Validation of Self-Assessment of Community Pharmacy Services

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Abstract

Quality improvement measures support community pharmacist professional practice and may serve to improve service provision. The aim of the research was to develop, validate, and evaluate a self-assessment tool for clinical community pharmacy services.

The methodology involved: 1) identification of quality standards for clinical community pharmacy services, 2) development of a self-assessment tool for community pharmacists, 3) content validation using a two-round Delphi study with a nine-member expert panel, where a mean score ≥4.5 was used as a threshold for acceptance, 4) reliability testing using the test-retest method performed by ten pharmacists, 5) criterion validation using the 2016 self-assessment tool of the National Competency Standards of the Pharmaceutical Society of Australia used as the gold standard, and 6) implementation of the tool in 30 community pharmacies.

Quality standards for professional pharmacy services were identified from Australia, Malta, the United Kingdom and the United States of America. The self-assessment tool developed consists of 7 domains namely: 1) professional practice, 2) patient care and medicine management, 3) dispensing practices and counselling, 4) collaboration with health care professionals and colleagues, 5) pharmacist training and professional development, 6) management of stock and pharmacy environment, 7) quality assurance and quality management. The self-assessment tool relies on performance rating using a Likert scale from 1 (Poor) to 5 (Excellent). Each domain consists of a self-reflection section, where the pharmacist reflects to highlight strengths, weaknesses, and plan for improvement.

Following round I of the Delphi study, statements were amended according to the recommendations and all statements obtained a mean rating score greater than 4.5 after round II. Reliability testing resulted in a Cronbach's Alpha value of 0.991, indicating high

internal consistency. For criterion validation, the paired sample t-test was applied. Criterion validation was established for Domains 5, 6 and 7 ($p > 0.05$). Domains 1, 2, 3 and 4 showed a significant difference between the developed tool and the gold standard ($p < 0.05$). From the implementation study, 9 participants rated the practicality of the tool as 'Excellent,' while 2 rated it as 'Poor', 10 participants rated the applicability of the tool as 'Excellent', while 1 rated it as 'Poor'. Most participants are likely to perform quality indicators (n=20), participate in training (n=25) and plan for training of pharmacy personnel (n=21) to improve the quality of their pharmaceutical service.

The psychometrically evaluated self-assessment tool may be used as a quality indicator for community pharmacies. The tool allows for accountability, continuous improvement and consistency in the provision of quality care. Further studies may look into the impact of the tool towards improved trust in the community pharmacist.

Keywords

Community pharmacist - Community pharmacy services - Quality assurance - Quality indicators - Self-assessment

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List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CPRA	Community Pharmacy Regulatory Audits
EQuIPP	Electronic Quality Improvement Platform for Plans and Pharmacies
FIP	International Pharmaceutical Federation
GPP	Good Pharmacy Practice
IT	Information Technology
MTM	Medication Therapy Management
NHS	National Health Service
PQA	Pharmacy Quality Alliance
PSA	Pharmaceutical Society of Australia
QCPP	Quality Care Pharmacy Program
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Chapter 1

Introduction

1.1. Community pharmacy services

Community pharmacy is an easily accessible, often underutilised, healthcare unit where a professional pharmacist applies knowledge in a variety of services with the aim to improve patient health outcomes and quality of life (Moullin et al, 2013; Tsuyuki et al, 2018; Dubbai et al, 2019; Carter et al, 2021; Chagas et al, 2022). The community pharmacist offers traditional services, including dispensing prescription and non-prescription medication, counselling on minor ailments, providing information on the safe and effective use of medicines, increasing medication adherence, and participating in health promotion (Dubbai et al, 2019; Grew et al, 2019; Ilardo et al, 2020; Carter et al, 2021; Sepp et al, 2021).

The increase in healthcare costs and demands on primary care over the years have resulted in the community pharmacist's focus to shift strongly to the provision of patient-centric services. Such focus broadens the community pharmacist's scope of practice and exposes the clinical pharmacy interventions. Clinical community services are extended responsibilities of a community pharmacist that focus on providing patient-centred pharmaceutical care with a more significant role in managing chronic conditions, patient education on the rational use of medication, non-pharmacological counselling, supporting adherence, vaccination services, and point-of-care testing (Milosavljevic et al, 2018; Dubbai et al, 2019; Grew et al, 2019; Yla-Rautio et al, 2020; Carter et al, 2021; Sepp et al, 2021; Chagas et al, 2022). Through the years, it has been recognised that optimal use of medicines and patient-centred pharmaceutical care during the dispensing of medication is significant to achieve treatment goals (Milosavljevic et al, 2018; Carter et al, 2021).

