Clinical Pharmacy Services in Primary Care

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La mente percepisce ciò

che la mente crede.

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Abstract

The evolvement and implementation of clinical pharmacy services in primary care is a response by healthcare systems to meet healthcare needs. Comprehensive models that describe clinical pharmacy services support service development. This research aimed to develop and assess the feasibility of a framework to standardise clinical intervention by pharmacists in primary care. The study was divided into four phases. Phase 1: Review and critical analysis of the literature regarding clinical pharmacy services in primary care. Phase 2: Development and validation of a self-administered questionnaire to support framework elaboration. The questionnaire, available in English, Italian and Maltese, was disseminated to consumers (N=800) online and in community pharmacies. The mean rating scores of the participants' responses to the questionnaire were calculated. These mean scores range from 0 to 4, where 0 corresponds to 'strongly disagree' and 4 corresponds to 'strongly agree'. Phase 3: Focus group discussion with an interprofessional panel of six healthcare professionals and two laypersons to generate consensus on the services covered in the framework. Phase 4: Framework design and validation of the Standard Operating Procedures (SOPs) developed as part of the framework through a Delphi method consisting of two rounds. An expert panel of seven pharmacists and three physicians validated the SOPs for content, readability, and feasibility. The results from the four phases were: Phase 1 - Community pharmacist-led services identified from the literature review that demonstrated improvements in patient outcomes comprised management of chronic diseases, such as hypertension, dyslipidaemia, diabetes, and the provision of advice and treatment for smoking

cessation and minor ailments. Phase 2 - Of the 800 respondents 74% (n=590) were female, 77% (n=621) were Maltese, and 43% (n=345) had tertiary level education. Consumers agreed that community pharmacists are knowledgeable about minor illnesses (mean=3.5 ±0.62) and chronic conditions (mean=3.2 ±0.85). The public agreed that they felt comfortable with the community pharmacist reviewing their medicines (mean=3.3 ±1.1) and performing diagnostic testing (mean=3.1 ±1.1). The pharmacist services for which the respondents showed the highest agreement were management of infections of the throat (n=674), skin (n=642), ears and eyes (n=635), and urinary system (n=565), provision of travel health advice (n=645), recommendations on routine immunisations (n=640), Medicine Use Review (n=487) and smoking cessation (n=322). Phase 3 - Consensus was reached among the focus group panel for the framework to include all the services obtaining the highest agreement in the questionnaire. Phase 4 - The developed framework defined the standards for service provision and included 22 SOPs covering the following aspects: General documents on conducting clinical services (n=5), patient review and point-of-care testing services (n=4), advice and treatment related to minor ailments, immunisation, and international travel health (n=8), and ancillary documents (n=5). This study put forward a validated framework to support clinical pharmacy expansion in primary care settings and highlights expectations of pharmacist's role in delivering clinical services from stakeholders, particularly patients. The clinical pharmacy services provided in primary care settings improve safe and timely access to care, increase patient choice to health services, and promote self-care.

Keywords: clinical framework, clinical pharmacist, pharmaceutical care, pharmacist-led service, primary care.

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List of Abbreviations

ADR	Adverse drug reaction
BP	Blood pressure
CG	Control group
CI	Confidence interval
CP	Community pharmacist
CPI	Clinical pharmacist intervention
DR	Doctor
DRP	Drug-related problem
ECG	Electrocardiogram
FIP	International Pharmaceutical Federation
GP	General practice
GPhC	General Pharmaceutical Council
HbA1c	Glycosylated haemoglobin
HDL-c	High-density lipoprotein cholesterol
HP	Hospital pharmacist
HRQoL	Health-related quality of life
IG	Intervention group
INR	International Normalised Ratio
IP	Independent prescribing
LDL-c	Low-density lipoprotein cholesterol
MUR	Medicines Use Review
NICE	National Institute for Health and Care Excellence
NRT	Nicotine replacement therapy
PMR	Patient Medicines Record
POYC	Pharmacy Of Your Choice
QALM	Quality-adjusted fife months
QoL	Quality of life
RCT	Randomised controlled trial
SOP	Standard Operating Procedure
STD	Sexually Transmitted Disease
UK	United Kingdom
USA	United State of America
UTI	Urinary tract infection
WHO	World Health Organization

Chapter 1: Introduction

1.1 Dimensions of clinical pharmacy

The American College of Clinical Pharmacy describes clinical pharmacy as the discipline contributing to advancements in pharmacy practice where pharmacists with specialised advanced education, training and skills provide patient care through rational use of medicines and interventions to prevent diseases, improve health, and promote well-being.[1] A more recent description of clinical pharmacy is presented by Dreischulte and Fernandez-Llimos (2016) as a "set of professional activities, behaviours and values" targeting medicines safety, effectiveness, cost-effectiveness and patient-centeredness at the population and individual level. The two concepts align with the pharmaceutical care principle introduced in the early 1990s by Hepler and Strand (1990) as the provision of medication therapy intending to improve patient outcomes and quality of life.

Over the decades, advancements in technology and increased demand to meet patients' needs shifted the main focus of pharmacy practice from product-oriented to patient-centred practice.[2] This transition enabled clinical pharmacy to become a multidimensional aspect of pharmacy practice ranging from safe provision of medicines and health information to health screening, monitoring drug therapy and counselling on rational and appropriate use of drugs and medical devices (Scahill et al, 2017). The modern definition of pharmaceutical care embraced internationally is the "pharmacist's contribution to the care of individuals in order to optimise medicines use and improve

[1] American College of Clinical Pharmacy. The Definition of Clinical Pharmacy [Internet]; 2008 [cited 2022 Mar 13]. Available from: https://www.accp.com/docs/positions/commentaries/Clinpharmdefnfinal.pdf.
[2] Wiedenmayer K, Summers RS, Mackie CA, Gous AGS, Everard M, Tromp D, et al. Developing pharmacy practice: a focus on patient care: handbook [Internet]. The Hague, Netherlands: World Health Organization; 2006 [cited 2022 May 25]. Available from: http://www.who.int/iris/handle/10665/69399

health outcomes".[3] In the context of clinical practice, the clinical pharmacist's role goes beyond counselling and promoting rational use of drugs, incorporating the patients' physical, mental and social-economic status as these aspects have a profound impact on their health (Hassali et al, 2016).

Although there are differences in the delivery of pharmaceutical care based on the clinician setting where pharmacists practise, clinical pharmacy is centred around patient care (McRobbie et al, 2018). The role of community pharmacists has expanded towards the provision of services intended to detect, prevent and manage diseases.[4] These pharmacist-led interventions include medicines optimisation and advanced clinical services such as point-of-care testing, medicines use review, screening tests, and managing patients with chronic diseases (Sinclair et al, 2019; Azzopardi & Serracino-Inglott, 2020).

While these efforts attempt to improve life expectancy and reduce health threats, an ageing population means an increased number of people suffering from long-term conditions. This scenario implies a considerable rise in morbidity and mortality associated with chronic diseases. To address these health concerns, the World Health

[3] Hersberger KE, Griese N, Cordina M, Tully MP, Foulon V, Rossing C, et al. Position Paper on the PCNE definition of Pharmaceutical Care 2013. Pharmaceutical Care Network Europe. 2013 [cited 2022 Mar 13]. Available from: https://www.pcne.org/upload/files/3_PCNE_Definition_Position_Paper_final.pdf.

[4] Vision 2020-2025 - Pharmacists at the heart of our communities. Community Pharmacy Section [Internet]. The Hague, Netherlands: International Pharmaceutical Federation (FIP); 2020 [cited 2022 Mar 13]. Available from: https://www.fip.org/files/CPS_vision_FINAL.pdf

Organization[5] and the International Pharmaceutical Federation[6] have emphasised the urgency to prevent and control non-communicable diseases by developing and expanding pharmacy services in primary and ambulatory care settings. These pharmacist-led interventions delivered in the community would meet the fast-growing demand for safe and rational use of medicines and ensure more sustainable and affordable healthcare services.[2]

1.2 Community pharmacy and healthcare provision

Community pharmacists are considered the first point of contact for many patients due to high-quality services, accessibility, increased opening times, and geographical distribution, making community pharmacies ideal for providing patient-centred care and reducing health inequalities (Agomo, 2012; Mossialos et al, 2015). The traditional role of the community pharmacist is centred around dispensing prescriptions, counselling patients on medicines-related issues, and managing self-limiting acute conditions with advice and over-the-counter product recommendations. Their unique knowledge, skills, competence and experience enable pharmacists to be experts in therapeutics and medicines use, working independently and collaborating with other healthcare professionals to deliver patient care (Saseen et al, 2017).

[5] World Health Organization (WHO). Global action plan for the prevention and control of noncommunicable diseases 2013 - 2020 [Internet]. Switzerland: World Health Organization (WHO); 2013 [cited 2022 Mar 13]. Available from: https://www.who.int/publications/i/item/9789241506236

[6] International Pharmaceutical Federation. Beating non-communicable diseases in the community — The contribution of pharmacists [Internet]. The Hague, Netherlands: International Pharmaceutical Federation (FIP); 2019 [cited 2022 Mar 13]. Available from: http://bit.ly/2DI9bQo

Pharmacists' interventions addressing the appropriateness of prescriptions, patient adherence to therapy, and other pharmaceutical issues improve patient care (Melchiors et al, 2011; Smith et al, 2016; Hindi et al, 2019). In addition, community pharmacies offer a broad range of public health services such as medicines use review, minor ailment services, chronic disease management, health screening, point-of-care testing, vaccination, smoking cessation and other health-related advice. These pharmacist interventions have been shown to reduce hospital admissions, mortality and complications associated with chronic conditions such as cardiovascular disease, diabetes, and hypertension (Roughead et al, 2005; Barra et al, 2018; Moore et al, 2020).

The movement toward delivering clinical services in primary care settings is an opportunity to meet healthcare expectations and maximize pharmacists' skills to their full potential.[2,4]

1.2.1 Patient-focused services: An international perspective

The role of clinical pharmacists in the community is gaining momentum in a global context where the pharmacist is recognised as an essential member of the patient care team. Countries such as Canada, New Zealand, the United Kingdom (UK) and the United States of America (USA) acknowledged the importance of primary care interventions by implementing action plans to extend the pharmacists' scope of practice for the multidisciplinary provision of healthcare.

In Canada, pharmacists deliver clinical services through chronic disease management, minor ailment advice, and wellness programmes. Although there are differences across

the provincial governments, community pharmacists are authorised to prescribe medicines to treat gastrointestinal, urinary, musculoskeletal, and dermatologic conditions.[7] In Alberta, pharmacists working in collaborative practice settings can initiate drugs, make therapeutic substitutions, change drug dosage, formulation, regimen, and extend or repeat prescriptions. Their full scope of practice includes the administration of vaccines and other injectable drugs and ordering and interpretation of investigative laboratory tests.[7]

Similarly, clinical pharmacists in New Zealand practising in primary care provide advanced services to patients through medicines review, health screening, interpretation of biochemical and investigative tests, anticoagulation clinics and vaccination. Pharmacists with specialised postgraduate qualifications can prescribe medicines within their competence and scope of practice. Although the pharmacist prescriber role is a new concept, the regulatory bodies have considered extending the prescribing rights as the value of clinical pharmacists' skills is recognised.[8]

In Europe, the UK has an advanced leading role in integrating pharmacists into the primary care system. Community pharmacists provide nationally and locally commissioned clinical services to the population, including minor ailment schemes, medicines review, management of chronic conditions, medicines optimisation in care

[7] Canadian Pharmacist Association. Scope of practice [Internet]. Ottawa: Canadian Pharmacists Association; 2022 [updated 2022; cited 2022 Mar 13]. Available from: https://www.pharmacists.ca/advocacy/scope-of-practice/

[8] Pharmaceutical Society of New Zealand. Pharmacists framework [Internet]. New Zealand: Pharmaceutical Society of New Zealand; 2022 [updated 2022; cited 2022 Mar 13]. Available from: https://www.psnz.org.nz/practicesupport/pharmacyservices/frameworks

homes, and vaccination.[9] In 2015, the National Health Service launched a pilot scheme[10] employing clinical pharmacists in general practice to support general practitioners and utilise pharmacists' skills in managing chronic conditions. The scheme's success allowed full integration of clinical pharmacists in general practices across the UK.

In addition, pharmacists are an integral part of managing acute conditions in community settings through the 'urgent care pathway' and the 'community pharmacist consultation service'. Through these schemes, general practitioners, emergency response teams, and other healthcare professionals working in primary and secondary care can refer patients to pharmacists to supply emergency medicines and treat minor illnesses.[7] The role of prescribing pharmacists in the UK was first introduced in 2003. Practitioners with vast clinical experience and knowledge acquired through a postgraduate course were allowed to prescribe prescription-only medicines to patients in a partnership with a physician and independently following specific inclusion criteria. In the UK, this role is regulated by the General Pharmaceutical Council (GPhC), which sets the standards and competencies of prescribing practice.[11]

Following a public and expert consultation in 2021, the GPhC introduced prescribing rights to qualifying pharmacists, amending competencies for undergraduate pharmacy

[9] National Health System. Pharmacy Integration Programme [Internet]. London: National Health System; 2022 [update 2021; cited 2022 Mar 13]. Available from: https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-integration-fund/

[10] National Health System. Clinical pharmacist [Internet]. London: National Health System; 2022 [update 2022; cited 2022 Mar 13]. Available from: https://www.england.nhs.uk/gp/expanding-our-workforce/cp-gp/

[11] General Pharmaceutical Council. Standards [Internet]. London: General Pharmaceutical Council; 2022 [update 2022; cited 2022 Mar 13]. Available from: https://www.pharmacyregulation.org/standards

students, and removing the requirement for pharmacists to have two years of post-graduation experience to become independent prescribers.[12]

The American College of Clinical Pharmacy is the professional body that provides education and guidelines for clinical pharmacists in the USA. Since each State's board of pharmacy regulates pharmacist practitioners, there are differences in the scope of practice and the level of services provided from State to State. The primary role of the community pharmacist is centred on preventive screening tests, point-of-care diagnostic tests, vaccinations and management of acute and chronic conditions. Some States extend the authority to prescribe medications, order and interpret laboratory tests, and administer injectable medications (Mossialos et al, 2015).

1.2.2 Patient-focused services: Malta perspective

Community practice in Malta is focused on safe dispensing, advice on drug use, educating patients, and providing point-of-care testing. Practising pharmacists provide counselling and medical advice to patients presenting with minor ailments and those attending the pharmacy with a medical prescription. Pharmacists offer blood pressure measurements, health checks, and point-of-care testing mainly for blood glucose and cholesterol levels to promote well-being and prevent and manage chronic diseases.

[12] General Pharmaceutical Council. Initial education and training for pharmacists [Internet]. London: General Pharmaceutical Council; 2022 [update 2022; cited 2022 Mar 13]. Available from: https://www.pharmacyregulation.org/initial-training

Patients suffering from chronic conditions are eligible for free-of-charge medicines through a government scheme called Pharmacy Of Your Choice (POYC). This scheme allows patients to select their preferred pharmacy to collect repeat prescriptions monthly or bimonthly (Magno, 2021). The dispensing of medicines is managed through a computer system that maintains an electronic copy of patient medication records and the medicines or pharmaceutical products issued. Pharmacists can recommend and amend the medicines' dose, frequency, and strength in collaboration with the patient and the physician in charge. The community pharmacist participating in the scheme plays a crucial role in assessing patient adherence to therapy. The regularity of patient interactions with the community pharmacist creates an opportunity to establish a trusted relationship with patients and review the medicines for interactions and drug-related issues.

Many community pharmacies have private consultation rooms or clinics available to general practitioners, specialist physicians, and other healthcare professionals such as physiotherapists, podiatrists, and speech-language therapists. Patients can attend these outpatient clinics, receive the necessary treatment, and collect the medicines or medical certificates from the pharmacy. This setting supports an inter-professional relationship between pharmacists and other healthcare professionals, and allows patients to access the care they need when it is most suitable for them under comprehensive, collaborative care pathways.

The role of the clinical pharmacist in Malta is expanding, with pharmacists undertaking postgraduate training whilst practising in community pharmacies, hospitals or

government bodies (Vella et al, 2021). Recent studies show a positive attitude towards the expansion of the community pharmacist's role in providing clinical services such as blood pressure measurement, comprehensive point-of-care testing, and monitoring of medicines (Wirth et al, 2010; Vella et al, 2015). Results of two studies highlighted the encouraging public perception of pharmacists monitoring warfarin levels (Mifsud et al, 2019) and the pharmacists' view on prescribing antibiotics to treat minor ailments (Attard Pizzuto et al, 2019). A recent study from Parnis (2020) investigated the Maltese perception of community pharmacy services, demonstrating a statistically significant association between consumers' positive attitudes and achieved desirable positive outcomes following pharmacist-led interventions such as medicines recommendations.

The results from these studies present an opportunity to explore further the potential of community pharmacists as a professional integrated into primary care pathways and taking the lead in managing patients with chronic conditions.

1.3 The value of pharmacists integrated into primary care

Pharmacists play an essential role in the healthcare system by providing safe, efficient and collaborative patient care. Community pharmacies improve access and choice to healthcare with patient education and counselling points that promote self-care, health and wellness, together with interventions to prevent, manage and reduce the burden of illnesses.[4] Community pharmacist interventions have been shown to increase immunisation uptake, early detection of diseases through screening tests, and improved clinical outcomes in diabetes, hyperlipidaemia, cardiovascular, respiratory and mental health disease (Sinclair et al, 2019; Newman et al, 2020).

Pharmacist-led services delivered in primary care, such as comprehensive medication management, have positively impacted patient outcomes, clinician and patient experience and contributed to cost-effective medicines optimisation strategies.[13] In addition, pharmacists' interventions have a positive economic impact on decreasing unnecessary use of medicines and reducing health expenditure and societal costs (Murphy et al, 2020). Since pharmacists have unique skills and knowledge of medications, they could play a significant role in promoting patients' health and disease prevention (Moore et al, 2019).

While the pharmacist's expertise is a valuable resource in the primary care setting, the role of the clinical pharmacist is not used to its full potential.[14] A report from the American Association of Colleges of Pharmacy emphasises the importance of including pharmacists in primary care teams as an essential element that benefits patients, physicians and the healthcare system (Moore et al, 2020). Implementing clinical pharmacists' services in primary care would enable a collaborative approach to pharmacist-physician management of patients' conditions (McMillan et al, 2013), which significantly improves quality of care and access to care (Moore et al, 2020; Strand et al, 2020).

[13] American College of Clinical Pharmacy. Comprehensive Medication Management: Landmark Study's Findings and Future Directions [Internet]; 2021 [updated 2022, cited 2022 May 13]. Available from: https://careers.accp.com/article/comprehensive-medication-management-landmark-study-s-findings-and-future-directions

[14] Creating community-clinical linkages between community pharmacists and physicians [Internet]. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2017 [cited 2022 Mar 13]. Available from: https://www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf

Demonstrating the positive outcomes of pharmacist-led interventions such as comprehensive medicines management on patient care and cost-effective medicines optimisation is crucial to ensure a sustainable model of care supporting the widespread scale of clinical services delivered in primary care contexts (Livet et al, 2018; Pestka et al, 2020). This multidisciplinary approach would deliver more comprehensive person-centred care and add value to the health system (Awdishu et al, 2019; Khaira et al, 2020).

1.4 Relevance of the study

Although there is emerging evidence supporting the integration of pharmacists in the primary care team, there is a significant knowledge gap regarding models of care able to demonstrate the benefit of clinical pharmacists' interventions to other healthcare providers and the impact on the health system (Hayhoe et al, 2019). The uncertainties regarding the effectiveness of pharmacists' interventions could be associated with study heterogeneity, lack of impact of the service, and poor design and methodology (Watkins et al, 2015; Newman et al, 2020). Another significant factor that weakens the evidence supporting the benefit of pharmacists' interventions is the lack of standardised guidelines and procedures for delivering clinical services in primary care (Van Mil & Schulz, 2006; Martins et al, 2015).

The use of clinical guidelines can assist in overcoming these barriers to implementing evidence-based clinical pharmacy services (Watkins et al, 2015). A clear description of the interventions, expected patient benefits, and defined processes are fundamental to producing reliable evidence (Tonin et al, 2021).

In Malta, while the public and the pharmacist perception regarding clinical services available in community pharmacies is optimistic, the clinical pharmacist's role in primary care is not formally defined. Standardisation and documentation of pharmacists' interventions in primary care settings are essential to ensure the successful and sustainable provision of clinical pharmacists' services (Mifsud et al, 2019; Azzopardi & Serracino-Inglott, 2020).

This is the first national large-scale cross-sectional multi-language study that captures the public perception of clinical pharmacy services in primary care. The study hypothesis was that a structured, validated framework developed to support pharmacists delivering clinical services improves access to care and patient experience and expands clinical pharmacy practice at the primary care level.

1.5 Research questions

The research questions were:

- What is the scientific evidence supporting clinical pharmacy services in primary care?
- What standardised model can be used by pharmacists providing clinical services in the community?

1.6 Aim and objectives

The study aimed to develop and assess the feasibility of a framework to standardise clinical intervention by pharmacists in primary care contexts. The objectives of the research were to:

i. Review and critically analyse the literature to identify strengths and weaknesses of pharmaceutical services currently provided by clinical pharmacists in primary care settings.

ii. Capture best practices concerning clinical pharmacy services.

iii. Identify issues and opportunities for setting up and improving pharmacist-led services in community practice.

iv. Develop and validate a standardised framework consisting of standard operating procedures for providing clinical pharmacist services in primary care contexts.

Chapter 2: Methodology

2.1 Research design

The methodology was a mixed-method of quantitative and qualitative research. A quantitative approach was adopted with respect to the questionnaire, and a qualitative approach was used to validate the framework using a focus group discussion and a Delphi method. The research design adopted for this study included a literature review, the development and validation of a self-administered questionnaire, a focus group discussion with an expert panel, and a Delphi method of consensus development. A cross-sectional study using a multi-language questionnaire was selected to explore public beliefs and awareness of the pharmacist's role and public perception of clinical pharmacy services available in the community. The data gathered from the questionnaire was used to design and develop a framework that was validated by an interprofessional expert panel.

The study was divided into four phases:

1. The first phase entailed a review and critical analysis of the literature to identify relevant studies supporting improvement in clinical outcomes following pharmacist interventions in primary care settings. The literature was explored to capture best practices and evaluate the impact of pharmacist-led services on the healthcare system. The gaps in this field were identified and addressed to recommend opportunities for innovative clinical pharmacist services.

2. The second phase consisted of a self-administered questionnaire developed and disseminated to capture consumers' perception about current and potentially new pharmacist-led services to be delivered in primary care.

3. The third phase consisted of a focus group discussion with an expert panel to inform the development of the framework. The group discussion was used as a qualitative approach to understanding the strengths, opportunities, and barriers surrounding clinical pharmacist services.

4. The final phase of the study entailed the planning, designing, developing, and validating the framework to be followed in the provision of clinical pharmacy services. A Delphi technique was used as a structured process to validate the framework until consensus was obtained.

2.2 Ethics review

A self-assessment ethics form for Human Subjects Research was filed with the Faculty of Medicine and Surgery Research and Ethics Committee under the General Data Protection Regulation (FRECMDS_2021_174) (Appendix 1).

2.3 Phase I: Literature review

A systematic literature review was conducted to identify the scientific evidence supporting improvements in patient outcomes following pharmacist interventions. The PICOS (Population, Intervention, Comparison, Outcome, Study design) method was applied to formulate the search strategy and select relevant keywords (Liberati et al, 2009). The PICOS search strategy is listed in Table 2.1.

Table 2.1 Search strategy using the PICOS method

Population	- Adults - Outpatient - Not hospitalised
Interventions	- Clinical pharmacist interventions (counselling, advice, treatment, medicines optimisation, medicines review, point-of-care or another diagnostic testing) - Interventions delivered in primary care settings (community pharmacy, General Practitioner practice, health centres)
Comparators	- Usual care - Advice and recommendations only
Outcomes	Any results or changes in: - Patient outcome (adherence to therapy, behavioural changes) - Health outcomes (changes in health status, function or quality of life) - Clinical outcomes (biomarkers, laboratory tests)
Study design	- Primary research studies (randomised controlled trials, observational) - Reviews (literature review, systematic review, meta-analysis)

2.3.1 Information sources and search strategy

A literature search was undertaken to identify relevant records regarding clinical pharmacy services in primary care. Searches were limited to articles published between January 2012 and March 2022 and for which full-text access was available. Only articles published in English were included in the final review. The databases used included PubMed (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL EBSCOhost), SCOPUS, the Cochrane Database of Systematic Reviews, and Google Scholar. A hand search was performed using the reference lists of selected papers to identify any additional relevant studies and minimise the risk of missing key articles. Given the indexing and controlled vocabulary differences between the databases used for the literature review, a combination of terms was employed. The search strategy

used Medical Subject Headings (MeSH) terms and natural language combined with Boolean operators. The free-text search mode was used to search for keywords not listed as MeSH. Terms included: (((pharmacist) OR (clinical pharmacist) OR (community pharmacist) OR (pharmacist-led)) AND ((clinical service) OR (pharmacy service) OR (pharmacist intervention)) AND ((community pharmacy) OR (primary care) OR (health centre) OR (outpatient)) AND ((clinical outcomes) OR (patient outcomes) OR (health outcomes) OR (outcome measures))). The full description of the search strategies is provided in Appendix 2.

2.3.2 Data screening

Studies were considered for initial screening if they discussed or compared interventions conducted by pharmacists in community pharmacies, health centres, or outpatient clinics that aimed to improve clinical, behavioural or economic outcomes in adult patients. The pharmacist's eligible interventions included patient education and counselling, medicines review and optimisation, lifestyle modification, physical assessment, monitoring of clinical outcomes, prescribing for, dispensing, and recommending minor ailment therapies.

The search results were imported in Microsoft Excel® for screening and removal of duplicated records found in different databases. The full-text publications of potentially relevant papers were subsequently screened and excluded if they belonged to any of the criteria shown in Table 2.2. Additional articles identified from the reference lists of screened records were included in the screening process.

Table 2.2 Criteria for record exclusion

Title and abstract	No mention of pharmacist or pharmacy team No community pharmacy or primary care setting Refers to public or healthcare professionals' perceptions or views Refers to interventions on children or young adults Duplicate
Full text	Full text cannot be obtained or accessed No intervention or clinical outcome was described Study design or implementation of services without application

2.3.3 Data extraction and synthesis

The full references of the articles included in the literature review were imported into the reference management package RefWorks®. Data extracted from relevant studies included authors, year of publication, study design, countries and aim of the study, population, type of pharmacist interventions, key findings and study limitations. The statistical significance ($P<0.05$) and clinical significance of the clinical, humanistic, and economic outcomes following clinical pharmacist interventions were considered.

2.4 Phase II: Questionnaire development

The literature review informed the development of a questionnaire to measure the public belief and awareness of the clinical pharmacist's role and their perception of clinical pharmacy services available in primary care. The development and validation of the questionnaire followed the stepwise approach described by Boateng et al, (2018). The first step consisted of generating the domains and items to include in the questionnaire and validating its contents. The second stage entailed sampling the

questionnaire and optimising the items and scale. The final phase involved testing the questionnaire for validity and reliability (Boateng et al, 2018).

