2050.[1] The largest increase is mainly seen within developing countries. With an increase in the number of elderly, a shift in the reasons for mortality and morbidity has been documented. In the recent pre-COVID-19 era, the leading cause of death was due to chronic non-communicable diseases (NCD) and not

---

[1] World Health Organisation. WHO Ageing [Internet]. Switzerland: WHO; 2021 [Cited 2021 Jun 04]. Available from: https://www.who.int/health-topics/ageing#tab=tab_1

due to infectious diseases. NCDs are considered a heavy burden which are negatively affecting healthcare systems. Strategies need to be implemented to prepare healthcare systems for the eventuality of a continued increase in NCDs within ageing populations. Strategies and targets are already being implemented by individual countries, but other countries require further support. Pharmacists are respected, knowledgeable and accessible members of the healthcare team. By having tools ready at their disposal, pharmacists can maximise their potential, strengthen public health and provide sustainable healthcare services for overall better patient health outcomes. By having the majority of community pharmacies providing POCT services, community and patient health has the potential to be greatly improved (Kovačević et al., 2018; Goode et al., 2019; Smith and Rains, 2020).

1.2   Non-communicable diseases

According to the WHO, NCDs, which are known as chronic diseases, include non-infectious diseases of long duration.[2] The most common diseases include heart disease, stroke, cancer, respiratory diseases and diabetes mellitus. This group of diseases are commonly referred to as 'silent killers' due to showing no symptoms until the disease progresses to an advanced stage (Budreviciute et al., 2020). NCDs are mostly associated with the elderly, however all ages can be affected, even before birth, in both developed and developing countries (Islam et el., 2014; Mossialos et al., 2015). The WHO states that NCDs are responsible for 80% of deaths worldwide and are responsible for the

---

[2] World Health Organisation. WHO Noncommunicable Diseases [Internet]. Switzerland: WHO; 2021 [Cited 2021 Jun 04]. Available from: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

majority of 'premature' deaths of persons between the ages of 30 and 69 years, and of these, 85% of 'premature' deaths occur in low-and middle-income countries.[2] The United Nations Sustainable Development Goals have put forward a goal for the year 2030, which estimates to have a third of premature deaths decreased (Nugent et al., 2018). NCDs have a negative impact on health and on economic status (Matheson et al., 2013).

In 2018, a report was published by the WHO on the progress noted by individual countries to overcome NCDs.[3] The report indicated that for Malta, with a population of 429,000, 90% of deaths are due to NCDs.[3] The most common causes of deaths in Malta recorded between 2009 and 2019 include; ischaemic heart disease, stroke, Alzheimer's disease, lung cancer, lower respiratory infections, colorectal cancer, diabetes, chronic obstructive pulmonary disease, chronic kidney disease and breast cancer (Vos et al., 2019). The report indicates the effort which Malta is implementing in the fight towards preventing NCDs. Malta has targets in place, an action plan is set, and focus is being made for the reduction of modifiable risk factors.[3]

Predisposition of individuals to NCDs is affected by a number of risk factors. These numerous risk factors are demonstrated at community level (Allen et al., 2020), and can be a result of a combination of factors, including genetic, physiological, environmental and behavioural factors (Esmailnasab et al., 2012). The risk factors are modifiable and non-modifiable. Non-modifiable risk factors include age, gender and genetics, and the

---

[3] World Health Organisation. WHO Noncommunicable Diseases (NCDs) Country Profiles [Internet]. Switzerland: WHO; 2018 [Cited 2021 Jun 04]. Available from: https://www.who.int/nmh/countries/mlt_en.pdf.

key modifiable risk factors include tobacco use, unhealthy diet, lack of physical activity, harmful use of alcohol and chronic diseases. These risk factors play an important role in the progression of NCDs which can start from an early age. At the foetal stage, lifestyle choices made by the mother, such as smoking or drinking alcohol, and environmental factors which are not directly controlled by the mother, can contribute to the development of NCDs. Evidence shows that environmental factors early in life have an impact on the possibility of the development of NCDs in the future (Baird et al., 2017). An approach which is taken into consideration for the prevention of NCDs is 'life course epidemiology' (Kuh et al., 2003). 'Life course epidemiology' is the study of biological, behavioural, and psychosocial processes which link adult health and disease risk to physical or social exposures (Kuh et al., 2003; Baird et al., 2017). This concept aims at focusing on the opportunity to make decisions in life to prevent the development of chronic diseases (Baird et al., 2017). Since risk is accumulated over the course of many years, with the peak risk reached in adulthood, early identification is favoured through testing together with lifestyle interventions or modifications to identify and manage diseases in the early stages (Baird et al., 2017).

Modifiable risk factors can be modified in a behavioural manner, which can be supported by healthcare professionals, the government and specialised programmes (Lim et al., 2013; Islam et al., 2014). Although the risk factors are modifiable, they are considered to provide an extensive burden of disease. Metabolic risk factors increase the risk for NCDs, including patients with raised blood pressure, obesity or overweight, hyperglycaemia and hyperlipidaemia (Esmailnasab et al., 2012). High blood pressure is

the leading metabolic factor attributing to global disease burden and 19% of deaths annually, followed by obesity and high blood glucose (Tanaka and Itoh 2019).

In addition to the major key risk factors, a number of social determinants play a role in the development of NCDs (Sharma et al., 2020). The major social determinants include poverty, lack of educational opportunities for individuals and unemployment or minimum or low wage employment (Allen et al., 2020). A relationship is observed between people of lower economic class and having a higher risk of developing NCDs (Marmot and Bell, 2019). These risk factors are a target for the governments to implement strategies to overcome the social determinants which will improve public health, quality of life and reduce the prevalence of NCDs, leading to a reduced burden on the healthcare systems (Allen et al., 2020).

Healthcare professionals play an important role in the management of NCDs. The method of management is based on prevention and screening, where each country will adopt a strategic plan which best suits the resources available. In this way, NCDs targets are aimed to be met. Cost effective and feasible services offered by healthcare professionals should aim at contributing to the reduction of NCDs, which will lead to a decrease in morbidity, mortality and improve overall health outcomes (Sousa Pinto et al., 2019).

1.2.1 Prevention and Screening

The need to discuss improvements which are required when focusing on NCDs are inevitable due to the rising mortality and morbidity (Waszyk- Nowaczyk et al., 2018). A contribution by Wendimagegn and Bezuidenhout (2019), reports that nearly each person will experience and possibly succumb to chronic conditions and their complications in his or her lifetime, and that it is crucial to focus on preventative services which are cost-effective and have a high health impact. The authors put forward aspects when taking into consideration the number of risk factors which contribute to the development of NCDs, a 'small' number of risk factors are responsible for a 'large' number of diseases and disease burden, which is observed worldwide. An approach that recognises the reality and impact of chronic diseases aims at preventing and managing the conditions whilst maintaining a healthy lifestyle over the lifetime of the patient (Mc Namara et al., 2017). Developed and developing countries are focusing their strategies towards reducing the overall burden of NCDs by emphasising on feasible and sustainable methods for prevention, management and screening (Mc Namara et al., 2017; Wendimagegn and Bezuidenhout, 2019).

Prevention and screening methods are vast and are dependent on the resources and budget available for the community. By offering POCT services and incorporating community pharmacist intervention to identify risk factors for NCDs, a preventative care plan can be developed (Bacci et al., 2018). A preventative healthcare plan has been shown to be effective in preventing a large proportion of deaths (Sousa Pinto et al., 2019). For this reason, screening programmes which are pharmacy-based and run by

community pharmacists using uncomplicated medical devices with appropriate result interpretation and action planning, can help in reducing the NCDs invisible epidemic (Bacci et al., 2018).

A suggested method for prevention of NCDs can be achieved with the use of POCT (Malcolm et al., 2019). POCT can be used to prevent persons from developing chronic diseases or reducing disease progression. Testing should be performed on both symptomatic and asymptomatic individuals as a valuable opportunity for health promotion and prevention (Wendimagegn and Bezuidenhout, 2019). Pharmacist intervention should consist of basic screening for NCDs with the use of available POCT devices, obtaining a detailed past history and assessing relevant risk factors which may affect the prognosis of the patient (Choudhary et al., 2020).

Through screening for unidentified diseases or risk factors by pharmacists, diseases can be identified in the early stages (Waszyk- Nowaczyk et al., 2018). With the intervention of pharmacists in offering POCT services, educational care follows as an important role, mainly with regards to diet, physical activity, smoking and alcohol. Clear interpretation of results is deemed necessary, together with a detailed educational plan for the patient to follow. Patients are to be referred to their general practitioner (GP) or specialist based on the results obtained, and in this way GP services are used more effectively and efficiently due to avoiding unnecessary GP visits (Sousa Pinto et al., 2019). This structure highlights the collaborative practice between pharmacists and GPs. A similar collaborative practice model between healthcare professionals and taking into consideration POCT, was described by Gubbins et al., (2017), who presented a

comprehensive literature review on POCT for infectious diseases. Gubbins et al explain that by providing and strengthening community health and improving health care delivery, infectious diseases can be identified at the point-of-care (POC), in the fight against antibiotic resistance. By outlining a collaborative workforce with the use of POCT by community pharmacists and communicating with GPs, Gubbins et al., conclude that such services will collaboratively reduce excessive and unnecessary use of antibiotics. By using a similar model for NCDs, the services offered by community pharmacists are capable of identifying disease states early, monitoring known conditions and reducing disease progression. Poor communication and collaborative practice between healthcare professionals can negatively affect the health services and patient care offered (Freeman et al., 2016).

1.2.2   Cardiovascular Disease

CVDs are the leading NCD globally and account for the largest number of deaths, with a higher number of deaths compared to cancer or respiratory diseases (Hunter and Reddy 2013; Budreviciute et al., 2020). CVDs are responsible for 17.9 million deaths annually worldwide (Budreviciute et al., 2020). CVDs are not only affecting older populations but an increase in younger adults being diagnosed with CVDs has been observed. At the POC, blood pressure monitoring is an easy parameter which can be monitored. Blood pressure is an important risk factor to be monitored for CVD together with other tests such as total cholesterol, triglycerides, body mass index (BMI) and blood glucose. These parameters are identified by the American Heart Association

together which other risk factors such as diet, physical inactivity, smoking and obesity or overweight (Budreviciute et al., 2020).

Elevated blood pressure is a major health problem leading to a number of cardiovascular problems, namely myocardial infarction, heart failure and stroke. By providing optimal management and appropriate recommendations to significantly reduce risk factors which lead to CVD a significant risk reduction in the population is noted (Amadi et al., 2020). According to the WHO, it is estimated that 1.13 billion people worldwide have hypertension and it is a major cause of premature deaths.[4] CVDs can easily go unnoticed as symptoms develop when the disease has progressed, and at this stage the disease is commonly complicated, for example leading to myocardial infarction.[4] Screening programs have been shown to detect high risk patients during the early stages of the disease (Jahangard-Rafsanjani et al., 2017). In this way by identifying such patients, the disease state can be managed and support is provided in controlling modifiable risk factors to reduce overall mortality and morbidity (Jahangard-Rafsanjani et al., 2017).

Elevated total cholesterol and triglycerides are two parameters which increase the risk for CVDs. In addition to changes in behavioural risk factors, available literature shows the effects of red yeast extract, a natural ingredient which has been used for centuries and has recently been exposed to research interest due to its positive effects (Mach et al., 2020). Red yeast extract is produced by culturing the yeast Monascuspurpureus on

---

[4] World Health Organisation. WHO Hypertension [Internet]. Switzerland: WHO; 2021 [Cited 2021 Jun 10]. Available from: https://www.who.int/news-room/fact-sheets/detail/hypertension

rice (Verhoeven et al., 2013), which forms a mixture of monacolins that inhibit hydroxymethylglutaryl- coenzyme A (HMG-CoA) reductase and hence decrease cholesterol synthesis in the liver (Verhoeven et al., 2013). A study by Verhoeven et al. (2013), shows a statistically significant decrease in cholesterol levels after the consumption of red yeast extract when compared to placeboAnother study by Heinz et al., (2016), documented a 15% decreased in LDL levels. Community pharmacists can consider recommending this over-the-counter supplement for patients with elevated cholesterol levels.

1.2.3   Diabetes Mellitus

Diabetes and elevated blood glucose are leading contributors to the global burden of disease (Alzubaidi et al., 2019). Although patients can solely suffer from diabetes, a number of complications are associated with the longstanding condition and diabetes commonly co-exists with CVD (Alzubaidi et al., 2019). Diabetes is a leading problem around the world and is prominent in Malta. Attention is generally given to diabetes since it is a major NCD and is associated with severe life-threatening complications which are responsible for long duration hospital admissions and polypharmacy (Budreviciute et al., 2020). Diabetes-related complications include ischaemic heart disease, stroke, kidney failure, blindness, depression and limb amputation (Papastergiou et al., 2016). Significant contributors are inappropriate diet and physical inactivity (Chaudhury et al.,2017). In the United States, 9.3% of the population had diabetes in 2012, and out of these 29.1 million persons, 8.1 million were undiagnosed (Alfayez et al., 2017).

When analysing worldwide data, 45.8% of diabetes cases are undiagnosed and this can be overcome by focusing on early detection through screening programmes with effective prevention interventions and patient education (Alzubaidi et al., 2019). A report by Papastergiou et al., (2016), explains that the increasing number of patients diagnosed with diabetes has an effect on the healthcare system sustainability. This report highlights that the annual cost for diabetes care in Canada amounted to $11.7 billion up until 2016, and this expense is anticipated to increase over the years, with diabetes-related complications accounting for 80% of the costs (Papastergiou et al., 2016). Apart from the economic burden, the disease has a negative impact on the patients' quality of life regardless of gender, as well as with imposed difficulties for family members and caregivers (Prajapati et al., 2017).

With the community pharmacist being ideally positioned, blood glucose testing can be offered to increase awareness of monitoring and to maintain appropriate blood glucose levels (Nowak et al., 2002; Papastergiou et al., 2016; Yaghoubi et al., 2017; Bukhsh et al., 2018). In addition to fasting blood glucose, HbA1c testing is another POCT which allows pharmacist involvement in diabetes care (Papastergiou et al., 2016; Alfayez et al., 2017; van Eikenhorst et al., 2017; Kharjul et al., 2018). The benefit to having POCT performed by pharmacists for the management of diabetes, and offering testing and patient education have been explored by a number of studies (Collins et al., 2011; Alfayez et al., 2017; Fazel et al., 2017; van Eikenhorst et al., 2017; Roszak and Ferreri, 2020). A study conducted by Peasah et al. (2020), demonstrated the effectiveness of student pharmacist-led telephone calls for the improvement of HbA1c levels. Clinical sessions offered by pharmacists have positively affected disease management and

reduced GP visits (Odegard et al., 2015) and literature highlights the importance and benefit of interprofessional collaborative practice for diabetes management (Nagelkerk et al., 2017; Pascucci et al., 2021).

1.2.4   Obesity

Diet and physical inactivity are the largest hurdle faced in the fight to reduce NCDs (Cammock et al., 2021). A patient being obese or overweight is a common risk factor for NCDs, including CVDs and diabetes mellitus. A study conducted by Wolfenden et al., in 2019 reviewed 40 trials performed in the United States and Australia, and showed that the most common risk factor for obesity was unhealthy diet. Although poor diet is common in childhood, the introduction of processed foods, sugar-containing drinks, and an overall high BMI have had a direct negative impact on NCDs (Baird et al., 2017, Budreviciute et al., 2020). Natural foods are now replaced by unhealthy food options, together with a decline in physical activity, which have shown a rapid increase in NCDs (Budreviciute et al., 2020). Patients should be educated by different platforms at all ages, including governmental and non-governmental organisations, and to provide information on the importance of dietary changes to achieve progress on a larger scale. Education starts from school for young children, advertisements for the general public, followed by healthcare professionals who should address diet and lifestyle issues with their patients (Wolfenden et al., 2019).

For this reason, a healthy lifestyle should be promoted to all patients. Diet forms part of a self-management programme, together with smoking cessation, decrease in alcohol

intake and increase in physical activity. Lifestyle activities include healthy diets and focus on limiting the use of salt, sugar, and saturated fats (Budreviciute et al., 2020). Patients should be guided by evidence-based practices of leading a healthy lifestyle. This is a role of community pharmacists and of health authorities where health promotion should be a priority. Common health promotions which are noted in Malta and in other countries are health campaigns, social media promotion, use of leaflets and advertisements (Couch et al., 2017; Kite et al., 2018).

1.3   Economic Burden of NCDs

One in three adults live with multiple chronic condition, or multiple chronic conditions which cause a health and economic burden (Marengoni et al., 2011; Hajat and Stein, 2018). Healthcare is one of the largest portions of a country's yearly budget. With the increase in NCDs more money is being invested to cover the costs associated with these chronic conditions, with the largest costs being dedicated to hospital admissions (Damery et al., 2015). A relationship exists between population health and economic growth (Bloom et al., 2018) in both developed and low and middle-income countries (Chen et al., 2018). Prevention and screening of NCDs is an investment where behavioural and lifestyle risk factors need to be addressed (Yang et al., 2018). The investment to control NCDs leads to a high economic return for countries in the long term as conditions are identified in the early stages and would require less intensive and costly interventions (Nugent et al., 2018).

This is well described by the 'Lancet Taskforce on NCDs and Economics', who report that NCDs are a burden on the economic growth and development of a country (Nugent et al., 2018). The authors explain that there is evidence which shows that it is important to have a work environment of good health together with the promotion of a healthy working life and maintaining a person's wellbeing to achieve sustainable economic growth. Due to the presence of a high mortality and morbidity rate, a decreased income for households is observed, since individuals are required to retire earlier than is intended (Bertram et al., 2018). The decreased income negatively impacts the economic status of families and the country. The vicious cycle of NCDs affects patients during their most productive years, hence certain conditions do not render individuals to continue working, which leaves families struggling and at a high financial risk (Bloom et al., 2018; Nugent et al., 2018).

Interventions to reduce the burden of NCDs need to be cost-effective together with producing the maximum health benefits for patients, with the use of minimum resources (Wendimagegn and Bezuidenhout, 2019). Investing in policies aids in reducing risk factors which include tobacco smoking, alcohol, diet and physical inactivity. Overall, implementation of effective, feasible and cost-effective policies are beneficial for NCDs (Phulkerd et al., 2016).

1.4   Community Pharmacist Practice

Globally, changes have been observed in the quality and processes of healthcare professionals. An example is with respect to the role of pharmacists which has been

evolving for a number of years (Saavedra-Mitjans et al., 2018). The duties and responsibilities of pharmacists have evolved towards patient-centric activities and direct patient care (George et al., 2010; Sadek et al., 2016). The conventional perception of pharmacist duties to only dispensing medications nowadays no longer applies and a clinical aspect of pharmacy and pharmacist roles has become a more appropriate description of pharmacist duties (Inamdar et al., 2018). An example can be taken with the changes in regulation and legislation in Canada, who have supported the transition in pharmacy practice through regulations and promoting pharmacist renewal, adjustments, initiation and substitution of prescriptions, together with interpretation of laboratory results (Donald et al., 2017). Other countries such as United Kingdom, Australia and the United States have recognised the extended roles of pharmacists and in these countries, pharmacists provide a wide range of interventions reflecting direct patient care (George et al., 2010; Kelling et al., 2016; Koehler and Brown, 2017; Sousa Pinto et al., 2019). Pharmacists have the appropriate training and knowledge and are very well positioned to improve the healthcare system and to empower patients to take care of their own health (Kibicho and Owczarzak 2012; Gordon et al., 2017; Smith and Wick, 2018; Newman et al., 2019).

The pharmacist in community is a pivot of care to a number of patients and to no specific patient age group, although the elderly population show to avail of the services offered by pharmacists more compared to younger persons. The community pharmacist is easily accessible to patients with a large number of patients visiting their community pharmacist on a daily basis. This makes community pharmacists well positioned for contribution towards identifying and monitoring minor ailments and chronic conditions.

In general, a number of patients may rarely visit their primary healthcare provider or do not have a primary healthcare provider. Since pharmacists are one of the most accessible healthcare professionals, patients frequently seek advice from a pharmacist (Jahangard-Rafsanjani et al., 2017; Kember et al., 2018). A local study by Wirth et al (2011), determined the perception of Maltese consumers towards community pharmacists and the services which they offer. The study observed a positive overall perception by consumers and consumers were in favour of the extended roles of the community pharmacist. Another local study by Vella et al (2015), was in agreement that Maltese consumers perceive community pharmacist extended professional roles as important.

Various studies show that with the accessibility of the community pharmacist, a large contribution is made towards the management of chronic conditions together with health promotion and disease prevention (Brown et al., 2016; Kelling et al., 2016; Jahangard-Rafsanjani et al., 2017; Agomo et al., 2018; San-Juan-Rodriguez et al., 2018). Pharmacist intervention results in improvement in overall patient outcomes and lowering of healthcare costs (Marra et al., 2017; Cutler et al., 2019; Newman et al., 2019). A study performed in Australia showed that with pharmacist-led interventions focusing on medication non-adherence, a reduction in financial burden is absorbed after funding medication adherence programmes, and this will overall reduce the current burden and improve patient health outcomes in the future (Cutler et al., 2019).

The community pharmacist has evolved to be involved in clinical settings and has further engaged with healthcare professionals (Sousa Pinto et al., 2019). For health

targets to be met in Malta, community pharmacists must continue to evolve and improve their vital role in public health promotion, engage in preventative screening, and refer patients who are at moderate or high risk for developing NCDs, support prescribing together with improving patient safety and adherence to therapy.

A local study by Ungaro et al., (2015), explored the implementation of POCT services within a community pharmacy setting for the analysis of microalbuminuria in urine for diabetic patient management. Testing was performed for all the patients recruited and for patients who tested positive for microalbuminuria, HbA1c testing was further performed. The majority of the patients tested in this study agreed that testing in community pharmacies is useful, accessible and that they would avail of such services if offered. Another local study by Muscat et al., (2017), implemented chronic disease management services within a community pharmacy setting and aimed to identify drug related problems (DRPs). During the intervention, blood pressure, blood glucose, HbA1c and lifestyle advice was offered to all patients. An individual care plan was developed and recommendations on DRPs were discussed with the patients. Follow-up was performed after four months to assess health improvements following intervention. The study concluded that the implemented service had a significant positive impact and the role of pharmacists should be expanded in offering chronic disease management and patient monitoring.

Another local study by Scicluna et al., (2019) explored the efficacy of haemoglobin POCT in patients suffering from chronic kidney disease as a screening tool to monitor

patients using two POCT devices.[5] This study evaluated pharmacist and patient perspectives for the introduction of the service within community pharmacy, and the majority of both groups were willing to offer or pay for the service respectively. Another local study by Mifsud et al., (2019), implemented a pharmacist-led medication use review which included POCT for INR in patients on warfarin, identification of DRPs and clinical recommendations for patients tested. This study concluded that pharmacist-led medication use review services offered within community pharmacy contribute to the improvement of INR control. Another local study by Micallef and Azzopardi in 2019, planned the design of a structure for pharmacist-led POCT and pharmacist prescribing for the most common NCDs, namely hypertension and diabetes mellitus in adults.[6]

A number of factors have been identified from literature which indicate difficulties for the expansion of the roles of pharmacists (Patton et al., 2018). These factors include time which the community pharmacist has available to offer services, lack of relationship between pharmacist and physicians, lack of patient medical information and absence of financial compensation for pharmacists (George et al., 2010; Bergman et al., 2016; Patton et al., 2018). The approach needed is a holistic one since pharmacists cannot work alone in the fight against NCDs. During a WHO Global Conference held in 2018, "Global dialogue on partnerships for sustainable financing of NCD prevention

---

[5] Scicluna M, Wirth F, Azzopardi LM. Haemoglobin point-of-care testing. Poster presented at the 48th ESCP Symposium on Clinical Pharmacy, Ljubljana, Slovenia; 2019 [Cited 2021 Jun 04]. Available from: https://www.um.edu.mt/library/oar/handle/123456789/54054

[6] Micallef T, Azzopardi LM. Supplementary pharmacist prescribing and point-of-care testing in community pharmacy. Poster presented at the 48th ESCP Symposium on Clinical Pharmacy, Ljubljana, Slovenia; 2019 [Cited 2021 Jun 04]. Available from: https://www.um.edu.mt/library/oar/handle/123456789/54053

and control" a number of key points were discussed (Sousa Pinto et al., 2019). One of the key points discussed was that all healthcare professionals play an important role in the healthcare chain. Within the primary healthcare setting, prevention, diagnosis, drug delivery, medication adherence and early screening need to take priority in practice. For this reason, a community pharmacist plays an important role in the screening, testing, advanced counselling and long-term management of chronic conditions (Sousa Pinto et al., 2019).

1.5   Point-of-Care Testing Feasibility

For the implementation of screening services for the prevention of NCDs, methods used need to be analysed and recognised as being feasible (Ayorinde et al., 2013). The methods identified need to be performed by a number of pharmacists within different environments and settings. For this reason, the methods or services chosen need to be validated, standardised and proven feasible. A number of testing methods can be taken into consideration and the preferred methods are chosen according to resources available and identifying the best fit for the chosen setting. For this study, POCT within community pharmacy was taken into consideration and the feasibility of performing POCT needs to be evaluated in the Maltese setting. For the purpose of this study, literature regarding the preferred testing methods in other countries and the assessment of their feasibility were analysed. POCT identifies patients who are at high or moderate risk of developing NCDs, in monitoring changes in increasing or decreasing the risk and aiding in drug therapy management. The benefit of testing is to identify disease at early stages so that an immediate action plan can be implemented.

A study performed by Jahangard-Rafsanjani et al. (2017), aimed at assessing the feasibility of implementing a CVD screening service within community pharmacy in Iran. In the study, the investigator evaluated patient demographics, past history, risk factors and measured patients' height, weight, waist circumference, blood pressure, random blood glucose level, cholesterol levels through capillary blood samples. Referral criteria were developed and recommendations on diet, weight management, reduction in risk factors and education on the testing which was performed was offered to patients. The results showed feasibility of testing and that screening services are capable of identifying patients at high risk. From this study, around 50% of the patients tested had one risk factor for CVD and were referred to the GP. Lipid abnormalities were greatly identified together with patients who required additional treatment for hypertension. Overall, a positive impact of services offered by community pharmacist was observed.

Another study which aimed at identifying feasibility of novel screening approaches was by Kachimanga et al., (2017). This study was performed in Malawi and describes three screening programmes for the identification and prevention of NCDs using simple POCT services in community pharmacies. The main focus was on diabetes and hypertensive patients. This study describes that by offering screening services for NCDs, entry into primary care and routine monitoring are observed. An important point from this study included development of guidelines and protocols for the screening programmes to enable training of staff who are performing the tests to take standardised clinical decisions to ensure consistency. During the programme, 8133 patients were screened for hypertension and 3% were referred to a chronic care clinic, and with

regards to diabetes, 4016 patients were screened of which 3% were referred. The overall outcome of the study suggested that the merging of diabetes and hypertension screening programmes in community pharmacy is feasible and can help in recruiting patients into primary care. This is a feasible method to continue identifying patients at risk of or with present disease.

1.6   Study Setting and Rationale

The setting for the study is community pharmacy. Community pharmacies in Malta are all privately owned, and the majority of chronic medications are collected free of charge from the community pharmacy of the patient's choice every 56 days through the government funded Pharmacy of your Choice (POYC) scheme. Pre-COVID-19, patients visited their general practice or primary healthcare physicians to have their prescriptions refilled every 6 months. Due to the COVID-19 situation, the system went paperless and patients were not required to have prescriptions for medication collection at each dispensing activity. Within the COVID and post-COVID practice, a framework for a collaborative care model needs to be developed, whereby requirements for patients to be referred to a GP are established. Community pharmacist patient monitoring of chronic diseases needs to be supported through POCT and patient reviews, and this puts forward the rationale for the research.

1.7 Aims, Objectives and Research Question

The aims of this study were to assess the feasibility and impact of POCT services offered by community pharmacists. The objective was to develop a framework for a collaborative care model to ensure consistency and standardisation in the provision of POCT services.

The research question looks at the added-value and contribution to improving primary healthcare services and reducing NCDs when POCT is offered by community pharmacists.

Chapter 2

Methodology

A literature search was conducted by searching several bibliographic databases. Keywords used included; 'point-of-care testing', 'community pharmacist intervention', 'pharmaceutical care', 'non-communicable diseases' and 'collaborative practice'.

2.1 Study Design

The study was divided into two phases to develop and implement a framework for provision of POCT services. The first phase involved development of the framework which consisted of a data collection sheet and an action plan which was used during pharmacist intervention and for a one-to-one session with another community pharmacist to ensure consistency and standardisation in POCT performance. Phase 2 involved implementing the framework by performing the service together with data collection, interpretation of results, taking action and putting forward recommendations to patients.

2.2 Establishing Study Sites

The community pharmacies were selected by convenience sampling. A chain of twenty-one community pharmacies were selected for this study. Out of the twenty-one pharmacies, four main pharmacies were chosen for POCT to be performed. From the Northern Harbour District, three pharmacies located in Qormi, Hamrun and San Gwann were selected, and from the Southern Harbour District, a pharmacy in Kalkara was selected. The study was carried out over a seven-month period, between June 2020 and January 2021.

2.3   Study Approvals

Approval for the study was sought from Browns Pharma Ltd. Approval from the managing pharmacist of each of the four selected pharmacies was sought. Ethical approval was granted by the University of Malta Faculty of Medicine and Surgery Research Ethics Committee with reference number: FRECMDS_1920_200 (Appendix 1).

2.4   Development of Framework

A data collection sheet (Appendix 2) was developed. The data collection sheet includes the specific patient study number which is given to each individual patient to keep anonymity. The sheet includes the date and interval of testing, namely initial session (t1), retest after 3 months (t2) and retest after 6 months (t3).

The data collection sheet is divided into four parts. Part one, 'Patient demographics' included locality of the pharmacy in which the tests were performed, gender and age. The second part of the data collection sheet included the test results, divided according to the POCT being conducted, namely fasting blood glucose testing, total cholesterol, triglycerides, blood pressure and BMI measurement. These POC tests were chosen since they are already offered within the community pharmacies selected for the study. Reference ranges and associated risks of test results were included in this section. The third part included an action plan consisting of five actions which could be taken, which

differ for each patient based on result interpretation. The five action plans were identified from evidence-based guidelines (Figure 2.1).
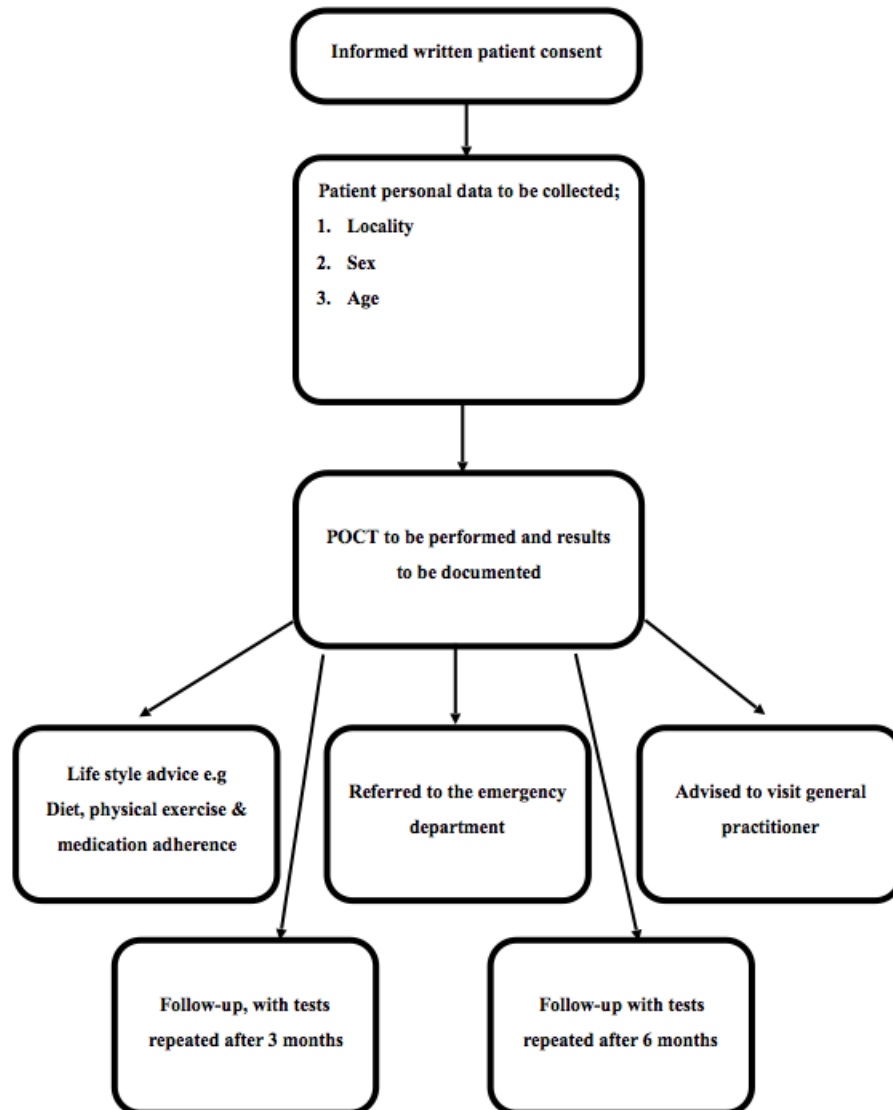
Figure 2.1: Flowchart of study methodology

The action plan was developed for the prevention and control of NCDs to be offered in a standardised way by the community pharmacists. For each action, criteria for the action were explained and included in the data collection sheet. More than one action could be selected for each individual depending on the results obtained. The action plan identified is summarised in Table 2.1.

Table 2.1: Action plan

Action Plan	Criteria
Patient follow-up after 3 months, all tests to be repeated	1. Moderate to high risk blood glucose 2. Total cholesterol >5 mmol/L 3. Triglycerides >2.3 mmol/L 4. Systolic blood pressure between 130-139 mm Hg and diastolic blood pressure between 85- 89 mm Hg
Patient Follow-up after 6 months, all tests to be repeated	1. Moderate blood glucose level <4 mmol/L 2. Total cholesterol < 5 mmol/L 3. Triglycerides < 2.3 mmol/L 4. Blood pressure result of systolic level ≤ 139 mm Hg and diastolic ≤ 89 mm Hg.

Patient advised to visit general practitioner or specialist, all tests to be repeated after 3 months	1. Fasting blood glucose level ≥6.9 mmol/L 2. High blood pressure measuring systolic level ≥140 mm Hg and diastolic level ≥90 mm Hg 3. Total cholesterol >9 mmol/L
Patient referred to the emergency department	1. Blood pressure with values of systolic blood pressure ≥180 mm Hg and diastolic ≥120 mm Hg 2. Younger patients (< 40 years) with grade 2 hypertension should be referred to hospital based- care 3. Blood glucose levels of 13 mmol/L together with hyperglycaemic symptoms
Provide patient with lifestyle advise based on diet, physical activity, tobacco and alcohol reduction	To be provided to all patients and the advice is dependent on the interpreted results which were not within the healthy and advised range.

The fourth part of the data collection sheet includes additional patient information covering current medications, relevant comorbidities and relevant risk factors. The data collection sheet follows a simple design so as to be easily used by community pharmacists in performing the service.

2.4.1 Blood Glucose Testing and Action Plan

The guidelines chosen for the interpretation of the fasting blood glucose result were the National Institute for Health and Care Excellence (NICE) guideline 'Type 2 diabetes: Prevention in people at high risk (PH 38)'[7] and NICE guideline 'Type 2 diabetes prevention: population and community level interventions (PH 35)'[8].

The NICE guidelines provide the risk (moderate or high) of chronic diabetes and recommendations are individualised depending on the risk. For 'low' risk, patients were advised that this does not mean that there is no risk at all, and that an increase in risk can be noted during future testing. All patients were given lifestyle advice and were asked to retested after 3 or 6 months respectively based on the action plan. The NICE guidelines explain the importance of assessing risk according to patient characteristics, hence the data collection sheet included sex, age, relevant risk factors, namely family history, BMI and blood pressure monitoring. The fasting blood glucose value, associated risk, modifiable and non-modifiable risk factors associated with patient characteristics will help to determine the action plan for the patient. In addition to BMI and blood pressure monitoring values, the guidelines emphasise on the monitoring of other parameters, namely lipid profile.

---

[7] National Institute for Health and Care Excellence. NICE Type 2 Diabetes: prevention in people at high risk [Internet]. United Kingdom: NICE; 2017 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph38/resources/type-2-diabetes-prevention-in-people-at-high-risk-pdf-1996304192197

[8] National Institute for Health and Care Excellence. NICE Type 2 Diabetes prevention: population and community level interventions [Internet]. United Kingdom: NICE; 2020 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph35/resources/type-2-diabetes-prevention-population-and-communitylevel-interventions-pdf-1996299153349

For the control and reduction of impaired levels of fasting blood glucose values, the NICE guidelines focus on diet and physical exercise recommendations. The recommendations are based on glucose levels and BMI especially in patients with an elevated BMI value (>25 kg/m²). The NICE guidelines provide recommendations based on the different risks, and this provides a clear, focused and individualised action plan for patients being tested.

The NICE guidelines chosen describe the importance of one-to-one contact with patients, of keeping all medical professionals involved and communicating with the patient in a simple manner with both verbal and written information. This method was adopted during pharmacist intervention. The advice and action plan provided to patients was dependent on risk after testing for fasting blood glucose (Appendix 3).

In patients with low and moderate risk, the individual risk factors were discussed and recommendations for reducing the risk factors were explained. The focus was on how to reduce these risk factors and on how to improve lifestyle. For patients with moderate risk emphasis was made on the importance of self-care. A method which was recommended through the guidelines, and was put into practice was to offer verbal education and written explanations. The written information provided included a diet plan the patient should follow and identification of common foods which form part of the Maltese diet which if consumed in high amounts may increase blood glucose levels (Appendix 3). The importance of increasing physical activity and reducing time spent sedentary was explained to patients. Increase in physical activity should be slow and regular for the body to adapt and build stamina to the exercise. As a general rule, 180

minutes of brisk walking per week was recommended. Tobacco and alcohol reduction was recommended. Smokers and alcohol consumers in this study were recorded.

The NICE guidelines state that in patients who are at 'high' risk of developing type 2 diabetes, intensive lifestyle changes must be adhered to. It is recommended to offer follow-up sessions at shorter intervals, such as 3 months, to support the patient. Diet plans and physical exercise regimens were recommended for patients at high risk of developing diabetes and to those with a BMI classification $\geq$ 25 kg/m^2 (Appendix 3). Patients with a high BMI were encouraged to lose 5%- 10% of their body weight to reduce their risk of chronic diabetes.