This section provides an overview of the questionnaire's development, testing and validation process used to construct the questionnaire.

2.4.1 Domains and items development

The questionnaire included pharmacists' interventions and services identified through the literature review that demonstrated clinical outcomes improvements. Two studies (Wirth et al, 2010; Vella et al, 2015) that measured the Maltese population's knowledge and perception were consulted to identify relevant questions and appropriate assessment scales to include in the questionnaire.

The survey developed by Wirth et al (2010) was used as a template for the consumer's characteristics section and formulating the beliefs and awareness questions. The items related to the consumers' perception of clinical services available in primary care were developed de novo. The questionnaire was developed utilising clear and unambiguous language and integrating a 5-point Likert scale that respondents could easily understand. The questionnaire contained statements instead of questions and did not contain negatively worded items (Artino et al, 2011). The draft questionnaire included a large number of items which were revised later in the design process.

The questionnaire was composed of five domains A to E: consumer demographics, beliefs, awareness, perception of services available in the community, and perception of new pharmacy services. The consumer demographics section (A) collected

information about the participant's age, gender, country of residence, nationality, level of education and occupation. The belief (B) and awareness (C) sections investigated the participant's level of agreement and awareness with statements regarding the pharmacist's role in managing acute and chronic conditions. The fourth domain (D) explored the consumer's agreement level with hypothetical scenarios involving pharmacists providing clinical services in community pharmacies, such as point-of-care testing, counselling, and treatment recommendations for minor ailments. The questionnaire's last domain (E), which explored new pharmacy services, was divided into three parts. The first part investigated the participants' point of view about the potential for new pharmacist-led services available in community pharmacies. The second part of this section assessed the public willingness to use and pay a fee for thirteen proposed clinical services. The last part comprised three questions to enable participants to elaborate on their responses.

Section A contained nominal and ordinal scales to gather participants' demographics. The items in sections B, C, D and E (perception of potentially new pharmacist-led services) were constructed to measure the consumer's belief, awareness and perception using a Likert scale of 5 points. The scale ranged from 0 to 4, where 0 corresponded to "Strongly disagree" or "Not aware", and 4 corresponded to "Strongly agree" or "Very much aware". The scale included a neutral option to generate sufficient variance among the respondents. The Likert scale for the domain analysing the consumer's perception included a "Not applicable" option category to prevent respondents from taking a side that may produce biased data (Chyung et al, 2017). For instance, the question regarding the willingness to use a smoking cessation service included the "Not applicable" option

for those who do not smoke. Section E (willingness to use and willingness to pay for the proposed new clinical service) contained a nominal scale with three options to assess the participants' inclination to use and pay for the proposed clinical services. Three open-ended questions were introduced at the end of section E to allow participants to comment and suggest improvements (Table 2.3).

Table 2.3 Questionnaire domains, items, type and number of questions

Section	Domain	Item description	Type of question	Number of questions
A	Consumer demographics	Age	Ordinal	6
		Gender	Nominal	
		Country of residence		
		Nationality		
		Level of education	Ordinal	
		Occupation	Nominal	
B	Belief	Perception of the pharmacist's role in understanding minor ailments and chronic diseases	Ordinal 5-point Likert scale	3
C	Awareness	Awareness about the pharmacist's clinical role in patient care		4
D	Perception	Perception of pharmacist-led services available in community pharmacies	Ordinal 5-point Likert scale	4
E	Perception	Perception of potential new pharmacist-led services	Ordinal 5-point Likert scale	13
		Willingness to use the proposed new clinical service	Nominal 3 options	13
		Willingness to pay for the proposed new clinical service	Nominal 3 options	13
		Justify answer	Open-ended	3
		Additional comments		
		Suggestions for improvement		

2.4.2 Translation and back translation

The 59-item self-administered questionnaire was developed in English and translated into Italian and Maltese to capture the consumers' multicultural diversity of the Maltese population. The researcher and a second independent professional translated the English version into Italian. Two independent bilingual professionals converted the English version into their mother tongue (Maltese). One translator was aware of the questionnaire's objective, whereas the second translator was naïve to its concept. This approach was adopted to reflect the nuances and differences of the target language (Tsang et al, 2017). The Italian and Maltese versions of the questionnaire were translated back into the source language (English) by two separate bilingual individuals. The back-translators were not involved in the previous translation and were unaware of the questionnaire's objective to avoid bias and ensure the accuracy of the translation (Guillemin et al, 1993; Tsang et al, 2017). Discrepancies between the translated versions and the original questionnaire were discussed and resolved among the relevant translators.

2.4.3 Content validation

A panel of experts was recruited for each language version of the questionnaire and consulted for face and content validation. The Maltese version was validated by two community pharmacists, one hospital pharmacist, two academics, two physicians and two laypersons. The English version was validated by a panel of two community pharmacists, two hospital pharmacists, two academics, two physicians and one layperson. The Italian questionnaire was validated by two community pharmacists, two

hospital pharmacists, one academic, one physician and two laypersons. The panel of experts recruited for the Maltese and Italian version of the questionnaire were chosen based on their ability to speak and understand English as a second language. This approach was taken to avoid bias caused by the tendency of bilingual individuals to adopt their second language's cultural values that cannot be generalised to the monolingual population (Sperber, 2004; Sousa & Rojjanasrirat, 2011).

A tool was created as an instrument to support the validation of the questionnaire. The tool included an invitation letter with clear instructions about the panel of experts' expectations and the tasks required for validation. The tool provided four domains with definitions and defined the scale to facilitate scoring. A comments section was included in the validation tool to encourage and enable suggestions for improvement.

The translated version of the questionnaire and the validation tool were distributed via email to the panel according to their native language. Validation involved reviewing the questionnaire using a Likert scale ranging from 1 (Poor) to 5 (Excellent) for content relevance, comprehensiveness, readability and presentation of the items and instructions. The experts were asked to submit the responses to the researcher within two weeks. A reminder was sent after a week and two days before the proposed deadline.

The panel's comments and recommendations were reviewed by the researcher and used to refine the questionnaire's domains and items. Amendments were presented to the expert panel for validation until consensus was obtained. The consensus threshold

was defined as ≥75% agreement on the Likert-type scale for all criteria (sum of 4 or 5). The non-consensus threshold was set as ≥75% of disagreement (sum of 1 or 2 of the Likert scale). The final versions of the questionnaires are included in Appendix 3.

2.4.4 Questionnaire pilot testing

Each validated version of the questionnaires was pilot tested on a sample of 20 consumers recruited by convenience sampling in community pharmacies. The respondents were asked to comment on the questionnaire's length, legibility, and vocabulary to ensure that the questions were meaningful, clear and unbiased.

2.4.5 Reliability testing

Test-retest reliability was used to evaluate how an individual's responses were consistent when the questionnaire was administered twice with a specific time interval. Twelve individuals selected by convenience sampling were asked to complete the same questionnaires twice two weeks apart. Test-retest reliability was evaluated using Cohen's kappa test for questions with a nominal scale and the Kendall-tau test for ordinal scale. The threshold of reliability of both tests was set at 0.7 and considered satisfactory for $p<0.05$ (Kimberlin & Winterstein, 2008). The consumer's demographic domain was excluded from the correlation analysis.

2.4.6 Questionnaire dissemination

The revised version of the questionnaire was distributed between August and November 2021 to customers in ten community pharmacies in Malta and was made available on

social media using Google Forms®. The pharmacies selected to disseminate the questionnaire were geographically spread out across Malta to catch a representative sample of participants. The pharmacies were in the Northern area (Mellieħa, Mosta and Naxxar), Northern Harbour (Pieta') and Southern Harbour (Paola and Kalkara). Consumers attending one of the selected pharmacies were invited to complete the questionnaire in their preferred language. The managing pharmacist of each location described the aim of the study and handed the questionnaire to those interested in participating. Participants were allowed to return the completed questionnaire on another occasion. All the completed anonymised questionnaires were kept in a sealed box and collected weekly by the researcher.

The link for the online version of the questionnaire was posted on the researcher's personal Facebook® and LinkedIn® accounts and distributed on social media to attract potential participants. No personal accounts were directly contacted by the researcher. Before publishing the invitation, permission to publish the questionnaire was sought from each page administrator. The Google Form® link and a brief introduction about the aim of the study were sent to each page administrator that granted permission to disseminate the questionnaire. The administrator of each Facebook® page was asked to post the invitation every two weeks to increase visibility and recruitment. No identifiable information was recorded or stored using social media. The Google Form® link was accessible from August to November 2021. By clicking on the link, participants were invited to select the preferred language and read the introductory section explaining the aim of the study and what participating in the questionnaire entailed. To access the questionnaire, participants had to declare to be over 18 years old and accept the

informed consent condition by clicking on a mandatory button. Recruitment of participants ended when the number of responses was less than five a week for three consecutive weeks.

2.4.7 Data handling

The responses from the paper-based and online questionnaires, excluding data collected from piloting, were transferred into a Microsoft Excel® spreadsheet for analysis and computation. Data were analysed using Statistical Package for the Social Sciences (SPSS) version 28 (SPSS Inc., Chicago, USA). The Cronbach's α (alpha) coefficient for internal consistency was calculated for the five domains of the questionnaire, using the value of 0.7 and above to indicate good internal consistency (Taherdoost, 2016).

The Friedman test was used to compare the mean rating scores of the Likert scale between related statements in each domain. These mean rating scores range from 0 to 4, where 0 corresponds to 'Strongly disagree' or 'Not aware' and 4 corresponds to 'Strongly agree' or 'Very much aware'. Statistical significance is accepted if the p-value is less than 0.05. The Kruskal Wallis test was used to compare the mean rating scores provided to a statement between groups of participants clustered by gender, age, level of education and occupation. These mean rating scores range from 0 to 4, where 0 corresponds to 'Strongly disagree' and 4 to 'Strongly agree'. Statistical significance is accepted for p-values less than 0.05.

2.5 Phase III: Focus group

The focus group discussion aimed to inform the development of the framework. An invitation email was sent to practising healthcare professionals and laypersons who completed the questionnaire and expressed their interest in participating in further study developments. The invitation was extended to other participants selected from the researcher's contacts. The email invitation contained information regarding the aim of the study and the objectives of the focus group. A link to join the online focus group was provided.

An expert panel of two physicians, two pharmacists (community and hospital), two healthcare professionals (audiologist and podiatrist) and two laypersons participated in the focus group that was held online using the videoconferencing platform Zoom® in December 2021, and lasted 70 minutes. A note keeper was invited to take notes whilst the researcher moderated the discussion.

A Microsoft PowerPoint® presentation was used to guide the discussion. The focus group was divided into a question-driven phase and a discussion phase. During the first phase, the expert panel was presented with thirteen clinical services and asked to select which of these would benefit patients if provided by community pharmacists. Participants were asked to rank the services based on their feasibility and applicability in practice and justify their answers. The services presented to the focus group were the same services included in the questionnaire. The expert panel was unaware of the questionnaire's outcomes to avoid selection bias. The second phase of the focus group

entailed discussing one of the Standard Operating Procedures (SOP) developed by the researcher. Participants were asked to discuss the structure, language used and the contents of the SOP. The comments presented by individual participants were discussed and analysed during the focus group.

2.6 Phase IV: Framework development

A framework was designed to support pharmacists during the provision of clinical interventions. The advanced pharmacy framework[15] developed by the Royal Pharmaceutical Society was used as a guideline. The developed framework consisted of two components: An introduction and a set of SOPs.

The introduction is a thirteen-page document explaining the framework's purpose and defining the standards for the service provision. These standards relate to patient's consent, consultation room, documentation requirements, role and responsibility of the clinical pharmacist, interpretation of test results, referral to the general practitioner, and reporting of adverse drug reactions.

Twenty-two SOPs were developed to guide and assist pharmacists with step-by-step instructions for providing the thirteen clinical services selected by the public through the questionnaire and validated by the expert panel in the focus group. The SOPs were divided into four sections: General, patient review, advice and treatment, and ancillary.

[15] Royal Pharmaceutical Society. The RPS advanced pharmacy framework [Internet]. London; 2013 [cited 2022 Feb 03]. Available from: https://www.rpharms.com/resources /frameworks/advanced-pharmacy-framework-apf

Each SOP contains the SOP name and number, a box for the accountable pharmacist's name and signature, and a section to insert when the SOP is implemented and the review date. The main body of the SOP is divided into three sections named process step, interpreting results and references. The first section provides step-by-step instructions to guide the pharmacist during service provision. The second section includes information about the test to be performed, such as standard and abnormal reference value ranges and recommendations for interpreting the results. The last section of the SOP includes the references to be consulted for the specific test. The International Pharmaceutical Federation toolkits[16] and the National Institute for Health and Care Excellence (NICE) guidelines[17] were consulted to develop the SOPs. A copy of the framework is available in Appendix 4.

The SOPs include four data collection forms named 'Patient consent form', 'Patient Medication Record form', 'Medicines Use Review form', and 'General practitioner information letter'. These forms allow recording of data related to the patient's details, test results and advice during the consultation, pharmacist's recommendations, and relevant information for referring the patient to the physician.

[16] International Pharmaceutical Federation. FIP Library [Internet]. 2021 [cited 2022 May 27]. Available from: https://www.fip.org/publications?publicationCategory=6&publicationYear=&publicationKeyword=

[17] National Institute for Health and Care Excellence (NICE). NICE guidelines [Internet]. 2022 [cited 2022 may 27]. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines

2.6.1 Framework validation

The proposed framework was validated by an expert panel using a two round Delphi technique to determine a consensus position about the framework's content relevance, comprehensiveness, readability, presentation, and practicality.

An invitation email was sent to the pharmacists and physicians who attended the focus group discussion. The invitation was also extended to practising pharmacists, pharmacy technicians and doctors involved in assessing patients, prescribing medicines, delivering patients-faced interventions or counselling patients on health-related issues. The email explained the study's aim and objectives and defined the steps required to complete the validation. The expert panel consisted of three community pharmacists, three hospital pharmacists (two of whom had prescribing rights), one registered pharmacy technician and three doctors (one general practitioner, one registrar in obstetrics, and one basic specialist trainee). Two prescribing pharmacists and the pharmacy technician practise in the United Kingdom, whereas the rest of the panellists practise in Malta.

A tool was created for the validation and consisted of eight statements, the scale used for the scoring process, and a comments box to enable panellists' suggestions for improvements. Clear instructions about the tasks required for the validation were provided in an invitation letter. Participants were asked to read the framework (introduction and SOPs) and leave any comments directly on the Microsoft Office Word® document. Consequently, the panel was required to score each statement of the

validation tool using the Likert scale provided, ranging from 1 (Strongly disagree) to 5 (Strongly agree).

Following ranking evaluation, the expert panel was asked to resolve items of non-consensus during the second Delphi round. The consensus threshold was defined as ≥75% of agreement (sum of "Strongly agree" and "Agree") on the Likert-type scale for all criteria. The validated framework was sent to the panel for further comments and approval. All participants returned the SOPs validation tool by the stipulated two weeks with follow up emails sent after ten days.

Chapter 3: Results

3.1 Literature analysis

The initial search produced a total of 6721 articles. After removing the duplicates, the title and abstracts of 6440 records were screened. In addition to the 540 reports sought for retrieval, 12 additional records were selected from the references of relevant articles. The full-text records of 376 articles were screened, resulting in 21 articles included in the literature review (Figure 3.1). Out of the 355 studies excluded following the full-text screening, 94 papers could not be accessed.

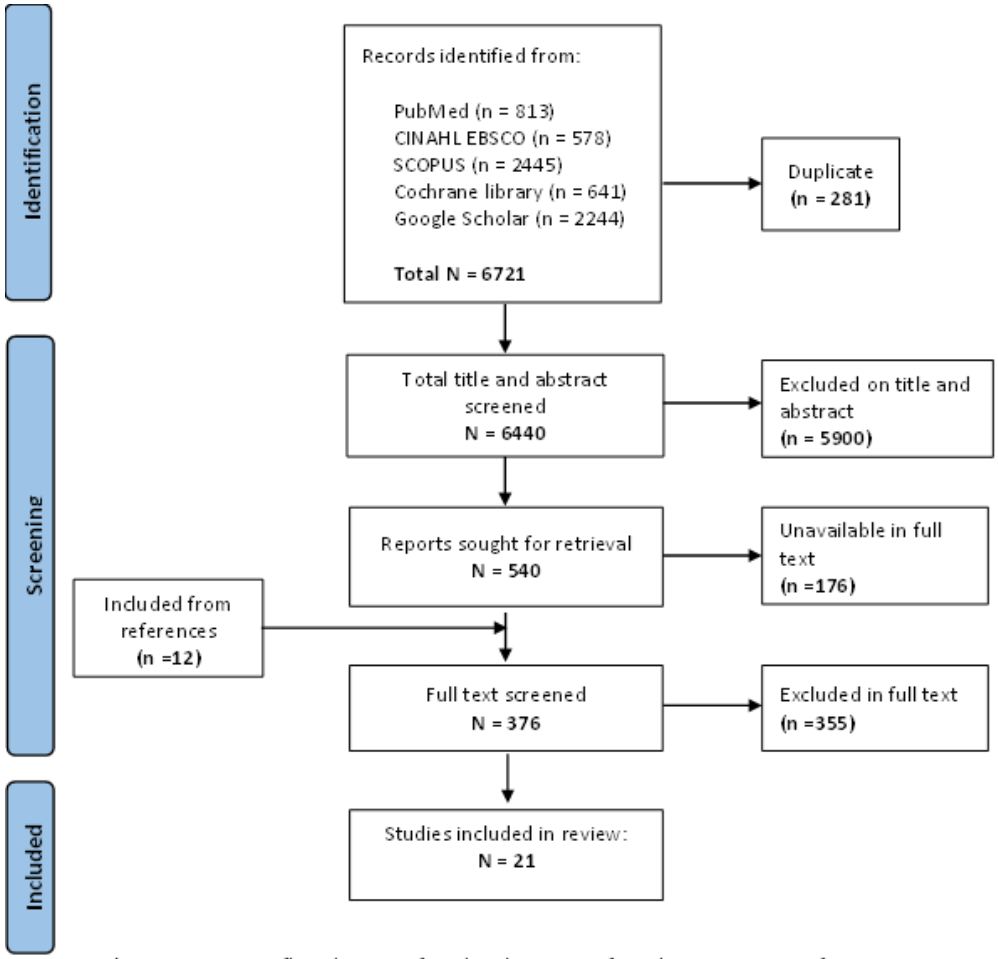

Figure 3.1. PRISMA flow diagram of study selection. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

A total of 5900 records were excluded during the title and abstract screening using the criteria reasons shown in Table 3.1. The main reason for exclusion included no mention of a pharmacist or pharmacy team in the article, interventions performed in setting

different from community pharmacies or primary care, and no intervention or clinical outcome described in the paper.

Table 3.1 Criteria used to exclude records during the screening process

Reason for record exclusion	Number of records excluded during the screening of:	
	titles and abstracts	full-text screening
No mention of pharmacist or pharmacy team	2224	74
Setting different from community pharmacy or primary care	1890	87
No intervention or clinical outcome was described	591	48
Refers to public or healthcare professionals' perceptions or views	494	6
Duplicate	344	22
Study design or implementation of services without application	208	23
Full text cannot be obtained or accessed	76	94
Refers to interventions on children or young adults	73	1
	5900	**355**

The literature review included thirteen randomised controlled trials (RCT) (Lowrie et al, 2012; Burford et al, 2013; Wong et al, 2013; Geurts et al, 2016; Messerli et al, 2016; Tsuyuki et al, 2016; El Hajj et al, 2017; Choudhry et al, 2018; Beahm et al, 2018; Ali et al, 2019; Varas-Doval et al, 2020; Amador-Fernández et al, 2021; Phillips et al, 2021), five observational studies (Ledford et al, 2013; Watson et al, 2015; Maeng et al, 2018; Narain et al, 2020; Peletidi & Kayyali, 2021), one pilot study (Kirkdale et al, 2020), a systematic review (Carson-Chahhoud et al, 2019), and one meta-analysis (Santschi et al, 2012). Of the 21 studies included in the review, 12 were published between 2017 and 2021. These studies were conducted in the USA (n=5), in the UK (n=3), Canada (n=2), and Spain (n=2). The systematic review referred to data collected in the UK, USA, Italy, and Qatar,

whereas the meta-analysis included studies conducted across Asia, Australia, Canada, Europe, and the USA.

3.1.1 Type of pharmacist-led interventions

Of the 21 studies, 16 compared pharmacist-led interventions with usual care defined either as no pharmacists' interventions or minimal pharmacist input. The interventions identified included patient counselling, lifestyle advice, medicines review, laboratory results monitoring, and therapy adherence. Counselling patients and medicines review were the two interventions discussed in all the studies included in this analysis. Two studies included the provision of medicines (El Hajj et al, 2017; Carson-Chahhoud et al, 2019), and four articles involved patient assessment and initiation, discontinuation, or modification of drug therapy (Lowrie et al, 2012; Santschi et al, 2012; Ledford et al, 2013; Tsuyuki et al, 2016).

Of the 12 RCTs included in the literature review, three studies involving 1509 patients (Wong et al, 2013; Geurts et al, 2016; Tsuyuki et al, 2016) reported outcomes related to blood pressure, two studies (Tsuyuki et al, 2016; Phillips et al, 2021) described glycaemic control in 834 patients, and two studies (Geurts et al, 2016; Tsuyuki et al, 2016) discussed outcomes related to lipid profile observed in 1235 patients. The pharmacist interventions reviewed in these studies included patient counselling, medicines review, the assessment of patient's therapies and the interpretation of laboratory results.

Three observational studies discussed outcomes related to blood pressure in 7125 patients following pharmacist-led counselling, medicines review and monitoring of

laboratory results (Maeng et al, 2018; Narain et al, 2020; Peletidi & Kayyali, 2021). Similar interventions were used for glycaemic control in 6720 participants (Ledford et al, 2013; Maeng et al, 2018; Narain et al, 2020). To evaluate the impact of pharmacist interventions on dyslipidaemia, Maeng et al (2018), investigated how medication therapy disease management affected 5500 patients equally divided into two interventional groups. The meta-analysis of RCTs led by Santschi et al in 2012 addressed blood pressure measurement, lipid profile, medicines reviews, and patient counselling outcomes resulting from pharmacist-led interventions seen in 9111 patients.

Patient counselling and behavioural support were interventions used in studies involving smoking cessation and nicotine replacement therapy (Burford et al, 2013; Tsuyuki et al, 2016; El Hajj et al, 2017; Carson-Chahhoud et al, 2019), and monitoring adherence to therapy (Wong et al, 2013; Messerli et al, 2016; Choudhry et al, 2018). Pharmacists' counselling interventions were assessed in studies investigating improvements in the quality of life in patients (Watson et al, 2015; Ali et al, 2019; Amador-Fernández et al, 2021), reduce drug-related problems (Geurts et al, 2016; Messerli et al, 2016), and the impact of polypharmacy in an elderly population (Varas-Doval et al, 2020).

Three RCTs included in this review discussed pharmacist-led interventions aimed to improve hepatitis-C viral load (Ali et al, 2019), reduce urinary tract infection symptoms (Beahm et al, 2018), and diagnose skin conditions through mole scanning (Kirkdale et al, 2020). The cost-effectiveness of pharmacist interventions was discussed in four out of the 21 studies (Watson et al, 2015; Maeng et al, 2018; Carson-Chahhoud et al, 2019; Amador-Fernández et al, 2021).

Table 3.2 summarises the characteristics of the articles included in the literature review.