For previously diagnosed diabetic patients who are on antidiabetic treatment, diet plans and physical exercise regimens were recommended. Risk factors for having diabetes were firstly discussed with the patient and recommendations were put forward for improvement in lifestyle and to reduce complications (Appendix 3).

2.4.2   Total Cholesterol, Triglycerides Testing and Action Plan

The guideline chosen for the interpretation of the reference ranges for Total Cholesterol and Triglycerides was the NICE guideline 'Cardiovascular disease risk assessment and reduction, including lipid modification (CG 181)'.[9] This guideline is intended to assess

_____

[9] National Institute for Health and Care Excellence. NICE Cardiovascular disease risk assessment and reduction, including lipid modification [Internet]. United Kingdom: NICE; 2016 [cited 2021 Jun 04]. Available from: https://www.nice.org.uk/guidance/cg181/resources/cardiovascular-disease-risk-assessment-and-reduction-including-lipid-modification-pdf-35109807660997

and identify those who are at risk of developing cardiovascular diseases by describing lifestyle changes to reduce this risk.

Lifestyle modifications are the most crucial for a person at high risk. Lifestyle modifications based on diet and physical exercise are the main target for cardiovascular risk reduction. The NICE guidelines state that a person at 'moderate or high risk' should consume a diet with 30% or less of total energy intake, saturated fats 7% or less of total energy intake and the intake of cholesterol in the diet should be less than 300mg/day. These recommendations were provided to patients who obtained these results (Appendix 3).

In conjunction to diet, increase in physical activity was recommended; at least 150 minutes of moderate intensity or 75 minutes of vigorous physical activity on a weekly basis. Individualised advice was given to patients not able to perform moderate or intensive physical activity due to other comorbidities. For these patients, light exercise, even when sitting down was recommended. Smoking cessation was recommended and increased amounts of alcohol was recommended to be avoided. In this study, patients with a moderate or high total cholesterol level were recommended to take over the counter nutritional products containing red yeast extract.

2.4.3 Blood Pressure Measurement and Action Plan

The guideline used for interpretation of the blood pressure result and for the identification of risk associated with the result obtained was the '2018 European Society

of Cardiology (ESC)/ European Society of Hypertension (ESH) guideline for the management of arterial hypertension' (Williams et al., 2018).

The guideline chosen was compared to the NICE guideline: 'Hypertension in adults: diagnosis and management (NG 136)'.[10] Both guidelines focus on recommendations for healthcare professionals to diagnose hypertension accurately and to provide patients with effective and simple treatment strategies. Although the guidelines are in agreement for the majority of the points, there are some differences in the recommendations.

The ESC/ESH guidelines emphasise the importance of having a blood pressure level lower than 140/90 mm Hg for all patients and the treatment threshold is a systolic blood pressure >140 mm Hg and a diastolic blood pressure >90 mm Hg. Both guidelines take patient characteristics into consideration. Similar patient characteristics are required by other guidelines for other chronic conditions. The patient characteristics which are being taken into consideration for this study include; gender, age, total cholesterol, overweight or obesity and family history of the patient. For the monitoring of cardiovascular events, all the tests being investigated in this study aid in assessing cardiovascular risk. The treatment threshold is the same for the NICE guidelines but this value is the target, hence there are no lower treatment targets in the NICE guidelines. The reason for having a higher target value is since it is best suited to the clinical scenario in the United Kingdom (McCormack et al., 2019). The NICE guideline does not provide a complete and clear list of blood pressure classification, which is clearly

---

[10] National Institute for Health and Care Excellence. NICE Hypertension in adults: diagnosis and management [Internet]. United Kingdom: NICE; 2019 [cited 2021 Jun 04]. Available from: https:// www.nice.org.uk/guidance/ng136/resources/hypertension-in-adults-diagnosis-and-management-pdf-66141722710213

provided by the ESC/ESH guidelines. For the purpose of this study, ESC/ESH guidelines were selected. The reference ranges taken from the ESC/ESH guidelines are summarised in Appendix 3 (Williams et al., 2018).

Lifestyle changes are beneficial in lowering elevated blood pressure values, and to prevent or delay CVDs and to delay starting medications. Lifestyle changes are important for patients who are already on pharmacotherapy by augmenting the effects of blood pressure lowering medications. The guideline emphasises the importance of increasing vegetables, fruits and maintaining the patient's ideal body weight. Dietary modifications were recommended to all patients irrespective of their blood pressure result (Appendix 3).

Two of the most common modifiable risk factors in Malta are obesity and physical inactivity. When a patient aims at reducing total body weight to achieve an ideal weight, a lowering in blood pressure is achieved. Overweight and obese persons are associated with having a higher blood pressure value. This links the importance of testing BMI which was included as a test in this study. By providing patients with a diet plan (Appendix 3) and providing the patient with motivational counselling, a change in their lifestyle can lead to a reduction in weight.

2.4.4   Body Mass Index Measurement and Action Plan

The different BMI classes according to the WHO are summarised in Appendix 3. The guideline followed for the recommendations provided to the patients was the NICE

guideline 'Obesity: identification, assessment and management Clinical guideline [CG 189]'.[11] This guideline was chosen due to the great detail it provided to build a clear and simple explanation to the patients during the service being provided. The guideline explains the method which must be adopted to provide the intervention. The two key points which were discussed include lifestyle changes focused on dietary and physical activity changes (Appendix 3).

2.5   Point-of-Care Testing Medical Devices

A number of POCT devices and equipment were required for this study. The same equipment except for the equipment needed for BMI testing were used for all the tests performed in the different localities, by carefully transporting the equipment in their original covers and boxes.

For blood pressure testing a validated Hartmann Tensoval® electronic upper arm blood pressure monitor was used. Calibration of the blood pressure monitor is performed annually and certified by the responsible person performing the calibration. For fasting blood glucose, total cholesterol and triglycerides, the Accutrend® Plus (Roche) device was used together with the three different test strips. Quality control for the device was performed with a control solution when a new bottle of test strips was needed to be used and after transporting between localities.

---

[11] National Institute for Health and Care Excellence. NICE Obesity: identification, assessment and management Clinical guideline [Internet]. United Kingdom: NICE; 2018 [cited 2021 Jun 04]. Available from: https://www.nice.org.uk/guidance/cg189/resources/obesity-identification-assessment-and-management-pdf-35109821097925

For BMI testing, a weighing scale, an inch tape and a calculator were required. Analog scales were used to measure body weight. For calibration, it was ensured that the measuring line is aligned with 0 before each patient was measured. If this was not the case, the measure line was moved manually.

2.6   Validation of Framework

The developed framework was validated by an expert panel consisting of a community pharmacist, a clinical pharmacist, two GPs and one pharmacist in academia. The expert panel were provided with the data collection sheet and were asked to put forward feedback and suggestions. Members of the panel agreed that the tool was effective in collecting the data required. Comments put forward by one community pharmacist included that the data collection sheet was practical to use and results can be easily interpreted. Another recommendation by a community pharmacist was to formulate a clear summary which community pharmacists can follow when explaining test results to patients, namely for diet plans and exercise recommendations. The recommendations for dietary and exercise plans were included in the 'Documentation to ensure standardisation and consistency in the provision of POCT services by community pharmacists' (Appendix 3). It was recommended by the pharmacist in academia to include the criteria as part of the data collection sheet and this was agreed upon and included. The pharmacist in academia described the data collection tool as being 'comprehensive'. Both GPs who run a practice commented that POCT is an innovative method for monitoring patients and provides an area within the healthcare field to promote interprofessional practice between pharmacists and doctors. After amending

and finalising the data collection sheet as recommended by the expert panel members, a community pharmacist was chosen and a one-to-one session was offered on the performance of POCT, result interpretation and patient recommendations according to the action plan to ensure standardisation and consistency of the services.

2.7   Ensuring Consistency in Community Pharmacist Intervention

Standardisation and consistency of service provision is fundamental when offering health services. Standardisation is important for the method used to perform testing, for the interpretation of results and for the recommendations provided to patients. For this reason, a community pharmacist was trained on a one-to-one basis by the researcher on the services related to this study.

The researcher prepared a document titled 'Documentation to ensure standardisation and consistency in the provision of POCT services by community pharmacists' (Appendix 3). The document explains that testing can be offered to adults over the age of 18 years and are to be recommended as a routine check- up for young adults, for adults who have a family history of chronic conditions and for adults who suffer from known NCDs. It highlighted the importance for patients to be fasting at least 8 hours before their scheduled appointment. The document is divided into two sections. The first section includes background information about POCT and the method used to perform the tests offered in this study. The second section includes diet plans and recommendations for the community pharmacist to follow during result interpretation.

The first section was dedicated to testing which included health and safety and a step-by-step explanation for performing each individual test. Health and safety are crucial when offering POCT services. The information provided in the document included hand hygiene, the importance of wearing and changing gloves between each patient and the appropriate disposal of waste. A subsection was dedicated for each test. For blood pressure monitoring, a step-by-step explanation on how blood pressure is to be taken was provided, followed by taking an average of the three readings. Following this, the results table was included together with the associated risk. Blood glucose, total cholesterol and triglycerides testing were included in the same section since the same device was used for testing. For this section, another step-by-step guide was provided followed by three tables reflecting the test results and associated risks. The final test explained was body composition measurement. A step-by-step explanation was highlighted on how body composition is performed, indicating which values are needed and computing the BMI with the formula provided. A table was provided which shows how the results should be interpreted. This section was concluded with a table indicating the action plan based on the criteria to be taken once results are interpreted. This document can be used during one-to-one sessions with other pharmacists to provide the services ensuring standardisation.

During the one-to-one session, the 'Documentation to ensure standardisation and consistency in the provision of POCT services by community pharmacists' document was firstly read through and any questions by the community pharmacist were answered by the researcher. The developed data collection sheet was explained to the community pharmacist. All the sections which were to be filled were highlighted. A practical hands-

on session followed. By following the documentation provided, each test was performed by the community pharmacist on the researcher. A hands-on session was the preferred method and the testing methods followed the step-by-step points provided in the document with particular attention given to operating the devices. By using this method, each step during testing was performed and any queries or comments by the community pharmacist and the researcher were put forward and discussed. The session tested the way by which data is to be included in the data collection sheet and the way by which the action plan is to be implemented depending on the results obtained. The community pharmacist participating in the one-to-one session with the researcher described the session to be fruitful and the session provided added knowledge and technique in performing POCT.

2.8   Reliability and Feasibility Testing

Reliability of the framework developed including the data collection sheet and the decision outcome from the POCT service provided was tested. For reliability and feasibility testing, the community pharmacist who participated in the one-to-one session with the researcher was invited to participate in a pilot study. By convenience sampling, the researcher, who is the managing pharmacist of one of the selected pharmacies, invited 5 participants to participate, 4 female and 1 male. All persons invited accepted and were asked to fast for a minimum of 8 hours. The researcher performed the POCT on the 5 individuals, documented information and results in the data collection sheet and identified an action plan. The other community pharmacist performed the same POCT services on the same 5 participants by following the documents provided. The

action plan based on the test results obtained was compared for both pharmacists and agreement on the decision outcome based on the action plan and criteria chosen was observed.

Feasibility of the framework including POCT service duration, application of the data collection sheet and action plan and reproducibility of the framework to be implemented by other community pharmacists were assessed. The researcher and the community pharmacist who participated agreed that the framework is effective, practical, easy to follow and comprehensive to guide community pharmacists in offering a seamless, standardised and reproducible POCT service. The feasibility study demonstrated that the time taken for the service to be offered was 15 minutes. Due to agreement in the decision outcome, the framework developed and service provided were deemed reliable and feasible and all data collected from the pilot study was included and analysed with the study data.

2.9   Patient Recruitment

Each managing pharmacist of the established study sites agreed to recruit participants for the study. The managing pharmacists were provided with two documents used to recruit participants in this study; a 'Patient Information Sheet' and an 'Invitation to Study Sheet' (Appendix 4), both were developed in English and Maltese.

The 'Invitation to Study' was used to invite persons to the study. Persons who were interested to participate in the study, were provided with the 'Patient Information Sheet'

which included the aims of the research, the method used for blood sample collection and patients were advised that they may be asked to be retested. Each patient was informed that s/he will be given a copy of the results obtained together with recommendations according to the test results and evidence-based guidelines.

The inclusion criteria were all persons who are 18 years or older. An appointment was set up by the managing pharmacists on specific days which were previously identified and communicated by the researcher for the testing to take place. All participants were contacted a day before testing to be reminded that they should fast at least 8 hours before their scheduled appointment. Participants were reminded not to take any other liquids except water and chronic medication should be taken.

2.10   Service Implementation

By providing the managing pharmacists of the selected pharmacies with dates and times for the clinical sessions, appointments for the participants were made. The duration of each appointment scheduled was 15 minutes per participant. Each appointment took place in private clinics within the community pharmacies chosen.

During each session, the participants were firstly asked to wash their hands. Hand washing is important to limit interference of results. The interference is relevant for blood glucose testing due to sugar deposited on hands and for triglycerides either due to hand creams or hand sanitisers, since these products commonly contain fatty bases and

may interfere with the test result. Following this, all the participants were asked if they are fasting as the tests being performed require fasting for at least 8 hours.

During the first sessions (t1), 80 patients were tested. The same method was used for each patient tested at t1, t3 and t6. A data collection sheet was completed for each patient. Each patient was given an individual code and the date of testing was noted. After having washed and dried their hands, the finger to be used for the capillary blood sample was massaged for appropriate blood circulation. The finger was cleaned with alcohol and a single use Accu-Chek® Safe- T Pro lancet was used to lance the finger (3 drops, 1 for each test). The first three blood tests were performed using the Accutrend® Plus device. Results for fasting blood glucose, total cholesterol and triglycerides were documented on the individualised data collection sheet. Testing continued with blood pressure measurement. Blood pressure testing was performed after the patient would have been seated and rested for at least 5-10 minutes. Three readings were taken and an average was calculated. The final test performed was BMI measurement. BMI testing requires measurement of height and weight, and the BMI is calculated using a formula. The final section of the data collection sheet was filled in by communicating with the patient during the session, which involved obtaining the past medical history. Information documented included; current medications including generic name, dose and dosage regimen, relevant comorbidities and relevant risk factors. This information is important to guide disease management and lifestyle recommendations.

After having all the results documented and assessed, the criteria were used to guide an action plan which was discussed with each patient. Results were explained to the patient

and target results were discussed for patients who had results out of range. This method served as education for the patient to understand what needs to be done to achieve lower test results which is mainly based on lifestyle changes. For patients with results out-of-range, specifically for total cholesterol and triglycerides, natural vitamin products indicated for lowering cholesterol were recommended to be started together with lifestyle changes until the retesting appointment.

2.11   Statistical Analysis

All data gathered was inputted in Microsoft Excel and the data was analysed with IBM SPSS version 27. Descriptive statistics were used for patient characteristics, results obtained at t1, patient information on medications, risk factors and comorbidities. The test results at t2 and t3 were compared to t1 using the paired samples t-test. This statistical test was used to compare the mean testing parameter scores before and after the pharmacist intervention. The 0.05 level of significance was adopted.

Chapter 3

Results

3.1   Patient Characteristics

A total of 135 persons were approached to participate. A total of 80 individuals agreed to participate. Reasons for refusal included; patients do not feel comfortable due to the COVID-19 situation (n=23), prefer testing at GP (n=18), recently performed blood tests at GP (n=9), and not available to attend morning appointments due to other commitments (n=5). The majority of tests were performed in the locality of Qormi (36, 45%) followed by Kalkara (18, 23%), Hamrun (16, 20%) and San Gwann (10, 13%). Patient characteristics are described in Table 3.1.

Table 3.1: Patient Characteristics (N=80)

Patient Characteristics		Number of patients	
Gender	Male	43	
	Female	37	
Age (Years)	18-25	7	
	26-35	7	
	36-45	5	Mean Age : 60
	46-55	6	Age Range : 19-85
	56-65	17	
	66 and older	38	
Risk Factors	Current Smokers	Male	17
		Female	14
	Alcohol Users	Male	20
		Female	25

Family History	Diabetes	7	
	Hypertension	6	
	Hyperlipidaemia	5	
	Carcinoma	1	
	Ischemic Heart Disease	1	
	Raynauds Disease	1	
Chronic Conditions	Hypertension	27	
	Hyperlipidaemia	22	
	Diabetes	10	
	Mood Disorder	9	
	Hypothyroidism	5	
	GORD	3	
	ADHD	1	
	Arrythmias	1	
	Polycystic Ovaries	1	
	Prostate Carcinoma	1	
Chronic Medication	Statin	22	
	Diuretic	18	
	ACE Inhibitor	14	
	Calcium Channel Blocker	13	
	Metformin	9	
	SSRIs	6	Mean number of medications daily: 2
	Thyroxine	5	Range number of medications: 1-6
	ARB	5	
	Benzodiazepine	3	
	PPI	3	
	Contraceptives	3	
	Antipsychotics	3	

3.2   POCT Results

The results obtained during the clinical fieldwork were analysed according to the different sections in the data collection sheet. The results at t1 are summarised in Table 3.2.

Table 3.2: POCT results at t1 (N=80)

	Low Risk		Moderate Risk		High Risk	
	n	**%**	**n**	**%**	**n**	**%**
Blood Glucose	35	44	26	33	19	24
Total Cholesterol	46	58	34	43	0	0
Triglycerides	57	71	21	26	2	3
Blood Pressure	**Class**				**n**	**%**
	Optimal				14	18
	Normal				26	33
	High Normal				20	25
	Grade 1 Hypertension				17	21
	Grade 2 Hypertension				3	4
BMI	**Class**				**n**	**%**
	Underweight				2	2
	Normal Weight				31	38
	Overweight				35	43
	Obese				14	17

3.3   Action Taken

From the sample of 80 patients at t1, 56 patients were asked to be retested after three months, of which 23 patients were referred to the GP or specialist (Figure 3.1).
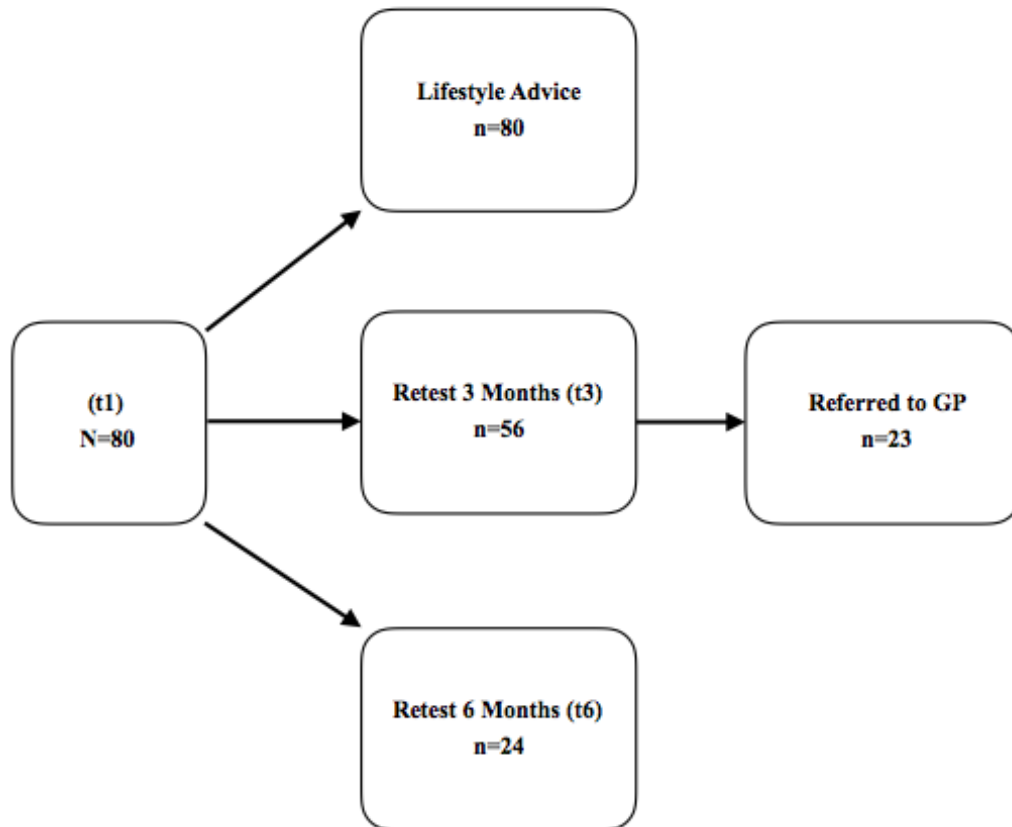
Figure 3.1: Action taken at t1

A total of 33 patients (41%) were retested after three months. These patients were not referred to their GP. Following the action plan developed, a number of reasons were responsible for retesting after three months (Table 3.3). Most of these patients (22, 67%) presented with more than one parameter at moderate or high risk for developing NCDs.

The remaining 11 patients (33%) only had one parameter which was at moderate or high risk. From these 11 patients, 6 patients had a moderate or high risk blood glucose level, 3 patients had a total cholesterol of moderate or high risk, 1 patient had moderate risk triglycerides and 1 patient had a high normal blood pressure reading.

Table 3.3: Reasons for retesting after 3 months (n=56)

Reason for Retest	Number of patients
Moderate or High Risk Blood Glucose	42
High Normal Blood Pressure	40
Moderate Risk Total Cholesterol	33
Moderate or High Risk for Triglycerides	19

The most common reason for GP referral was due to an elevated blood pressure (n=17) (Table 3.4). All the 23 patients who were referred to the GP were asked to retest in three months since test results met criteria for retesting.

Table 3.4: Reasons for GP referral (n=23)

Reason for GP Referral	Number of patients
Elevated Blood Pressure ($\geq$140 / $\geq$90 mmHg)	17
Elevated Blood Pressure and Fasting Blood Glucose ($\geq$6.9 mmol/L, $\geq$140 / $\geq$90 mmHg)	4
Elevated Fasting Blood Glucose ($\geq$6.9 mmol/L)	2

Upon referral to the patient's GPs, key interventions were identified. Two patients were started on antidiabetic treatment. Both patients were started with the first line treatment metformin. Treatment was started in the presence of the researcher by the respective GP. One patient was started on metformin 500 mg in three divided doses and the other on prolonged release metformin 1000 mg daily. One of the patients bought a blood glucose testing kit. The researcher offered in-depth education on the appropriate method to use the device and on how to interpret results. Apart from the addition of new treatment, one patient had their blood pressure medication dose increased by the GP due to constant high blood pressure. This trend was already being noted and followed up by the GP. The treatment increase was valsartan 160 mg from a daily regimen to a twice daily regimen. Another patient who was referred to the GP was started on treatment and the patient is being followed up regularly by the respective GP. The advice which was offered to the patients with elevated blood pressure is to monitor the blood pressure on three consecutive days. In the case that blood pressure readings remain 'high normal', the patient's GP should be consulted.

Another intervention highlighted involved patients who are non-adherent to medication and who have stopped treatment without seeking medical advice. One patient had stopped taking statin treatment (simvastatin). During pharmacist intervention, the researcher was in contact with the GP concerned and it was advised that the patient is to restart the treatment and the GP asked the researcher to offer education on adherence.

One patient was still awaiting a specialist appointment and another patient was advised by the GP that routine tests as performed in this study must be continued regularly in

addition to the yearly blood test screening to assess other parameters with are not available at the POC.

The remaining 24 patients at the start of the study (t1), were asked to be retested in six months. Patients who were advised to retest after six months had all their values at low risk, and at the time of testing were at low risk of developing NCDs.

All 80 patients at the start of the study (t1) were offered lifestyle advice irrespective if they were at low, moderate or high risk of developing NCDs. None of the patients were referred to the emergency department.

3.4   Patient Outcomes

From the 56 patients who were advised to be rested after three months, 23 patients accepted the invitation. The outcome of the tests at (t3) were compared with the results obtained at t1 to analyse the impact of pharmacist intervention. From the 24 patients who were asked to be retested after six months (t6), 10 patients accepted the invitation. For these patients, results were compared statistically to t1.

3.4.1   Drug Related Problems

During the first consultation with the patients (t1), 3 DRPs for 7 patients were identified. These problems were discussed with the patients. In addition, available

doctors or pharmacists at the time of consultation were informed about these DRPs to ensure that the DRPs are monitored and addressed.

The most common DRP involved non-adherence to medication, with 5 patients being identified as not taking their medications on a regular basis. One patient experienced an adverse drug reaction with the use of perindopril. The patient complained of a dry persistent cough and for this reason the patient was referred to the GP for a change in treatment. Another patient did not have sufficient knowledge on the medications being taken, and for this reason the medications could not be recorded during the session (t1).

The interventions identified key monitoring points for the patients, provided patients with individualised time to discuss pharmacotherapy or any queries with the pharmacist researcher and patient education was provided by the pharmacist researcher.

3.4.2   Retesting after three months

A total of 23 patients were retested after three months. Table 3.5 shows the mean scores, standard deviation and p-value for the individual parameters tested comparing t1 with t3. The paired samples t-test was used to compared the mean scores before and after pharmacist intervention.

The reduction in fasting blood glucose, total cholesterol and systolic BP between t1 and t3 was statistically significant ($p < 0.05$). Although a reduction in triglycerides, diastolic BP and BMI was observed, no statistical significance was obtained ($p > 0.05$) (Table 3.5).

Table 3.5: Paired samples t-test scores for POCT comparing t1 with t3 (n=23)

Paired Samples t-Test				
	Time point	Mean	Std. Deviation	p-value
Fasting Blood Glucose mmol/L	**t1**	4.73	1.212	**0.008***
	t3	4.33	1.057	
Total Cholesterol mmol/L	**t1**	4.34	1.804	**0.006***
	t3	4.02	1.513	
Triglycerides mmol/L	**t1**	2.00	1.751	0.451
	t3	1.75	0.980	
Systolic Blood Pressure mm Hg	**t1**	132.00	11.193	**0.037***
	t3	128.00	8.531	
Diastolic Blood Pressure Mm Hg	**t1**	80.00	17.882	0.703
	t3	79.00	4.560	
BMI	**t1**	27.51	3.801	0.155
	t3	27.14	3.751	

*p<0.05

In addition to comparing means, the change in risk for each parameter tested was noted at t3 (Table 3.6).

Table 3.6: Change in Risk at t3 (n=23)

	Risk Decrease		Risk No Change		Risk Increase	
	n	%	n	%	n	%
Blood Glucose	8	35	14	61	1	4
Total Cholesterol	8	35	15	65	0	0
Triglycerides	5	22	16	70	2	9
Blood Pressure	13	57	5	22	5	22
BMI	6	26	16	74	0	0

Changes in behavioural risk factors show the impact following pharmacist intervention. Self-reported changes were observed in daily routine for risk factors namely smoking, diet and exercise.

Four self-reported lifestyle changes were identified and discussed with the patients. Seven patients who were retested after three months changed their daily diet following pharmacist intervention (30%). In addition to change in diet, exercise was increased among 5 patients (22%). The diet and exercise plan provided by the pharmacist researcher was used by these patients, and positive results were obtained. These positive results included a decrease in weight loss and hence having a decrease in BMI (6, 26%).

The final risk factor for which change was identified was cigarette smoking; 3 patients (13%) decreased the amount of daily cigarette consumption.

3.4.3   Retesting after six Months

For the 10 patients who were asked to retest after 6 months, their initial results obtained at t1 were all classified as low risk.

The paired samples t-test was used for the different parameters tested to compare the mean scores between time 1 and time 6. All the parameters tested remained within the same risk region, hence there was no statistical difference between the two time points ($p > 0.05$) (Table 3.7).

Table 3.7: Paired samples t-test for POCT comparing t1 and t6 (n=10)

Paired Samples t-Test				
	Time point	Mean	Std. Deviation	p-value
Fasting Blood Glucose	**t1**	3.37	0.495	0.781
	t6	3.42	0.487	
Total Cholesterol mmol/L	**t1**	4.18	0.451	0.887
	t6	4.20	0.390	
Triglycerides mmol/L	**t1**	0.99	0.799	0.510
	t6	1.14	0.737	
Systolic Blood Pressure mm Hg	**t1**	118.00	5.911	0.210
	t6	120.00	3.300	
Diastolic Blood Pressure Mm Hg	**t1**	78.00	3.743	0.905
	t6	78.00	3.240	
Body Mass Index	**t1**	24.38	2.872	1.000
	t6	24.38	2.872	

Although all parameters when tested statistically were not significant, the study shows that patients who were at low risk of developing NCDs at t1 maintained positive results.

With regards to risk factors within this group of 10 patients who accepted to be retested after six months, 2 patients reduced the number of cigarettes being smoked per day following pharmacist intervention. One patient followed the pharmacist recommendation for bone mineral density monitoring. The patient was found to be osteoporotic and bisphosphonate treatment was initiated by the GP.

Chapter 4

Discussion

4.1   Current Situation of NCDs

Healthcare professionals have an important collaborative contribution in the screening, prevention and management of NCDs. Pharmacists are described as being one of the most trusted and accessible healthcare professionals (Steckowych et al., 2018; Yonel et al., 2020). Pharmacists possess knowledge and competence with respect to chronic diseases and medications, hence pharmacist-led services can be implemented and are easily accessible to patients. Various screening programmes for patients are being developed to identify patients at risk of developing NCDs and for the monitoring and management of patients with NCDs. Studies highlight the demand for pharmacists within the primary care field, as the number NCDs and medication-use problems are increasing (Winslade et al., 2016; Munger et al., 2017).

The COVID-19 situation has dramatically changed health services and provision of care for NCDs. During the pandemic, prevention and management of NCDs has gained more attention since it has been established that NCDs are major risk factors for patients with COVID-19, particularly amongst the elderly (Fauci et al., 2020; Agh et al., 2021). Although prevention and monitoring are greatly recommended, health screening services were disrupted due to the majority of healthcare professionals responding to the countries' needs during the pandemic (Azarpazhooh et al., 2020; Singh and Lal, 2020; Okereke et al., 2021; Agh et al., 2021). According to a survey completed by 155 countries published by the WHO in June 2020, prevention and treatment services were greatly disrupted namely, 53% of the countries experienced disruption in hypertension treatment services, 49% for treatment of diabetes and diabetes-related complications,

31% for cardiovascular emergencies and 42% for cancer treatment.[12] Within the local setting, health services offered by health centres and private clinics namely pharmacies were temporarily stopped for the reduction in spread of COVID-19. The COVID-19 pandemic highlights the importance of implementing a synergistic approach, where healthcare systems and strategies target both COVID-19 and NCDs simultaneously.

A number of strategies are utilised globally, however the most feasible and effective method to address the epidemic of NCDs is to be chosen after assessing all resources available (Bertram et al., 2018). The immediate results obtained with the use of POCT are beneficial to make rapid clinical decisions (Lehto et al., 2014), which was observed in the present study. In addition, POCT is beneficial to identify and to manage patients with or at high risk of disease. The present study has addressed the added-value and favourable community pharmacist intervention when POCT is offered in community pharmacies to address the fight against NCDs.

4.2   Contribution of the Developed Framework and Community Pharmacist Intervention

The role of pharmacists within multidisciplinary healthcare teams in reducing major risk factors which are responsible for the development of NCDs have been established in local and international studies (Brown et al., 2016; Jeet et al., 2017; Muscat et al., 2017; Alshehri et al., 2019; Hindi et al., 2019; Mifsud et al., 2019). Screening performed by

---

[12] World Health Organisation. WHO COVID-19 significantly impacts health services for noncommunicable diseases. [Internet]. Switzerland: WHO; 2020 [cited 2021 May 31]. Available from: https://www.who.int/news/item/01-06-2020-COVID-19-significantly-impacts-health-services-for-noncommunicable-diseases

community pharmacists, following guidelines and referring patients at high risk, is a service which aids the overall healthcare system by providing high quality healthcare and ensuring sustainability (Haggerty and Tran 2017; Bertram et al., 2018). In addition to risk factors, literature available describes the impact of pharmacist intervention with respect to patient counselling on lifestyle and medication therapy management, assessing adherence, addressing DRPs, and POCT of essential parameters (Melton, Lai 2017; Alshehri et al., 2019; Sousa Pinto et al., 2019). A local study by Muscat et al., (2017), demonstrated the positive impact of a patient-centred approach for chronic disease management services by pharmacists on patient satisfaction and health outcomes when taking into consideration DRPs.

Identifying the risk factors for NCDs which are highly dominant in the local setting is needed to address the problem of NCDs and to develop the appropriate strategies and frameworks to address these risk factors. According to the Global Health Metrics in 2019, the top 10 risk factors among the Maltese population included; tobacco smoking, elevated fasting plasma glucose, elevated blood pressure, dietary risks, high BMI, high LDL, kidney dysfunction, alcohol use, occupational risks and air pollution (Murray et al., 2019; Vos et al., 2019). When comparing the data with 2009, there was a great increase in persons with elevated fasting blood glucose (17.9%) and high BMI (11.0%) (Murray et al., 2019). Theoretically these figures should have decreased after a 10-year span due to implemented governmental strategies, but the opposite was observed and this warrants further work. Both international and local targets are set to significantly decrease the mentioned risk factors. This favours the need for pharmacist intervention and cost-effective screening services offered within community pharmacies to reduce

risk factors and their associated NCDs (Finkelstein et al., 2019; Mc Namara et al., 2019). The data obtained from this study has shown the prevalence of these out-of-range parameters and patients who have previously been diagnosed with a chronic condition. The majority of patients tested in this study suffer from hypertension (34%), followed by hyperlipidemia (22%) and diabetes (13%).

For the identification and management of these risk factors, POCT has been identified and proven feasible to be performed within community pharmacies. POCT provides the opportunity for early detection of risk factors for NCDs, which in the present study was shown to significantly improve, even over short period of time of three months. Although patients (n=24) at the time of testing (t1) were at low risk of developing NCDs, after testing at six months, a favourable result was observed since parameters were maintained within low risk, indicating that patients adhered to recommendations and were managing to control their condition.

The present study has shown the importance of following a framework to standardise the POCT service provided. The developed framework was followed by a community pharmacist other than the researcher and agreement in action plan implemented was demonstrated, showing the standardisation, consistency and potential for service replication by community pharmacists.The importance of standardisation was highlighted by an international study by Martínez-Mardones et al., (2019), where a statistical difference in results was noted due to the lack of standardisation in the POCT method used.

The present study has shown a positive and significant impact of pharmacist intervention on patient health outcomes. A statistically significant decrease in blood glucose level (mean decrease of 0.4 mmol/L) was achieved in the patients retested after three months and 8 patients (35%) had a decrease in risk recorded. The present study shows that pharmacist intervention with regards to blood glucose monitoring is favourable. This finding has been observed in other studies where both a reduction in fasting blood glucose and HbA1C were demonstrated and pharmacist intervention was significant and impactful (Fazel et al., 2017; Korcegez et al., 2017; Benedict et al, 2018; Muscat et al, 2019; Alshehri et al., 2019).

A statistically significant mean decrease in total cholesterol (0.32 mmol/L) was observed in the present study and 8 patients (35%) had a decrease in risk observed. With regards to triglycerides, a mean decrease (0.25 mmol/L) was achieved, but this decrease was not statistically significant. Although not statistically significant, 5 patients (22%) had a decrease in risk recorded. Both these parameters are important to consider when assessing cardiovascular risk together with other major modifiable risk factors. At the start of the study (t1) the mean value for total cholesterol and triglycerides of the 23 patients being retested was classified as low risk, 4.34 mmol/L and 2.00 mmol/L, respectively. Although within range, a number of patients followed the researcher's recommendations and a risk reduction was observed. A review of the current literature conducted by Haggerty and Tran (2017), summarised the significant impact of pharmacist intervention on total cholesterol assessment using POC equipment within community pharmacy. The authors highlighted that screening for cholesterol was used to identify patients at risk and to educate patients, similarly to the present study. A large

randomised controlled trial conducted involving 675 patients at high risk of vascular events in 2000 was described as having a very high significant rating in lipid profile since 57% of the patients had a reduction in cholesterol following pharmacist intervention compared to 31% of patients tested who did not have pharmacist intervention (Haggerty and Tran, 2017).

Findings from the present study revealed a statistically significant decrease in mean systolic blood pressure (3.87 mm Hg) following pharmacist intervention. The pooled mean reduction in diastolic blood pressure was 1.26 mm Hg, which was not statistically significant post-pharmacist intervention. In addition, 57% of the patients retested after 3 months had an overall decrease in risk for hypertension. A study by Cheema et al., (2014) explored 11 randomised controlled trials on community pharmacist intervention in the management of hypertension and showed that pharmacist interventions regarding patient education on lifestyle advice and identification of DRPs had a significant benefit on both systolic and diastolic blood pressure measurement with a decrease of 6.1 mm Hg and 2.5 mm Hg respectively.

International studies which are relevant to the present study have highlighted the impact of pharmacists in lowering blood glucose, total cholesterol, systolic and diastolic blood pressure levels to reduce the CVD overall risk (Tsuyuki et al, 2016; Al Hamarneh et al., 2018; Martínez-Mardones et al., 2019). Alshehri et al (2019) performed a systematic review and meta-analysis of randomised controlled trials focusing on the impact of pharmacist intervention to manage cardiovascular risk factors. The risk factors taken into consideration included hypertension, type 2 diabetes and dyslipidaemia. The

interventions included were the same as those performed in the present study namely interventions regarding patient education on lifestyle modifications and medication adherence, POCT and identification of DRPs. The outcomes assessed yielded statistically significant results when assessing the changes observed in fasting blood glucose, total cholesterol, systolic and diastolic blood pressure. In addition, 5 studies demonstrated a decrease in HbA1C but this parameter was not tested in the present study. Lipid profile was included in the meta-analysis where 5 studies looked at total cholesterol, LDL, HDL and triglycerides. Similarly, to the present study, the reduction of total cholesterol was statistically significant, however unlike in the present study, the reduction of triglycerides was also statistically significant.

Similarly to international and local studies, the present study highlighted that POCT within community pharmacy is feasible and screening is effective in identifying patients who are at high risk or who are suffering from CVDs or diabetes. From the present study, two patients were found to have high blood glucose which led to start of treatment. One patient decided to purchase a blood glucose testing kit to self-monitor blood glucose on a daily basis as recommended by the researcher. Education by the researcher was offered on the use of the device and the patient was educated on how to correctly interpret test results. The importance of patient education was similarly reported by Kehrer and James, (2016) and Nichols (2020). Following pharmacist intervention in the present study, a patient had the antihypertensive medication dose increased. This shows the favourable intervention and the collaboration between the pharmacist and general practitioner and how the roles complement eachother in the early identification of new or worsened chronic conditions.