Table 3.2 Summary of studies included in the literature review

Authors, Year, (Country)	Study design, population	Aim	Pharmacist interventions	Key findings and limitations
Ali et al, 2019 (Pakistan)	RCT 931 patients (IG=465, CG=466)	To evaluate the impact of CPIs on treatment outcomes, HRQoL, and adherence to therapy in hepatitis C patients	Monitoring, counselling, lifestyle advice CG: usual care	• Improved adherence in IG vs CG (886% vs 779%, p<0001) • Significant improvement in sustained virological response at 12 weeks in IG vs CG (860% vs 693% p<0001) • Significant improvement in HRQoL with no statistically significant difference between groups • Reduction of ADRs in IG vs CG (82% vs 105%, p<0001) **Limitations:** • Underreporting of HRQoL • High no attendance
Amador-Fernández et al, 2021 (Spain)	Cluster RCT 808 patients (IG=323, CG=485)	To assess the clinical, humanistic and economic outcomes of a minor ailment service delivered in community pharmacies	Counselling, lifestyle advice using a standardised protocol and educational material CG: usual care	• Significant improvement in HRQoL compared to usual care with no statistically significant differences between groups • CPIs might be more cost-effective and improve patient safety **Limitations:** • Study conducted in a specific geographic area only • Patient's perception and self-reported data
Beahm et al, 2018 (Canada)	Prospective registry trial 750 patients with two arms (pharmacist-arm=656, physician-arm=94)	To evaluate the effectiveness, patient safety and satisfaction with pharmacist prescribing for uncomplicated UTIs	Patient assessment, counselling, prescribing antibacterial, patient education, referral to physician 2 weeks follow-up	• Initial cure achieved in 945% of patients (p=00025), 55% had early recurrence of infection • 889% had sustained symptomatic resolution at follow-up • Positive patient satisfaction • 5 patients referred to physician or emergency department for pyelonephritis complications **Limitations:** • No CG for ethical reasons • Patients' perception and self-reported data • High loss of follow-up
Burford et al, 2013 (Australia)	RCT 160 subjects (IG=80, CG=80)	To promote smoking cessation using computer-generated photoaging interventions	2-minute smoking cessation advice, computer-generated photoaging	• Statistically significant difference in no-smoking at 6 months compared to CG (138% vs 13) based on carbon monoxide levels tests • Increased quit attempts **Limitations:** • Selection population bias

			CG: 2-minutes advice only	• Study not blinded • No group allocation
Carson-Chahhoud et al, 2019 (Australia, Italy, Qatar, UK, USA)	Systematic review of 7 RCT 1774 participants	To assess the effectiveness of CPIs with or without pharmacotherapy in smoking cessation	Counselling, provision of NRT products, face-to-face behavioural support CG: standard care or less intensive support	• Statistically and clinically significant benefit compared to CG • CPIs are cost-effective **Limitations:** • High level of heterogeneity • Risk of bias • Gaps in reporting data • Differences in CG CPIs
Choudhry et al, 2018 (USA)	Cluster RCT 4078 patients (IG=2038, CG=2040)	To evaluate the effect of remote interventions on medicines adherence for hyperlipidaemia, hypertension, and diabetes	Behavioural interventions, telephone interviews, text messages and progress reports CG: usual care	• Significant improvement of 4.7% (95% CI, 3.0–6.4%) in medication adherence vs usual care • No significant changes in clinical outcomes, disease control, hospitalisation, or GP visit **Limitations:** • Clinical outcomes evaluated using electronic health records • Adherence based on drugs collection from pharmacies
El Hajj et al, 2017 (Qatar)	Prospective RCT 314 patients (IG=167, CG=147)	To assess the effect of CPIs on smoking cessation	Structured interview and counselling over 8 weeks, carbon monoxide measurement, dispensing of NRT products CG: brief unstructured advice on cessation rates, offering of NRT products	• No statistically significant difference in smoking cessation rate at 12 months between the groups • Increased smoking cessation rate in IG • At 12 months, IG smoked on average 3.2 cigarettes less per day vs CG. Not statistically significant **Limitations:** • Patient's perception • Brief pharmacist training • Clinical staff involved in both arms • High loss of follow-up
Ledford et al, 2013 (USA)	Retrospective, cross-sectional 25 patients	To measure clinical and qualitative outcomes in patients with diabetes changing from multiple daily insulin injections to continuous subcutaneous infusion	Medicines review, initiation, discontinuation, or modification of drug therapy, follow-up consultation	• Absolute HbA1c reduction (−1.17% $p < 0.001$) • BMI decreased by 0.7 kg/m2 ($p = 0.085$) • Decrease in physician visits • Reduction in diabetes medications prescribed post-intervention **Limitations:** • Population size with no CG • Confounding factors not measured

Lowrie et al, 2012 (UK)	Clustered, event-driven RCT 2164 patients (IG=1090, CG=1074)	To test whether CPIs reduce the composite of hospital admission and clinical outcomes	Medicines review, initiation, discontinuation, or modification of drug therapy CG: usual care	• Modest improvements in prescribing disease-modifying medications • No difference in hospitalisation between groups **Limitations:** • Staff training • Some clinical data were not available to the pharmacist
Geurts et al, 2016 (Netherlands)	RCT 512 patients (IG=248, CG=264)	To determine whether medicines review and a pharmaceutical care plan decrease DRPs, evaluate the impact on cardiovascular risk factors and safety issues for polypharmacy in elderly patients with cardiovascular disease	Medicines review, propose and implement interventions for DRP. 1 year follow up CG: usual care	• Almost 50% of DRP were resolved • Significant diastolic BP reduction at follow-up (79.8–76.8 mmHg; p=0.008) • Significant increase in HDL-C for both groups (IG with intervention: 1.29–1.37 mmol/L; p=0.021; IG without intervention: 1.26–1.37 mmol/L; p=0.039) • Significant decrease in LDL-C in CG (2.61–2.58 mmol/L; p = 0.032) • No significant effect in other parameters **Limitations:** • Low power due to limited participation • 70 IG patients did not receive any interventions. • CG was aware of the study.
Kirkdale et al, 2020 (UK)	Pilot 6354 customers	To describe the population, the outcomes, and the general practice's cost saving of mole scanning service in the community pharmacy	Consultation, mole scanning and referral to dermatologist or physician	• 11.3% (n=1118) were referred to dermatologist. 11.0% of which confirmed basal cell carcinoma diagnosis, 6.2% for malignant melanoma, and 0.4% for squamous cell carcinoma **Limitations:** • Paid service provided by a multi-chain pharmacy • High loss of follow-up
Maeng et al, 2018 (USA)	Retrospective cohort, observational 5500 patients equally divided into two cohorts	To evaluate the impact of pharmacist-led medication therapy management on clinical outcomes and cost in patients with diabetes	Medication therapy disease management CG: no pharmacist-led interventions	• No differences between groups in composite HbA1c, BP, or low-density lipoprotein cholesterol goal attainment at 12 months • CPIs were associated with a reduction in hospital admission and cost of care **Limitations:** • Selection bias • Unclear CPI • Inconsistent endpoint measure

Messerli et al, 2016 (Switzerland)	Prospective RCT 450 patients (IG=218, CG=232)	To evaluate the impact of CPIs on medicine use and adherence over 28 weeks	Face-to-face and phone consultation following a protocol, structured medicine review, self-reported questionnaire, documentation, advice CG: no specific documentation and no intervention	• No significant improvement in DRP or adherence between the groups • No significant difference in unplanned physicians visit or incidence of falls between the groups **Limitations:** • Staff training • Short period to assess adherence • Study not blinded
Narain et al, 2020 (USA)	Observational with two IG groups IG: HbA1C = 169 SBP = 210 CG: HbA1C = 1026 SBP = 1298	To examine the impact of CPIs on cardiovascular risk factors among black patients with diabetes	Laboratory results and vital signs review, medicines reconciliation, survey, counselling to improve medication adherence CG: usual care	• Significant reduction in HbA1c (-0.4%, p= 0.01) • No significant systolic BP impact in IG (- 0.051 mmHg, p= 0.74) **Limitations:** • Patients recruited from a single health centre • Only short-term interventions were analysed
Peletidi & Kayyali, 2021 (Greece)	Research-based observational 117 patients	To obtain a 5% weight reduction, body mass index, waist circumference, BP, and AUDIT-C score. To increase the Mediterranean diet score and physical activity levels	Counselling, lifestyle advice, distribution of printed material, monitoring parameters during 6 biweekly visits over 11 weeks	• Statistically significant results: - 50.4% (n=59) lost between 5 and 10% of their initial weight - 47% (n=55) lost ≥ 10% of their initial weight - 23.1% (n=27) achieved a normal body max index - Reduction of waist circumference, BP, alcohol consumption - Increased exercise and adherence to the Mediterranean diet **Limitations:** • Patients' perception and self-reported data • Small sample size
Phillips et al, 2021 (USA)	Single-site, single-blind, randomised prospective 111 patients	To evaluate the effects of a multidisciplinary approach on patient outcomes in patients with type 2 diabetes	Patient education, screening, behavioural counselling	• Statistically significant HbA1C score reduction (2.4 vs 1.1 point in IG, p=0.02) • Improved behavioural outcomes • Clinically significant HbA1c values difference at follow-up **Limitations:**

	(IG=55, CG=56)		CG: same interventions starting 6 months after the IG	• High loss of follow-up • Clinical staff involved in both arms
Santschi et al, 2012 (Asia, Australia, Canada, Europe, USA)	Meta-analysis of 15 RCT 9111 patients	To assess the effect CPIs on cardiovascular risk factors in outpatients with diabetes	Patient counselling, medicines review, physical assessment, adherence, lifestyle, prescribing, initiation, discontinuation, modification of drug therapy, administration of therapy, identification of DRP. CG: usual care	CPIs was associated with significant reductions in: • Systolic BP: 1,894 patients; 26.2 mm Hg (95% CI: 27.8 to 24.6 mm Hg) • Diastolic BP: 1,496 patients; 24.5 mm Hg (95% CI: 26.2 to 22.8 mm Hg) • Total cholesterol: 1,280 patients; 215.2 mg/dl (95% CI: 224.7 to 25.7 mg/dl) • LDL-c: 8,084 patients; 211.7 mg/dl (95% CI: 215.8 to 27.6 mg/dl) • BMI: 751 patients; 20.9 kg/m2 (95% CI: 21.7 to 20.1 kg/m2) **Limitations:** • No intervention uniformity
Tsuyuki et al, 2016 (Canada)	Multicentre RCT 723 patients (IG=370, CG=353)	To evaluate the effectiveness of CPIs on cardiovascular risk	Assessment of patient's therapies and laboratory results, cardiovascular risk assessment, medicines review, initiation, discontinuation, or modification of drug therapy, 3 months follow-up CG: usual care and 3 months follow-up	• Absolute reduction in cardiovascular risk • Absolute differences (95%CI): - LDL-C 9.9% (p=0.012), - BP 23.1% (p<0.001), - HbA1c 17.6% (p<0.001), - smoking 6.9% (p=0.032) **Limitations:** • Short follow-up duration. • Underestimation of clinical parameters • Generality due to different pharmacist's scope of practice in different jurisdictions
Varas–Doval et al, 2020 (Spain)	Open-label, multi-centre, cluster RCT 1403 patients	To measure the impact of CPIs on uncontrolled health problems in aged polypharmacy patients	Medication review, medicines optimisation, with monthly follow-up for 6 months	• Significant progressive reduction in the uncontrolled health issues in IG (-0.72, 95% CI: -0.80, -0.65) • No change in the CG (-0.03, 95% CI: -0.10, 0.04) **Limitations:** • None discussed in the study

	(IG=688, CG=715)		CG: Usual care	
Watson et al, 2015 (UK)	Observational 377 patients	To compare health-related outcomes and cost-related outcomes of CPIs in emergency department, health centres and community pharmacies	Counselling, advice, medicines provision, pre- and post-intervention, follow-up CG: usual care	• Similar symptom resolution and QoL improvement across the settings • CPIs costs significantly lower than other settings, with no significant difference in outcomes **Limitations:** • High loss of follow-up. Patient's perception and self-reported data
Wong et al, 2013 (Hong Kong)	RCT 274 patients (IG=113, CG=161)	To establish the effect of counselling on adherence to therapy	Counselling, patient education, provision of compliance-aid boxes. Follow-up: 3 and 6 months CG: usual care	• CPIs improved BP control and adherence • No significant differences in outcome measures between the groups **Limitations:** • Brief observation (6 months) • No comparison between groups
Acronyms and abbreviations: ADR = adverse drug reaction, BP = blood pressure, CG= control group, CI = Confidence interval, CPI = clinical pharmacist intervention, DRP = drug related problem, GP = general practice, HbA1c = Glycosylated haemoglobin, HDL-c = high-density lipoprotein, HRQoL = health-related quality of life, IG = Intervention group, LDL-c = low-density lipoprotein, NRT = nicotine replacement therapy, QALM = quality-adjusted fife months, QoL = quality of life, RCT = randomised controlled trial, UK = United Kingdom, USA = United States of America, UTI = urinary tract infection.				

3.1.2 Impact of pharmacist-led interventions

A significant improvement ($p<0.05$) in systolic blood pressure following pharmacists' interventions was observed in four studies (Santschi et al, 2012; Geurts et al, 2016; Tsuyuki et al, 2016; Peletidi & Kayyali, 2021). No significant improvement in diastolic blood pressure was seen between the intervention group and the usual care group, in Wong et al (2013) and Narain et al (2020) studies. The discrepancy between these results may be related to the type of interventions and the limitations of the studies. In their observational study, Wong et al (2013) compared the effect of counselling and educating patients on medicines adherence at three- and six-month follow-up visits.

Similarly, Narain et al, (2020) investigated the impact of medicines review on the patients' systolic blood pressure for a short period. In contrast, both Santschi et al (2012) and Tsuyuki et al (2016) studies incorporated medicines review interventions with initiation, discontinuation, or modification of drug therapy, which could positively affect blood pressure measurements.

Two observational studies (Ledford et al, 2013; Narain et al, 2020) stated a clinically significant reduction in HbA1c values following pharmacist interventions of - 1.17% ($p < 0.001$) and - 0.4% ($p=0.01$), respectively. A RCT (Tsuyuki et al, 2016) reported glycaemic reading improvements ($p<0.001$) in 370 patients receiving pharmacist-led interventions. Similarly, the RCT conducted by Phillips et al (2021) demonstrated statistically significant HbA1C score reduction ($p=0.02$) in 111 patients due to pharmacist-led behavioural counselling, patient education and drug monitoring.

Three studies (Santschi et al, 2012; Geurts et al, 2016; Tsuyuki et al, 2016) involving counselling, reviewing laboratory results, and modifying drug therapy led by pharmacists reported a significant reduction in low-density lipoprotein-cholesterol and improvement in high-density lipoprotein-cholesterol. In contrast, Maeng et al (2018) observed no difference in HbA1c, blood pressure, and cholesterol resulting from medication therapy disease management conducted by a pharmacist.

Other research papers (Burford et al, 2013; Tsuyuki et al, 2016; Carson-Chahhoud et al, 2019) reporting data on smoking interventions demonstrated a statistically significant reduction in smoking and increased quit attempts (Burford et al, 2013; El Hajj et al, 2017)

in favour of pharmacist care. These studies supported patient counselling with other pharmacist-led interventions. Burford et al (2013) used photoaging to motivate patients to quit smoking, whereas El Hajj et al (2017) and Carson-Chahhoud et al (2019) used structured face-to-face behavioural support and nicotine replacement products to encourage smoking cessation.

Medicines review and patient counselling produced significant improvements in adherence to therapy in four studies (Wong et al, 2013; Messerli et al, 2016; Choudhry et al, 2018; Ali et al, 2019), while improvements in quality of life were seen in three other papers (Watson et al, 2015; Ali et al, 2019; Amador-Fernández et al, 2021). Hospital admission and unplanned physician visits also decreased due to pharmacist-led counselling and medicines review (Lowrie et al, 2012; Ledford et al, 2013; Messerli et al, 2016; Beahm et al, 2018; Maeng et al, 2018; Choudhry et al, 2018).

In addition, pharmacist interventions included in this review were deemed cost-effective in three studies (Watson et al, 2015; Carson-Chahhoud et al, 2019; Amador-Fernández et al, 2021).

3.2 Questionnaire

3.2.1 Validity

The mean scores and standard deviation of the experts' responses to each questionnaire version are shown in Table 3.3. The majority of the experts selected either 4 "Very good" or 5 "Excellent". One panellist attributed a score of 3 "Good" to the readability of the

Maltese version, and one expert gave a score of 3 "Good" for the readability of the Italian version. Both experts mentioned increasing the space in the comment box and amending section E (perception on potential new pharmacist-led service) with more choices in the response.

Table 3.3 Expert panel scoring means (standard deviation) for the three versions of the questionnaire

Criteria	English version	Italian version	Maltese version
Relevance of contents	4.73 (± 0.46)	5.00 (-)	4.76 (± 0.44)
Comprehensiveness	4.73 (± 0.46)	5.00 (-)	4.88 (± 0.33)
Readability	4.11 (± 0.35)	4.08 (± 0.64)	4.39 (± 0.73)
Presentation	4.88 (± 0.33)	4.60 (± 0.52)	5.00 (-)
The mean values refer to the Likert scale ranging from 1 to 5 where 1 = "Poor", 2 = "Fair", 3 = "Good", 4 = "Very Good", 5 = "Excellent"			

The panel's comments and recommendations were reviewed by the researcher and used to refine the questionnaire. Minor grammatical amendments were made to all three versions of the questionnaire. Section E of the three questionnaires, which investigated the public perception, was restructured to improve readability and presentation. The amended versions of the questionnaires were sent to the relevant expert panel for revision.

The expert panel comments included suggestions to improve the comprehensiveness of the questionnaire, such as the language and the terminology used in some questions. Since the threshold of ≥75% of agreement on the Likert-type scale for all criteria was met, the questionnaire achieved a satisfactory face and content validity level. The validation was considered concluded at the end of the second round.

3.2.2 Reliability testing

The test-retest correlations ranged from 0.866 to 1.0 ($p< 0.001$) for the belief domain, 0.889 to 0.917 ($p<0.001$) for the awareness domain and 0.864 to 0.954 ($p<0.001$) for the perception domains. The coefficient k for the perception domain with a nominal scale ranged from 0.824 to 1 ($p<0.001$). Two statements out of 13 returned a value below the threshold. The coefficient $k=0.4$ ($p=0.166$) for the question 'Would you use the service for advice and treatment of urinary tract infection?' and $k=0.636$ ($p=0.002$) for the question 'Would you use the service for routine immunisation?'. Since the test-retest reliability showed overall satisfactory results, the questionnaire was confirmed to be reliable, and no further modifications were needed before dissemination.

3.2.3 Questionnaire results

A total of 251 consumers were recruited through community pharmacies in Malta. Fifteen people (7%) refused to participate, and seven participants (3%) did not return the completed questionnaire. The response rate for the paper-based questionnaire was 91%. The online questionnaire was completed by 571 respondents. In total, 800 respondents participated in the study.

3.2.4 Study population

The mean age of the participants was 39.3 (± 14.1) years. Of the 800 respondents 74% (n=590) were female, 77% (n=612) were Maltese and 43% (n=345) had tertiary level education. The detailed characteristics of the population are shown in Table 3.4.

Table 3.4 Respondents' characteristics and frequencies (N=800)

Characteristic	Category	Percentage (%)
Age (years)	18 - 29	31
	30 - 49	47
	50 - 69	20
	70 and over	2
Gender	Female	74
	Male	26
	Other	< 1
Country of residence	Malta	85
	England	7
	Italy	6
	Others*	2
Nationality	Maltese	77
	English	10
	Italian	8
	Others**	5
Level of education	Primary	2
	Secondary	29
	Post-secondary	26
	Tertiary	43
Occupation	Professional	26
	Administrator	19
	Clerical and technical	15
	Skilled	13
	Unskilled	10
	Student	8
	Pensioner	5
	Housewife	3
	Unemployed	2

* Countries of residence include Australia, Belgium, Bulgaria, Croatia, Estonia, Ireland, Korea, Netherlands, Philippines, Scotland, and Switzerland.
** Nationalities include Croatian, Egyptian, Pilipino, Greek, Irish, Korean, and Spanish.

3.2.5 Belief of the pharmacist's role

This study revealed a positive perception of participants towards the pharmacist's role. The majority of respondents "Strongly agreed" or "Agreed" with the three statements shown in Figure 3.2. Out of the 800 participants, 18 (2%) believe that the pharmacist cannot recommend medicines to improve the condition or symptoms. Thirty-nine consumers (5%) believe that the pharmacists are not knowledgeable about chronic conditions, and four participants believe that pharmacists are not knowledgeable about

minor ailments. While most participants acknowledged the pharmacist's understanding of long-term conditions, 13% (n=107) indicated an unsure position.

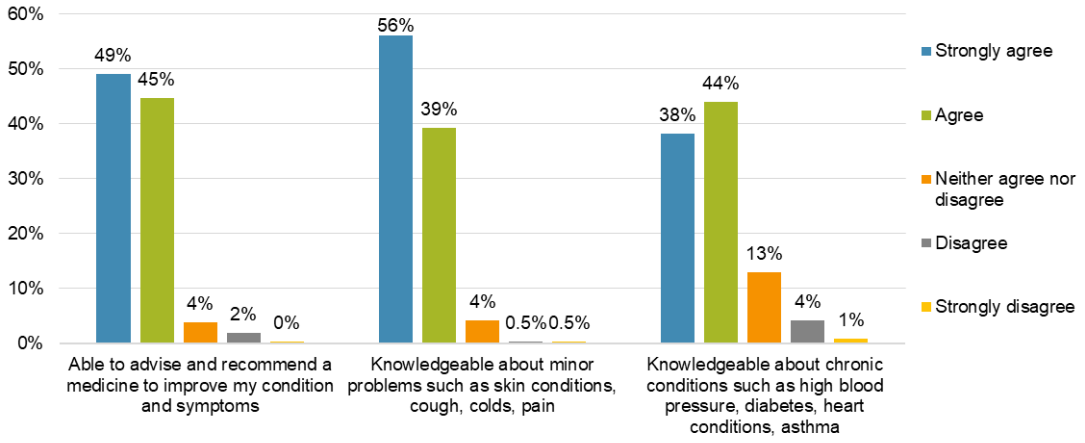

Figure 3.2. Respondents' belief towards pharmacist's role (N=800)

A total of six female respondents aged between 30 and 49 years chose "Strongly disagree" for this statement. Their level of education was either post-secondary or tertiary, with one consumer being a pharmacist. None of the consumers who disagreed with the three statements has commented on their response.

3.2.6 Awareness of the pharmacist's role

Figure 3.3 describes the consumers' awareness of the pharmacist's role. Respondents indicated a high level of awareness of the pharmacist's role in understanding medical conditions, interpreting test results, and managing minor ailments whilst observing patient confidentiality. Nearly half of the respondents were either "Very much aware" 45% (n=361) or "Aware" 42% (n=334) that the pharmacist would keep their health information confidential, indicating a high level of trust.

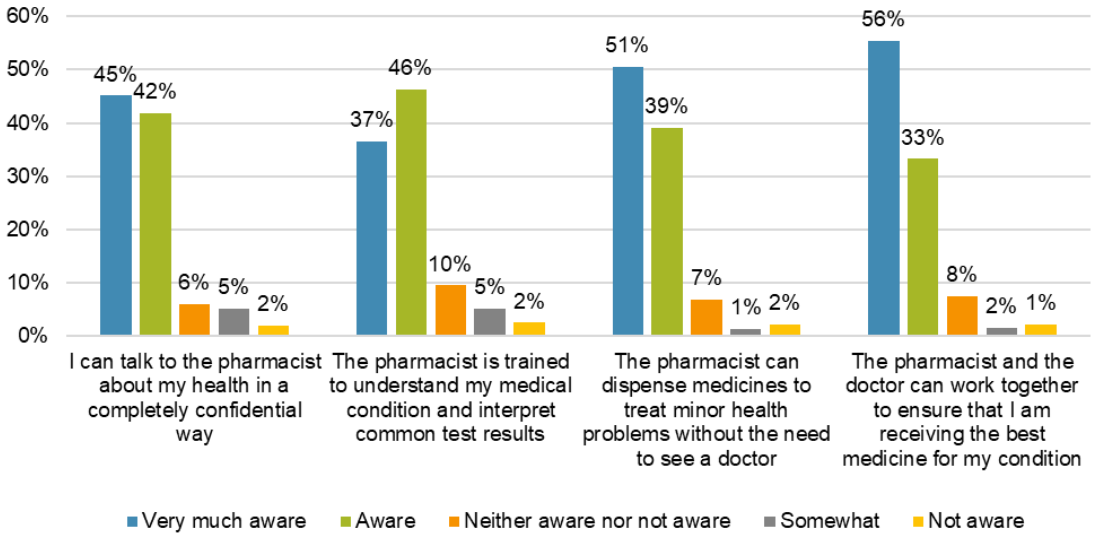

Figure 3.3. Respondents' awareness towards pharmacist's role (N=800)

A minority of the participants, 5% (n=41), were "Somewhat" aware that the pharmacist is trained to understand medical conditions and test results, and 2% of them were "Not aware" of this. Out of the 800 participants, 90% (n=717) were "Very much aware" or "Aware" that the pharmacist can provide minor ailment treatments without the need of a prescription, and 89% (n=710) were aware of the collaborative relationship between the pharmacist and the physician. Between 6 and 10% of the respondents stated they were "neither aware nor not aware" of the four statements presented in the questionnaire.

3.2.7 Perception of pharmacist-led services available in community pharmacy

The majority of the consumers 80% (n=641) confirmed that they would seek advice from the pharmacist for health-related issues, whereas 47% (n=373) would consult the pharmacist to monitor their blood pressure, blood glucose and cholesterol level. Of the

800 respondents, 9% (n=71) "Disagree" or "Strongly disagree" they would see the pharmacist first. When asked how comfortable the consumers would be in having the pharmacist review their medications, 75% (n=602) agreed, and 8% (n=60) disagreed. Similar results were seen for the pharmacist performing diagnostic tests, 67% (n=540) agreed, and 13% (n=101) disagreed.

Out of the four statements, consumers were less in favour of the pharmacist performing blood pressure measurement and glucose or cholesterol monitoring, 24% (n=191) of the participants neither agreed nor disagreed, and 7% (n=57) of the consumers found that this was not applicable for them (Figure 3.4).

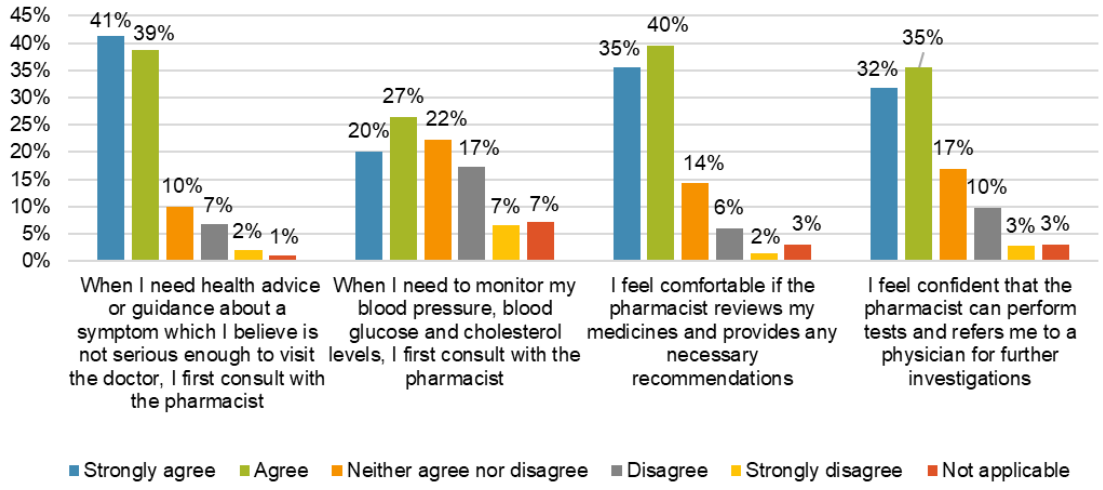

Figure 3.4. Participants perception of pharmacist-led services available in comunity pharmacies (N=800)

3.2.8 Perception of potential new pharmacist-led services

Thirteen services were presented in the questionnaire. Participants were asked to express their agreement on which pharmacist-led services should be available in

community pharmacies. The majority of the participants agreed that all the proposed services should be available in community pharmacies (Table 3.5).

Table 3.5 Participants' perception of pharmacist-led services available in pharmacies (N=800)

Service proposed	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Not applicable
Travel health advice	49%	37%	8%	4%	1%	2%
A&T throat infections	46%	42%	8%	3%	1%	< 1%
Stop smoking service	46%	40%	10%	1%	< 1%	4%
Routine immunisations advice	46%	37%	8%	5%	2%	2%
A&T eye and ear infections	43%	41%	11%	4%	1%	< 1%
A&T skin conditions	42%	45%	9%	3%	1%	< 1%
A&T urinary tract infections	42%	39%	11%	6%	2%	1%
Medicines use review	40%	41%	11%	4%	1%	2%
Advice on sexual related issues	40%	35%	14%	6%	3%	3%
Blood tests	40%	35%	13%	8%	2%	3%
INR for warfarin levels	31%	38%	18%	7%	3%	4%
Screening and management STD	30%	34%	18%	12%	4%	2%
ECG test monitoring	23%	36%	19%	14%	5%	3%

Acronyms and abbreviations: A&T = Advice and treatment, ECG = Electrocardiogram, INR = International Normalised Ratio, STD = Sexually Transmitted Disease

The highest agreement was seen for services that involved providing advice and treatment for common throat infections 88% (n=703), skin conditions 87% (n=695), eyes and ears infections 84% (n=672), and urinary tract infections 81% (n=648). An equally high level of agreement was noted for services that involved expert advice on smoking cessation 86% (n=686), international travel health 86% (n=683), routine immunisation 83% (n=661), and medicines review 82% (n=654). The most unsure services for respondents were point-of-care testing for warfarin levels 18% (n=300) and recommendations on sexual-related issues 14% (n=109). Respondents stated the highest disagreement for pharmacist-led services related to electrocardiogram

monitoring 19% (n=151) and the proposed service for screening and managing sexually transmitted diseases in community pharmacies 16% (n=122).