In the present study, behavioural risk factors including smoking, alcohol use, diet and physical inactivity were investigated. A total of 45 (56%) patients claimed that they drink alcohol very regularly describing the intake to be more than once or twice per week and 1 patient was a heavy drinker, and 31 patients (39%) are smokers. A positive outcome was observed following pharmacist intervention and education, where 5 patients decreased the amount of cigarettes smoked per day. A Cochrane review showed the positive impact of pharmacist intervention on smoking cessation, where following pharmacist counselling and support groups, higher rates of smoking cessation was observed (Steed et al., 2017). The positive impact of the time spent during the pharmacist intervention on focusing on diet and physical exercise has led to positive results in reduction in weight and BMI risk for 6 patients who had a decrease in overall weight and decrease in risk related to BMI. Taking into consideration all risk factors and offering written and verbal education aids in having a reduction in modifiable behavioural and metabolic risk factors.

Obesity is a critical risk factor for NCDs and Malta has one of the highest rates of obesity among both children and adults. The increase in NCDs over the years has focused on the negative effect which food has on developing or present chronic conditions (Di Renzo et al., 2015). During the present study, BMI for each patient was calculated. More than half of the patients (60%) had a BMI value of 25 kg/m^2 or greater at t1 which classifies weight status as overweight or obese. Excess weight together with leading an unhealthy lifestyle with no physical activity is a major risk factor for developing NCDs. The present study follows on the continued importance of all healthcare professionals and public health officials towards providing education to

increase healthy diets and physical activity to help decrease BMI. Food insecurity is a major social problem faced within the community. From the present study it can be deduced that patients need to be correctly informed on what to eat, the amount of daily food required and which foods need to be avoided in respective chronic conditions. Confusion and misconception of which food is best for who was highlighted. During pharmacist intervention, the majority of the time taken during the consultation involved writing diet plans and lists of foods to be avoided.

The communication and collaboration between pharmacists and GPs were greatly highlighted in the present study. As the traditional role of the pharmacist is being enhanced with new services such as focusing on the prevention, diagnosis and monitoring of chronic conditions in collaboration with physicians (Gordan et al., 2017). Collaboration between healthcare professionals reduces the burden on healthcare systems (Cutler et al., 2019; Al AdAwi et al., 2020). Efforts are required to enhance a team-based approach practice and this can be achieved by highlighting the services offered by pharmacists and by recognising the importance and impact a pharmacist can contribute within the healthcare team.

Doctors present in close proximity or available within community pharmacies, help to provide fast and effective decisions in relation to diagnosis, additional or change in treatment, clinical opinions and interventions. These methods are beneficial tools for community pharmacists to communicate immediately with the respective practitioner. Immediate action following POCT was observed with the initiation of anti-diabetic treatment for two patients by two private GPs in the present study. The doctors were

readily available to initiate treatment following an elevated fasting blood glucose reading since the respective patients were already observed to having a high trend for fasting blood glucose and HbA1C levels in previous blood tests over the years. In addition to starting new treatment, a GP was contacted for an opinion due to a patient stopping statin treatment. After communication with the GP, the statin treatment was restarted. Another GP, highlighted to the researcher and the patient the importance of having these basic yet effective POCT performed regularly and keeping a yearly appointment for venous blood tests.

Good communication with GPs and with patients enhances continuity of care. Continuity of care is a strong factor in improving health across communities and to obtain better outcomes in relation to NCDs (Barzegari et al., 2021). The method used in the present study to enhance continuity of care was that all test results were provided to the patients tested, and these can be provided to GPs by the respective patients. The current situation in Malta leaves pharmacists within the community with little to no information about previous testing results unless provided by patients. During this study, patients provided the researcher with printed test results and previous hospital admission case summaries. Due to these flaws within the current healthcare system in Malta, continuity of care for the majority patients is lost. Working on enhancing communication with GPs and improving systems where information can be shared, has the potential to improve overall healthcare and quality of life. Currently the best way to achieve and communicate results is direct face to face contact with the GP if present, via email or telephone.

A difference was observed between patients who are fully monitored and supported by their doctor or pharmacist compared to patients who do not visit their pharmacist or doctor frequently. By supporting patients, better treatment outcomes are achieved, patients are more adherent to medications, educated on their chronic conditions, more aware of risk factors and tend to attend for check-ups more regularly. Patients need to be guided and pharmacists are ideal candidates to guide and motivate patients to monitor chronic conditions and their overall health (Jones et al., 2017). The present study identified patients who do not attend regular GP or hospital visits. POC screening services by community pharmacists are especially beneficial for these patient groups. Screening and prevention services can be used to draw patients into the healthcare system and referral to GPs will then link these patients upstream. For this reason, it was recommended that apart from providing patients with test results to show them to their GP, a referral note can be considered to be sent to the GP or government health centre of choice to inform the practitioner of the biochemical findings.

Although the present study identified very good communication between the community pharmacist researcher and GPs, studies highlight that communication is still improving and strategies to improve collaboration are still needed. A study conducted in the United States in 2017 by Gordan et al., highlights that for better collaboration interprofessional education and practice is required. Physicians during this study emphasised that medication reviews and medication errors should be dealt with by the pharmacist due to the knowledge they possess. On the other hand, Willis et al. (2014) observed a trend towards more general referrals by pharmacists following chronic disease screening in pharmacies. This trend observed by Willis et al., (2014) shows that

efforts have been documented to strengthen the practice relationship between pharmacists. The study by Willis et al., showed similarity to the current study with regards to patient follow-up and referral. Willis et al., identified that in the majority of studies analysed, less than half of the people who participate in opportunistic screening are referred to their GP. From this study a total of 23 patients were referred to their GP corresponding to 29% of the total tested individuals.

4.3   Limitations of the Study

A limitation of this study was the sample size. Although a larger sample size was anticipated at the start of the study, the COVID-19 pandemic impacted the data collection process and patient dropouts resulted. No control group was used in this study and the POCT results were not compared to standard laboratory values. Another limitation was that the duration of the chronic conditions was not known for the participants tested. The study sites were restricted to a group of pharmacies from a common chain selected by convenience sampling and did not represent the different districts in Malta. Patients not able to attend morning appointments were excluded since sessions were not held in the afternoon/evening. A limitation of self-reported behavioural changes needs to be taken into consideration. A limitation with regards to assessing smoking cessation in the present study was not possible. Smoking cessation takes a longer duration to be achieved and a three-to-six-month window is too short to have patients present with complete smoking cessation. Another limitation of the study is that no pharmacoeconomic considerations were evaluated.

4.4   Recommendations

A longitudinal study can be conducted using the same parameters on a larger sample size and for a longer duration, where patient monitoring can be continued for up to 12 months and longer. The same study consisting of a control group can be taken into consideration. A study comparing participants in the pre-diagnosis phase to participants with a confirmed diagnosis can be undertaken. This study design gives the opportunity to identify NCDs early and the impact of POCT by community pharmacists can be better assessed.

Performing other POCT namely HbA1C and full lipid profile testing which consists of total cholesterol, triglycerides, HDL, LDL, Non-HDL and Chol/HDL is recommended. The equipment to test for these parameters is available to be used at the POC and studies including their use help in further exploring the impact of pharmacist intervention with respect to NCDs diagnosis, management and prevention together with improved provision of individualised lifestyle advice.

In addition to a larger sample size, more localities for testing can be taken into consideration. In this way a larger picture of the situation can be described and it will be interesting to assess if results vary according to locality. An international study performed in Haiti compared testing of risk factors within the rural and urban area. In this study a statistical significance between areas was demonstrated for diabetes (DeGennaro et al., 2018). A similar study can be performed to establish the economic and sustainability aspects of the service.

4.5   Conclusion

This study has shown the significant positive contribution of community pharmacists towards the NCDs epidemic. By offering fast and accurate POCT to patients within community pharmacy, providing patient education and collaborating with general practitioners, high-quality and patient-centred care is delivered. POCT has been proven to be sustainable during the COVID-19 pandemic when the healthcare system was not functioning in its normal capacity.

This study has shown that POCT within community pharmacy is feasible and the service can be replicated by other community pharmacists by following the developed framework. NCDs are present and more attention is needed to prevent worsening of these conditions. The pharmacist intervention led to a significant improvement after a three-month interval for the tested parameters namely a decreased mean value of fasting blood glucose, total cholesterol and systolic blood pressure. Although testing after six months was not statistically significant, all parameters remained within range and this shows a positive contribution since patients tested maintained low risk results.

Improvements were noted in behavioural risk factors, namely less cigarettes smoked per day, change in diet and increase in exercise which decreased BMI. During the consultation with the patients, DRPs were identified and discussed with the patients and the GPs. This study has shown the importance of pharmacists collaborating within a multidisciplinary healthcare team and the benefits of having a GP clinic within close

proximity of a community pharmacy. Immediate action for initiation or change in treatment was demonstrated.

References

Agh T, van Boven JFM, Wettermark B, Menditto E, Pinnock H, Tsiligianni I et al., A Cross-Sectional Survey on Medication Management Practices for Noncommunicable Diseases in Europe During the Second Wave of the COVID-19 Pandemic. Frontiers in Pharmacology 2021; 12: 685696.

Al AdAwi RM, Stewart D, Ryan C, Tonna AP. A systematic review of pharmacist input to metabolic syndrome screening, management and prevention. International Journal of Clinical Pharmacy 2020; 42(4): 995-1015.

Al Hamarneh YN, Tsuyuki RT, Jones CA, Manns B, Tonelli M, Scott-Douglass N, Jindal K, Tink W, Hemmelgarn BR. Effectiveness of Pharmacist Interventions on Cardiovascular Risk in Patients With CKD: A Subgroup Analysis of the Randomized Controlled RxEACH Trial. American Journal of Kidney Disease 2018; 71(1):42-51.

Alfayez OM, Al Yami MS, Fazel MT. The impact of pharmacists providing direct patient care as members of interprofessional teams on diabetes management. Saudi Pharmaceutical Journal 2017; 25(7): 1019-1021.

Allen LN, Smith RW, Simmons-Jones F, Roberts N, Honney R, Currie J. Addressing social determinants of noncommunicable diseases in primary care: a systematic review. Bulletin of the World Health Organisation 2020; 98(11): 754-765.

Alizadeh G, Gholipour K, Farough Khosravi M, Khodayari-Zarnaq R. Preventive Community-Based Strategies of Cardiovascular Diseases in Iran: A Multi-Method Study. Social Work in Public Health 2020; 35(4): 177-186.

Alshehri AA, Jalal Z, Cheema E, Haque MS, Jenkins D, Yahyouche A. Impact of the pharmacist-led intervention on the control of medical cardiovascular risk factors for the primary prevention of cardiovascular disease in general practice: A systematic review and meta-analysis of randomised controlled trials. British Journal of Clinical Pharmacology 2019; 86: 29-38.

Alzubaidi HT, Chandir S, Hasan S, McNamara K, Cox R, Krass I. Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: a feasibility study. British Medical Journal 2019; 9(11): e031246.

Amadi C, Lawal F, Ajiboye W, Agbim R, Mbakwem A, Ajuluchukwu J et al. Opportunistic screening of cardiovascular disease risk factors in community pharmacies in Nigeria: a cross-sectional study. International Journal of Clinical Pharmacy 2020; 42(6):1469–1479.

Agomo C, Udoh A, Kpokiri E, Osuku-Opio J. Community pharmacists' contribution to public health: assessing the global evidence base. Clinical Pharmacist [Internet] 2018[cited 2021 Jun 16]. Available from: https://pharmaceutical-journal.com/article/research/community-pharmacists-contribution-to-public-health-assessing-the-global-evidence-base.

Ayorinde AA, Porteous T, Sharma P, Screening for major diseases in community pharmacies: a systematic review. International Journal of Pharmacy Practice 2013; 21(6): 349–361.

Azarpazhooh MR, Morovatdar N, Avan A, Phan TG, Divani AA, Yassi N et al. COVID-19 Pandemic and Burden of Non-Communicable Diseases: An Ecological Study on Data of 185 Countries. Journal of Stroke and Cerebrovascular Disease 2020; 29(9):105089.

Bacci JL, Klepser D, Tilley H, Smith JK, Klepser ME. Community pharmacy based point- of-care testing: A case study of pharmaicst- physician collaborative working relationships. Research in Social and Administrative Pharmacy 2018; 14(1): 112-115.

Baird J, Jacob C, Barker M, Fall Caroline HD, Hanson M, Harvey NC et al. Developmental Origins of Health and Disease: A Lifecourse Approach to the Prevention of Non-Communicable Diseases. Healthcare (Basel) 2017; 5(1): 14.

Barzegari J, Aryankhesal A, Moinfar Z, Abolhassani F. Non-Communicable diseases units: continuity of care factors. Journal of Public Health 2021; 29: 653-657.

Benedict AW, Spence MM, Sie JL, Chin HA, Ngo CD, Salmingo JF, et al. Evaluation of a Pharmacist-Managed Diabetes Program in a Primary Care Setting Within an Integrated Health Care System. Journal of Managed Care and Speciality Pharmacy 2018; 24(2):114-122.

Bergman AA, Jaynes HA, Gonzalvo JD, Hudmon KS, Frankel RM, Kobylinski AL et al. Pharmaceutical Role Expansion and Developments in Pharmacist-Physician Communication. Health Communication 2016; 31(2): 161-170.

Bertram MY, Sweeny K, Lauer JA, Chisholm D, Sheehan P, Rasmussen B et al. Investing in non-communicable diseases: an estimation of the return on investment for prevention and treatment services. Lancet 2018; 19; 391(10134):2071-2078.

Bloom DE, Chen S, McGovern ME. The economic burden of noncommunicable diseases and mental health conditions: results for Costa Rica, Jamaica, and Peru. Pan American Journal of Public Health 2018; 42: 1-8.

Brown TJ, Todd A, O'Malley C, Moor HJ, Husband AK, Bambra C et al. Community pharmacy-delivered interventions for public health priorities: a systematic review of interventions for alcohol reduction, smoking cessation and weight management, including meta-analysis for smoking cessation. British Medical Journal 2016; 6(2):1-18.

Budreviciute A, Damiati S, Sabir DK, Onder K, Schuller-Goetzburg P, Plakys G et al. Management and Prevention Strategies for Non-communicable Diseases (NCDs) and Their Risk Factors. Frontiers in Public Health 2020; 8:574111.

Bukhsh A, Khan TM, Lee SWH, Lee LH, Chan KG, Goh BH. Efficacy of Pharmacist Based Diabetes Educational Interventions on Clinical Outcomes of Adults With Type 2 Diabetes Mellitus: A Network Meta-Analysis. Frontiers in Pharmacology 2018; 9:339.

Buss VH, Deeks LS, Shield A, Kosari S, Naunton M. Analytical quality and effectiveness of point-of-care community pharmacies: A systematic literature review. Research in Social and Administrative Pharmacy 2019; 15(5): 483- 495.

Buss VH, Deeks LS, Shield A, Kosari S, Naunton M. The impact of clinical services provided by community pharmacies on the Australian healthcare system: a review of the literature. Journal of Pharmaceutical Policy and Practice 2018; 11(22).

Cammock R, Tonumaipe'a D, Conn C, Sa'uLilo L, Tautolo ES, Nayar S. From individual behaviour strategies to sustainable food systems: Countering the obesity and non communicable diseases epidemic in New Zealand. Health Policy 2021; 125(2): 229-238.

Chaudhury A, Duvoor C, Reddy Dendi VS, Kraleti S, Chada A, Ravilla R. Clinical Review of Antidiabetic Drugs: Implications for Type 2 Diabetes Mellitus Management. Frontiers in Endocrinology 2017; 8(6).

Cheema E, Sutcliffe P, Singer DR. The impact of interventions by pharmacists in community pharmacies on control of hypertension: a systematic review and meta-analysis of randomized controlled trials. British Journal of Clinical Pharmacology 2014; 78(6):1238–1247.

Chen S, Kuhn M, Prettner K, Bloom DE. The macroeconomic burden of noncommunicable diseases in the United States: Estimates and projections. PLoS ONE 2018; 13(11): e0206702.

Choudhary N, Sangra S, Narangyal A. Risk assessment for non-communicable diseases among out patients visiting urban health centre in Jammu region: A cross sectional study. International Journal of Advanced Community Medicine 2020; 3(1): 109-111.

Collins C, Limone BL, Scholle JM, Coleman CI. Effect of pharmacist intervention on glycemic control in diabetes. Diabetes Research and Clinical Pharmacy 2011; 92(2): 145-52.

Couch D, Fried A, Komesaroff P. Public health and obesity prevention campaigns – a case study and critical discussion. Communication Research and Practice 2018 4(2): 149-166.

Cutler RL, Torres-Robles A, Wiecek E, Drake B, Van der Linden N, Benrimoj S, et al. Pharmacist-led medication non-adherence intervention: reducing the economic burden placed on the Australian health care system. Patient Preference and Adherence 2019; 13: 853–862.

Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. Integrated Pharmacy Practice and Research 2017; 6: 37-46.

Damery S, Flanagan S, Combes G. The effectiveness of interventions to achieve co-ordinated multidisciplinary care and reduce hospital use for people with chronic diseases: study protocol for a systematic review of reviews. Systematic Reviews 2015; 4(64).

DeGennaro V, Malcolm S, Cromptom L, Vaddiparti K, Mramba L K, Striley C et al. Community-based diagnosis of non- communicable diseases and their risk factors in rural and urban Haiti: a cross- sectional prevalence study. British Medical Journal 2018; 8(4): 1-9.

Di Renzo L, Colica C, Carraro A, Cenci Goga B, Marsella LT, Botta R et al. Food safety and nutritional quality for the prevention of non communicable diseases: the Nutrient, hazard Analysis and Critical Control Point process (NACCP). Journal of Transational Medicine 2015; 13(1): 1-11.

Donald M, King-Shier K, Tsuyuki RT, Al Hamarneh YN, Jones CA, Manns B et al. Patient, family physician and community pharmacist perspectives on expanded pharmacy scope of practice: a qualitative study. Canadian Medical Association Journal 2017; 5(1): 205-212.

Donovan J, Tsuyuki RT, Al Hamarneh YN, Bajorek B. Barriers to a full scope of pharmacy practice in primary care: A systematic review of pharmacists' access to laboratory testing. Canadian Pharmacists Journal 2019; 152(5):317- 333.

Esmailnasab N, Moradi G, Delaveri A. Risk Factors of Non-Communicable Diseases and Metabolic Syndrome. Iranian Journal of Public Health 2012; 41(7): 77-85.

Fauci AS, Lane C, Redfield RR. COVID-19 — Navigating the Uncharted. The New England Journal of Medicine 2020; 382:1268-1269.

Fazel MT, Bagalagel A, Lee JK, Martin JR, Slack MK. Impact of Diabetes Care by Pharmacists as Part of Health Care Team in Ambulatory Settings: A Systematic Review and Meta-analysis. Annals of Pharmacotherapy 2017; 51(10): 890-907.

Finkelstein E, Bilger M, Baid D. Effectiveness and cost-effectiveness of incentives as a tool for prevention of non-communicable diseases: A systematic review. Social Science and Medicine 2019; 232: 340-350.

Florkowski C, Don-Wauchope A, Gimenez N, Rodrigues-Capote K, Wils J, Zemlin A. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) – does it leverage any advantage in clinical decision making? Clinical Reviews in Clinical Laboratory Sciences 2017; 54(7-8): 471-494.

Francis AJ, Martin CL. A practical example of POCT working in community. Clinical BioChemist Reviews 2010; 31(3): 91-97.

Freeman C, Rigby D, Aloizos J AM, Williams I. The practice pharmacist: natural fit in the general practice team. Australian Prescriber 2016; 39(6): 211-214.

George PP, Molina J AD, Cheah J, Chan SC, Lim BP. The Evolving Role of the Community Pharmacist in Chronic Disease Management - A Literature Review. Annals Academy of Medicine 2010; 39(11): 861- 867.

Goode JV, Owen J, Page A, Gatewood S. Community-Based Pharmacy Practice Innovation and the Role of the Community-Based Pharmacist Practitioner in the United States. Pharmacy 2019; 7(3): 106.

Gordon C, Unni E, Montuoro J, Ogborn DB. Community pharmacist-led clinical services: physician's understanding, perception and readiness to collaborate in a Midwestern state in the United States. International Journal of Pharmacy Practice 2017; 26(5):1-7.

Gubbins PO, Klepser ME, Adams A J, Jacobs DM, Percival KM, Tallman GB. Potential for Pharmacy–Public Health Collaborations Using Pharmacy-Based Point-of-Care Testing Services for Infectious Diseases. Journal of Public Health Management and Practice 2017; 23(6): 593–600.

Haggerty L and Tran D. Cholesterol Point-of-Care Testing for Community Pharmacies: A Review of the Current Literature. Journal of Pharmacy Practice 2017; 30(4): 451-458.

Hajat C, Stein E. The global burden of multiple chronic conditions: A narrative review. Preventative Medicine Reports 2018; 12: 284-293.

Hardy V, Thompson M, Alto W, Keppel GA, Hornecker J, Linares A et al. Exploring the barriers and facilitators to use of point of care tests in family medicine clinics in the United States. BioMed Central Family Practice 2016; 17(1): 149.

Heinz T, Schuchardt JP, Möller K, Hadji P, Hahn A. Low daily dose of 3 mg monacolin K from RYR reduces the concentration of LDL-C in a randomized, placebo-controlled intervention, Nutrition Research 2016; 36 (10): 1162-1170.

Herd GCE, Musaad SMA. Point-of-Care Testing in Rural and Remote Settings to Improve Access and Improve Outcomes: A Snapshot of the New Zealand Experience. Archives of Pathology and Laboratory Medicine 2021;145(3):327-335.

Hindi AMK, Schafheutle EL, Jacobs S. Community pharmacy integration within the primary care pathway for people with long-term conditions: a focus group study of patients', pharmacists' and GPs' experiences and expectations. BioMedical Family Practice 2019; 20(1):26.

Hohmeier KC, McDonough SLK, Wang J. Co- creation of market expansion in point-of-care testing in the United States: Industry leadership perspectives on the community pharmacy segment. Research in Social and Administrative Pharmacy 2017; 13(4): 746-753.

Hunter DJ, Reddy KS. Noncommunicable Diseases. The New England Journal of Medicine 2013; 369(14):1336-1343.

Inamdar SZ, Apsy P, Kulkarni RV, Gazala K, Kavaya H, Bhuneshvari A, et al. Assessment of knowledge, attitude and practice of community pharmacist towards the provision of pharmaceutical care: A community based study. Indian Journal of Pharmacy Practice 2018; 11(3): 158-163.

Islam SM, Purnat TD, Phuong NT, Mwingira U, Schacht K, Fröschl G. Non-communicable diseases (NCDs) in developing countries: a symposium report. Global Health 2014; 10(1).

Jahangard-Rafsanjani Z, Hakimzadeh N, Sarayani A, Najafi S, Heidari K, Javadi MR et al. A community pharmacy- based cardiovascular risk screening service implemented in Iran. Pharmacy Practice 2017; 15(2): 919.

Jeet G, Thakur JS, Prinja S, Singh M. Community health workers for non-communicable diseases prevention and control in developing countries: Evidence and implications. PLoS ONE 2017; 12(7):e0180640.

Jones HDC, Howick J, Roberts NW, Price CP, Heneghan C, Plüddemann A et al. Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies. BioMed Central Family Practice 2013; 14: 117.

Kachimanga C, Cundale K, Wroe E, Nazimera L, Jumbe A, Dunbar E et al. Novel approaches to screening for noncommunicable diseases: Lessons from Neno, Malawi. Malawi Medical Journal 2017; 29(2): 78-83.

Kehrer JP, James DE. The Role of Pharmacists and Pharmacy Education in Point-of-Care Testing. American Journal of Pharmaceutical Education 2016; 80(8):129.

Kelling SE, Rondon-Begazo A, DiPietro Mager NA, Murphy BL, Bright DR. Provision of Clinical Preventive Services by Community Pharmacists. Preventing Chronic Diseases 2016; 13: e161.

Kember J, Hodson K, James DH. The public's perception of the role of community pharmacists in Wales. International Journal of Pharmacy Practice 2018; 26(2): 120-128.

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

Kibicho J, Owczarzak J. A patient- centered pharmacy services model of HIV patient care in community pharmacy settings: a theoretical and empirical framework. AIDS Patient Care STDS 2012; 26(1): 20-8.

Kite J, Grunseit A, Bohn- Goldbaum E, Beleg B, Carroll T, Batman A. A Systematic Search and Review of Adult-Targeted Overweight and Obesity Prevention Mass Media Campaigns and Their Evaluation: 2000–2017. Journal of Health Communication 2018; 23(2):207-232.

Koehler T, Brown A. Documenting the evolution of the relationship between the pharmacy support workforce and pharmacists to support patient care. Research in Social and Administrative Pharmacy 2017; 13(2): 280-285.

Korcegez EI, Sancar M, Demirkan K. Effect of a Pharmacist-Led Program on Improving Outcomes in Patients with Type 2 Diabetes Mellitus from Northern Cyprus: A Randomized Controlled Trial. Journal of Managed Care and Speciality Pharmacy 2017; 23(5): 573-582.

Kovačević M, Ćulafić M, Jovanović M, Vučićević K, Kovačević SV, Miljković B. Impact of community pharmacists' interventions on asthma self-management care. Research in Social and Administrative Pharmacy 2018; 14(6):603-611.

Kuh D, Ben-Shlomo Y, Lynch J, Hallqvist J, Power C. Life course epidemiology. Journal of Epidemiology and Community Health 2003; 57(11): 914-914.

Lehto LA, Bloigu A, Liikanen E, Ruokonen Aimo. Interactive 2-Step Strategy for Training Nurses; A Practical Tool for Achieving Better-Quality Point-of-Care Glucose Testing in Hospital and Primary Healthcare Unit. The Journal of Near- Patient Testing and Technology 2014; 13(2): 41-47.

Lim SS, Vos T, Flaxman AD, Danaei G, Shibuya K, Adair-Rohani H et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2019; 380: (9859), 2224–2260.

Lingervelder D, Koffijberg H, Kusters R, IJzerman MJ. Point-of-care testing in primary care: A systematic review on implementation aspects addressed in test evaluations. The International Journal of Clinical Practice 2019; 73(10): e13392.

Luppa PB, Muller C, Schlichtiger A, Schlebusch H. Point-of-care testing (POCT): Current techniques and future perspectives. Trends in Analytical Chemistry 2011; 30(6): 887-898.

Mach F, Baigent C, Catapano AL, Koskinas KC, Casula M, Badimon L et al. ESC Scientific Document Group. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. European Heart Journal 2020; 41(1):111-188.

Malcolm S, Cadet J, Crompton L, DeGennaro V. A model for point of care testing for non-communicable disease diagnosis in resource-limited countries. Global Health, Epidemiology and Genomics 2019; 4: 1–6.

Marengoni A, Angleman S, Melis R, Mangialasche F, Karp A, Garmen A et al. Aging with multimorbidity: a systematic review of the literature. Ageing Research Reviews 2011;10(4):430-439.

Marmot M, Bell R. Social determinants and non-communicable diseases: time for integrated action. British Medical Journal 2019; 365: 10-12.

Martínez-Mardones F, Fernandez-Llimos F, Benrimoj SI, Ahumada-Canale A, Plaza-Plaza JC, S Tonin F et al. Systematic Review and Meta-Analysis of Medication Reviews Conducted by Pharmacists on Cardiovascular Diseases Risk Factors in Ambulatory Care. American Heart Association 2019; 8(22): e013627.

Marra C, Johnston K, Santschi V. Cost-effectiveness of pharmacist care for managing hypertension in Canada. Canadian Pharmacists Journal 2017; 150(3): 184-197.

Matheson GO, Klugl M, Engebretsen L, Bendiksen F, Blair SN, Borjesson M, et al. Prevention and management of noncommunicable disease: the IOC consensus statement, Lausanne 2013. Clinical Journal of Sport Medicine 2013; 23(6): 419–29.

McCormack T, Boffa R, Jones N , Carville S, McManusR J. The 2018 ESC/ESH hypertension guideline and the 2019 NICE hypertension guideline, how and why they differ. European Heart Journal 2019; 40(42): 3456-3458.

Mc Namara K, Peterson G, Hughes J, Krass I, Versace V, Clark R et al. Cardiovascular Risk Assessment in Australian Community Pharmacy. Heart, Lung and Circulation 2017; 26(7): 667-676.

Mc Namara K, Alzubaidi H, Jackson JK. Cardiovascular disease as a leading cause of death: how are pharmacists getting involved? Integrated Pharmacy Research and Practice 2019; 8: 1-11.

Melton BL, Lai Z. Review of community pharmacy services: what is being performed, and where are the opportunities for improvement? Integrated Pharmacy Research and Practice 2017; 6: 79-89.

Mifsud EM, Wirth F, Camilleri L, Azzopardi LM, Serracino- Inglott A. Pharmacist-led medicine use review in community pharmacy for patients on warfarin. International Journal of Clinical Pharmacy 2019; 41:741–750.

Morengoni A, Angleman S, Melis R, Mangialasche F, Karp A, Garmen A et al. Aging with multimorbidity: A systematic review of the literature. Ageing Research Reviews 2011; 10(4): 430-439.

Mossialos E, Courtin E, Naci H, Benrimoj S, Bouvy M, Farris K et al. From "retailers" to health care providers: Transforming the role of community pharmacists in chronic disease management. Healthy Policy 2015; 119(5): 628- 639.

Motta LA, Shephard DSM, Brink J, Lawson S, Rheeder P. Point-of-care testing improves diabetes management in a primary care clinic in South Africa. Primary Care Diabetes 2017; 11(3): 248- 253.

Munger MA, Walsh M, Godin J, Feehan M. Pharmacist's Demand for Optimal Primary Care Service Delivery in a Community Pharmacy: The OPTiPharm Study. Annals of Pharmacotherapy 2017; 51(12): 1069-1076.

Murray CJL, Aravkin AY, Zheng P, Abbafati C, Abbas K.M, Abbasi-Kangevari M et al. (GBD 2019 Diseases and Injuries Collaborators). Global burden of 87 risk factors in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study. Lancet 2019; 396: 1223- 1249.

Muscat M. Patient-centred monitoring in chronic disease management in the community pharmacy [Dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2017.

Nagelkerk J, Thompson ME, Bouthillier M, Tompkins A, Bear LJ, Trytko J et al. Improving outcomes in adults with diabetes through an interprofessional collaborative practice program. Journal of Interprofessional Care 2017; 32(1): 4-13.

Nichols JH. Point-of-Care Testing. Contemporary Practice in Clinical Chemistry. 2020; 19: 323-336.

Newman TV, Hernandez I, Keyser D, San-Juan-Rodriguez A, Swart ECS, Shrank WH et al. Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations. Journal of Managed Care and Speciality Pharmacy 2019; 25(9):995-1000.

Nowak SN, Singh R, Clarke A, Campbell E, Jaber LA. Metabolic Control and Adherence to American Diabetes Association Practice Guidelines in a Pharmacist-Managed Diabetes Clinic. Diabetes Care 2002; 25(8): 1479-1479.

Nugent R, Bertram MY, Jan S, Niessen LW, Sassi F, Jamison DT et al. Investing in non-communicable disease prevention and management to advance the Sustainable Development Goals. Lancet 2018; 391: 2029- 2035.

Odegard PS, Goo A, Hummel J, Williams KL, Gray SL. Caring for poorly controlled diabetes mellitus: A randomised pharmacist intervention. Annals of Pharmacotherapy 2005; 39(3):433-40.

Okereke M, Ukor NA, Adebisi YA, Ogunkola IO, Iyagbaye EF, Owhor GA et al. Impact of COVID-19 on access to healthcare in low- and middle-income countries: Current evidence and future recommendations. The International Journal of Health Planning and Management 2021; 36: 13-17.

Papastergiou J, Folkins C, Li W. Community pharmacy - based A1c screening: A Canadian model for diabetes care. International Journal for Pharmacy Practice 2016; 24(3): 189-195.

Park HD. Current Status of Clinical Application of Point-of-Care Testing. Archives of Pathology and Laboratory Medicine 2021; 145(2): 168-175.

Pascucci D, Sassano M, Nurchis MC, Cicconi M, Acampora A, Park D et al. Impact of interprofessional collaboration on chronic disease management: Findings from a systematic review of clinical trial and meta-analysis. Health Policy 2021; 125(2): 191-202.

Patton SJ, Miller FA, Abrahamyan L, Rac VE. Expanding the clinical role of community pharmacy: A qualitative ethnographic study of medication reviews in Ontario, Canada. Health Policy 2018; 122(3): 256- 262.

Peasah SK, Granitz K, Vu M, Jacob B. Effectiveness of a Student Pharmacist–Led Telephone Follow-Up Intervention to Improve Hemoglobin A1C in Diabetic Patients. Journal of Pharmacy Practice 2020; 33(6):832-837.

Phulkerd S, Lawrence M, Vandevijvere S, Sacks G, Worsley A, Tangcharoensathien V. A review of methods and tools to assess the implementation of government policies to create healthy food environments for preventing obesity and diet-related non-communicable diseases. Implementation Science 2016; 11:15.

Prajapati VB, Blake R, Acharya LD, Seshadri S. Assessment of quality of life in type II diabetic patients using the modified diabetes quality of life (MDQoL)-17 questionnaire. Brazilian Journal of Pharmaceutical Science 2017; 53(4):e17144.

Price CP, St John A. The value proposition for point-of-care testing in healthcare: HbA1c for monitoring in diabetes management as an exemplar. The Scandinavian Journal of Clinical and Laboratory Investigation 2019; 79(5).

Rajendran R, Rayman G. Point-of-Care Blood Glucose Testing for Diabetes Care in Hospitalized Patients: An Evidence-Based Review. Journal of Diabetes Science and Technology 2014; 8(6): 1081–1090.

Rodis JL, Sevin A, Awad MH, Porter B, Glasgow K, Hornbeck Fox C et al. Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers 2017; 8(4): 324-331.

Rooney KD, Schilling UM. Point-of-care Testing in the Overcrowded Emergency Department- can it make a difference? Critical Care 2014; 18: 692.

Roszak SE, Ferreri SP. Community Pharmacy Engagement in Diabetes Prevention: Key Informant Interviews with Pharmacy Executives. Preventing Chronic Disease 2020; 17:e200050.

Saavedra-Mitjans M, Ferrand E, Garin N, Bussières JP. Role and impact of pharmacists in Spain: a scoping review. International Journal of Clinical Pharmacy 2018; 40(6): 1430–1442.

Sadek MM, Elnour AA, Al Kalbani NMS, Bhagavathula AS, Baraka MA, Aziz AMA et al. Community pharmacy and the extended communitypharmacist practice roles: The UAE experiences. Saudi Pharmaceutical Journal 2016; 24(5): 563- 570.

Saleem SM. The need for point-of-care testing (POCT) in healthcare settings. Emergency Medicine and Critical Care 2018; 1-3.

San-Juan-Rodriguez A, Newman TV, Hernandez I, Swart ECS, Klein-Fedyshin M, Shrank WH et al. Impact of community pharmacist-provided preventive services on clinical, utilization, and economic outcomes: An umbrella review. Preventative Medicine 2018; 115: 145-155.

Sharma SR, Matheson A, Lambrick D, Faulkner J, Lounsbury DW, Vaidya A et al. The role of tobacco and alcohol use in the interaction of social determinants of non-communicable diseases in Nepal: a systems perspective. BMC Public Health 2020; 20(1): 1368.

Singh M, Lal P. Non-Communicable Diseases: Challenges and Impact of COVID-19 Pandemic. The Indian Practitioner 2020; 73(11): 30-36.

Smith M, Wick JY. New Models of Care: How Pharmacists Can Provide Better Care at Lower Costs. The Consultant Pharmacists 2018; 33(6):294-304.

Smith MG, Rains L. Evaluation of an accredited training program on implementation of point-of-care testing in community pharmacies. Journal of the American Pharmacists Association 2020; 60(6): 140-144.

Sousa Pinto G, Bader L, Billbery K, Criddle D, Duggan C, El Bizri L et al. Beating non-communicable diseases in primary health care: The contribution of pharmacists and guidance from FIP to support WHO goals. Research in Social and Administrative Pharmacy 2019; 16(7): 974- 977.

Steckowych K, Smith M, Spiggle S, Stevens A, Li H. Building the Case: Changing Consumer Perceptions of the Value of Expanded Community Pharmacist Services. Journal of Pharmacy Practice 2018; 32(6):637-647.

Steed L, Sohanpal R, James WY, Rivas C, Jumbe S, Chater A et al. Equipping community pharmacy workers as agents for health behaviour change: developing and testing a theory- based smoking cessation intervention. British Medical Journal 2017; 7:e015637.

Steltenpohl EA, Barry BK, Coley KC, McGivney MS, Olenak JL, Berenbrok LA. Point- of- care testing in Community Pharmacies: Key success from Pennsylvania Pharmacists. Journal of Pharmacy Practice 2018; 31(6): 629-635.

Tabaszewski R. The role of local and regional authorities in prevention and control of NCDs: the case of Poland. BMC International Health and Human Rights 2020; 20 (17): 1-9.

Tanaka M, Itoh H. Hypertension as a Metabolic Disorder and the Novel Role of the Gut. Current Hypertension Reports 2019; 21(8):63.

Tanyanyiwa D, Dandara C, Bhana SA, PaulyB, Marule F, Ramokoka M et al. Implementation of POCT in the diabetic clinic in a large hospital. African Health Sciences 2015; 15(3): 902-907.

Tsuyuki RT, Al Hamarneh YN, Jones CA, Hemmelgarn BR. The Effectiveness of Pharmacist Interventions on Cardiovascular Risk: The Multicenter Randomized Controlled RxEACH Trial. Journal of the American College of Cardiology 2016; 67(24): 2846-2854.

Ungaro S, Wirth F, Azzopardi LM, Serracino- Inglott A. Point-of-care testing for urine analysis of microalbuminuria for diabetic patient management. Point of Care: The Journal of Near-Patient Testing & Technology. 2015; 14(3): 71-71.

Van Eikenhorst L, Taxis K, van Dijk L, de Gier H. Pharmacist-Led Self-management Interventions to Improve Diabetes Outcomes. A Systematic Literature Review and Meta-Analysis. Frontiers in Pharmacology 2017; 8:891.

Vashist SK. Point-of-Care Diagnostics: Recent Advances and Trends. Biosensors 2017; 7(62): 1-4.

Vella M, Grima M, Wirth F, Attard Pizzuto M, Sammut Bartolo N, Vella J, et al. Consumer perception of community pharmacist extended professional services. Journal of Pharmaceutical Health Services Research 2015; 6(2): 91–96.