Figure 3.5 shows the participants' willingness to use the proposed services if they were available in community pharmacies. The majority of the respondents would be inclined to attend a pharmacist-led appointment for advice and treatment of common minor ailment infections such as throat infections 84% (n=674), skin infections 80% (n=642), eyes and ears infections 79% (n=635), and urinary tract infections 70% (n=565). Consumers also would seek the pharmacist's advice for travel health vaccination 81% (n=645), routine immunisation 80% (n=640), and review of the medicines taken 61% (n=487).

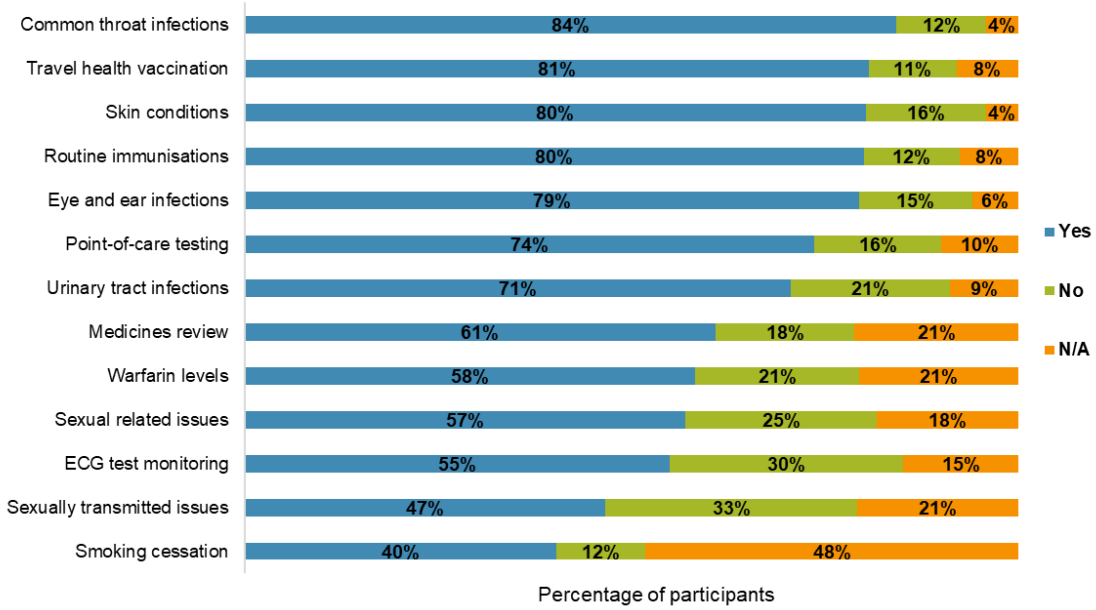

Figure 3.5. Participants' willingness to use proposed clinical pharmacist services (N=800)

The two services with the highest disagreement were sexually transmitted issues advice 33% (n=260) and the electrocardiogram test monitoring 30% (n=242), even if half of the

participants would still consider using these services. Although the smoking cessation service has received low disagreement 12% (n=92), nearly half of the participants 48% (n=386) declared that this service did not apply to them.

When asked to express their willingness to pay for the clinical services, most participants answered they would pay a fee for the service, indicated as either between 5 and 10 Euro or between 10 and 20 Euros (Figure 3.6).

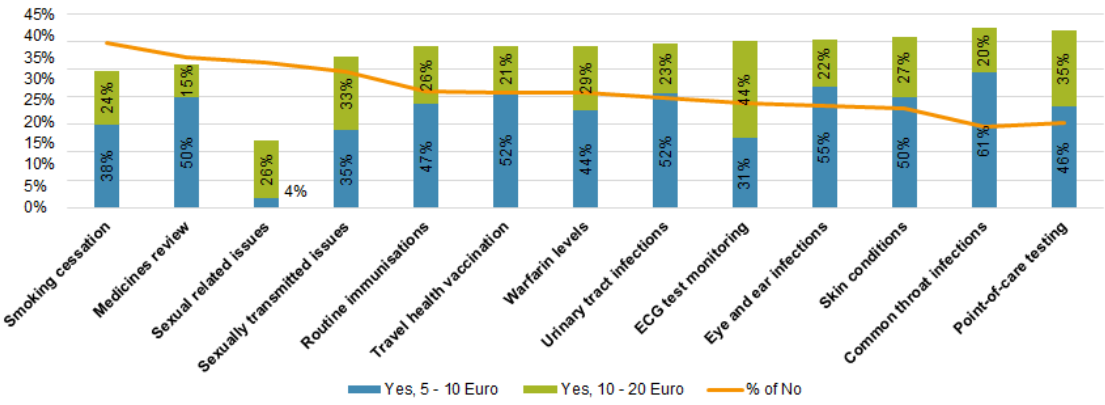

Figure 3.6. Participants' willingness to pay for proposed clinical services (N=800)

Forty-five percent (n=358) of respondents commented on their answers, specifying why they would not pay for the services. Thirty-five percent (n=125) of the comments reported that the service did not apply to them, and a 27% (n=97) of respondents indicated that they believe the service should be free or subsidised by the national health system. The remaining participants, which accounts to 29% (n=103), stated that they would prefer to visit a doctor or specialist if they had to pay any fee.

3.2.9 Statistical analysis

The Cronbach's α coefficient of items regarding consumer's beliefs was 0.75, awareness α=0.74, and perception α=0.71, showing acceptable internal consistency between responses within a given domain. The "if-item-deleted" alpha sensitive analysis was performed to understand whether removing a question from the test would modify the level of alpha. Removing any of the items from each domain would lower the overall Cronbach's α coefficient. For this reason, none of the items was removed from the questionnaire.

The Friedman test applied to the three domains of the questionnaire showed that the mean rating scores exceed the value of 3, indicating that the participants tended to agree considerably with all the statements (Table 3.6). Respondents agreed with the first two statements of the belief domain (able to advise and recommend, and knowledgeable about minor problems) significantly more than the third statement (knowledgeable about chronic conditions) with a p-value less than the 0.05. Similarly, the statement related to the participants' awareness shows that consumers are generally aware of the extended role of the pharmacist but significantly less aware ($p<0.001$) that the pharmacist is trained to understand medical conditions and interpret standard test results. A statistically significant difference ($p<0.001$) is noted in the mean rating score of the statements belonging to the perception domain.

Table 3.6 Friedman test applied to the three domains of questionnaire (N=800)

Domain	Statement	Mean ± SD
Belief	Able to advise and recommend a medicine to improve my condition and symptoms	3.40 ± 0.690
	Knowledgeable about minor problems such as skin conditions, cough, colds, pain	3.51 ± 0.615
	Knowledgeable about chronic conditions such as high blood pressure, diabetes, heart conditions, asthma	3.15 ± 0.850
$X^2(2) = 178.94, p < 0.001$		
Domain	**Statement**	**Mean ± SD**
Awareness	I can talk to the pharmacist about my health in a completely confidential way	3.23 ± 0.919
	The pharmacist is trained to understand my medical condition and interpret common test results	3.09 ± 0.940
	The pharmacist can dispense medicines to treat minor health problems without the need to see a doctor	3.35 ± 0.838
	The pharmacist and the doctor can work together to ensure that I am receiving the best medicine for my condition	3.38 ± 0.864
$X^2(3) = 104.580, p < 0.001$		
Domain	**Statement**	**Mean ± SD**
Perception	When I need health advice or guidance about a symptom which I believe is not serious enough to visit the doctor, I first consult with the pharmacist	4.07 ± 1.063
	When I need to monitor my blood pressure, blood glucose and cholesterol levels, I first consult with the pharmacist	3.15 ± 1.459
	feel comfortable if the pharmacist reviews my medicines and provides any necessary recommendations	3.93 ± 1.162
	I feel confident that the pharmacist can perform tests and refers me to a physician for further investigations	3.75 ± 1.245
$X^2(3) = 423.882, p < 0.001$		

If the sample of respondents increases from 800 to a considerably larger number of participants, the mean scores would only vary by around 3%. The confidence intervals of the three statements do not overlap, indicating that their mean rating scores differ significantly.

Table 3.7 depicts the statistically significant p-values for the statements clustered by gender and age. A significant difference (p=0.024) was noted between the responses of males and females for the statement investigating the public belief of the pharmacist's role in advising and recommending medicines to improve a medical condition. Females agreed more than males that the pharmacist is able to recommend a medicine to improve symptoms. Similarly, a significant difference (p=0.048) was noted in the responses to the statement investigating the public belief about the pharmacist's knowledge of chronic conditions. Older people tended to agree more than young respondents. Regarding the awareness domain of the questionnaire, the test revealed no statistically significant difference in the mean scores of the responses based on age and level of education (p>0.05).

Table 3.7 Kruskal Wallis test for belief domain clustered by gender and age (N=800)

Statement	Gender	Sample size	Mean ± SD	P-value
Able to advise and recommend a medicine to improve my condition and symptoms	Male	210	3.32 ± 0.711	**0.024**
	Female	590	3.43 ± 0.681	
Statement	**Age group (years)**	**Sample size**	**Mean ± SD**	**P-value**
Knowledgeable about chronic conditions such as high blood pressure, diabetes, heart conditions, asthma	18-29	251	3.06 ± 0.842	**0.048**
	30-49	373	3.14 ± 0.892	
	59-70	161	3.27 ± 0.765	
	> 70	15	3.40 ± 0.632	
Mean rating scores range from 0 "Strongly disagree" to 4 "Strongly agree"				

A statistically significant difference (p=0.035) was reported in the responses provided by participants toward the statement regarding the collaboration between doctors and pharmacists based on the consumers' level of education. Consumers with a higher level

of education were more aware of the interprofessional relationship in providing patient care (Table 3.8).

Table 3.8 Kruskal Wallis test for awareness domain clustered by level of education (N=800)

Statement	Education level	Sample size	Mean ± SD	P-value
The pharmacist and the doctor can work together to ensure that I am receiving the best medicine for my condition	Primary	15	2.80 ± 1.320	**0.035**
	Secondary	235	3.32 ± 0.870	
	Post-secondary	205	3.43 ± 0.762	
	Tertiary	345	3.42 ± 0.886	
Mean rating scores range from 0 "Not aware" to 4 "Very much aware"				

Table 3.9 shows the Kruskal Wallis test applied to the perception of pharmacist-led services available in community pharmacies. A statistically significant difference in the responses provided by participants toward the statement regarding blood pressure measurement and point-of-care testing for blood glucose and cholesterol levels was noted based on the participants' age ($p=0.042$) and level of education ($p<0.001$).

Participants aged between 59 and 70 years where more likely to agree that they consulted the pharmacist for blood pressure measurements, and check the blood glucose and cholesterol levels. Younger respondents were less in agreement with the statement. In regard to the participants' level of education, respondents with a higher level of education were more likely to disagree that they would consult with the pharmacist first.

Table 3.9 Kruskal Wallis test for perception domain clustered by age and level of education (N=800)

Statement	Age group (years)	Sample size	Mean ± SD	P-value
When I need to monitor my blood pressure, blood glucose and cholesterol levels, I first consult with the pharmacist	18-29	251	2.94 ± 0.1533	**0.042**
	30-49	373	3.21 ± 1.428	
	59-70	161	3.35 ± 1.338	
	> 70	15	3.27 ± 1.870	
Statement	**Education level**	**Sample size**	**Mean ± SD**	**P-value**
When I need to monitor my blood pressure, blood glucose and cholesterol levels, I first consult with the pharmacist	Primary	15	3.93 ± 1.792	**< 0.001**
	Secondary	235	3.52 ± 1.305	
	Post-secondary	205	3.12 ± 1.462	
	Tertiary	345	2.89 ± 1.482	
Mean rating scores range from 0 "Strongly disagree" to 5 "Strongly agree"				

A statistically significant difference in the mean rating scores of the responses toward the perception of potential new pharmacist-led services was noted for the statements shown in Table 3.10. These statements included pharmacist-led services available in community pharmacies for advice and treatment of urinary tract infections ($p<0.01$), sexually transmitted diseases ($p<0.01$), sexually related issues ($p<0.01$), blood tests ($p=0.016$), travel health advice ($p<0.01$), and advice on routine immunisation ($p=0.02$).

The mean rating scores of the consumers aged between 18 and 29 were higher than the remaining age groups on five out of six statements provided. This age group agreed slightly less than those aged 30 years and over on the service proposed in the questionnaire regarding blood tests performed by a pharmacist.

Table 3.10 Kruskal Wallis test for the perception of potential pharmacist-led services clustered by age (N=800)

Services available in pharmacies should include:	Age group (years)	Sample size	Mean ± SD	P-value
Advice and treatment for urinary tract infections	18-29	251	4.24 ± 0.923	**<0.01**
	30-49	373	4.15 ± 1.016	
	59-70	161	3.89 ± 0.991	
	> 70	15	4.00 ± 1.254	
Screening and management of sexually transmitted diseases such as chlamydia and HIV	18-29	251	3.92 ± 1.032	**<0.01**
	30-49	373	3.68 ± 1.313	
	59-70	161	3.41 ± 1.292	
	> 70	15	3.20 ± 1.424	
Advice on sexual related issues such as erectile disfunction and emergency contraception (morning after pill)	18-29	251	4.22 ± 1.006	**<0.01**
	30-49	373	3.99 ± 1.245	
	59-70	161	3.54 ± 1.230	
	> 70	15	3.53 ± 1.407	
Blood tests such as check HbA1C for diabetes, anaemias and vitamin levels	18-29	251	3.99 ± 1.159	**0.016**
	30-49	373	3.98 ± 1.254	
	59-70	161	3.78 ± 1.135	
	> 70	15	4.20 ± 1.320	
Travel health advice and international travel vaccinations such as malaria, hepatitis A and B	18-29	251	4.37 ± 0.918	**<0.01**
	30-49	373	4.24 ± 1.046	
	59-70	161	4.01 ± 1.043	
	> 70	15	3.87 ± 1.457	
Routine immunisations such as Influenza, Pneumococcal, Meningococcal, and Hepatitis vaccines	18-29	251	4.29 ± 0.951	**0.02**
	30-49	373	4.10 ± 1.234	
	59-70	161	3.95 ± 1.036	
	> 70	15	4.07 ± 1.335	
Mean rating scores range from 0 "Strongly disagree" to 5 "Strongly agree"				

The mean rating scores provided to the question investigating the participants' willingness to pay for the services were compared between participants clustered by gender, age, and level of education. These mean rating scores range from 0 to 2, where 0 corresponds to "Yes", 1 corresponds to "No", and 2 corresponds to "Not applicable". Table 3.11 summarised the statistically significant differences in mean rating scores

between the participants' groups provided to each statement (statistical significance $p < 0.05$).

A statistically significant difference in mean rating scores was noted for the willingness to use the services in the age groups. Younger respondents were more likely to answer "Yes" to smoking cessation, sexually transmitted and sexual related issues advice services than older participants. Participants who considered themselves to belong to the 70 years and over age group were more prone to refuse to use the medicines review service (mean 0.93 ± 0.88) and the blood test for anaemia and vitamin levels (mean 0.6 ± 0.74). Female participants were considerably more inclined to say "Yes" to all the services listed in the questionnaire compared to their male counterparts.

The Kruskal Wallis test revealed that English respondents answered "Yes" more often than the other participants for services that involved providing advice and treatment for infections and international travel health advice. Italian respondents were significantly more interested in using the smoking cessation services (mean 0.43 ± 0.75). Consumers who possessed a higher education level were more likely to use all the proposed services since this group's mean rating scores were significantly closer to "Yes". Participants who possessed a primary education level were more likely not to use many of the services listed; however, it should be mentioned that the number of participants belonging to this group was very small (n=15).

Table 3.11 Kruskal Wallis test: p-values of the differences in mean rating scores between the participants' groups for the proposed clinical services

	Use the service				Pay for this service		
	Gender	Age	Level of education	Nationality	Gender	Level of education	Nationality
Medicines review	-	0.08	<0.001	-	-	-	<0.001
Smoking cessation	-	0.006	0.050	<0.001	-	-	0.013
Eye and ear infection	0.030	-	-	<0.001	-	0.022	0.001
Throat infection	0.004	-	-	0.02	-	-	<0.001
Skin condition	<0.001	-	-	0.011	-	-	<0.001
Urinary tract infection	<0.001	-	-	0.004	-	-	<0.001
Sexually transmitted issues	-	0.011	-	-	0.004	-	-
Sexual related issues	<0.001	<0.001	-	-	-	-	-
ECG test monitoring	-	-	-	-	-	-	<0.001
Warfarin levels	-	-	0.02	-	-	-	0.012
Point-of-care testing	0.008	0.055	0.014	-	-	-	0.006
Travel health vaccination	-	-	<0.001	0.002	-	-	-
Routine immunisation	-	-	<0.001	-	-	<0.001	0.033

Statistically significant differences in mean rating scores are provided if $p<0.05$. Non statistically significant differences are listed as (-)

ECG = Electrocardiogram

The Likert scale provided for the willingness to pay section of the questionnaire ranged from 0 to 2, with 0 corresponding to " Yes, between 5 and 10 Euro", 1 corresponding to " Yes, between 10 and 20 Euro", and 2 corresponding to "No". There was no significant difference in the mean rating scores for the willingness to pay for the services statement based on age groups, and only two based on level of education. However, there was a significant difference in the mean scores for most services based on nationality groups. The mean scores of Maltese participants were considerably closer to 0 (Yes, between 5 and 10 Euro) compared to any other nationality.

The participants' comments were analysed and categorised into four thematic domains: (a) the service should be free, (b) I prefer seeing or paying a specialist, (c) I am not comfortable with the pharmacist performing these services, (d) not applicable to me. The results are presented in Table 3.12. A total of 357 participants (45%) commented on their choice of not using or paying for the services listed in the questionnaire. Out of the 357 participants who responded "Not applicable", 95 were female (27%), 56 were aged between 18 and 29 years (16%), 102 were from Malta (29%), and 50 possessed a high degree of education (14%). These participants stated that the services such as smoking cessation, ECG test monitoring, advice on sexually transmitted diseases, and medicines review did not apply to them. Ninety-seven respondents (27%) also commented that services such as advice and treatment for minor ailments and medicines review should be free at the point of access.

Those commenting on their choice to pay a specialist doctor for the services proposed in the questionnaire were primarily male participants (n=70, 19%) aged between 30 and 49 years old (n=53, 15%) living in Malta (n=66, 18%) with tertiary education (n=55 15%). This group of participants claimed that they would instead visit a doctor or a specialist in a hospital for a full consultation and prescription medicines because it is free of charge. Two female respondents commented that discussing sexually related issues is personal or intimate to discuss with the pharmacist.

Table 3.12 Thematic analysis of the participants' comments (N = 357)

Respondents' characteristic		The service should be free	I prefer seeing or paying a specialist	I am not comfortable with the pharmacist	Not applicable
Age	18 - 29	10%	4%	3%	16%
	30 - 49	13%	15%	2%	13%
	50 - 69	3%	8%	2%	7%
	70 and over	< 1%	1%	< 1%	1%
Gender	Female	18%	8%	5%	27%
	Male	9%	19%	3%	10%
Nationality	English	2%	4%	1%	1%
	Italian	4%	1%	2%	< 1%
	Maltese	18%	19%	4%	30%
	Others*	3%	4%	1%	5%
Country of residence	England	3%	6%	1%	5%
	Italy	4%	1%	2%	2%
	Malta	18%	21%	5%	29%
	Others**	1%	1%	1%	2%
Level of education	Primary	< 1%	1%	-	1%
	Secondary	4%	4%	2%	12%
	Post-secondary	8%	9%	2%	10%
	Tertiary	15%	14%	4%	14%
	Totals	27%	28%	8%	37%

* Countries of residence include Belgium, Croatia, Ireland, Netherlands, Philippines, Scotland, and Switzerland.

** Nationalities include Croatian, Egyptian, Pilipino, Greek, and Irish.

A minority of respondents (n=28, 8%) stated that they are not feeling comfortable discussing specific issues with the pharmacist. Four participants believe that the pharmacist does not possess the suitable qualification to perform these services.

3.3 Focus group

The pharmacist-led services that received the most agreement were advice and treatment for common throat infections (n=6), followed by advice on eyes and ears infections (n=5), skin conditions (n=5) and advice on routine immunisation (n=5). Medicines review, point-of-care testing, advice and treatment for urinary tract

infections were selected by four panellists. Figure 3.7 shows the number of votes given by the expert panel to each proposed service.

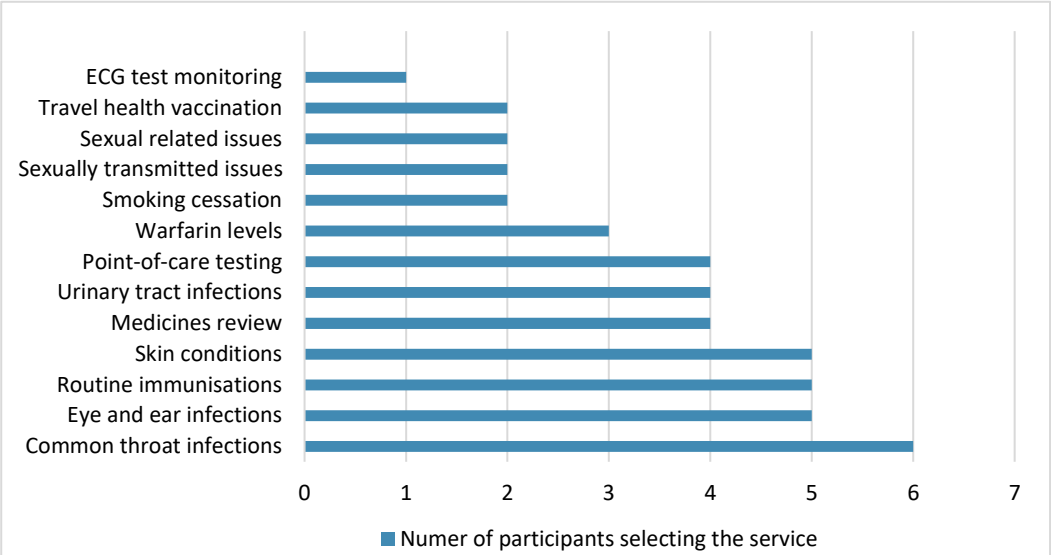

Figure 3.7. Services selected by expert panel in ascending order (N=8)

The expert panel agreed that some of the proposed clinical services were difficult to implement in community pharmacies due to the current scope of practice and practicality issues. Pharmacists in Malta do not possess prescribing rights to dispense the most appropriate medication to treat a condition requiring a prescription-only medicine. Some pharmacies do not have an adequate consultation room to perform the proposed services.

The expert panel raised some concerns about time constraints, lack of resources, lack of training, low public awareness of the pharmacist's role, and physician resistance to services currently performed by doctors. These services included electrocardiogram test monitoring, advice and treatment for sexually transmitted diseases, monitoring of sexual-related issues, and warfarin levels testing. Each participant explained the

rationale for selecting the services that would benefit patients and those easy to introduce and put into practice.

The consensus was reached among the focus group panel for the framework to include all the services obtaining the highest agreement from the questionnaire (Figure 3.7). The expert panel agreed that the SOP proposed during the focus group was easy to read, follow and implement in practice. The SOP structure and contents were considered validated at the end of the focus group.

3.4 Developed framework

Based on the feedback from the focus group, the draft framework was organised for validation. The SOPs were divided into four sections, as shown in Table 3.14: general (5 SOPs), patient review (4 SOPs), advice and treatment (8 SOPs), and ancillary (5 SOPs).

Table 3.13 List of SOPs developed

Standard Operating Procedure (SOP) Index		
SOP classification and number		**Title**
General	1	Conducting a clinical service and informed consent
	2	Providing advice to customers
	3	Completing the Patient Medication Record
	4	Conducting a Medicines Use Review (MUR)
	5	Referral to other healthcare providers
Patient review	6	Blood Pressure measurement
	7	Weight management
	8	Glycaemic control monitoring
	9	Lipid profile monitoring
Advice and treatment	10	Smoking cessation service
	11	Eye conditions
	12	Ear conditions
	13	Sore throat
	14	Skin conditions
	15	Urinary Tract Infections
	16	International travel health advice
	17	Routine immunisation advice
Ancillary	18	Pharmacy consultation room standards
	19	Record keeping and storage requirements
	20	Dealing with customers' complaints
	21	Dealing with needle-stick injuries
	22	SOP training log

3.4.1 Validation

The individual scores with the mean scoring and the standard deviation are shown in Table 3.14. The experts rated the eight statements included in the validation tool with a score of either 4 "Agree" or 5 "Strongly agree".

Table 3.14 Expert panel scoring means and standard deviation for SOP validation

Criteria	CP	CP	CP	HP	HIP	HIP	PT	DR	DR	DR	Mean	SD
Relevance of content	5	5	5	5	5	5	5	5	5	5	5.00	-
Comprehensiveness	5	5	5	5	5	5	5	5	5	5	5.00	-
Readability	4	5	5	4	4	5	5	5	4	5	4.60	0.52
Presentation	5	4	5	5	5	5	5	5	4	5	4.86	0.35
Practicality (SOPs are):												
easy to understand	5	5	5	5	5	5	5	5	5	5	5.00	-
easy to read	5	5	5	4	5	5	5	5	5	5	4.86	0.35
easy to follow	5	5	5	4	5	5	5	5	5	5	4.86	0.35
easy to implement	4	5	5	5	5	5	5	5	4	5	4.86	0.35

The mean values refer to the Likert scale ranging from 1 to 5 where 1 = "Strongly disagree", 2 = "Disagree", 3 = "Neutral", 4 = "Agree", 5 = "Strongly agree"

Abbreviations: CP = community pharmacist, DR = doctor, HIP = hospital pharmacist with prescribing rights, HP = hospital pharmacist, SD = Standard deviation

The experts' comments were analysed, and two minor changes were implemented. A recommendation was made to include that nicotine patches are unsuitable for pregnant women in the smoking cessation SOP. A second pharmacist suggested changing the words "preventing measures" into "preventative measures". No further changes were recommended. The expert panel's comments regarding the SOP comprehensiveness, readability, presentation and practicality were positive (Table 3.15).

Table 3.15 Example of comments from the expert panellists

Comment	Healthcare professional
I think all of the SOPs are really clear and easy to follow. I think they are completely appropriate for the target audience- they are informative but still allow pharmacists to input clinical knowledge aside them	JP - Independent Prescribing pharmacist
I read all the SOPs and they are excellent. Very straightforward and easy to read and very straight to the point. Well done	ABA - Basic Specialist Trainee doctor
Very comprehensive and practical, presented beautifully	AG - Registered Pharmacy Technician
SOPs are complete and well-structured. No further comments from my end. Well-done	ML - Community pharmacist
To be honest, I was left without words. These SOPs are so brilliantly written, they are very easy to read and to follow, and I think they are perfect. I also learnt some new stuff from them. Thanks for sharing	MR – Registrar doctor

Since the threshold of ≥75% of agreement on the Likert-type scale for all criteria was met, the framework achieved a satisfactory face and content validity level. The validation was considered concluded at the end of the second Delphi method round.

Chapter 4: Discussion

Non-communicable diseases such as cardiovascular diseases, cancer, diabetes, respiratory diseases and stroke are the most significant cause of mortality worldwide and have considerable social and economic impact.[13] The most common risk factors for these chronic conditions are high blood pressure, high cholesterol levels, tobacco use, obesity, unhealthy lifestyle and lack of physical activity.[5] Investing in screening, early detection and prevention through comprehensive interventions on the leading causes of chronic conditions would reduce the burden of these diseases and bring health and economic benefits to the healthcare system.[6] In response to the World Health Organization's[5] call emphasising the urgency to prevent and control long-term conditions, there has been a shift towards clinical services delivered in primary and ambulatory care settings.

As person-centred care advances in today's clinical practice, pharmacists are becoming the first point of contact for many patients due to their unique skills and knowledge of medications, the high-quality services provided, and accessibility to the public (Agomo, 2012; Mossialos et al, 2015). These qualities make community pharmacies an optimal environment for patient-centred care focused on these amenable and avoidable risk factors.[6]

A study by Moore et al (2020) highlighted that an active partnership between pharmacists and physicians significantly improved patients' outcomes. Integrating pharmacists into the multidisciplinary team would deliver more comprehensive patient care and add value to the health system (Hayhoe et al, 2019; Awdishu et al, 2019). In

addition to the benefit on patient outcomes, pharmacist interventions have been shown to be cost-effective (Dalton & Byrne, 2017).

Although there is emerging evidence supporting the integration of pharmacists in the primary care team, the benefit of clinical pharmacists' interventions on patients' outcomes and the impact of these services on the health system remains unclear (Hayhoe et al, 2019). This study explored the scientific evidence supporting clinical pharmacist services in primary care and put forward a framework to support pharmacist-led interventions to improve short-term clinical outcomes in patients with acute and chronic conditions in primary care settings.

4.1 Pharmacy services and impact on patient outcomes

There is strong evidence supporting the effectiveness of pharmacists' interventions on clinical, humanistic and economic outcomes. Pharmacist interventions focus on three main areas: educational activities (patient counselling, advice and education), direct interventions (point-of-care testing, blood pressure measurement, minor ailments treatment), and monitoring (medicines review and optimisation, adverse drug reactions, dose titration and adjustment).

Patient education and counselling about the safe and effective use of medication are the core activities provided by pharmacists. These interventions aim to enhance the patient's understanding of the condition, the medicines used to prevent and control diseases and reinforce the physician's treatment plan facilitating adherence to therapy. The literature review highlighted that patient education and counselling improve

humanistic outcomes, such as adherence (Wong et al, 2013; Choudhry et al, 2018; Ali et al, 2019; Amador-Fernández et al, 2021), smoking cessation (Burford et al, 2013; Tsuyuki et al, 2016; El Hajj et al, 2017; Carson-Chahhoud et al, 2019), quality of life (Watson et al, 2015; Ali et al, 2019), and positively reduce hospital (Maeng et al, 2018; Kirkdale et al, 2020), physician visits (Ledford et al, 2013) and drug-related issues (Geurts et al, 2016; Ali et al, 2019; Varas-Doval et al, 2020). These results are comparable to the finding of other studies. A systematic review of RCTs conducted by Reeves et al, (2021) showed statistically significant improvement in adherence to therapy in patients receiving pharmacist-led counselling and advice. Similarly, a Cochrane review published by Steed et al, (2019) suggests that community pharmacist interventions improve behavioural outcomes in smoking cessation and increase adherence to diabetes and hypertensive therapy.

While improvements in intermediate clinical outcomes are seen in many studies (Santschi et al, 2012; Ledford et al, 2013; Geurts et al, 2016; Tsuyuki et al, 2016; Narain et al, 2020; Phillips et al, 2021), counselling interventions alone have minimal effect on short-term outcomes such as blood pressure measurement, glycated haemoglobin and cholesterol levels. These results were also seen by Tan et al (2014) in their systematic review of RCTs. The authors emphasised that medicines review and educational advice delivered in isolation were less likely to influence patient outcomes positively. Better results were seen in interventions that incorporated counselling with medication initiation, dose adjustment, and monitoring of laboratory markers (Roughead et al, 2005; Ellitt et al, 2009; Morgado et al, 2011). This aspect highlights that direct interventions for detecting, preventing and controlling specific risk factors produce

better patient outcomes. In order words, structured pharmacist-led services such as blood pressure measurement, diagnostic tests for blood glucose and lipids levels, and management of minor ailments have a more substantial impact on patient wellbeing when complemented with counselling and advice.

The pharmacist's role in patient care has been recognised worldwide by integrating community pharmacists' services in primary care pathways to increase access to care and assess and monitor health outcomes (Hayhoe et al, 2019; Hindi et al, 2019; Moore et al, 2020; Khaira et al, 2020). In Canada, New Zealand, and the USA, the community pharmacist's role is centred around dispensing and providing health screening tests and point-of-care testing, delivering vaccinations, and managing acute and chronic conditions. Some States and Federations extend the authority to prescribe medications, order and interpret laboratory tests, and administer injectable medications to practising pharmacists working in collaborative agreements with medical doctors.

In Europe, the community pharmacist's role varies according to the legislation and scope of practice in each country. France, Italy, Portugal and Spain have similar scenarios with pharmacists responsible for the safe dispensing of medicines, providing advice to patients, and participating in health education and campaigns to promote vaccination uptake, smoking cessation and adherence to therapy.[18] Germany, Portugal, Netherlands, and Switzerland have a remuneration system to reimburse pharmacy services delivered in community pharmacies (Van Mil & Schulz, 2006). In the United

[18] Institute for Evidence Based Health. Pharmacy services in Europe: evaluating trends and value report [Internet]; 2020 [cited 2022 May 27]. Available from: http://lfaa.lv/wp-content/uploads/2021/07/Pharmacy-Services-in-Europe-Evaluating-Trends-and-Value.pdf

Kingdom, community pharmacists deliver nationally commissioned essential services such as dispensing and locally commissioned advanced and enhanced services, such as medicines review, health checks and smoking cessation.[19] While every pharmacy must provide essential services, the enhanced services are commissioned by the Local Pharmaceutical Services, Clinical Commissioning Groups or Local Authorities based on the local population's needs. Pharmacists in the UK can diagnose and prescribe medicines autonomously, providing they completed a postgraduate prescribing course and meet the experience, skill and knowledge requirements set by the GPhC.[12]

Pharmacy practice in Malta shares elements with the international scenario. Community pharmacists deliver clinical services intended to detect, prevent and manage chronic diseases, such as point-of-care testing, triaging patients with minor ailments, managing patients with long-term conditions, and referring complex patients to a general practitioner (Azzopardi & Serracino-Inglott, 2020). Pharmacists actively monitor adherence to therapy and manage adverse drug reactions through a repeat dispensing service called POYC. Many community pharmacies have an in-house GP, specialist doctor or healthcare professionals operating outpatient clinics within the pharmacy premises. The community pharmacist becomes an active participant in the primary care team. This holistic approach to patient management creates an opportunity for interprofessional collaboration, allowing prompt, efficient, and safer patient care.

[19] Murray R. Community Pharmacy Clinical Services Review [Internet]. King's Fund. NHS 2016 [cited 2022 May 25]; Available from: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/12/community-pharm-clncl-serv-rev.pdf

4.2 Challenges and opportunities for service implementation

Although evidence supports clinical pharmacist interventions, data emerging from studies evaluating the implementation of pharmacist-led interventions in community pharmacies is unclear (Costa et al, 2019). The uncertainties about the effectiveness of pharmacist interventions are associated with study heterogeneity (Tonin et al, 2021), missing data related to clinical outcomes (Elnaem et al, 2020), lack of impact of the service and poor study design (Newman et al, 2020; Tonin et al, 2021). The lack of standardised procedures for delivering pharmacist interventions has been recognised as one of the main contributing factors to low implementation in community practice (Van Mil & Schulz, 2006; Martins et al, 2015).

To promote standardised procedures in community pharmacies, Hindi et al, (2019) identified some enablers to reduce the challenges associated with clinical pharmacy services implementation. The authors suggest adopting better engagement with the pharmacy team, physicians and consumers to improve collaboration and raise awareness of pharmacist skills. To ensure that a new concept, such as the interventions proposed in this study, is accepted and introduced into complex systems, it is essential to engage with the relevant stakeholders and evaluate its feasibility (O'Cathain et al, 2019). The present study explored the public willingness to participate and pay for thirteen defined clinical services using a questionnaire and established the feasibility of these services in the Maltese scenario by adopting a focus group discussion with an expert panel. Consumers participating in the questionnaire agreed that pharmacy services available in community pharmacies should include advice and treatment for

common throat infections (88%), skin conditions (87%), eyes and ears infections (84%), and urinary tract infections (81%). Participants expressed interest in services involving pharmacist advice on smoking cessation (86%), international travel health (86%), routine immunisation (83%), and medicines review (82%). Between 60% and 80% of the respondents were willing to pay a fee for the services presented in the questionnaire, showing that consumers are interested in pharmacist-led services provided in community pharmacies.

These findings are consistent with the results of previous studies. Parnis (2020) investigated the public perception of community pharmacy services, highlighting the positive attitude and beliefs of people living in Malta toward community pharmacy services. Parnis noted a statistically significant association between the consumers' positive attitude, satisfaction with the pharmacist recommendation, and adherence to over-the-counter medication. Previous studies evaluated the consumers' perception of community pharmacists in Malta (Wirth et al, 2010; Vella et al, 2015), the pharmacists perception of prescribing mild antibiotics (Attard Pizzuto et al, 2019) and the public views on pharmacists involved in an anticoagulation clinic (Mifsud et al, 2019). These studies show a positive attitude towards the advancement of pharmacy practice and consumers' acceptance of the extended pharmacist's role in the community. Similar results were found in the present study, where consumers agreed that they felt comfortable with the community pharmacist reviewing their medicines (mean=3.3 ±1.1) and performing diagnostic testing (mean=3.1 ±1.1).

This research builds on the findings of these local studies by investigating key stakeholders' views on community pharmacy services to understand better the context in which these clinical services are intended to be implemented. Patients, doctors and other members of the healthcare profession are vital components of the primary care team, and their views can positively influence the implementation of clinical pharmacy services (Hossain et al, 2017). The focus group discussion between practising community and hospital pharmacists, physicians, laypersons and allied healthcare professionals (audiologist and podiatrist) emphasised the importance of clinical services available in community pharmacies. The expert panel acknowledged that community pharmacists already provide medicines review and point-of-care testing; however, there is an opportunity to expand clinical services in community pharmacies. The panel recognised that community pharmacists should be involved in managing minor ailments and supported the proposal of the services that involve advice and treatment for sore throat, eye and ear infections, urinary tract infections, skin conditions, and advice on routine immunisation.

While pharmacists in Malta review patients' medicines regularly and provide blood pressure measuring and point-of-care testing, these interventions do not follow a structured protocol. In addition, the point-of-care results are generally not documented or shared with the patient's physician unless the test shows abnormal results. Recent studies show that time constraints could be a reason for not adhering to guidelines (Hindi et al, 2019; Qumseya et al, 2021). The lack of documentation has been recognised as a factor influencing the impact of pharmacist-led services on the health system in many European countries (Costa et al, 2017). It is globally accepted that standardised,

evidence-based procedures reduce variations in clinical practice and improve quality of care and patient outcomes (Rozich et al, 2004; Evans-Lacko et al, 2010; Wears, 2014). Adopting a standardised method to document medication-related information in clinical practice ensures uniformity and continuity of care amongst healthcare professionals, improves patient safety and reduces the error rate in communication between clinicians (Rozich et al, 2004; McLachlan et al, 2020). Adopting standardised operating procedures in the medical and pharmaceutical fields is essential to ensure efficiency and a high standard of practice when dealing with medical procedures and medications (Amare, 2012). To facilitate the implementation of clinical pharmacy practice, the framework proposed in this study provides a level of standardisation for collecting patients' data, recording the test results performed, and documenting the interventions and advice given to the patients. The step-by-step approach adopted in the framework would promote evidence-based practice, encourage systematic thinking, and foster consistency in the ongoing data collection and monitoring.

Cabana et al (1999) identified attitude-related barriers from clinicians concerned about following guidelines such as SOPs. The authors suggested that some clinicians may disagree with the rationale behind standardised procedures because such guidelines are driven by cost savings and managerial obligations rather than “decision-support tools.” Physicians and pharmacists fear that care pathways and overly detailed procedures can threaten professional judgement and clinical autonomy, taking away the flexibility to decide an alternative course of action for the best interest of patients (Jones, 2004; Thomas et al, 2016). The involvement of clinical and management staff in developing and implementing clinical guidelines can be a potential solution to address the clinicians’

concerns about applying these guidelines in practice (Evans-Lacko et al, 2010). The SOPs developed in this study were not intended to override the professional's clinical judgement but rather enable a systematic approach to patient care and support decision-making. Pharmacists are encouraged to make decisions appropriate to each patient's circumstances and condition, considering the legal and ethical requirements when applying the recommendations included in the framework. It is important to reiterate that patients should always be active participants in decisions about their care and be informed about the options available to treat their medical condition. The framework was validated by an expert panel consisting of pharmacists and doctors practising in Malta and England. This process broadened the perspective and assessed the feasibility of applying the framework on an international level.

Studies carried out internationally share concerns around the lack of public awareness and knowledge about community pharmacy services, patient confidentiality, and pharmacy training and competencies (Saramunee et al, 2014; Weir et al, 2019). Strengthening the relationship between pharmacists and patients increases awareness of pharmaceutical services available in the community.[2] In addition, a strong relationship with patients would build up trust and create opportunities for counselling and engagement in healthy lifestyle conversations. Patient confidentiality is paramount when delivering clinical services in community pharmacies. Pharmacists must ensure that sensible and sensitive conversations with patients are not heard by the public, particularly when discussing personal information over the counter.[20] Hindi et al, (2019)

[20] General Pharmaceutical Council. In practice: Guidance on confidentiality [Internet]. London: General Pharmaceutical Council; 2018 [update 2022; cited 2022 May 27]. Available from: https://www.pharmacyregulation.org/guidance/guidance-support-standards-pharmacy-professionals

identified some enablers to reduce the challenges associated with clinical pharmacy services implementation. The authors suggest providing training to enhance the pharmacist competencies and involving all the pharmacy team members in promoting the service. Training the whole pharmacy team on using the SOPs would increase their competence and confidence in providing and promoting the clinical service. Training and continuing professional development should include evidence-based information, updates on new clinical guidelines and opportunities to learn and improve practice (Qumseya et al, 2021). Before providing the clinical services proposed in this framework, it is recommended that pharmacists demonstrate continuous professional development by undergoing postgraduate training, participating in site-based training, or undertaking self-directed learning. A list of resources is presented within the framework.

4.2 Limitations

The questionnaire was distributed online using social media, meaning that only those who had access to these platforms could participate in the study. In addition, out of the 250 pharmacies distributed in Malta, only ten were selected for distributing the paper-based questionnaires. Hence, the results might not accurately reflect the perception of the whole community. The length of the questionnaire could have lowered the response rates. A self-administered questionnaire also brings a level of bias due to self-reporting data.

The researcher made several efforts to provide comprehensive SOPs for the provision of clinical pharmacy services. The interpretation of the test results and the range values provided in the framework are based on current guidelines, which may change over

time. It is recommended to update the framework regularly before delivering these services. The SOPs were not piloted to assess their feasibility and determine whether changes were needed prior to full-scale dissemination.

4.3 Recommendations for further studies

This study has shown the positive attitude of consumers toward the extended role of the clinical pharmacist and the feasibility of implementing pharmacist-led services in community settings. Further studies should explore the healthcare professionals' opinions about the pharmacist's involvement in primary care pathways. Identifying pharmacists' and physicians' concerns would be beneficial to overcome some barriers and create opportunities for collaboration.

The standards provided in this framework should be used as an opportunity to design and develop new clinical services and expand those already provided in community pharmacies. It would be beneficial to explore the pharmacist's needs and establish the competencies required to deliver the services. The framework could be used as a starting point to encourage the development of training modules and approved accreditation for pharmacists and pharmaceutical workforce in collaboration with the University of Malta and the Pharmacy Council.

Future research should consider piloting the framework in community pharmacies to establish the feasibility of the SOPs and ensure standardisation and uniformity in delivering the service, documenting interventions, collecting data, and reporting results.

As the expansion of the pharmacists' role is gaining momentum on an international scale (Funk et al, 2019), further research is recommended to determine how the professional role and current practice should evolve to fully integrate pharmacists into primary care teams.

4.4 Conclusion

This study provides evidence supporting the integration of clinical pharmacists as part of the multidisciplinary primary care team. Despite incongruent data regarding the impact of pharmacist interventions on the healthcare system, the benefit that these interventions bring to patient care is robust. Patient counselling and medicines review produce the best humanistic and clinical outcomes when combined with other pharmaceutical services such as medicines optimisation and monitoring drug response through point-of-care testing and laboratory results.

The outcomes of this study demonstrate a positive attitude of relevant stakeholders toward the expansion of clinical services available in community pharmacies. These findings are consistent with the results found in other national and international studies. The consumers' willingness to participate in and pay a fee for a pharmacist-led service indicates that patients trust the pharmacist and have confidence in the extended role of the community pharmacists.

The developed framework is a facilitator to overcome different barriers in practice settings to fully integrating pharmacists into the multidisciplinary primary care team. Such barriers and challenges could include lack of training and resources and concerns

about confidentiality. Stronger collaborations with physicians and better communication with pharmacy consumers through awareness campaigns could create opportunities for extending the pharmacist's role in patient care.

More research with a clear and defined study design is required to demonstrate the clinical pharmacy services' true value on patient outcomes. More focus should be paid to adopting standardised methods for collecting and analysing clinical outcomes in pharmacy research.

The contribution of this research is the developed framework that can be used to support clinical pharmacy expansion and highlight the pharmacist's role in patient care as an integral member of the primary care team. The validated framework put forward in this study informs future interventions and assists in developing potentially new clinical services delivered in community pharmacies. These services improve safe and timely access to care, increase patient choice to health services, and promote self-care.

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Appendices

Appendix 1

Ethics review

FRECMDS_2021_174 ID:- 9497_13082021_Osvaldo Cancellu Inbox ×

On Wed, 18 Aug 2021 at 09:05, FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt> wrote:

Dear Mr Cancellu,

Good morning and apologies for the late reply, but we are really caught up at the moment with the September examinations coming.

Since your self-assessment resulted in no issues being identified, FREC will file your application for record and audit purposes but will not review it.

Any ethical and legal issues including data protection issues are your responsibility.

Kindly **confirm** that you sent all the documents which you attached to the UREC form together with other documents related to your study.

Kindly note that these documents are also requested for audit purposes.

Regards,
Annalise

L-Università ta' Malta

Annalise Mallia Duca | Secretary

Faculty Research Ethics Committee
Faculty of Medicine and Surgery
Medical School, Mater Dei Hospital
+356 2340 1803

FRECMDS_2021_174 ID:- 9497_13082021_Osvaldo Cancellu Inbox ×

FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt> 19 Aug 2021, 08:49
to me, Lilian, Francesca

Dear Mr Cancellu,

Thank you and good luck with your research!

Regards,
Annalise

L-Università ta' Malta

Annalise Mallia Duca | Secretary

Faculty Research Ethics Committee
Faculty of Medicine and Surgery
Medical School, Mater Dei Hospital
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Appendix 2

Search strategy

PubMed search strategy.

Search number	Query	Filters	Results
1	clinical pharmacist	[MeSH Terms] OR [AllFields]	41,417
2	clinical pharmacy	[AllFields]	157,067
3	community pharmacist	[AllFields]	38,867
4	pharmacist-led	[AllFields]	1,319
5	#1 OR #2 OR #3 OR #4	[AllFields]	185,952
6	pharmacist intervention	[AllFields]	23,255
7	clinical pharmacist services	[AllFields]	19,949
8	community pharmacy services	[MeSH Terms] OR [AllFields]	10,519
9	#6 OR #7 OR #8	[AllFields]	36,504
10	clinical outcomes	[MeSH Terms] OR [AllFields]	1,399,117
11	patient outcomes	[MeSH Terms] OR [AllFields]	1,902,077
12	health outcomes	[MeSH Terms] OR [AllFields]	988,949
13	outcome measures	[MeSH Terms] OR [AllFields]	1,498,908
14	#10 OR #11 OR #12 OR #13	[MeSH Terms] OR [AllFields]	2,727,780
15	community pharmacy	[MeSH Terms] OR [AllFields]	37,519
16	primary care	[MeSH Terms] OR [AllFields]	527,263
17	outpatient	[MeSH Terms] OR [AllFields]	227,632
18	community health centers	[MeSH Terms] OR [AllFields]	43,742
19	#16 OR #17 OR #18 OR #19	[MeSH Terms] OR [AllFields]	793,399
20	#5 AND #9 AND #14 AND #19	[MeSH Terms] OR [AllFields]	4,147
21	#5 AND #9 AND #14 AND #20	[MeSH Terms] OR [AllFields] Filters: Free full text, from 2012 - 2022	813

CINAHL (EBSCOhost) search strategy.

Search number	Query	Limiters / Expanders	Results
1	"clinical service" OR "pharmacy service" OR "community service"	Expanders - Apply equivalent subjects. Search modes: Boolean / Phrase	10,584
2	pharmacist OR "clinical pharmacist" OR pharmacist-led	Expanders - Apply equivalent subjects Search modes: Boolean/Phrase	33,269
3	"primary care" OR pharmacy OR "community pharmac*"	Expanders - Apply equivalent subjects Search modes: Boolean/Phrase	167,940
4	outcome OR "health outcome" OR "patient outcome" OR intervention	Expanders - Apply equivalent subjects Search modes: Boolean/Phrase	678,976
5	S1 AND S2 AND S3 AND S4	Expanders - Apply equivalent subjects Search modes: Boolean/Phrase	2,105
6	S5	Expanders - Apply equivalent subjects Search mores: Boolean/Phrase Full Text; Published Date: 20120101-20221231	578

SCOPUS search strategy.		
Search number	Query	Results
1	(TITLE-ABS-KEY ("clinical service" OR "pharmacy service" OR "community service")	102,245
2	(TITLE-ABS-KEY ("clinical service" OR "pharmacy service" OR "community service") AND TITLE-ABS-KEY ((pharmacist OR "clinical pharmacist" OR pharmacist-led)) AND TITLE-ABS-KEY ("primary care" OR pharmacy OR "community pharmac*"))	10,416
3	(TITLE-ABS-KEY ("clinical service" OR "pharmacy service" OR "community service") AND TITLE-ABS-KEY ((pharmacist OR "clinical pharmacist" OR pharmacist-led)) AND TITLE-ABS-KEY ("primary care" OR pharmacy OR "community pharmac*")) AND TITLE-ABS-KEY (outcome OR "health outcome" OR "patient outcome" OR intervention))	4,069
4	(TITLE-ABS-KEY ("clinical service" OR "pharmacy service" OR "community service") AND TITLE-ABS-KEY ((pharmacist OR "clinical pharmacist" OR pharmacist-led)) AND TITLE-ABS-KEY ("primary care" OR pharmacy OR "community pharmac*")) AND TITLE-ABS-KEY (outcome OR "health outcome" OR "patient outcome" OR intervention)) AND PUBYEAR > 2012	2,519
5	(TITLE-ABS-KEY ("clinical service" OR "pharmacy service" OR "community service") AND TITLE-ABS-KEY ((pharmacist OR "clinical pharmacist" OR pharmacist-led)) AND TITLE-ABS-KEY ("primary care" OR pharmacy OR "community pharmac*")) AND TITLE-ABS-KEY (outcome OR "health outcome" OR "patient outcome" OR intervention)) AND PUBYEAR > 2012 AND (LIMIT–TO (LANGUAGE, "english"))	2,445
Cochrane library search strategy.		
Search number	Query	Results
1	(pharmacist OR "clinical pharmacist" OR "clinical pharmacy" OR "community pharmacist" OR pharmacist-led):ti,ab,kw	4452
2	("community pharmacy" OR outpatient OR "primary care" OR "health centers"):ti,ab,kw	56285
3	("intervention" OR "clinical service" OR "community pharmacy service"):ti,ab,kw	413654
4	(outcome OR "clinical outcomes" OR "patient outcomes" OR "health outcomes" OR "outcomes measure"):ti,ab,kw	571304
5	#1 AND #2 AND #3 AND #4	641

Appendix 3

Questionnaire in English, Italian and Maltese

Clinical pharmacy services in primary care

My name is Osvaldo Cancellu, and I am a pharmacist reading for a Doctorate in Pharmacy degree at the University of Malta. I am undertaking a research project entitled "**Clinical pharmacy services in primary care**" under the supervision of Prof. Lilian M. Azzopardi and Dr Francesca Wirth from the Department of Pharmacy, University of Malta**.**

Aim of the research

The aim of this questionnaire is to collect information about consumer perception of current and potential new clinical services provided by the pharmacist in the community.

Your involvement

You are invited to complete this anonymous questionnaire which is expected to take approximately 10 minutes. Your participation in this research is entirely voluntary and you may withdraw your consent at any time without any prejudice.

This data is used solely for the purpose of the research according to the General Data Protection Regulation (GDPR). The information gathered will be destroyed once the study is concluded.

In case of queries, I may contact Osvaldo Cancellu on osvaldo.cancellu.19@um.edu.mt

By completing this questionnaire, I give my informed consent to participate in this study. [printed version].

I give my informed consent to participate in this study by clicking on the consent box below. [online version].

Questionnaire

Section A: Consumer demographics

This section aims to better understand your background to customise pharmacist services that meet your needs.

Please select **one answer** for each question.

Age	□ 18-29	□ 30-49	□ 50-69	□ 70 and over
Gender	□ Male	□ Female	□ Other	□ Prefer not to answer
Country of residence				
Nationality				
Level of education	□ Primary	□ Secondary	□ Post-secondary	□ Tertiary
Occupation				

Section B: Beliefs

This section aims to understand your beliefs about the statements below.

Please select **one answer** for each statement that best describes your opinion.

The pharmacist is….	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Able to advise and recommend a medicine to improve my condition and symptoms.					
Knowledgeable about **minor problems** such as skin conditions, cough, colds, pain.					
Knowledgeable about **chronic conditions** such as high blood pressure, diabetes, heart conditions, asthma.					

Section C: Awareness

This section aims to explore your awareness about the statements below.

Please select **one answer** for each statement that best describes your opinion.

I am aware that…	Very much aware	Aware	Neither aware nor not aware	Somewhat aware	Not aware
I can talk to the pharmacist about my health in a completely confidential way					
The pharmacist is trained to understand my medical condition and interpret common test results					
The pharmacist can dispense medicines to treat minor health problems without the need to see a doctor					
The pharmacist and the doctor can work together to ensure that I am receiving the best medicine for my condition					

Section D: Perception on pharmacist-led services available at my pharmacy

This section aims to understand your point of view about the scenarios below.