Verhoeven V, Lopez Hartmann M, Remmen R, Wens J, Apers S, Van Royen P. Red yeast rice lowers cholesterol in physicians - a double blind, placebo controlled randomized trial. BMC Complementary Medicine and Therapies 2013; 18(13):178.

Vos T, Lim SS, Abbafati C, Abbas KM, Abbasi M, Abbasifard M et al. (GBD 2019 Diseases and Injuries Collaborators). Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study. Lancet 2019; 396: 1204-1222.

Wang P, Kricka LJ. Current and Emerging Trends in Point-of-Care Technology and Strategies for Clinical Validation and Implementation. Clinical Chemistry 2018; 64(10): 1439–1452.

Waszyk- Nowaczyk M, Skura O, Michalak M, Ratka A. Opinions of Pharmacists n Community Pharmacy- Based Health Screening for Common Chronic Diseases. Polish Pharmaceutical Society 2018; 75(3): 819- 826.

Wendimagegn NF, Bezuidenhout M. The integrated health service model: the approach to restrain the vicious cycle to chronic diseases. BMC Health Services Research 2019; 19(347): 1-12.

Williams B, Mancia G, Spiereg W, Rosei EA, Azizi M, Burnier M et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH). European Heart Journal 2018; 39(33): 3021-3104.

Willis A, Rivers P, Gray L, Davies M, Khunti K. The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting. PLoS One 2014; 9(4):e91157.

Winslade N, Eguale T, Tamblyn R. Optimising the changing role of the community pharmacist: a randomised trial of the impact of audit and feedback. British Journal of Medicine 2016; 6:e010865.

Wirth F, Tabone F, Azzopardi LM, Gauci M, Zarb-Adami M, Serracino- Inglott A. Consumer perception of the community pharmacist and community pharmacy services in Malta. Journal of Pharmaceutical Health Services Research 2011; 1(4): 189-194.

Wolfenden L, Reilly K, Kingsland M, Grady A, Williamsa CM, Nathan N et al. Identifying opportunities to develop the science of implementation for community-based non-communicable disease prevention: A review of implementation trials. Journal of Preventative Medicine 2019; 118:279- 285.

Yaghoubi M, Mansell K, Vatanparastc H, Steeves M, Zeng W, Farag M. Effects of pharmacy-based interventions on the control and management of diabetes in adults: a systematic review and meta-analysis. Canadian Journal of Diabetes 2017; 41(6): 628-641.

Yang JS, Mamudu HA, John R. Incorporating a structural approach to reducing the burden of non-communicable diseases. Globalization and Health 2018; 14(66).

Yonel Z, Yahyouche A, Jalal Z, James A, Dietrich T, Chapple LCI. Patient acceptability of targeted risk-based detection of non-communicable diseases in a dental and pharmacy setting. BMC Public Health 2020; 20(1): 1-11.

Appendices

Appendix 1

Faculty of
Medicine & Surgery

University of Malta
Msida MSD 2080, Malta

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

www.um.edu.mt/ms

Ref No: FRECMDS_1920_200

16 November 2020

Ms Rebecca Zammit
71, Triq Wied Ghollieqa,
San Gwann. SGN 4467

Dear Ms Zammit,

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

Point - of - Care Testing in Community Pharmacy Practice

The Faculty Research Ethics Committee granted ethical approval for the above mentioned application following amendments last received on 10 November 2020.

Yours sincerely,

Professor Pierre Mallia
Chairman
Faculty Research Ethics Committee

brown's
PHARMACY

Brown's Pharma Limited

Triq l-Industrija,

Qormi

Date: 4/3/2020

Dear Rebecca Zammit,

I am pleased to inform you that your request to carry out research on your project 'Point-of-care testing in community pharmacy practice' within Brown's Pharma's pharmacies has been fully approved.

Regards

Dr Elena Mifsud

BSc Pharm Sci (Hons), M.Pharm, Pharm D

Health Services Executive

Brown's Pharma Limited

Appendix 2

Point- of -Care Testing in Community Pharmacy Practice
Rebecca Zammit, Doctorate in Pharmacy student
Data Collection Sheet

Patient Study Number: _____

☐   t1

☐   t3

☐   t6

Date: _____

Part 1: Patient Demographics

Locality of Pharmacy	
Sex	☐ Male ☐ Female ☐ Other
Age (years)	

Part 2: Test Results

1. Fasting Blood Glucose[1,2]

    _____ mmol/L

---

[1] National Institute for Health and Care Excellence. NICE Type 2 Diabetes: prevention in people at high risk [Internet]. United Kingdom: NICE; 2017 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph38/resources/type-2-diabetes-prevention-in-people-at-high-risk-pdf-1996304192197

[2] National Institute for Health and Care Excellence. NICE Type 2 Diabetes prevention: population and community level interventions [Internet]. United Kingdom: NICE; 2018 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph35/resources/type-2-diabetes-prevention-population-and-communitylevel-interventions-pdf-1996299153349

Fasting blood glucose (mmol/L)	Risk	
<4.0	Low	☐
4.0- <5.5	Moderate	☐
5.5- 6.9	High	☐

2. Fasting Total Cholesterol & Triglycerides[3]

Total Cholesterol _____ mmol/L

Triglycerides _____ mmol/L

Total Cholesterol (mmol/L)	Risk	
< 5.0	Low	☐
5.0- <6.1	Moderate	☐
6.2 or higher	High	☐
Triglycerides (mmol/L)	Risk	
< 2.3	Low	☐
2.3- <4.5	Moderate	☐
4.5- 9.9 or higher	High	☐

---

[3]National Institute for Health and Care Excellence. NICE Cardiovascular disease risk assessment and reduction, including lipid modification [Internet]. United Kingdom: NICE; 2016 [cited 2021 Jun 04]. Available from: https://www.nice.org.uk/guidance/cg181/resources/cardiovascular-disease-risk-assessment-and-reduction-including-lipid-modification-pdf-35109807660997

3. Blood Pressure[4]

_____ mm Hg

_____ mm Hg

_____ mm Hg

Average:

_____ mm Hg

Blood Pressure (mm Hg)	Risk	
Systolic <120 & Diastolic <80	Optimal	☐
Systolic 120-129 &/or Diastolic 80-84	Normal	☐
Systolic 130- 139 &/or Diastolic 85- 89	High Normal	☐
Systolic 140- 159 &/or Diastolic 90-99	Grade 1 Hypertension	☐
Systolic 160- 179 &/or Diastolic 100-109	Grade 2 Hypertension	☐
Systolic ≥180 &/or Diastolic ≥ 110	Grade 3 Hypertension	☐

---

[4]Williams B, Mancia G, Spiereg W, Rosei EA, Azizi M, Burnier M et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH). European Heart Journal 2018; 39(33): 3021-3104.

4. Body Composition (BMI)[5]

BMI (kg/m²)	Weight Status	
Below 18.5	Underweight	☐
18.5- 24.9	Normal or healthy weight	☐
25.0- 29.9	Overweight	☐
30.0 or above	Obese	☐

Part 3: Action Taken

Action Taken	
Patient follow- up after 3 months, all tests to be repeated (t3)	
Patient follow- up after 6 months, all tests to be repeated (t6)	
Patient advised to visit general practitioner or specialist	
Patient referred to emergency department	
Provide patient with lifestyle advice based on diet, physical activity, tobacco and alcohol reduction	

---

[5] Centres for Disease Control and Prevention. CDC Healthy Weight [Internet]. United States: CDC; 2020 [cited 2021 Jun 05]. Available from: https://www.cdc.gov/healthyweight/assessing/index.html

Part 4: Current medications and comorbidities

(If applicable)

1. Current medications (generic name, dose, dosage regimen)

2.

2. Relevant comorbidities

3. Relevant risk factors

Criteria for action taken:

1. Resting after **3 months** based on the results interpreted for moderate to high risk blood glucose, a total cholesterol value >5 mmol/L, a total triglycerides value >2.3 mmol/L and a systolic blood pressure value between 130- 139 mm Hg and diastolic blood pressure value between 85- 89 mm Hg.

2. Retesting after **6 months** due to results interpreted to be within range namely a blood glucose level obtained to be less than 4 mmol/L, a blood cholesterol level lower than 5 mmol/L, a triglyceride level lower than 2.3 mmol/L and a blood pressure result of systolic level 139 mm Hg or lower and diastolic 89 mm Hg or lower.

3. Advice the patient to visit general practitioner or specialist based on; a fasting blood glucose level of 6.9 mmol/L or higher, a high blood pressure measuring systolic level 140 mm Hg or higher and diastolic level 90 mm Hg or higher. The patient may also be referred based on a high total cholesterol of 9 mmol/L as per the NICE guidelines specialist attention is required. These patients are also be advised to perform the tests again after **3 months**.

4. Refer the patient to the emergency department due to results which may cause immediate harm to the patient. In community pharmacy this is based on values obtained for severe high blood pressure with values of systolic blood pressure 180 mm Hg and diastolic 120 mm Hg or higher or high blood glucose levels of 13 mmol/L together with hyperglycaemic symptoms. In addition, younger patients (< 40 years) with grade 2 hypertension should be referred to hospital based- care.

5. Provide lifestyle advice focusing on risk factors such as diet, increasing physical exercise, tobacco and alcohol reduction and ensuring that medications are being

taken at appropriate times and correct dosage regimens are being adhered to. The advice will be dependent on the interpreted results which were not within the healthy and advised range.

Appendix 3

Documentation to ensure standardisation and consistency in the provision of POCT services

Point-of-care testing refers to the testing of biomarkers at close proximity to the patient. This is a growing sector in healthcare and these tests have now been expanded from clinical and hospital settings to pharmacy. This document has been developed as a framework for educational purposes on how point-of-care testing devices are to be used and handled, as a handbook for result interpretation and diet/ physical activity advice to ensure consistency and standardisation by all community pharmacists.

The tests can be offered to adults over the age of 18 years. They are recommended as a routine check- up for young adults, for adults who have a family history of chronic conditions and also for adults who suffer from known chronic conditions. For the blood tests to be performed, the patient should be fasting for at least 8 hours.

The tests included are:

1. Blood Pressure

2. Blood Glucose

3. Blood Cholesterol

4. Blood Triglycerides

5. Body Mass Index (BMI)

Testing

Health and Safety

1. Disposable gloves are to be worn at all times to carry out the above mentioned activities. They will protect from the risk of exposure when handling blood. These activities also include the handling of sharps or contaminated equipment. Gloves are to be immediately replaced if thorn. Removal of gloves needs to be done carefully to ensure that any contamination will not come in contact with the skin. Should always be changed between each patient.

2. All sharps and consumables must be discarded in the sharps bin. All other waste is to be discarded in the general waste bin.

3. Hands should be washed at all times before and after services are provided.

Blood Pressure Testing

For blood pressure testing, the device used is Hartmann® Tensoval upper arm automatic blood pressure monitor.

1. When the patient arrives, it is important to allow 5-10 minutes sitting down until the pulse and blood pressure returns to normal. Ensure that the patient is relaxed and is not speaking whilst the test is being taken.

2. Ensure that the correct cuff size is used to obtained accurate readings. It is to be positioned at the level of the heart. The test is to be taken sitting down.

3. The cuff should not be too tight or loose, approximately 2 fingers should fit between the cuff and the patient's arm.

4. Three readings are to be taken, 2 minutes apart. An average should then be calculated.

5. The following table indicates how blood pressure[1] results should be interpreted:

Blood Pressure (mm Hg)	Risk
Systolic <120 & Diastolic <80	Optimal
Systolic 120-129 &/or Diastolic 80-84	Normal
Systolic 130- 139 &/or Diastolic 85- 89	High Normal
Systolic 140- 159 &/or Diastolic 90-99	Grade 1 Hypertension
Systolic 160- 179 &/or Diastolic 100-109	Grade 2 Hypertension
Systolic ≥180 &/or Diastolic ≥ 110	Grade 3 Hypertension

<u>Blood Glucose, Triglycerides and Total Cholesterol Testing</u>

For these tests the Roche Accutrend® Plus device, test strips and control solutions for testing will be used. A finger prick blood sample is required (3 drops, 1 for each test) using a single-use lancet. The following steps are to be followed:

1. Ask the patient to wash their hands, this is due to the possible residue of hand creams or sugar which will effect test results.

---

[1] Williams B, Mancia G, Spiereg W, Rosei EA, Azizi M, Burnier M et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH). European Heart Journal 2018; 39(33): 3021-3104.

2. Clean the finger with surgical spirit and prick the finger using the single use lancet. The first drop of blood must always be cleaned. Throw the lancet away in the sharps bin.

3. Code the machine with the test strips and tests may be commenced; blood glucose, total cholesterol and triglycerides. All test strips should be discarded in sharps bin.

4. The following tables indicates how the results should be interpreted for fasting blood glucose[1,2], Total cholesterol and Triglycerides[3]:

Fasting blood glucose (mmol/L)	Risk
<4.0	Low
4.0- <5.5	Moderate
5.5- 6.9	High

Total Cholesterol (mmol/L)	Risk
< 5.0	Low
5.0- <6.1	Moderate
6.2 or higher	High

---

[2] National Institute for Health and Care Excellence. NICE Type 2 Diabetes: prevention in people at high risk [Internet]. United Kingdom: NICE; 2017 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph38/resources/type-2-diabetes-prevention-in-people-at-high-risk-pdf-1996304192197

[3] National Institute for Health and Care Excellence. NICE Type 2 Diabetes prevention: population and community level interventions [Internet]. United Kingdom: NICE; 2018 [Cited 2021 Feb 05]. Available from: https://www.nice.org.uk/guidance/ph35/resources/type-2-diabetes-prevention-population-and-communitylevel-interventions-pdf-1996299153349

[4] National Institute for Health and Care Excellence. NICE Cardiovascular disease risk assessment and reduction, including lipid modification [Internet]. United Kingdom: NICE; 2016 [cited 2021 Jun 04]. Available from: https://www.nice.org.uk/guidance/cg181/resources/cardiovascular-disease-risk-assessment-and-reduction-including-lipid-modification-pdf-35109807660997

Triglycerides (mmol/L)	Risk
< 2.3	Low
2.3- <4.5	Moderate
4.5- 9.9 or higher	High

Body Composition

BMI is the value devised from the mass (weight) and the height of a person. This is a simple test which is important as it is an indicator of health risk. This value is important in treatment of a number of comorbidities.

1. For this this, the weight of the person is taken by using validated weighing scales and an inch tape for the height of the person.

2. The weight in Kg and the height in m are then used in the metric BMI formula which is:

$$BMI= Weight\ (Kg)\ /\ Height\ (m^2)$$

3. The following table indicates how BMI[5] result should be interpreted:

BMI (kg/m^2)	Weight Status
Below 18.5	Underweight
18.5- 24.9	Normal or healthy weight
25.0- 29.9	Overweight
30.0 or above	Obese

---

[5] Centres for Disease Control and Prevention. CDC Healthy Weight [Internet]. United States: CDC; 2020 [cited 2021 Jun 05]. Available from: https://www.cdc.gov/healthyweight/assessing/index.html

Action Plan

Action Plan	Criteria
Patient follow-up after 3 months, all tests to be repeated	1. Moderate to high risk blood glucose 2. Total cholesterol >5 mmol/L 3. Triglycerides >2.3 mmol/L 4. Systolic blood pressure between 130-139 mm Hg and diastolic blood pressure between 85- 89 mm Hg
Patient Follow-up after 6 months, all tests to be repeated	1. Moderate blood glucose level <4 mmol/L 2. Total cholesterol < 5 mmol/L 3. Triglycerides < 2.3 mmol/L 4. Blood pressure result of systolic level ≤ 139 mm Hg and diastolic ≤ 89 mm Hg.
Patient advised to visit general practitioner or specialist, all tests to be repeated after 3 months	1. Fasting blood glucose level ≥6.9 mmol/L 2. High blood pressure measuring systolic level ≥140 mm Hg and diastolic level ≥90 mm Hg 3. Total cholesterol >9 mmol/L

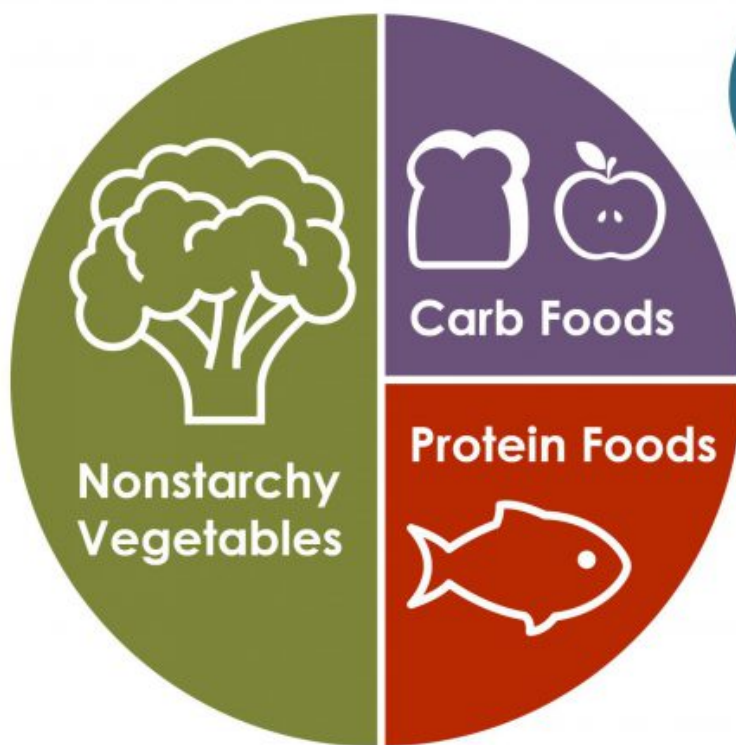|	
Patient referred to the emergency department	1. Blood pressure with values of systolic blood pressure ≥180 mm Hg and diastolic ≥120 mm Hg 2. Younger patients (< 40 years) with grade 2 hypertension should be referred to hospital based- care 3. Blood glucose levels of 13 mmol/L together with hyperglycaemic symptoms
Provide patient with lifestyle advise based on diet, physical activity, tobacco and alcohol reduction	To be provided to all patients and the advice is dependent on the interpreted results which were not within the healthy and advised range.

Diet Plans

Diet related noncommunicable diseases are increasing rapidly. Appropriate dietary practices, increased physical activity, weight management, abstinence from tobacco/ substance use and alcohol abuse play an important role in their prevention and management of the most common chronic diseases namely cardiovascular diseases and diabetes. By interpreting POCT results, standard basic diet plans can be recommended to patients. The diet plans below are dependent on the individual test results. Lifestyle advise is to be recommended to all patients irrespective of the test results, more importance is to be given to patients with out of range (moderate/high risk) test results. Diet plans provided need to take into consideration medications taken by patients. Advice is to be offered both verbal and written.

General tips;

- Alcohol intake reduction

- Smoking cessation; recommendation of smoking cessation devices example nicotine chewing gum, patches, inhalers and inhalators.

- Reduce daily intake of salt

- Increase water intake (2-2.5L/day)

- Limit to 4 teas or coffees per day

- Increase Physical Exercise (150-180 mins/week or 75 minutes of vigorous exercise weekly); Start slow but frequent exercise. Exercises sitting down with the use of weights recommended for patient with impaired movement.