Please select **one answer** for each statement that best describes your opinion.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
When I need health advice or guidance about a symptom which I believe is not serious enough to visit the doctor, I first consult with the pharmacist						
When I need to monitor my blood pressure, blood glucose and cholesterol levels, I first consult with the pharmacist						
I feel comfortable if the pharmacist reviews my medicines and provides any necessary recommendations						
I feel confident that the pharmacist can perform tests and refers me to a physician for further investigations						

Section E: Perception on potential new pharmacist-led services

This section aims to understand your point of view about the potential for new pharmacist-led services. Please select **one answer** for each service.

Services available at the community pharmacy should include:	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
Yearly review of the medicines I am taking (Medicine Use Review)						
Stop smoking service / Nicotine replacement therapy						
Advice and treatment for eye and ear infections						
Screening and treatment of common throat infections						
Advice and treatment for skin infections and skin conditions						
Advice and treatment for urinary tract infections (UTI)						
Screening and management of sexually transmitted diseases such as chlamydia and HIV						
Advice on sexual related issues such as erectile dysfunction and emergency contraception (morning after pill)						
Electrocardiogram (ECG) test to check the heart's rhythm for atrial fibrillation						
Blood testing (International Normalised Ratio - INR) for warfarin levels						
Blood tests such as check HbA1C for diabetes, anaemias and vitamin levels						
Travel health advice and international travel vaccinations such as malaria, hepatitis A and B						
Routine immunisations such as Influenza, Pneumococcal, Meningococcal, and Hepatitis vaccines						

If the proposed services provided by the pharmacist are implemented in your local pharmacy, please indicate which services you would be willing to use and those that you would be prepared to pay for.

	Would you use this service?		**Would you be willing to pay a fee for this service?**
Yearly review of the medicines I am taking	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Stop smoking service / Nicotine replacement therapy	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Advice and treatment for eye and ear infections	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Screening and treatment of common throat infections	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Advice and treatment for skin infections and other skin conditions.	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Advice and treatment for urinary tract infections (UTI)	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Screening and management of sexually transmitted diseases such as chlamydia and HIV	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Advice on sexual related issues such as erectile disfunction and emergency contraception (morning after pill)	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Electrocardiogram (ECG) test	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Blood testing (International Normalised Ratio - INR) for warfarin levels	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Blood tests such as check HbA1C for diabetes, anaemias, and vitamin levels	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Travel health advice and international travel vaccinations	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No
Routine immunisations according to the National immunisation schedule	□ Yes □ No □ Not applicable		□ Yes, between 5 and 10 Euro □ Yes, between 10 and 20 Euro □ No

If you selected "**NO**" to any of the questions above, please indicate the reason/s why you would not be willing to pay for these services.	
Is/are there any other service/s you would like to see being provided from your local pharmacy?	Please write you answer in here:
Do you have any suggestions to improve the service provided from community pharmacies?	Please write your answer in here:
If you would like to discover more about this project and participate to further development, please leave your email address below. _____@_____	

Thank you very much for completing this survey.

Clinical pharmacy services in primary care

Mi chiamo Osvaldo Cancellu e sono un farmacista iscritto al secondo anno del Dottorato in Farmacia presso l'Università di Malta. Sto intraprendendo un progetto di ricerca intitolato "**Clinical pharmacy services in primary care**" sotto la supervisione della Prof.ssa Lilian M. Azzopardi e della Dr.ssa Francesca Wirth del Dipartimento di Farmacia presso l'Università di Malta.

Obiettivo della ricerca

Lo scopo di questo questionario è quello di raccogliere informazioni riguardanti la percezione dei consumatori su nuovi servizi clinici forniti dal farmacista nella farmacia territoriale.

Il vostro coinvolgimento

La invito a compilare questo questionario anonimo che dovrebbe richiedere circa 10 minuti. La sua partecipazione è interamente volontaria ed è possibile interrompere il questionario e revocare il consenso in qualsiasi momento senza alcun pregiudizio.

I dati raccolti con il questionario sono utilizzati esclusivamente ai fini della ricerca ai sensi del Regolamento Generale per la Protezione dei Dati Personali (GDPR). Le informazioni raccolte saranno distrutte una volta concluso lo studio.

In caso di domande, potrà contattarmi all'indirizzo e-mail: osvaldo.cancellu.19@um.edu.mt

Compilando questo questionario, do il mio consenso informato a partecipare a questo studio. [versione stampata].

Do il mio consenso informato a partecipare a questo studio cliccando sulla casella di consenso qui sotto. [versione online].

Questionario

Sezione A: Dati generali dei consumatori

Questa sezione ha lo scopo di comprendere meglio le sue preferenze per personalizzare i servizi forniti dal farmacista clinico che soddisfino le sue esigenze.

Per ogni domanda si prega di selezionare **una risposta**.

Fascia di età	□ 18-29	□ 30-49	□ 50-69	□ 70 anni e oltre
Sesso	□ Maschio	□ Femmina	□ Altro	□ Preferisco non rispondere
Paese di provenienza				
Nazionalità				
Livello di istruzione	□ Primaria	□ Secondaria	□ Università	□ Post universitaria
Occupazione				

Sezione B: Opinione

Questa sezione ha lo scopo di comprendere il suo grado di accordo/disaccordo con le seguenti frasi.

Per ogni domanda si prega di selezionare **una risposta** che descriva al meglio la sua opinione.

Il farmacista è. . .	Fortemente d'accordo	D'accordo	Né d' accordo né disaccordo	Disaccordo	Fortemente in disaccordo
In grado di consigliare un medicinale per migliorare la mia condizione e i miei sintomi					
Competente in merito a **disturbi minori** come condizioni della pelle, tosse, raffreddore e dolore					
Competente in merito a **malattie croniche** come ipertensione, diabete, malattie cardiache e asma					

Sezione C: Sensibilizzazione

Questa sezione ha lo scopo di esplorare la sua consapevolezza riguardo le affermazioni sottoelencate.

Per ogni domanda si prega di selezionare **una risposta** che descriva al meglio la sua opinione.

Sono consapevole che...	Molto consapevole	Consapevole	Neutrale	Non consapevole	Per niente consapevole
Posso parlare con il farmacista della mia salute in modo del tutto confidenziale					
Il farmacista è formato per comprendere la mia condizione medica e interpretare i risultati dei referti medici					
Il farmacista può dispensare farmaci per curare disturbi minori senza la necessità di consultare un medico					
Il farmacista e il medico possono lavorare insieme per assicurarsi che stia ricevendo il miglior farmaco					

Sezione D: Percezione sui servizi disponibili in farmacia

Questa sezione ha lo scopo di comprendere il suo punto di vista nei seguenti scenari.

Per ogni domanda si prega di selezionare **una risposta** che descriva al meglio la sua opinione.

	Fortemente d'accordo	D'accordo	Né d' accordo né disaccordo	Disaccordo	Fortemente in disaccordo	Non saprei, non ne ho usufruito
Quando ho bisogno di consigli sulla salute o su un sintomo che ritengo non sia serio, consulto il farmacista prima di contattare il medico di famiglia						
Quando ho bisogno di controllare la pressione sanguigna, la glicemia e i livelli di colesterolo consulto il farmacista prima di contattare il medico di famiglia						
Mi sento a mio agio se il farmacista controlla i miei medicinali e fornisce tutte le raccomandazioni necessarie						
Sono fiducioso se il farmacista esegue dei test clinici e mi indirizza ad un medico per ulteriori indagini						

Sezione E: Percezione su potenziali nuovi servizi eseguiti dal farmacista

Questa sezione ha lo scopo di comprendere il suo punto di vista su potenziali nuovi servizi eseguiti dal farmacista territoriale.

Per ogni domanda si prega di selezionare **una risposta** che descriva al meglio la sua opinione.

I servizi disponibili presso la farmacia comunitaria dovrebbero includere:	Fortemente d'accordo	D'accordo	Né d' accordo né disaccordo	Disaccordo	Fortemente in disaccordo	Non pertinente
Controllo annuale dei farmaci che sto assumendo						
Consulenza per smettere di fumare / terapia sostitutiva con nicotina						
Consulenza e trattamento delle infezioni oculari e dell'orecchio						
Consulenza e trattamento di infezioni comuni della gola						
Consulenza e trattamento delle infezioni della pelle e altre condizioni dermatologiche						
Consulenza e trattamento delle infezioni del tratto urinario						
Consulenza e gestione di malattie sessualmente trasmissibili come clamidia e HIV						
Consulenza e gestione di disturbi sessuali come la disfunzione erettile e consulenza sulla contraccezione di emergenza (pillola del giorno dopo)						
Elettrocardiogramma (ECG) per valutare l'attività elettrica del cuore nella fibrillazione atriale						
Monitoraggio dell'intervallo terapeutico (INR) per i livelli di warfarin sodico						
Analisi del sangue per controllare i livelli di glucosio, anemie e profilo metabolico						
Consulenza sulle vaccinazioni per i viaggi all'estero come malaria, epatite A e B						
Programmi nazionali di immunizzazione come il vaccino influenzale, anti-pneumococcico, anti-meningococco, vaccino contro l'epatite						

Per ogni domanda si prega di selezionare **una risposta** che descriva al meglio la sua opinione.

Se i seguenti servizi fossero eseguiti dal farmacista presso l farmacia sarei disposto a ...	Usufruire di questo servizio		Pagare un contributo per tale servizio
Controllo annuale dei farmaci che sto assumendo	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza per smettere di fumare / terapia sostitutiva con nicotina	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e trattamento delle infezioni oculari e dell'orecchio	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e trattamento di infezioni comuni della gola	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e trattamento delle infezioni della pelle e altre condizioni dermatologiche	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e trattamento delle infezioni del tratto urinario	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e gestione di malattie sessualmente trasmissibili come clamidia e HIV	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza e gestione di disturbi sessuali come la disfunzione erettile e consulenza sulla contraccezione di emergenza (pillola del giorno dopo)	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Elettrocardiogramma (ECG) per valutare l'attività elettrica del cuore nella fibrillazione atriale	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Monitoraggio dell'intervallo terapeutico (INR) per i livelli di warfarin sodico	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Analisi del sangue per controllare i livelli di glucosio, anemie e profilo metabolico	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Consulenza sulle vaccinazioni per i viaggi all'estero come malaria, epatite A e B	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No
Programmi nazionali di immunizzazione come il vaccino influenzale, anti-pneumococcico, anti-meningococco, vaccino contro l'epatite	□ Sì □ No □ Non pertinente		□ Sì, tra 5 e 10 Euro □ Sì, tra 10 e 20 Euro □ No

Se la risposta ad uno o più servizi è **NO**, si prega di indicare i motivi per i quali non è disposto/a a pagare per questi servizi.	
C'è / ci sono altri servizi che vorrebbe fossero forniti dalla sua farmacia di fiducia?	Si prega di scrivere qui la risposta:
Ha qualche suggerimento per migliorare il servizio fornito dalle farmacie?	Si prega di scrivere qui la risposta:
Se vuole partecipare ad ulteriori sviluppi di questo progetto, si prega di lasciare il proprio indirizzo e-mail qui sotto. _____@_____	

Grazie mille per aver completato questo questionario.

Clinical pharmacy services in primary care

Jien Osvaldo Cancellu, spiżjar li qed insegwi il-kors li jwassal ghal Dottorat fil-Farmacija mal-Università ta' Malta. Qed nagħmel riċerka bit-titlu ta' **"Clinical pharmacy services in primary care"** taħt is-superviżjoni tal-Prof. Lilian M. Azzopardi u Dr Francesca Wirth mid-Dipartiment tal-Farmaċija, tal-Università ta' Malta.

L-għan tar-riċerka

L-għan ta' dan il- kwestjonarju huwa biex tiġi miġbura informazzjoni dwar il-perċezzjoni tal-konsumatur dwar servizzi eżistenti u servizzi ġodda li potenzjalment jistgħu jiġu provduti mill-ispiżjara.

L-involviment tiegħek

Inti mistieden/na timla dan il-kwestjonarju anonimu li mistenni t/jeħodlok madwar 10 minuti. Il-parteċipazzjoni tiegħek hija kompletament voluntarja u tista' tieqaf fi kwalunkwe stadju tal-kwestjonarju mingħajr ebda preġudizzju.

Din l-informazzjoni ser tintuża biss għall-fini tar-riċerka skond l-Att Dwar il-Protezzjoni u l-Privatezza tad-Data (GDPR). L-informazzjoni miġbura tiġi meqruda ladarba jiġi konkluż l-istudju.

F'każ ta' mistoqsijiet, tista' tikkuntattjani billi tibgħtli e-mail fuq osvaldo.cancellu.19@um.edu.mt

Billi nimla dan il-kwestjonarju, jien qed nagħti l-kunsens infurmat tiegħi biex nipparteċipa f'dan l- istudju. [printed version]

Jiena nagħti l-kunsens infurmat tiegħi biex nipparteċipa f'dan l-istudju, billi nikklikkja fuq il-kaxxa tal-kunsens ta' hawn taħt. [Online version]

Kwestjonarju

Taqsima A: Demografiċi tal-konsumatur

L- għan ta' din it-taqsima hu biex jiġi mifhum aħjar l-isfond tiegħek biex tippersonaliża s-servizzi tal- ispiżjar li jissodisfaw il-ħtiġijet tiegħek.

Jekk jogħġbok **agħżel tweġiba waħda** għal kull dikjarazzjoni.

Età	□ 18-29	□ 30-49	□ 50-69	□ 70 sena jew aktar
Sess	□ Raġel	□ Mara	□ Newtru	□ Nippreferi li ma nweġibx
Pajjiż tar- residenza				
Nazzjonalità				
Livell ta' edukazzjoni	□ Primarja	□ Sekondarja	□ Post-sekondarja	□ Terzjarja
Xogħol				

Taqsima B: Attitudnijiet u Twemmin

L- għan ta' din it-taqsima hu biex jiġi mifhum il-perċezzjoni tiegħek dwar id-dikjarazzjonijiet ta' hawn taħt.

Jekk jogħġbok **agħżel tweġiba waħda** għal kull dikjarazzjoni li l-aħjar tiddeskrivi l-opinjoni tiegħek.

L-ispiżjar huwa	Naqbel ħafna	Naqbel	Newtrali	Ma naqbilx	Ma naqbel xejn
Kapaċi jagħti parir u jirrakkomanda mediċina biex itejjeb il-kundizzjoni u s-sintomi tiegħi					
Mistħarreġ fuq **problemi minuri** bħal kundizzjonijiet tal-ġilda, sogħla, irjiħat, uġigħ					
Mistħarreġ dwar **kundizzjonijiet kroniċi** bħal pressjoni tad-demm għolja, dijabete, kundizzjonijiet tal-qalb,ażma					

Taqsima Ċ: Għarfien tal-Pazjent

L- għan ta’ din it-taqsima hu biex jiġi mifhum l-għarfien tiegħek dwar id-dikjarazzjonijiet ta' hawn taħt. Jekk jogħġbok **agħżel tweġiba waħda** għal kull dikjarazzjoni li tiddeskrivi bl-aħjar mod l-opinjoni tiegħek.

Jiena konxju/a li....	Konxju/a ħafna	Konxju/a	Newtrali	Mhux konxju/a	Kompletament mhux konxju/a
Kapaċi nitkellem mal-ispiżjar dwar saħħti b'mod kompletament kunfidenzjali					
L-ispiżjar huwa mħarreġ biex jifhem il-kundizzjoni medika tiegħi u jinterpreta r-riżultati tat-testijiet komuni					
L-ispiżjar jista' jagħti mediċini għall-kura ta' problemi minuri tas-saħħa mingħajr il-ħtieġa li nara tabib					
L-ispiżjar u t-tabib jistgħu jaħdmu flimkien biex jiżguraw li qed nirċievi l-aħjar mediċina għall-kundizzjoni tiegħi					

Sezzjoni D: L-Perċezzjoni tiegħek dwar servizzi mmexxija mill-ispiżjar disponibbli fl-ispiżerija lokali tiegħi

L-għan ta’ din it-taqsima hu biex jiġi mifhum il-fehma tiegħek dwar ix-xenarji ta’ hawn taħt.

Jekk jogħġbok **agħżel tweġiba waħda** għal kull dikjarazzjoni li tiddeskrivi bl-aħjar mod l-opinjoni tiegħek.

	Naqbel ħafna	Naqbel	Newtrali	Ma naqbilx	Ma naqbel xejn
Meta jkolli bżonn pariri dwar saħħti jew gwida dwar xi sintomi li naħseb li m’humiex serji biżżejjed biex inżur it-tabib, jien nikkonsulta mal-ispiżjar qabel					
Meta jkolli bżonn niccekkja l-pressjoni tad-demm tiegħi, iz-zokkor fid-demm u l-livelli tal-kolesterol fid-demm jien nikkonsulta mal-ispiżjar qabel ma nikkuntattja t-tabib					
Inħossni komdu/a jekk l-ispiżjar jirrevedi l-mediċini tiegħi u jipprovdi kwalunkwe’ rakkomandazzjoni meħtieġa					
Inħossni kunfidenti li l-ispiżjar jista' jwettaq testijiet u jirreferini ghat-tabib għal aktar investigazzjonijiet					

Taqsima E: L-Perċezzjoni tiegħek dwar servizzi potenzjali ġodda mmexxija mill-ispiżjar

L- għan ta' din it-taqsima hu biex jiġi mifhum il-fehma tiegħek dwar dawn id-dikjarazzjonijiet. Jekk jogħġbok agħżel tweġiba waħda għal kull servizz.

Is-servizzi disponibbli fl-ispiżerija tal-komunità għandhom jinkludu:	Naqbel ħafna	Naqbel	Newtrali	Ma naqbilx	Ma naqbel xejn	Mhux applikabbli
Reviżjoni darba fis-sena tal-mediċini li qed nieħu (Reviżjoni tal-Użu tal-Mediċina)						
Servizz sabiex twaqqaf it-tipjip / Pariri (terapija) dwar sostituzzjoni tan-nikotina biex tgħin lin-nies jieqfu jpejpu						
Pariri u trattament għal infezzjonijiet fl- għajnejn u fil-widnejn						
Screening u trattament ta' infezzjonijiet komuni fil-gerżuma						
Pariri u trattament għal infezzjonijiet tal- ġilda u kundizzjonijiet oħra tal-ġilda						
Pariri u trattament għal infezzjonijiet tal-pipi						
Screening u trattment ta' mard trażmess sesswalment bħall-klamidja u l-HIV.						
Pariri u trattament ta' kwistjonijiet relatati mas-sess bħal disfunzjoni erettili u kontraċezzjoni ta' emerġenza						
Test elettrokardjogramma (ECG) biex jiċċekkja r-ritmu tal-qalb u l-attività elettrika għal kundizzjonijiet bħall-qalb tgħaġġel						
Test ta' monitoraġġ tal-warfarina (INR)						
Testijiet tad-demm ezempju biex jiġu eżaminati id-dijabete (HbA1C), l-anemija u l-livelli ta' vitamini						
Pariri dwar is-saħħa waqt-ivvjaġġar u tilqim relatat mas-safar bħall-malarja, l-epatite A u B						
Tilqim nazzjonali bħal vaċċini kontra l-Influwenza, pnewmonja, meningite, epatite						

Jekk is-servizzi proposti pprovduti mill-ispiżjar jiġu implimentati fl-ispiżerija lokali tiegħi, inkun lest/a li nuża u nħallas għas-servizzi li ġejjin: Jekk jogħġbok **agħżel tweġiba waħda** għal kull dikjarazzjoni.

	Tuża dan is-servizz?		**Tkun lest/a li tħallas tariffa biex tirċievi xi wieħed mis-servizzi ta' hawn taħt?**
Reviżjoni darba fis-sena tal-mediċini li qed nieħu (Reviżjoni tal-Użu tal-Mediċina)	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Servizz sabiex twaqqaf it-tipjip / Pariri (terapija) dwar sostituzzjoni tan-nikotina biex tgħin lin-nies jieqfu jpejpu	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Pariri u trattament għal infezzjonijiet fl-għajnejn u fil-widnejn	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Screening u trattament ta' infezzjonijiet komuni fil-gerżuma	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Pariri u trattament għal infezzjonijiet tal- ġilda u kundizzjonijiet oħra tal- ġilda	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Pariri u trattament għal infezzjonijiet tal-pipi	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Screening u trattment ta' mard trażmess sesswalment bħall-klamidja u l-HIV	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Pariri u trattament ta' kwistjonijiet relatati mas-sess bħal disfunzjoni erettili u kontraċezzjoni ta' emerġenza	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Test elettrokardjogramma (ECG) biex jiċċekkja r-ritmu tal-qalb u l-attività elettrika għal kundizzjonijiet bħall-qalb tgħaġġel	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Test ta' monitoraġġ tal-warfarina (INR)	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Testijiet tad-demm ezempju biex jiġu eżaminati id-dijabete (HbA1C), l-anemija u l-livelli ta' vitamini	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Pariri dwar is-saħħa waqt-ivvjaġġar u tilqim relatat mas-safar bħall-malarja, l-epatite A u B	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le
Tilqim nazzjonali bħal vaċċini kontra l- Influwenza, pnewmonja, meningite, epatite.	□ Iva □ Le □ Mhux applikabbli		□ Iva, bejn 5 u 10 Ewro □ Iva, bejn 10 u 20 Ewro □ Le

Jekk **“LE”**, jekk jogħġbok indika r-raġuni għala ma tkunx lest/a li tħallas għal dawn is-servizzi.	
Hemm xi servizz/i ieħor/oħrajn li tixtieq tara jiġu pprovdut/i fl-ispiżerija lokali tiegħek?	Jekk jogħġbok ikteb hawn taħt:
Għandek xi suġġerimenti biex ittejjeb is-servizz ipprovdut mill-ispiżeriji tal-komunità?	Jekk jogħġbok ikteb it-tweġiba tiegħek hawn taħt:
Jekk tixtieq tiskopri aktar dwar dan il-proġett u tipparteċipa għal aktar żvilupp, jekk jogħġbok ħalli l-indirizz tal-email tiegħek hawn taħt. _____@_____	

Grazzi ħafna talli ppartecipajt f’dan l-istħarriġ.

Appendix 4

Framework document

Clinical pharmacy services in primary care: Framework

Table of Contents

1. Background

Clinical pharmacy focuses on pharmaceutical care, medicine optimisation, disease prevention, and promotion of health and wellbeing.[1] With an in-depth knowledge of medications and therapeutic use, pharmacists play an essential role in helping people achieve desired therapeutic goals and prevent and minimise adverse drug reactions.[2]

Clinical pharmacists are a primary source of information and advice regarding the safe, appropriate, and cost-effective use of medications and disseminate knowledge to improve health and quality of life.[3] Clinical pharmacists use their professional judgement and apply evidence-based interventions within the legal, ethical, and professional principles to provide health services. Clinical services, including medicine optimisation, advice and treatment of minor ailments and provision of diagnostic and point-of-care testing improve patient outcomes.[4]

As clinical pharmacy continues to evolve to meet the demand of patients and support modern healthcare service development, pharmacists are key players to support, initiate and participate in services provision that address healthcare needs in the community.[3-4]

2. Purpose

The framework put forward in this document is intended to serve as a standardised service provision by offering guidance in the delivery of clinical services in the primary care setting. The framework outlines responsibility and accountability for managing medication therapy, point-of-care diagnostic tests, and evidence-based interventions in primary care.

3. The framework

This framework defines clinical services standards (criteria for being offered the service, informed consent, consultation room standards, storage requirements) and pharmacist's roles and responsibilities (training requirements, interpretation of test results, reporting of adverse reactions, referral to physicians). The framework includes Standard Operating Procedures (SOPs) outlining the conduction of pharmaceutical clinical services, interpretation of outcome measures and point-of-care testing results, clinical decision-making process, improving efficiency, and optimising patient outcomes in clinical practice. The framework is not intended to replace professional judgment.

3.1 Clinical services

Clinical pharmacy services described in this framework include:

- Medicines Use Review
- Blood Pressure measurement
- Weight management
- Point-of-care testing for monitoring the glycaemic and lipid profile
- Smoking cessation advice
- Advice and treatment for eye and ear conditions, sore throat, skin conditions, and urinary tract infections
- International travel health advice
- Recommendations on routine immunisations

Each clinical service has a clearly defined SOP which outlines the activities and recommendations to deliver a safe and efficient service.

3.1.1 Inclusion and exclusion criteria

The services included in this framework cover clinical conditions or situations affecting adults. Elderly and pregnant or breastfeeding women can participate in these clinical services; however, particular caution should be applied to these groups when giving advice or recommending treatment. Children are excluded and should be referred to a paediatrician or general practitioner. Patients must give consent to participate in the service. Each SOP defines the specific inclusion or exclusion criteria for the named service.

3.1.2 Informed consent

Written patient consent must be obtained before requesting personal information and performing any clinical service involving the use of blood or bodily fluids. For follow-up consultations, consent should be obtained on each testing occasion. Patients' details and test results are confidential, access to personal information must be restricted to authorised pharmacists only. A copy of the patient medication record and tests results should be given to patients for their use.

3.1.3 Consultation room standards

Clinical services must be provided in a consultation room separate from the general public area and suitable for confidential consultations and counselling. Pharmacists and customers must be able to discuss in private at average speaking volumes without being overheard by any other person. The room should be furnished with a desk and enough chairs to accommodate the pharmacist and the customer. A reclinable clinical bed is recommended for services that require blood sample collection to accommodate customers who tend to faint. The room should be kept at high standards, clean, clutter-

free, with adequate lighting and comfortable temperature. The room should have enough space for the equipment and consumables necessary to perform the tests. These include the blood pressure machine, weighing scale, blood glucose and lipid devices, hand and surface sanitisers, alcohol wipes, one-use lancets, needles, capillary tubes, testing strips, and plasters. The room should be stocked with Personal Protective Equipment (gloves, surgical gown, aprons, mask, goggles) and the necessary documentation to perform the tests. The room should have a ventilation system or air purifier, a sink with hand soap to perform hand hygiene and clinical waste and sharp bins to safely dispose of consumables. The room should allow wheelchair access.

3.1.4 Documentation requirements

Pharmacists must maintain a record of patient consent for each service provided in line with the European General Data Protection Regulation. The patient's details should be stated on each page to prevent accidental mismatching of files. There should be a system for storing and retrieving documents efficiently, avoiding the risk of mixing different files. Completed patient medication records, medicine use review forms, consent forms, and other patients' identifiable information must be stored in a lockable cabinet in a secure area that is not accessible by the public. Access to the cabinet keys should be restricted to authorised pharmacists. The records should be retained for at least two years from when the service was provided. After this period, the files can be shredded and disposed of in a confidential bin.

3.2 The role of the clinical pharmacist

Pharmacists providing clinical services are expected to comply with the SOP at all times. This framework is not intended to override the pharmacist's clinical judgement.

Pharmacists should make decisions appropriate to each patient's circumstances and condition, considering the legal and ethical requirements when exercising their clinical judgment. Patients should always participate in decisions about their care and be aware of the choices for their medical treatment.

3.2.1 Responsibilities

Pharmacists providing clinical services are responsible for:

- Ensuring they are competent in providing the clinical service.
- Ensuring that the consultation room standards are met.
- Ensuring that all the equipment needed for diagnostic point-of-care testing is calibrated regularly according to the manufacturer's instructions.
- Ensuring that the equipment is clean, well maintained, and in good working order.
- Ensuring the consumables required to provide the service are available.
- Ensuring confidentiality and patient privacy are always maintained.
- Ensuring that patients' identifiable information is kept in a secure area.
- Determining the patient's eligibility for the service.
- Assessing the patient's condition and providing relevant advice or treatment.
- Documenting advice, recommendations and treatment provided.
- Recognising when signposting or referral to another health professional is needed.

Managing pharmacists are responsible for ensuring that SOPs are implemented, remain current and appropriate and that pharmacists conducting clinical services satisfy the required competence, knowledge, and skills necessary to perform the test or consultations.

3.2.2 Training and education

There are no specific training requirements for delivering the clinical services included in this framework. Pharmacists should be competent in performing the tasks and operate within their scope of practice in compliance with the code of conduct, professional standards, and legal obligations. It is recommended that pharmacists demonstrate continuous professional development by undergoing postgraduate training, participating in site-based training, or undertaking self-directed learning. A list of resources is available in the bibliography section. Before performing a clinical service for the first time, pharmacists must sign the SOP training log.

3.2.3 Interpretation of test results

Pharmacists should use their clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Test results should be interpreted in the context of the patient's medical history, medical status, age, gender, and previous results, if present. Pharmacists must counsel patients about the test, the meaning and significance of the results and the actions required. Written information should be provided.

3.2.4 Referral to other healthcare professionals

Pharmacists must use their professional judgement to decide whether referral to another healthcare professional is required. Patients should be counselled and encouraged to seek medical advice whilst avoiding the use of language and non-verbal signals which cause unduly alarm or inappropriate reactions.

Pharmacists should refer to the General Practitioner or Emergency Department those patients who:

- Require further support, advice, or treatment that the pharmacist cannot provide.
- Require further assessment from another healthcare professional.
- Present with side effects from any medicines used.
- Present with red flags or warning signs and symptoms.
- Present with recurrence of a condition previously treated.
- Present with abnormal test results suggesting a potentially serious disease.

3.2.5 Reporting adverse drug reactions

Pharmacists should report suspected adverse drug reactions, including known side effects, serious or non-serious reactions, and incidents with a medical device to the Malta Medicines Authority using the following link: http://medicinesauthority.gov.mt/reportingadversereactions?l=1

Pharmacists should advise patients on managing minor adverse reactions and refer them to the most appropriate healthcare professional as necessary. It may also be appropriate to record in the patient's notes and notify the prescriber upon the patient's consent to share information.

3.3 The Standard Operating Procedures

The SOPs are clustered into four groups: general, patient review, advice and treatment, and ancillary. The SOP name, number and version are indicated on each SOP. Each SOP describes the activities as a step-by-step instruction to guide pharmacists providing a specific clinical service, including the necessary forms to obtain the patient's consent, record the patient's details and medicines, and annotate the relevant advice and recommendations. SOPs involving measurement or point-of-care testing include the

reference values and the scales for interpreting the test results. The SOPs are authorised and reviewed by the responsible managing pharmacist yearly, and each time the document is amended.

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Standard Operating Procedures developed

Standard Operating Procedure (SOP) Index		
SOP classification and number		**Title**
General	1	Conducting a clinical service and informed consent
	2	Providing advice to customers
	3	Completing the Patient Medication Record
	4	Conducting a Medicines Use Review (MUR)
	5	Referral to other healthcare providers
Patient review	6	Blood Pressure measurement
	7	Weight management
	8	Glycaemic control monitoring
	9	Lipid profile monitoring
Advice and treatment	10	Smoking cessation service
	11	Eye conditions
	12	Ear conditions
	13	Sore throat
	14	Skin conditions
	15	Urinary Tract Infections
	16	International travel health advice
	17	Routine immunisation advice
Ancillary	18	Pharmacy consultation room standards
	19	Record keeping and storage requirements
	20	Dealing with customers' complaints
	21	Dealing with needle-stick injuries
	22	SOP training log

SOP 1. Conducting a clinical service and informed consent

Process step	
Before conducting any clinical service, the pharmacist should:	
1	Read and sign SOP training log and be familiar with equipment used for each test, procedures, and how to interpret test results.
2	Comply with code of conduct, professional standards and legal obligations.
Before the consultation takes place	
3	Ensure that consultation room is safe, clean, clutter-free, and suitable for the clinical service. General waste, clinical waste and sharps bin must be present.
4	Ensure that all equipment is clean, well maintained, and appears to be in good working order. Instruction manuals supplied with equipment must be readily available for reference.
5	Maintenance and calibration of equipment and medical devices must be performed regularly according to manufacturer's instructions. Records must be available.
6	Ensure that consumables required to provide the service are available. These include hand sanitiser, gloves and apron, alcohol wipes, tissues, swabs, gauze, plasters, lancets, blood capillary tubes, test strips.
Conducting the consultation	
7	Greet customer and introduce yourself.
8	Confirm name of customer and service they expect to receive.
9	Explain what the service consists of and ensure customer is willing to proceed. Inform customer if blood or bodily fluids samples are required for testing.
10	Ask customer to complete and sign consent form.
11	Complete customer details on Patient Medication Record (PMR) form.
12	Counsel customer about clinical service and provide relevant advice.
13	Perform measurement or test and dispose of consumables, sharps, and clinical waste accordingly. Clean device according to manufacturer's instructions.
14	Explain test results to customer and counsel customer.
15	Record results on PMR and give a copy to customer for own use.
16	Schedule a follow-up appointment if required.
17	Attach consent form to PMR form and store records securely.
18	If a referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	
Reference: General Pharmaceutical Council – Standards for pharmacy professionals. 2021	

Consent to participate in clinical service

Pharmacy details and stamp	
Pharmacist's name and registration number:	
Clinical service(s) provided:	
Customer name **Date of birth** **ID number** **Address**	

By signing this form:

- I agree to participate in the above service(s), including any required follow-up.
- I authorise the pharmacist to perform measurement/s and test/s required.
- I consent for my records to be kept safely by the pharmacist.

Customer's signature	Date

To be kept by the pharmacist – Confidential

SOP 2. Providing advice to customers

Process step	
Consider patient confidentiality when giving advice. The consultation for any clinical services must be conducted in a consultation room.	
Promoting healthy lifestyle	
1	Use clear, simple, and jargon-free language to communicate with customers.
2	Give adequate advice to improve customer's medical conditions, knowledge, and understanding of health issues. Ensure advice is non-judgemental.
3	Provide evidence-based healthy lifestyle advice and assistance to prevent disease, limit illness and restore health conditions.
4	Provide written directions and patient-information leaflets when necessary.
5	Promote self-management for long-term conditions to minimise impact of the illness on customer's health.
Advice on managing acute, self-limiting conditions	
6	Encourage self-care to customers presenting with self-limiting conditions.
7	Support customers requesting advice related to minor ailments with advice on managing the illness and preventing recurrence of the condition.
8	Counsel customer on safe and appropriate use of medicine/s or supplement/s, including dose, frequency, course duration, side effects, and drug interactions.
9	Consider handing patient information leaflets to support the conversation.
10	Record any advice given on Patient Medication Record (PMR) form.
11	Ask customer whether a copy of PMR form is required for own use.
Signposting customers	
Consider signposting to other healthcare professionals those customers who:	
12	Require further support, advice, or treatment that pharmacist cannot provide.
13	Present with warning signs and symptoms suggesting a potentially serious underlying disease.
14	Present with recurrence of a condition previously treated or abnormal test results.
15	If referral to physician is required, complete General Practitioner referral letter. Give the customer a copy and ask customer to give letter to GP.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	

References:

General Pharmaceutical Council – Standards for pharmacy professionals. 2017

International Pharmaceutical Federation – Standards for quality of pharmacy services. 2011

SOP 3. Completing the Patient Medication Record

Process step	
Use attached form to record any advice and recommendations given to customers and results of clinical service provided.	
Before the consultation takes place	
1	Prepare Patient Medication Record (PMR) form and consent form. Retrieve documents from filing system for follow-up appointments.
2	Confirm name of customer and introduce yourself.
3	Explain aim of service and ensure customer is willing to proceed.
4	Ask customer to complete and sign consent form.
5	Welcome customer to consultation room.
During the consultation	
6	Complete customer details section, including name, surname, date of birth, gender, ID number, and contact details.
7	Complete pharmacist section, including pharmacist name, registration number and signature. Complete pharmacy section using pharmacy stamp.
8	Record customer's allergies, intolerances, and medical conditions.
9	Record customer's medicines, including non-prescription medicines, supplements, herbal and alternative products. Record name, strength, dose, route, and frequency of use for each product.
10	Record customer's past and current medical conditions, including alcohol intake and smoking status, family history and recent hospital admissions.
11	Record test results or measurements in relevant section, if applicable.
12	Explain test results to customer and provide counselling.
13	Record any advice and recommendation given in notes section.
14	If applicable, record details of medicine(s) supplied during clinical service. Include name, strength, dose, route, and frequency of use.
15	Ask customer whether a copy of the PMR is required for his/her use.
Following the consultation	
16	Attach consent form to PMR form and store records securely.
17	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	

References:
General Pharmaceutical Council – Standards for pharmacy professionals. 2017
International Pharmaceutical Federation – Standards for quality of pharmacy services. 2011

Patient Medication Record form (to be attached to consent form)						
Customer details	Title:	Name and surname:	ID number:	Date of birth:	Gender:	Contact details:

Allergies and intolerances:	Medical conditions:	Medicines (POM, OTC, supplements, herbal and alternative products):			
		Drug name	Strength	Dose & route	Frequency
	Alcohol intake: Smoking status:				
Height (cm): Weight (Kg): Waist circumference (cm): BMI: Blood pressure:	Random glucose: Fasting glucose: HbA1C: Total cholesterol: Triglycerides: LDL: HDL: TC / HDL ratio:				

Service provided:	Advice and recommendation:	Medicine(s) supplied during clinical service:
☐ Smoking cessation advice ☐ Eye conditions ☐ Ear conditions ☐ Sore throat ☐ Skin conditions ☐ UTI infections ☐ International travel health advice service ☐ Routine immunisation service		

Pharmacist details	Name and surname:	Signature and reg. n:	Date:	Pharmacy details and stamp:

To be kept by the pharmacist – Confidential

SOP 4. Conducting a Medicine Use Review (MUR)

Process step	
Use form attached to record any advice and recommendations given to customer and results of clinical service provided.	
Before the consultation takes place	
1	Prepare Patient Medication Record (PMR) form and the consent form. Retrieve documents from filing system for follow-up appointments.
2	Confirm name of customer and introduce yourself.
3	Explain aim of service and ensure customer is willing to proceed.
4	Ask customer to complete and sign consent form.
5	Welcome customer to consultation room.
Undertaking the MUR consultation	
6	Discuss each medicine in turn, allowing customer to ask questions.
7	Record any side-effects, drug interactions and non-adherence issues identified or other drug-related problems including access to medicine.
8	Record any issues related to improper use of the medicine or medical device.
9	Record any advice and recommendations given in the notes section.
10	Ensure that customer is satisfied with recommendations.
11	Complete pharmacist section, including pharmacist's name, registration number and signature. Complete pharmacy section using pharmacy stamp.
12	Ask customer whether a copy is required for his/her use.
13	Store and retain any relevant records securely.
14	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.
Signposting customers	
Consider signposting to other healthcare professionals those customers who:	
15	Require further support, advice, or treatment that pharmacist cannot provide.
16	Present with side-effects or warning signs and symptoms or require updating in therapy.
17	Present with abnormal test results suggesting a potentially serious underlying condition.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	

References:

Pharmaceutical Services Negotiating Committee – Medicines Use Review. 2021

International Pharmaceutical Federation. Medicines use review: A toolkit for pharmacists. 2022

Medicine Use Review form (to be attached to consent form)						
Customer details	Title:	Name and surname:	ID number:	Date of birth:	Gender:	Contact details:

Allergies and intolerances:	Medical conditions:	Advice and recommendation:
Medicines (POM, OTC, supplements, herbal and alternative products):		

Drug name	Formulation	Strength	Dose	Frequency	Issues identified:

Pharmacist details	Name and surname:	Signature and reg. n:	Date:	Pharmacy details and stamp:

To be kept by the pharmacist – Confidential

SOP 5. Referral to other healthcare providers

Process step	
When conducting a clinical service, pharmacists must:	
Use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses.	
Use professional judgement to decide whether referral to a physician is required or treatment can be supplied.	
Use form attached to record any advice and recommendations given to customer and results of clinical service provided.	
Refer to General Practitioner or out of hours services those customers who:	
1	Require further support, advice, or treatment that pharmacist cannot provide.
2	Require monitoring or follow up following abnormal test results
3	Require changes in medication (strength, dose, formulation, frequency)
4	Require further assessment from another healthcare professional.
5	Require urgent medical attention.
6	Present with side-effects from any medicines used.
7	Present with warning signs and symptoms.
8	Present with recurrence of a condition recently treated.
9	Present with abnormal test results suggesting a potentially serious condition.
Reporting of adverse drug reactions and incidents with medical devices	
10	Report suspected adverse drug reactions, including known side-effects, serious or non-serious reactions, and incidents with a medical device to the Malta Medicines Authority
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	
Reference: European Medicine Agency - Good practice guide on recording, coding, reporting and assessment of medication errors. 2015	

General Practitioner notification letter

Dear Dr,

Please accept this referral for full assessment and investigation as a result of the following:

☐ point-of-care testing

☐ consultation with the patient

☐ side-effect from a medicine

☐ drug related issue

performed today at this pharmacy.

Please do not hesitate to contact this pharmacy for further details.

Sincerely,

Patient name: Date of birth: ID number: Address: Contact number:	

Reason for referral:

Additional information notes:

Pharmacy details:

Pharmacy contact number:

Pharmacist's name and registration number:	Date:

Confidential

SOP 6. Blood Pressure measurement

Process step

1	Ensure that device is clean and in good working condition.
2	Describe measurement procedure. Ensure customer is willing to proceed and take customer to consultation room.
3	Obtain written consent before starting the service.
4	Ask customer to remove any bulky or tight-fitting clothing and relax for five minutes.
5	Ensure customer is seated comfortably with back supported, legs uncrossed, and upper arm bare. Avoid talking or moving whilst cuff inflates and deflates.
6	Wash and dry own hands and wear a new pair of gloves.
7	Place appropriate cuff around customer's arm about 2-3 cm above elbow. The medium cuff size is suitable for arm circumferences of 22-34cm, the large cuff for up to 42cm. Rest customer's arm on a table at heart level. **Note:** Refer to physician customers with arm circumference outside this range and customers with arrhythmias.
8	Start BP reading according to manufacturer's instructions. When using auscultatory methods, use phase I and V Korotkoff sounds (sudden reduction/disappearance) to identify systolic and diastolic BP, respectively. **Note:** At first visit, measure BP in both arms. Use arm with higher value as a reference.
9	Record three BP measurements 1-2 minutes apart and calculate average of the two highest measurements taken from reference arm.
10	Record systolic, diastolic and heart rate values on PMR and provide relevant advice.

Interpreting results

Category	Systolic (mmHg)	Diastolic (mmHg)	Recommendations
Optimal	< 120	< 80	Monitor BP every 3-5 years. Lifestyle advice on diet and exercise.
Normal	120-129	80-84	
High normal	130-139	85-89	Repeat BP at least annually. Lifestyle advice on diet and exercise. Consider Out-of-Office BP measurement. Refer to physician for ambulatory or home BP monitoring.
Grade 1 hypertension	140-159	90-99	
Grade 2 hypertension	160-179	100-109	
Grade 3 hypertension	> 180	> 110	

Source: European Society of Cardiology. 2018

11	Attach consent form to PMR form and store records securely.
12	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:

ESC/ESH– Clinical Practice Guidelines for the Management of Arterial Hypertension. 2018

NICE guideline NG136: Hypertension in adults: diagnosis and management. 2019

SOP 7. Weight management

Process step

1	Ensure that device is clean and in good working condition.
2	Describe measurement procedure. Ensure customer is willing to proceed and take customer to consultation room.
3	Obtain written consent before starting the service.
4	Ask customer to empty pockets and remove bulky clothing and shoes.
5	Ensure customer is standing straight, looking straight ahead, and with feet joined together. Ask customer to relax and breathe normally.
6	Wash and dry own hands and wear a new pair of gloves.
7	Measure customer's weight in kilograms and height in metres.
8	Measure customer's waist circumference by placing a tape measure tightly around customer's body, halfway between rib cage and iliac crest (pelvis). Record measurement in centimetres.
9	Calculate Body Mass Index using the formula: $BMI = \frac{\text{Weight (kg)}}{\text{Height (m) x Height (m)}}$

Interpreting results

Risk of developing diabetes and cardiovascular disease according to gender, ethnicity, and waist measurement.

Gender	Ethnicity	Low (cm)	High (cm)	Very high (cm)
Male	White European, Black African, Middle Eastern, and mixed origin.	94	94-102	> 102
Female		< 80	80-88	> 88
Male	African Caribbean, South Asian, Chinese, and Japanese origin.	< 90	90	> 90
Female		< 80	80	> 80

Body Mass Index for adults using standard weight status categories

BMI (kg/m2)	Underweight	Normal	Overweight	Obesity	Extreme Obesity
	< 18.5	18.5 – 24.9	25.0 – 29.9	30.0 – 39.9	≥ 40

Source: National Institute for Health and Care Excellence date

10	Record measurements on PMR and provide relevant lifestyle advice.
11	Attach consent form to PMR form and store records securely.
12	If referral to a physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:
ESC/EAS– Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk.

NICE guideline CG 189 – Obesity: identification, assessment and management. 2014

SOP 8. Glycaemic control monitoring

Process step

1	Ensure that device is clean and in good working condition.
2	Describe measurement procedure. Ensure customer is willing to proceed and take customer to consultation room. Establish if customer is fasting.
3	Obtain written consent before starting the service.
4	Wash and dry own hands and wear a new pair of gloves.
5	Prepare blood glucose meter, test strips, a single-use lancing device, sterile swabs or cotton wool, and plasters. Switch device on and follow manufacturer's instructions to operate device.
6	Ask the customer to wash hand with warm water and soap, rinse and dry thoroughly. Alternatively, use an alcohol wipe to clean customer's finger.
7	Use a single-use lancet to obtain a small drop of blood from the side of the finger. Hold puncture site downward and gently apply pressure. Do not "milk" the finger. Apply drop to target area on test strip and wait for result.
8	Gently apply pressure on puncture site using sterile cotton wool or swab and apply a plaster if necessary. Discard lancet in sharps bin and test strip and cotton wool as clinical waste.
9	Clean outer part of device according to manufacturer's instructions.

Interpreting results

Glucose test	Normal	Prediabetes	Diabetes
Random	< 11.1 mmol/l or 200 mg/dl	N/A	> 11.1 mmol/l or 200 mg/dl
Fasting	< 5.5 mmol/l < 100 mg/dl	5.5 to 6.9 mmol/l 100 to 125 mg/dl	> 7.0 mmol/l > 126 mg/dl
2 hours post prandial	< 7.8 mmol/l < 140 mg/dl	7.8 to 11.0 mmol/l 140 to 199 mg/dl	> 11.1 mmol/l > 200 mg/dl
HbA1c	Less than 5.7.%	5.7% to 6.4%	6.5% or higher

Recommendations to all: Lifestyle advice on diet (reduced calorie intake, Mediterranean diet), physical exercise, smoking cessation. For new or known diabetes, refer to a physician for further testing.

Source: American Diabetes Association 2019

10	Record measurements on PMR and provide relevant lifestyle advice. Discuss medicines used, side-effects, drug interactions and non-adherence issues identified.
11	Attach consent form to PMR form and store records securely.
12	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:

ESC/EASD– Guidelines on diabetes, pre-diabetes, and cardiovascular diseases. 2019

NICE guideline NG28 – Type 2 diabetes in adults: management. 2022

SOP 9. Lipid profile monitoring

Process step	
1	Ensure that device is clean and in good working condition.
2	Describe measurement procedure. Ensure customer is willing to proceed and take customer to consultation room. Establish if customer is fasting.
3	Obtain written consent before starting the service.
4	Wash and dry own hands and wear a new pair of gloves.
5	Prepare device, test strips, a single-use lancing device, sterile swabs or cotton wool, and plasters. Follow manufacturer's instructions to operate device.
6	Ask customer to wash hand with warm water and soap, rinse and dry thoroughly. Alternatively, use an alcohol wipe to clean customer's finger.
7	Use a single-use lancet to obtain a small drop of blood from the side of the finger. Hold puncture site downward and gently apply pressure. Do not "milk" the finger. Apply drop to target area on the test strip and wait for result.
8	Gently apply pressure on puncture site using sterile cotton wool or swab, and apply a plaster if necessary. Discard lancet in sharps bin and test strip and cotton wool as clinical waste.
9	Clean outer part of device according to manufacturer's instructions.

Interpreting the results

Type of cholesterol	**Optimal**		**Acceptable**		**High**		**Very high**	
	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
Total	< 200	< 5.17			200-239	5.17-6.18	> 240	> 6.20
Triglycerides	< 150	< 1.70	150-199	1.70-2.25	200-499	2.26-5.64	> 500	> 5.65
LDL	< 100	< 2.59	100-129	2.59-3.34	130-189	3.37-4.90	> 190	> 4.92
HDL	< 40	< 1.04			> 60	> 1.55		

Recommendations to all: Lifestyle advice on diet (reduced calorie intake, Mediterranean diet), weight management, physical exercise, smoking cessation.

Source: ATP III Guidelines At-A-Glance Quick Desk Reference

10	Record measurements on PMR and provide relevant lifestyle advice. Discuss medicines used, side-effects, drug interactions and non-adherence issues identified.
11	Attach consent form to PMR form and store records securely.
12	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:
ESC/EAS– Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. 2019
NICE clinical guideline CG181 - cardiovascular disease: risk assessment and reduction, including lipid modification. 2016

SOP 10. Smoking cessation service

Pharmacists must use their professional judgment to identify those who may benefit from the service and advise appropriate nicotine replacement therapy (NRT).

Process step	
1	Describe aim of the service. Ensure customer is willing to proceed.
2	Take customer to consultation room.
3	Obtain written consent before starting the service.
Undertaking the consultation	
4	Take smoking history and smoking habits. Assess how many cigarettes are smoked per day and when first cigarette is smoked.
5	Recommend best NRT product(s) based on smoking history and customer's wishes.
6	Explain how to use NRT product, including duration of treatment, side-effects and management of withdrawal symptoms.
7	Schedule follow-up and inform customer about local support available. Note: When attempting to quit, behavioural therapy improves success rate.

NRT suggested guidance		
Smoke after one hour of waking	Smoke **fewer** than 10 a day	14 mg patch or 2 mg gum
	Smoke **10 or more** a day	21 mg patch with 2 mg gum
Smoke within one hour of waking	Smoke **fewer** than 10 a day	21 mg patch with 2 mg gum
	Smoke **10 or more** a day	21 mg patch with 4 mg gum

NRT product available and recommended use. Always refer to product instructions.	
Patches (21mg, 14mg, 7mg)	Apply ONE patch daily to clean, dry and hairless skin. Remove old patch overnight and apply new patch on alternating sites.
Gum (4mg, 2mg)	Recommend regular use. Chew gum, then rest inside of the mouth. Chew again when taste starts to fade.
Mouth spray (1mg/dose)	Recommend regular use when cravings occur. Spray one puff into mouth. Do not swallow for a few seconds after spraying.

Note: NRT is unsuitable for patients taking clozapine, warfarin, theophylline, aminophylline, lithium, insulin, olanzapine. Refer to GP if any of these are taken.

Patches are not suitable during pregnancy.

8	Attach consent form to PMR form and store records securely.
9	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:

NICE guideline NG209 - Tobacco: preventing uptake, promoting quitting and treating dependence.

National Centre for Smoking Cessation and Training. 2021

SOP 11. Eye conditions

Pharmacists should use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Pharmacists must use professional judgement to decide whether referral to a clinician is required or treatment can be supplied.

Process step	
1	Describe what the examination involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take history of presenting complaint: symptoms, onset (sudden or gradual), course (how it has progressed), duration, severity, location (involving one or both eyes), and whether it was treated with any medication.
4	Ask direct questions to explore associated symptoms (ocular pain, headache, nausea, vomiting, decreased sight, double or blurred vision). Investigate contact lenses use, past similar problems, family and medical history.
5	Wash and dry own hands and wear a new pair of gloves.
6	Examine both eyes to establish presence of redness, swelling, discharge, excessive watering, squinting, irregular pupils, haemorrhage, injury or foreign body.
7	**Warnings:** Photophobia, significant ocular pain, changes in visual acuity, suspected foreign objects, and distorted pupil or iris. Refer to physician or ophthalmologist.
Advice and treatment	

Give advice on the condition, management, treatment, preventative measures and hand-eye hygiene. If over-the-counter medicines are supplied, advise on correct use.

Eye hygiene: Wash hands, bathe/clean eyelids with cotton wool or wipes dipped in sterile saline or boiled (cooled) water, and gently press onto eyelid for 2-3 minutes. Use cotton wool or cotton bud soaked in saline water to remove possible crusting. Avoid touching or scratching eyes, sharing towels, or wearing contact lenses for a week.

Treatment: Minor eye conditions often resolve in 5-7 days without treatment. The following are common over-the-counter products.

Dry eyes: artificial tears, liquid paraffin, sodium hyaluronate, hypromellose, carmellose.

Allergic conjunctivitis: sodium cromoglicate 2%.

Minor infections: propamidine isethionate, dibrompropamidine isetionate.

8	Attach consent form to PMR form and store records securely.
9	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP or ophthalmologist.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References: Pharmaceutical Press: Minor illness of major disease. 6th Ed. 2016
CPPE: Common clinical conditions and minor ailments.

SOP 12. Ear conditions

Pharmacists should use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Pharmacists must use professional judgement to decide whether referral to a clinician is required or treatment can be supplied.

Process step	
1	Describe what the examination involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take history of presenting complaint: symptoms, onset (sudden or gradual), course (how it has progressed), duration, severity, location (involving one or both ears), and whether it was treated with any medication.
4	Ask direct questions to investigate associated symptoms (pain, nasal congestion, headache, nausea, vomiting, dizziness, unilateral hearing loss, tinnitus, vertigo). Investigate past similar problems, family and medical history.
5	Wash and dry own hands and wear a new pair of gloves.
6	Examine outer auricular areas and ear canal to establish presence of redness, swelling, discharge, excessive wax, haemorrhage, injury or foreign body.
7	Warnings: Significant ear pain, changes in hearing acuity, suspected foreign objects, periorbital cellulitis, fever and headaches. Refer to physician or otolaryngologist.
Advice and treatment	
Give advice on the condition, management, treatment, preventative measures and ear hygiene. If over-the-counter medicines are supplied, advise on correct use. <u>Ear hygiene</u>: Wash hands and use cotton wool or wipes dipped in sterile or saline water to remove excess wax. Avoid using cotton buds or leaving cotton buds in the ear. <u>Treatment:</u> Minor ear conditions and middle ear infections often resolve in 3-5 days without treatment. The following are common over-the-counter products. Wax softener: olive oil, almond oil, sodium bicarbonate 5%, urea-hydrogen peroxide. Acetic acid 2% solution. Analgesics: paracetamol, ibuprofen, codeine.	
8	Attach consent form to PMR form and store records securely.
9	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP or otolaryngologist.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	

References:

Pharmaceutical Press: Minor illness of major disease. 6th Ed. 2016

CPPE: Common clinical conditions and minor ailments. 2017

SOP 13. Sore throat

Pharmacists should use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Pharmacists must use professional judgement to decide whether referral to a clinician is required or treatment can be supplied.