- Use the plate method to explain portion size or weighing of raw ingredients

- Recommendation of meal plan and offer meal options (Brehm et al., 2003; Hu et al., 2016; Thom, Lean 2017)

Meal Plan

	Option 1	Option 2	Option 3	Option 4
Breakfast (7am)	X2 Slices of brown bread X1 Egg	X2 Slices of brown bread X1 Banana	40g Wholegrain cereal or oats 40ml of low-fat milk	Fruit Smoothie of choice 200 ml almond milk 20g oats
Snack (10am)	X1 Apple X1 Yogurt	X1 Small box of strawberries	X2 Pears or Kiwi	X3 Rice Cakes 40g low-fat cheese
Lunch (1pm)	100-150g protein of choice; chicken, turkey, egg, tuna, salmon, lean beef, white fish 50-70g of carbohydrates; brown pasta, rice, quinoa, bulgar wheat, couscous, wholegrain wraps or pita Unlimited amount of vegetables.			
Snack (4pm)	X2 Rye crackers 1/2 Avocado	X2 Rice Crackers X1 Small can of tuna	X2 Fruit	Homemade diet cake
Dinner (7pm)	200-250g protein of choice; chicken, turkey, egg, tuna, salmon, lean beef, white fish 50g of Carbohydrates; brown pasta, rice, quinoa, bulgar wheat, couscous, wholegrain wraps or pita (Limit Carbohydrates at night) Unlimited vegetables			

1. Blood Glucose

Main focus on reducing amount of carbohydrates and identifying which food are rich in carbohydrates (Elhayany et al., 2010; Hu et al., 2012; Hu et al., 2016). Encourage setting a limit of carbohydrates for each meal for blood sugar levels to remain target range. For patients with high blood glucose levels (high risk), the intensive lifestyle changes would include meal plans with the lowest amount (in grams) of carbohydrates on a daily basis.

Foods to be Recommended[6]

Protein	Fruit & Vegetables	Dairy	Grains
Beans	Berries	Low-fat dairy products	Brown Pasta
Nuts	Sweet Potatoes	Preferred cheese; goat	Brown Rice
Poultry	Non-strachy Vegetables		Quinoa
Eggs	Kale, Broccoli, asparagus, marrows, cabbage, cauliflower, peppers,		Bulgar Wheat
Oily Fish: Salmon & Tuna			Couscous
			Wholegrain Wraps or Pita
			Brown Bread

Food to Avoided[6]

White/Maltese Bread
Processed Grains: White pasta or rice
Processed Fruits: jam, fruit sauce, canned fruits (always recommend fresh)

---

[6] Diabetes UK. 10 Tips for Healthy Eating With Diabetes [Internet]. United Kingdom; 2021 [Cited 2021 Jun 15]. Available from: https://www.diabetes.org.uk/guide-to-diabetes/enjoy-food/eating-with-diabetes/10-ways-to-eat-well-with-diabetes

Full-fat dairy
Fried food
Food high in sugar
Food made from refined flour

2. **Cholesterol and Triglycerides**

Main focus on reducing amount of fats and identifying which food are rich in fats, and to distinguish between the good and bad fats.

Food to be Recommended[7]

Pulses
Nuts
Oats
Vegetables; avocado
Lean Red Meat (less than 350g weekly)
White meat: Chicken, turkey, rabbit
Fish

Food to be Avoided[7]

Processed Meat: Ham, Salami, Sausages, Burgers, Bacon
Full-fat dairy: butter, cream and cheese
Pastries
Red Meat
Pork

[7] National Health Service. NHS Lower your cholesterol [Internet]. United Kingdom: NHS; 2018 [Cited 2021 Jun 15]. Available from: https://www.nhs.uk/live-well/healthy-body/lower-your-cholesterol/

Fried Food
Shellfish

Tips[7]

- Limit take away food

- Limit salty, fatty and sugary snack foods to once a week

- Use healthy oils for cooking (extra virgin olive oil)

- Increase dietary fibre

3. **Blood Pressure**

Blood pressure is easily affected by dietary choices. Blood pressure also increases with weight increase and controlling the type of food eaten will help both weight and blood pressure control. Similar recommendations of food as mentioned for blood glucose and cholesterol can also be followed for controlling blood pressure.

Emphasis on avoiding foods rich in sodium.[8]

Decrease table salt intake
Canned Food
Processed Food
Snack Food
Junk-food
Food high in sugar
Food made from refined flour

[8] World Health Organisation. WHO Hypertension [Internet]. Switzerland: WHO; 2021 [Cited Jun 15]. Available from: https://www.who.int/news-room/fact-sheets/detail/hypertension

Tips[8]

- Reduce alcohol intake

- Smoking cessation

- Reduce caffeine intake

- Reduce stress

4. BMI

The diet plan explained above and the foods to avoid or foods which are recommended also apply for reducing BMI classification.

Tips offered to patients for a reduction in BMI included;

- Increase in the amount of water drank daily.
- Reducing calorie intake; weigh food (Brehm et al., 2003; Hu et al., 2012; Hu et al., 2016).
- Starting the day with a good breakfast and eating every 3 hours.
- Including more lean foods, fruits and vegetables in the diet.
- Reducing saturated fats (low-fat diets).

References

Brehm BJ, Seeley RJ, Daniels SR, D'Alessio DA. A Randomized Trial Comparing a Very Low Carbohydrate Diet and a Calorie-Restricted Low Fat Diet on Body Weight and Cardiovascular Risk Factors in Healthy Women. The Journal of Clinical Endocrinology & Metabolism 2003; 88(4): 1617–1623.

Elhayany A, Lustman A, Abel R, Attal-Singer J, Vinker S. A low carbohydrate Mediterranean diet improves cardiovascular risk factors and diabetes control among overweight patients with type 2 diabetes mellitus: a 1-year prospective randomized intervention study. Diabetes, Obesity and Metabolism 2010;12(3):204-209.

Hu T, Mills KT, Yao L, Demanelis K, Eloustaz M, Yancy WS Jr, et al. Effects of low-carbohydrate diets versus low-fat diets on metabolic risk factors: a meta-analysis of randomized controlled clinical trials. American Journal of Epidemiology 2012; 176(7): S44- S54.

Hu T, Yao L, Reynolds K, Niu T, Li S, Whelton P et al. The effects of a low-carbohydrate diet on appetite: A randomized controlled trial. Nutrition, Metabolism and Cardiovascular Diseases 2016; 26(6):476-488.

Thom G, Lean M. Is There an Optimal Diet for Weight Management and Metabolic Health? Gastroenterology 2017; 152(7): 1739- 1751.

Appendix 4

Invitation to Study

I, Rebecca Zammit, am a second year Doctorate in Pharmacy student carrying out a research study entitled **'Point-of-Care testing in Community Pharmacy Practice'** under the supervision of Dr Francesca Wirth and Professor Lilian M Azzopardi from the Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta.

We invite you to take part in a research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. We are therefore providing you with the following information. Please take time to read it carefully and feel free to ask any questions about the information provided. The test comes as a package at a fee (20 euro) to cover for the expenses in running the 5 tests.

Participation is completely voluntary and you may withdraw from the study at any time. All information gathered will be kept strictly confidential and used solely for the purpose of the research according to the Data Protection Act (Chapter 440). If you would like to participate in the study after reading the information provided, the researcher will provide a consent form to be filled in.

Your participation in the research will be of great importance in understanding the added- value and contribution to improving primary health care and reducing non- communicable diseases when Point- of- Care testing is offered from community pharmacies.

Stedina għal lis- Studju

Jien, Rebecca Zammit, studenta tat-tieni sena għal Dottorat fil-Farmaċija qed nagħmel studju ta' riċerka intitolat 'Point-of-Care Testing in Community Pharmacy Practice' taħt is-superviżjoni ta' Dr Francesca Wirth u l-Professur Lilian M Azzopardi mid-Dipartiment tal-Farmaċija, Fakultà tal-Mediċina u Kirurġija, Università ta' Malta.

Inti mistiedna sabiex tieħu sehem fi studju ta' riċerka. Qabel ma tiddeċiedi, nixtiequ li tifhmu għaliex qed issir ir-riċerka u x'tinvolvi. Hu l-ħin tiegħek biex taqra l-informazzjoni sew u tista' tistaqsi kwalunkwe mistoqsija dwar l-informazzjoni pprovduta. It-test jiġi bħala pakkett bi ħlas (20 euro) biex ikopri l-ispejjeż fit-tmexxija tal-5 testijiet individwali li huwa inklużi.

Il-parteċipazzjoni hija kompletament volontarja u tista' tieqaf mill-istudju f'kull ħin. L-informazzjoni kollha miġbura tinżamm strettament kunfidenzjali u tintuża biss għall-iskop tar-riċerka skont l-Att dwar il-Protezzjoni tad-Data (Kapitolu 440). Jekk tixtieq tieħu sehem fl-istudju, ir-riċerkatur ser tipprovdi formola għall-kunsens li għandha timtela.

Il-parteċipazzjoni tiegħek fir-riċerka se tkun ta' importanza kbira biex nifhmu il-valur miżjud u l-kontribut għat-titjieb tal-kura tas-saħħa primarja u t-tnaqqis tal-mard meta l-ittestjar jiġi offrut mill-ispiżeriji tal-komunita.

Patient Information Sheet

I, Rebecca Zammit, am a second year Doctorate in Pharmacy student carrying out a research study entitled **'Point-of-Care testing in Community Pharmacy Practice'** under the supervision of Dr Francesca Wirth and Professor Lilian M Azzopardi from the Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta.

The aims of the research are to analyse the impact within primary health care services when point-of-care testing (POCT) is offered from community pharmacies and to study the sustainability of POCT in community pharmacy. POCT involves testing performed near to the patient providing health care professionals with fast results. The research looks at the added-value and contribution to improving primary health care services and reducing non-communicable diseases such as heart disease and diabetes when POCT is offered from community pharmacies.

You will be invited by the managing pharmacist to participate in this research which involves measuring your blood pressure and body composition, and testing for blood glucose, total cholesterol and triglycerides (t=1). An appointment will be scheduled by the managing pharmacist for you to meet the researcher. Blood pressure measurement is performed 3 times using a validated electronic blood pressure monitor and body composition is measured once using a height and weight scale. For blood glucose, total cholesterol and triglycerides testing you will be asked to fast for at least 10-12 hours and a finger prick blood sample (3 drops, 1 for each test) using a single-use disposable lancet is obtained. The results obtained are documented in a data collection form and interpreted according to respective evidence-based guidelines. You will be provided with a copy of the results. Recommendations are put forward accordingly by the researcher. Based on the results you may be

advised to repeat the test after 3 or 6 months. A follow-up appointment is scheduled by the researcher at the same pharmacy.

Participation in this research is entirely voluntary. The information gathered will be kept strictly confidential and used solely for the purpose of the research according to the Data Protection Act (Chapter 440). Each participant will have their data compiled registered using a research code. All data will digitalised and encrypted. Only the researcher will have access to the data.

You may discontinue participation in the research at any time without any prejudice.

Kindly sign the attached consent form if you agree to participate in this research.

Many thanks for your time,

Rebecca Zammit 79366785

rebecca.zammit.13@um.edu.mt

Folja ta' Informazzjoni għall-Pazjent

Jien, Rebecca Zammit, studenta tat-tieni sena għal Dottorat fil-Farmaċija qed nagħmel studju ta' riċerka intitolat **'Point-of-Care testing in Community Pharmacy Practice'** taħt is-superviżjoni ta' Dr Francesca Wirth u l-Professur Lilian M Azzopardi mid-Dipartiment tal- Farmaċija, Fakultà tal-Mediċina u Kirurġija, Università ta' Malta.

L-għanijiet tar-riċerka huma li nanalizza l-impatt fi ħdan is-servizzi tal-kura primarja tas-saħħa meta l-ittestjar jiġu offruti mill-ispiżeriji komunitarji u biex nistudja s-sostenibbiltà ta' dawn it-testijiet fl-ispiżerija tal-komunità. Dawn it-testijiet baziċi jinvolvu, numru ta' testijiet li jsiru viċin il-pazjent u li jipprovdu lill-professjonisti tal-kura tas-saħħa b'riżultati immedjati. Ir-riċerka tħares lejn il-valur miżjud u l-kontribut għat-titjib tas-servizzi tal-kura tas-saħħa primarja u għat-tnaqqis tal-mard bħal mard tal-qalb u d-dijabete u dan meta t-testijiet ikunu offruti mill-ispiżerija tal-komunità.

Ser tkun mistiedna mill-ispiżjar maniġerjali biex tieħu sehem f'din ir-riċerka li tinvolvi l-kejl tal-pressjoni tad-demm u l-kompożizzjoni tal-ġisem tiegħek, kif ukoll testijiet taz-zokkor fid-demm, kolesterol totali u trigliċeridi (t = 1). L- ispiżjar maniġerjali ser tagħtik appuntament biex inti l-parteċipant tiltaqa' mar-riċerkatur. Il-kejl tal-pressjoni tad-demm isir tlett darbiet permezz ta' magna elettronika tal-pressjoni u l-kompożizzjoni tal-ġisem titkejjel skont it-tul u il-piż tal-persuna. Għaz-zokkor fid-demm, kolesterol totali u testijiet tat-trigliċeridi inti ser tkun mitlub is-sum bejn 10-12 il-siegħa u kampjun tad-demm mis-seba' (3 qatriet, 1 għal kull test) bl-użu ta' lancet. Ir-riżultati miksuba ser ikunu dokumentati f'forma ta' ġbir ta' data u interpretati skond il-linji gwida rispettivi bbażati fuq l-evidenza. Inti, il- participant ser ikollok kopja tar- riżultati. Ir-rakkomandazzjonijiet isiru a bazı ta' dan. Inti tista' tintalab li tirrepeti dan it-test wara tlett jew sitt xhur. Inti ser ikollok skedat appuntament ieħor mir-riċerkatur fl-istess spiżerija.

Il-parteċipazzjoni f'din ir-riċerka hija kompletament b'mod volontarju. L-informazzjoni miġbura tinżamm strettament kunfidenzjali u tintuża biss għall-iskop tar-riċerka skont l-Att dwar il-Protezzjoni tad-Data (Kapitolu 440). Kull parteċipant ikollu d-dejta tiegħu miġbura rreġistrata permezz ta' kodiċi ta' riċerka. Id-dejta kollha tkun diġitalizzata u kriptata, u d-dejta tista tiġi diskussa mas-superviżuri bl- użu tal-kodiċi tal-istudju tar-riċerka. Ir- Riċerkaturi biss jkollhom aċċess tad- data miksuba.

Tista' twaqqaf il-parteċipazzjoni fir-riċerka fi kwalunkwe ħin mingħajr preġudizzju.

Ġentilment iffirma l-formola ta' kunsens mehmuża jekk taqbel li tipparteċipa f'din ir-riċerka.

Grazzi ħafna għall-ħin tiegħek,

Rebecca Zammit 79366785

rebecca.zammit.13@um.edu.mt

CONSENT FORM

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

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

Point - of - Care Testing in Community Pharmacy Practice

The purpose and details of the research have been explained to me by *Rebecca Zammit* and any difficulties which I have raised have been adequately clarified. I give my consent to take the required samples and to make the applicable observations. I am aware of any inconveniences which this may cause.

I understand that the results of this research in which I am participating may be used for medical or scientific purposes and that the results of this research may be reported/published. However, I shall not be personally identified in any way, either individually or collectively, without my expressing written permission. My data will be registered using a research code. Only the researcher will have access to data and supervisors of this project will have data presented to them according to the research code. Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of the said Regulation, I have the right to obtain access to, rectify, and where applicable ask for the data concerning me to be erased.

I am under no obligation to participate in this research and am doing so voluntarily. I may withdraw from the research at any time, without giving any reason. All data collected will be digitalised and encrypted. All paper copies will be kept under lock and key by the researcher. All data collected will be securely disposed of at the end of the research. I am not receiving any remuneration for participating in this research.

In case of queries during the research I may contact: **Rebecca Zammit**

Signature of participant	_____
Name of participant	_____
Signature of Principal Investigator	_____
Name of Principal Investigator	Rebecca Zammit
Email of Principal Investigator	rebecca.zammit.13@um.edu.mt
Contact number of Principal Investigator	79366785
Name of principal supervisor	Dr. Francesca Wirth
Email of principal supervisor	francesca.wirth@um.edu.mt
Contact number of principal supervisor	23402902
Name of co-supervisor	Prof. Lilian M Azzopardi
Email of co-supervisor	lilian.m.azzopardi@um.edu.mt

PROPOSTA GĦALL-FORMULA TAL-KUNSENS

Jien/a ċittadin/a Malti/ja u għalaqt tmintax-il sena.

Talbuni biex nieħu sehem fi studju ta' riċerka bl-isem ta':

Point- of- Care Testing in Community Pharmacy Practice

L-għanijiet u d-dettalji tal-istudju spejgathomli **Rebecca Zammit** li wkoll iċċaratli xi mistoqsijiet li għamilt.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka biex tieħu l-kampjuni u tagħmel l-osservazzjonijiet li hemm bżonn, u nifhem li dan jista' jkun ta' skomdu għalija.

Jiena nifhem li r-riżultati ta' din ir-riċerka jistgħu jintużaw għal skopijiet xjentifiċi u jistgħu jiġu ppubblikati; jekk isir hekk jiena b'ebda mod ma nista' nkun identifikat/a individwalment jew bħala parti minn grupp mingħajr il-kunsens tiegħi bil-miktub. Id-dejta tiegħi ser tiġi rreġistrata bl-użu ta' kodiċi ta' riċerka. Ir-riċerkatur biss ikollu aċċess għad-dejta u s-superviżuri ta' dan il-proġett ikollhom dejta ppreżentata lilhom skont il-kodiċi tar-riċerka. Taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li timplimenta u tispeċifika aktar id-dispożizzjonijiet relevanti ta' l-imsemmi Regolament, għandi d-dritt li nikseb aċċess għal, nikkoreġi, u fejn applikabbli nitlob li d-data li tikkonċerna lili titħassar. Id-dejta kollha miġbura tkun diġitalizzata u kriptata. Il-kopji kollha tal-karta se jinżammu msakkra mir-riċerkatur.

Jiena m'għandi l-ebda dmir li nieħu sehem f'din ir-riċerka u dan qiegħed/qiegħda nagħmlu minn rajja. Jiena nista' meta rrid ma nkomplix nieħu sehem f'din ir-riċerka mingħajr ma' nagħti raġuni.

Kunfidenzjalità ta' data ser tinżamm matul ir-riċerka u l-informazzjoni miġbura ser tiġi abolita b'mod sigur wara li tintemm ir-riċerka.

Jiena **_mhux qed nitħallas_** biex nieħu sehem f'din ir- riċerka.

Jekk ikolli xi diffikulta' waqt ir- riċerka nista' nistaqsi għal: Rebecca Zammit

Firma tal-parteċipant/a   _____

Isem tal-parteċipant/a   _____

Firma tal-persuna responsabbli għal din ir-riċerka   _____

Isem tal-persuna responsabbli għal din ir-riċerka	Rebecca Zammit
Email tal-persuna responsabbli għal din ir-riċerka	_rebecca.zammit.13@um.edu.mt_
Numru tal-mowbajl tal-persuna responsabbli għal din ir-riċerka	79366785
Isem tas-superviżur prinċipali	Dr Francesca Wirth
Email tas-superviżur prinċipali	_francesca.wirth@um.edu.mt_
Numru tat-telefon tas-superviżur prinċipali	23402902
Isem tas-superviżur prinċipali	Prof. Lilian M Azzopardi
Email tas-superviżur prinċipali	_lilian.m.azzopardi@um.edu.mt_