Process step	
1	Describe what the examination involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take history of presenting complaint: symptoms, onset (sudden or gradual), course (how it has progressed), duration, severity, and whether it was treated with any medication.
4	Ask direct questions to investigate associated symptoms (fever, chills, headache, loss of appetite, swallowing and breathing difficulties). Investigate smoking status and alcohol intake, past similar problems, family and medical history.
5	Wash and dry own hands and wear a new pair of gloves.
6	Inspect neck and face for swelling. Examine throat to establish presence of inflammation, redness, swelling, abscess, exudate, ulcers, injury or foreign body.
7	Warnings: high fever, unilateral swelling, difficulty breathing, dysphagia, drooling, recurrent sore throat, neck lumps, suspected foreign objects. Refer to physician.
Advice and treatment	

Give advice on the condition, management, treatment, preventative measures and oral hygiene. If over-the-counter medicines are supplied, advise on correct use.

Oral hygiene: regular teeth brushing and use of mouthwash.

Treatment: Sore throat often resolves in 5-7 days without treatment. The following are common over-the-counter products.

Analgesics: paracetamol, ibuprofen, paracetamol plus codeine.

Local anaesthetics: benzocaine 0.15% or lidocaine 0.1% mouthwash, spray or lozenges.

Local antiseptics: benzalkonium chloride, hexylresorcinol, chlorhexidine.

Anti-inflammatory: benzydamine 0.15% spray and mouthwash.

8	Attach consent form to PMR form and store records securely.
9	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give the letter to their GP.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:
Pharmaceutical Press: Minor illness of major disease. 6th Ed. 2016
CPPE: Common clinical conditions and minor ailments. 2017
International Pharmaceutical Federation (FIP). Empowering self-care: A handbook for pharmacists. The Hague: International Pharmaceutical Federation. 2022

SOP 14. Skin conditions

Pharmacists should use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Pharmacists must use professional judgement to decide whether referral to a clinician is required or treatment can be supplied.

Process step	
1	Describe what the examination involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take history of presenting complaint: symptoms, onset (sudden or gradual), course (how it has progressed), duration, severity, and whether it was treated with any medication. Investigate about change in diet or medications.
4	Ask direct questions to investigate associated symptoms (widespread rash, painful rash, fever, blistering rash, red or purple spots, skin discoloration, intense pruritus, swelling). Investigate smoking status and alcohol intake, allergies, similar problems in the past, family and medical history.
5	Wash and dry own hands and wear a new pair of gloves.
6	Examine affected skin to establish the presence of inflammation, redness, swelling, bleeding, infections, abscess, exudate, ulcers or injury.
7	Warnings: fever, cellulitis, angioedema, pustulent crusts, crusted yellow lesions, broken skin, breathing difficulties, suspected foreign objects. Refer to physician or dermatologist.

Advice and treatment

Give advice on conditions, management, treatment, preventative measures and skin hygiene. If over-the-counter medicines are supplied, advise on the correct use.

Condition and appearance	Treatment	Advice
Contact dermatitis: Erythema, itchy, crusting, scaling, cracking, swelling of the skin.	Emollients: ointment or creams Soothing creams: Calamine lotion Mild steroids: hydrocortisone 1% (not on broken skin or face)	Remove irritants. Use mild soap. Avoid alcohol and fragrance products.
Urticaria: Erythema, itchy, superficial swelling (hives), small, raised blisters (weal). Insect bites and stings may cause it.	Emollients: ointment or creams Soothing creams: urea, Calamine lotion, panthenol cream 5% Antihistamine: eg. cetirizine, loratadine	Avoid common allergens (animal fur, chemicals, food). Avoid aspirin and NSAIDs.
Eczema: Erythematous plaque, itchy, vesicular, oozing, scaly, dry, poorly demarcated and crumbly borders.	Emollients: ointment or creams Soothing creams: calamine lotion, zinc oxide ointment Mild steroids: hydrocortisone 1% (not on broken skin or face)	Regular moisturiser. Use gloves when using irritants. Use mild soap. Avoid scratching, extremes temperatures, humidity, abrasive clothing fabrics.

Psoriasis: Scaly red patches covered with silver or white scales. Affect body and scalp. It can be itchy with cracks and blood.	Emollients: ointment for thick scales, lotion, solution or gel for the scalp or hair-bearing areas Anti-inflammatory: tar-based preparations Mild steroids: hydrocortisone 1% (not on broken skin or face)	Regular emollient use: lotion throughout the day, creams and ointments before sleeping. Use sun protection creams. Avoid scratching.
Wart: Hard raised papules with rough edges, look-like cauliflower. It grows outwards and may show black dots on the surface. ***Verruca:*** Plantar warts on soles of feet. It grows inwards. Black dots are visible under the skin.	Salicylic acid or lactic acid preparation Dimethyl ether and propane spray to freeze the wart	Extremely contagious. Treatment is not necessary unless painful. It can be filed weekly to remove dead skin. Advice to reduce spreading.
Herpes simplex (cold sore): Tingling, itchy and numb sensation followed by eruption of small red fluid-filled vesicles on the lips, mouth and nose. The lesions may burst and crust over.	Soothing creams: vaseline, lip balm Antivirals: aciclovir 5% lip cream.	Self-limiting condition with recovery in 10-14 days. Highly infective. Avoid exposure to the sun. Advice to reduce spreading. Lip balm can be used to avoid skin cracks.
Athlete's foot (tinea pedis): Scaling, itchy, soggy skin between toes. The soles of the feet can appear dry and scaly.	Emollients: moisturising creams Antifungals: Clotrimazole, ketoconazole, terbinafine creams or powder	Foot hygiene. Highly contagious. Avoid scratching. Continue for 7 days after the infection disappear.
Fungal nail infections: Discoloured, thickened, and raised nails. Affect toes and hand nails.	Antifungals: Amorolfine 5% liquid., Urea 40% ointment	Foot hygiene. Long treatment required.
8	Attach consent form to PMR form and store records securely.	
9	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP or dermatologist.	
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.		
References: Pharmaceutical Press: Minor illness of major disease. 6th Ed. 2016 CPPE: Common clinical conditions and minor ailments. 2017		

SOP 15. Urinary tract infections

Pharmacists should use clinical skills to distinguish acute self-limiting conditions from severe threatening diagnoses. Pharmacists must use professional judgement to decide whether referral to a clinician is required or treatment can be supplied.

Process step	
1	Describe what the examination involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take history of presenting complaint: symptoms, onset (sudden or gradual), course (how it has progressed), duration, severity, presence of blood, and whether it was treated with any medication. Investigate about hidration state.
4	Ask direct questions to investigate associated symptoms (fever, chills, nausea and vomiting, loss of appetite, lower back pain, infected discharge). Investigate smoking status and alcohol intake, past similar problems, family and medical history.
5	Wash and dry own hands and wear a new pair of gloves and an apron.
6	Perform urinalysis test: Inspect urine sample colour, clarity, and odour. Insert dipstick in sample, ensuring all reagents are fully immersed. Remove dipstick immediately and place it horizontally on clean paper. Allow sufficient time for test result to develop.
7	Use urinalysis guide on test strip container to interpret results, then discard strip as clinical waste.
8	Warnings: high fever, back pain, red or brown urine, offensive odour, abnormal test results, difficulty breathing, foreign objects. Refer to physician.
Advice and treatment	
Give advice on the condition, management, treatment, preventative measures and oral hygiene. If over-the-counter medicines are supplied, advise on the correct use. Give advice on what to do if symptoms do not improve or pain persists. <u>Treatment:</u> Uncomplicated cystitis resolves in 5-7 days without treatment. The following are common over-the-counter products. Alkalinising agents: potassium citrate, sodium citrate and sodium bicarbonate Antibacterial agents: cranberry products Analgesics: paracetamol, ibuprofen	
9	Attach consent form to PMR form and store records securely.
10	If referral to physician is required, complete General Practitioner referral letter. Give customer a copy and ask customer to give letter to GP.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	

References:

Pharmaceutical Press: Minor illness of major disease. 6th Ed. 2016

CPPE: Common clinical conditions and minor ailments. 2017

SOP 16. International travel health advice

Regulation and requirements regarding immunisation for travel purposes change frequently. Pharmacists should consult the most updated guidelines as a reference.

Process step	
1	Describe what the service involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take a complete medical history from customer, including family history, allergies, previous history of anaphylaxis, and smoking status.
4	Inspect vaccination record. If not available, ask direct questions to investigate customer's immunisation. Childhood immunisation should be up to date.
5	Establish whether any vaccination requires a booster dose (e.g. tetanus).
6	Obtain a comprehensive travel itinerary, duration of stay, and activities planned during travel, to establish whether preventive vaccination or chemoprophylaxis is required.
7	Provide advice regarding managing and monitoring pre-existing medical conditions (diabetes, respiratory or cardiovascular conditions).
8	Provide advice for insect bites prevention, sun exposure, and first aid kit.
9	If any vaccination is required, signpost customers to immunisation centre.
Advice	

General advice: Choose food and drinks carefully, only drink sealed bottled water, avoid drinks with ice cubes, wash hands or use a hand sanitiser frequently.

Risk of DVT: Consider wearing compression stockings for long haul flights.

Insect bites prevention: Wear long-sleeved shirts and long pants, use high socks, sleep under a mosquito net, use insect repellents such as DEET (N,N-diethyl-meta-toluamide) in adults and children over five years old.

Sun exposure: Stay in the shade, wear a hat and sunglasses with UVA and UVB ray protection, cover as much skin as possible, drink plenty of water, use sun protection with a high protection factor, avoid prolonged sun exposure.

First aid: Plasters, bandages, cotton wool, disinfectants, antiseptic cream. Consider medicines such as analgesic, antiemetic, anti-diarrhoeal, decongestant, oral rehydrating sachets.

10	Record advice given on PMR.
11	Attach consent form to PMR form and store records securely.

Important note: Customer's details and information contained in the PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

Reference:
National Travel Health Network and Centre. Department of Health England. 2022
European Centre for Disease Prevention and Control. 2022

SOP 17. Routine immunisation advice

Pharmacists should promote routine and recommended immunisation through screening, counselling, and educating the public.

Process step	
1	Describe what the service involves. Ensure customer is willing to proceed and take customer to consultation room.
2	Obtain written consent before starting the service.
Undertaking the consultation	
3	Take a complete medical history from the customer, including family history and allergies (eggs, gelatin, latex, antibiotics).
4	Inspect vaccination record. If not available, ask direct questions to investigate customer's immunisation. Childhood immunisation should be up to date.
5	Establish whether any vaccination requires a booster dose (e.g. tetanus, diphtheria, Covid-19).
6	Remind the importance of respecting recommended intervals between doses of multi-dose antigens to provide optimal protection.
7	If any vaccination is required, signpost customers to immunisation centre.
Advice	

General advice for managing localised site reactions: Apply a cold compress to the injection site. Consider giving an analgesic (paracetamol) or antipruritic medication. High body temperatures can be controlled with paracetamol.

General advice about immunisation: Full coverage may take two weeks. Tetanus and diphtheria toxoids require booster doses. Difference between live, attenuated and inactivated vaccines. Serology testing for immunity may be necessary for unknown or uncertain vaccination status for antigens (e.g., measles, rubella, hepatitis A, and tetanus).

Individuals at increased risk: Older people, pregnant women, individuals with respiratory or cardiac disease, immunosuppressed, occupational risk, carers of other people.

The recommended vaccines for this category of patients include seasonal influenza, Hepatitis A and B, Human papillomavirus, Meningitis A, C, W, Y (asplenia or splenic dysfunction), Typhoid, shingles (70-79 years old), Pneumococcal polysaccharide vaccine.

8	Record advice given on the PMR.
9	Attach consent form to PMR form and store records securely.

Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.

References:

European Centre for Disease Prevention and Control. 2022

World Health Organization: Tailoring Immunization Programmes. 2021

SOP 18. Pharmacy consultation room standards

Process step	
The managing pharmacist and pharmacists are responsible for ensuring that these standards are maintained at all times.	
Before starting any clinical service, the pharmacist must:	
1	Ensure that room is kept clean and clutter-free.
2	Ensure that temperature in the room is comfortable. Lights in the room should be functional and give good illumination.
3	Ensure that equipment (blood pressure monitor, weighing scale, blood glucose and lipid monitoring devices) is clean, well maintained, and in good working order.
4	Ensure that equipment is calibrated regularly according to the manufacturer's instructions. Calibration records should be readily available.
5	Ensure that consumables (hand and surface sanitisers, alcohol wipes, one-use lancets, needles, capillary tubes, testing strips, plasters) are available.
6	Ensure that instruction manuals supplied with equipment are available for reference.
7	Ensure that Personal Protective Equipment (gloves, surgical gown, aprons, mask, goggles) are available.
8	Ensure that necessary documentation to perform tests are available, including pens and white paper.
9	Ensure that general, clinical waste and sharps bin are available and placed safely far from the customers' reach. These bins must have a lid and should be emptied regularly.
10	Ensure that filing or storage cabinets are locked. The key must always be kept by the pharmacist.
Reference: General Pharmaceutical Council – Standards for pharmacy professionals. 2017	

SOP 19. Record keeping and storage requirements

Process step	
The manager and pharmacists are responsible for ensuring these standards are always maintained.	
When providing clinical service, the pharmacist must:	
1	Ensure that patient medication records, medicine use review forms, consent forms, and other customers' identifiable information are completed in full before filing them in the cabinet.
2	Ensure that patient consent and other documentation have clearly stated customer's details on each page.
3	Attach patient consent form to relevant documents before filing them.
4	Keep each customer file separate to prevent accidental mismatching of files.
5	Store customer files alphabetically for efficient and easy retrieval.
6	Ensure filing cabinet is not accessible by the public and is kept locked at all times.
7	Access to these records must be restricted to authorised pharmacists only.
8	Retain each file for at least two years, starting from when service was provided. Customer identifiable details must be anonymised before shredding.
9	Ensure that customer's identifiable details are anonymised using a black marker and shredded before disposal.
Reference: General Pharmaceutical Council – Standards for pharmacy professionals. 2017	

SOP 20. Dealing with customer's complaints

Process step	
The managing pharmacist and pharmacists are responsible for ensuring that customer's complaints are dealt with professionally and promptly.	
If the complaint involves a dispensing error or a professional issue, the pharmacist should:	
1	Apologise to the customer and inform them that the issue will be dealt with professionally.
2	Show empathy and respect towards the customer's concerns.
3	Ensure customer does not require immediate medical attention or did not suffer any harm caused by the incident.
4	Make a record of the complaint, conversation, and steps taken to resolve the issue.
5	Inform other staff members involved in the incident to obtain further information about the issue.
6	If the issue cannot be resolved immediately, keep the customer informed.
7	Ensure that customer is satisfied with outcome and whether further assistance is required.
8	Contact managing pharmacist or a senior pharmacist for further assistance if the complaint involves a serious allegation or has resulted in harm to the customer.
Important note: Customer's details and information contained in PMR are strictly confidential. Access to these records must be restricted to authorised pharmacists only.	
Reference: General Pharmaceutical Council – Standards for pharmacy professionals. 2017	

SOP 21. Dealing with needle-stick injuries

Process step	
In the event of a needle stick injury with a used needle or sharp, the pharmacist must:	
1	Treat all needle stick injuries as contaminated.
2	Apply pressure to encourage bleeding from puncture site.
3	DO NOT remove blood by sucking the wound.
4	Flush splashes water or saline solution to mouth and nose.
5	Rinse eyes with eyewash solution.
6	Wash area thoroughly with running water and soap. Avoid rubbing.
7	If a sink or basin is not available, sterile sodium chloride can be used.
8	Report incident to manager for further advice.
9	Proceed to nearest emergency department or hospital within 2 hours from exposure and not longer than 72 hours.
10	Ensure appropriate treatment for exposure to blood-borne viruses and post-exposure prophylaxis regimes have been offered.
11	Provide information from exposed person about vaccination status against blood-borne viruses.
12	Consider need for interviewing or testing the source person, pending informed consent. **Note:** Consent must be informed, specific, given voluntarily and documented.
13	Maintain confidentiality of the exposed person and source person, including diagnosis and treatment resulting from the injury.
Reference: European Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 – Guide for employers and employees. 2013	

SOP 22. SOP training log

The managing pharmacist and pharmacists are responsible for ensuring that these standards are always maintained.

By signing the training log, pharmacists providing clinical services in this pharmacy declare that:

- They have read and understood the content of the SOPs
- They are competent to perform the task included in the SOPs
- They always comply with the SOPs

Pharmacist's name and surname	**Pharmacist's signature and registration number**	**Date**

Appendix 5

List of publications

Abstract presented for poster discussion presentation at the Clinical Pharmacy Congress (CPC) in London, United Kingdom, May 2022

Title: Consumer perception of clinical pharmacy services in primary care

Authors and affiliation: Osvaldo Cancellu, Francesca Wirth, Lilian M Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Background and Introduction:

Clinical pharmacist services, such as point-of-care testing, medication review and counselling, play a significant role in managing acute and chronic conditions in primary care settings. These clinical services have been reported to improve health outcomes in diabetes, hypertension, cardiovascular disease, and asthma.[1,2]

Aims and Objective:

To explore consumer perceptions towards clinical pharmacy services in primary care.

Method:

This study required and received ethics approval. A 59-item self-administered questionnaire was developed in English and translated into Italian and Maltese by bilingual professionals. For each questionnaire version, a panel of ten experts was consulted for face and content validation. Items were categorised into five domains and included a Likert scale ranging from 0-4, open-ended and close-ended questions. Cronbach's coefficient alpha (α) was calculated for the items included in the questionnaire (α value ≥0.7 indicates acceptable internal consistency). The questionnaire was distributed between August and November 2021 to customers in ten community pharmacies and on social media using Google Forms®.

Results:

Cronbach's α coefficient for internal consistency of items regarding consumer's beliefs was 0.75, awareness α=0.74, and perception α=0.71, showing acceptable internal consistency between responses within the domains. The questionnaire was completed by 800 consumers (571 online, 229 in community pharmacies). Consumers agreed that community pharmacists are knowledgeable about minor illnesses (mean=3.5 ±0.62) and chronic conditions (mean=3.2 ±0.85). The public agreed that they felt comfortable with the community pharmacist reviewing their medicines (mean=3.3 ±1.1) and performing diagnostic testing (mean=3.1 ±1.1). These mean rating scores range from 0 to 4, where 0 corresponds to 'strongly disagree' and 4 corresponds to 'strongly agree'.

Discussion and Conclusions:

This study suggests that consumers are willing to use the proposed community pharmacist clinical services and pay a fee between 5 and 20 Sterling for the services included in the questionnaire, namely management of acute conditions and diagnostic testing. Limitations include the length of the questionnaire, generalisability, self-selection bias and non-response bias. Clinical community pharmacy services expand the community pharmacists' scope of practice within primary care.

References:

1. Alshehri A, et al. 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. 2020;86(1):29-38.

2. Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patient's medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 2018;26(5):387-397.

Poster presented at the Clinical Pharmacy Congress (CPC) in London, United Kingdom, May 2022

L-Università ta' Malta | Faculty of Medicine & Surgery | Department of Pharmacy

Consumer perception of clinical pharmacy services in primary care

Osvaldo Cancellu, Francesca Wirth, Lilian M Azzopardi

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

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Background and Introduction

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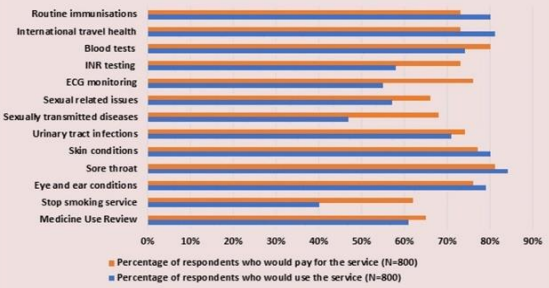
The questionnaire was distributed between August and November 2021 to customers in ten community pharmacies and on social media using Google Forms®.
The project involved the collection of primary data from human participants. A self-assessment ethics form was filed in accordance with GDPR with the Faculty of Medicine and Surgery Research and Ethics Committee. The Faculty of Medicine and Surgery Research Ethics Committee granted approval to conduct the study.

Results

Cronbach's α coefficient for internal consistency of items regarding consumer's beliefs was 0.75, awareness α=0.74, and perception α=0.71, showing acceptable internal consistency between responses within the domains.
The questionnaire was completed by 800 consumers (571 online, 229 in community pharmacies). Consumers agreed that community pharmacists are knowledgeable about minor illnesses (mean=3.5 ±0.62) and chronic conditions (mean=3.2 ±0.85). The public agreed that they felt comfortable with the community pharmacist reviewing their medicines (mean=3.3 ±1.1) and performing diagnostic testing (mean=3.1 ±1.1). These mean rating scores range from 0 to 4, where 0 corresponds to 'strongly disagree' and 4 corresponds to 'strongly agree'.

Table 1. Participants' responses regarding willingness to use and pay for the proposed clinical services.



Discussion and Conclusions

This study suggests that consumers are willing to use the proposed community pharmacist clinical services and pay a fee between 5 and 20 Sterling for the services included in the questionnaire, namely management of acute conditions and diagnostic testing.
Limitations include the length of the questionnaire, generalisability, self-selection bias and non-response bias. Clinical community pharmacy services expand the community pharmacists' scope of practice within primary care.

REFERENCES

1. Alshehri A, et al. 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. 2020;86(1):29-38.
2. Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patient's medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 2018;26(5):387-397.

Abstract presented for poster discussion presentation at ACCP Global Conference on Clinical Pharmacy in San Francisco, California, October 2022

Title: Development and validation of a framework to standardise clinical pharmacy services in primary care.

Authors and affiliation: Osvaldo Cancellu, MPharm., PGCertClinEdu., PGDipClinPharm., IP, MRPharmS., Francesca Wirth, B.Pharm.(Hons), M.Phil., Ph.D. and Lilian M. Azzopardi, BPharm. (Hons.). MPhil., PhD., MRPharmS, FFIP, FESCP

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

Service or Program: A multi-language questionnaire exploring public perception of clinical pharmacy services (CPS) and a multidisciplinary focus group evaluating feasibility of these services in primary care settings informed development of a framework to support patient-centric care in community pharmacy practice in Malta. An expert panel consisting of pharmacists and physicians practising in Malta and England validated the framework, broadening the perspective and assessing the feasibility of applying the framework internationally. The developed framework defined the standards for service provision and included 22 Standard Operating Procedures (SOPs) covering medicines review, point-of-care testing services, and advice and treatment for minor ailments.

Justification/Documentation: Community pharmacy services improve safe and timely access to care and promote self-care. This framework facilitates CPS implementation by providing a standardised process for collecting patient data, recording test results performed, and documenting interventions and advice given to patients. Adopting standardised procedures for delivering CPS in primary care will strengthen the evidence supporting the benefit of pharmacist interventions and ensure successful and sustainable provision of CPS.

Adaptability: The standards for service provision and SOPs developed as part of this framework are easily replicable in all settings where pharmacists provide patient care. This framework enables a systematic approach to patient care and supports decision-making, allowing adaptation to other international primary care models. The services included in the framework do not require additional certification; clinical skill proficiency and competency are recommended before delivering these CPS.

Significance: The developed framework can support standardisation for provision of CPS, reinforce the pharmacist's role as an integrated primary care team member in patient care, and assist policymakers and other stakeholders in developing services delivered in community pharmacies. The step-by-step approach adopted in this framework would promote evidence-based practice, encourage systematic thinking, and foster consistency in the ongoing patient documentation and monitoring of clinical and humanistic outcomes.

L-Università ta' Malta | Department of Pharmacy
Faculty of Medicine & Surgery

DEVELOPMENT AND VALIDATION OF A FRAMEWORK TO STANDARDISE CLINICAL PHARMACY SERVICES IN PRIMARY CARE

Osvaldo Cancellu, Francesca Wirth, Lilian M. Azzopardi

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SERVICE OR PROGRAM

A developed framework defined the standards for service provision and included 22 Standard Operating Procedures (SOPs) covering the following aspects:

- General documents on conducting clinical services (n=5)
- Patient review and point-of-care testing services (n=4)
- Advice and treatment for minor ailments, immunisation, and international travel (n=8)
- Ancillary documents (n=5)

A multi-language questionnaire exploring public perception of clinical pharmacy services (CPS) and a multidisciplinary focus group evaluating feasibility of these services in primary care settings informed framework development to support patient-centric care in community pharmacy practice in Malta.

An expert panel consisting of pharmacists and physicians practising in Malta and England validated the framework, broadening the perspective and assessing the feasibility of applying the framework internationally.

Framework Outline

Standard Operating Procedures (SOP) Index

SOP classification and number		Title
General	1	Conducting a clinical service and informed consent
	2	Providing advice to customers
	3	Completing the Patient Medication Record
	4	Conducting a Medicines Use Review (MUR)
	5	Referral to other healthcare providers
Patient review	6	Blood Pressure measurement
	7	Weight management
	8	Glycaemic control monitoring
	9	Lipid profile monitoring
Advice and treatment	10	Smoking cessation service
	11	Eye conditions
	12	Ear conditions
	13	Sore throat
	14	Skin conditions
	15	Urinary Tract Infections
	16	International travel health advice
	17	Routine immunisation advice
Ancillary	18	Pharmacy consultation room standards
	19	Record keeping and storage requirements
	20	Dealing with customers' complaints
	21	Dealing with needle-stick injuries
	22	SOP training log

SIGNIFICANCE

The developed framework supports standardisation for CPS provision in community pharmacies, reinforces pharmacist contribution to patient care, and assists policymakers and other stakeholders in elaborating CPS in primary care. The step-by-step approach in this framework promotes evidence-based practice, encourages systematic thinking, and fosters consistency in ongoing monitoring of clinical and humanistic outcomes.

JUSTIFICATION / DOCUMENTATION

CPS promote self-care and improve safe and timely access to care. This framework facilitates CPS implementation through a standardised process for collecting patient data, recording test results performed, documenting interventions and collaborative practice. Adopting standardised procedures strengthens evidence supporting the benefit of pharmacist interventions in primary care and ensures successful and sustainable provision of CPS.

ADAPTABILITY

The standards for service provision and SOPs developed are easily replicable in settings where pharmacists provide patient care. The services included in the framework enable a systematic approach to patient care, support decision-making and do not require additional certification, allowing adaptation to other international primary care models.

Poster presented at the ACCP Global Conference on Clinical Pharmacy in San Francisco, California, October 2022