Parallel to the clinical community pharmacy services, in the context of community pharmacy, management of the healthcare setting is essential to contribute to the pharmacy profession. Management of the pharmacy environment and operations is a significant responsibility that is often unacknowledged. The pharmacist has a role in effective stock management, such as ordering, managing expiry dates, storing medication, training personnel, and maintenance of the pharmacy setting, such as ensuring cleanliness and general upkeep of the premises (Mirzaei et al, 2019; Sepp et al, 2021). Good management of the pharmacy environment and operations ensures a high-quality pharmacy setting, and in turn, it supports the provision of high-quality professional services and ensures timely access to safe, effective, and quality medicinal products and medical devices. Such a context merges the clinical pharmacy service provision with a quality chasm that encompasses the professional service, environment, as well as legal and regulatory compliance.

Reflections on quality in community pharmacy services may be drawn on a parallel context of the bigger dimensions of quality in healthcare. The increased involvement of the community pharmacist within the healthcare team has dictated an increasing concern over the level of quality and safety of the pharmaceutical service (Hermansyah et al, 2018; Jacobs et al, 2018). Moreover, one must realise the organisational context of community pharmacies where they form part of the private sector and are to-date, dependent on product sales (Jacobs et al, 2018; Mirzaei et al, 2018). Community pharmacy is faced with increasing pressures to expand the patient-centred pharmaceutical service, uphold a high-quality and efficient service, while maintaining retail pharmacy profitability (Hermansyah et al, 2018; Jacobs et al, 2018; Mirzaei et al, 2018). The increasing pressures may pose a risk to the level of quality in community pharmacy, where service quantity is

favoured over quality of the service. The present research presents a tool which outlines the expected domains to ensure quality in community pharmacy practice. The tool may be utilised by community pharmacists, managers and policy-makers to obtain reliable information on the current scenario with the aim to expand pharmaceutical services while upholding high quality.

1.2. Quality in healthcare

Quality of care has been described by the World Health Organisation (WHO)[1] as the degree to which health services and evidence-based professionals increase the probability to achieve the desired health outcomes. Good quality healthcare is the provision of optimal care at the right time to respond to patient needs while working efficiently to minimise risks and waste of resources. Good quality healthcare optimises quality in terms of effectiveness, safety, efficiency, patient-centred care, timeliness, fairness, and integration of care (Carter et al, 2021).

Poor quality of care impacts the patient, the community, and the healthcare system as a whole.[1] Patients and caregivers are negatively influenced psychologically and financially by low quality of care. Low adherence to medication, lack of effective timely treatment and reduced vaccination rated may lead to increased health risks and increased health costs (Milosavljevic et al,2018; Urick et al, 2018; Carter et al, 2021). Poor quality of care leads to wastage of resources and high expenditure on damage control which depletes the budget for investments in innovative technology, infrastructure, and systems to improve the healthcare system (Rawy et al, 2020; Carter et al, 2021).[1] A marker of the level of

[1] Organisation for Economic Cooperation and Development (OECD), World Health Organisation (WHO), World Bank Group. Delivering Quality Health Services: A Global Imperative. WHO Geneva;2018. doi: 10.1787/9789264300309

quality of care includes occurrence or risk of medication errors. Medication errors cause avoidable and preventable harm and deaths. Medication errors are estimated to cost an estimated US$ 42 billion annually globally[2],while not factoring in the cost of lost wages, foregone productivity, or health care costs.

High-quality service has been linked to reliable and knowledgeable personnel who are available to provide support, deliver effective communication, and educate and support the patient. Patient experience is a fundamental determinant of quality of care (Carter et al, 2021). Patient dissatisfaction reduces trust in the healthcare system. Watson and Skea (2018) conducted various focus groups and interviews with UK stakeholders to assess attitudes and beliefs towards quality and quality improvement measures in community pharmacies. While noting that quality improvement is under-developed in community pharmacies, quality was defined by participants in terms of relational aspects, such as familiarity with patients, and mutual understanding, instrumental aspects, where the professional gives accurate and correct advice and continuation of care to ensure good clinical outcomes. Carter et al (2021) found that pharmacies that provide high-quality service are linked to a better patient experience and higher patient adherence to medication. The study confirmed the importance of investing in providing a high quality service and highlighted the importance of effective pharmacist communication and patient support (Carter et al, 2021).

[2] International Federation of Pharmacy (FIP), World Health Organisation (WHO). Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. Annex 8; 310–323. WHO Technical Report Series, No. 961 [Internet]. 2011 [cited 2023 May 21. Available from: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex8-fipwhoguidelinesgoodpharmacypractice.pdf

The role of healthcare workers in ensuring a high-quality service is to have good working knowledge, and adhere to standards and therapeutic pathways.[1] In the community pharmacy setting, intentions of the pharmacist towards ensuring the quality of care may include identification of drug-related problems, improving treatment adherence, encouraging antibiotic stewardship, managing chronic medication and polypharmacy, and optimising healthcare services (Moullin et al, 2013; Mossialos et al, 2015; Hermansyah et al, 2018; Dubbai et al, 2019; Carter et al, 2021; Lias et al, 2021). High-quality pharmaceutical services allow for improved health outcomes and better integration of care, which may reduce hospitalisation, unnecessary physician and emergency hospital visits, and overall healthcare costs (Mossialos et al, 2015; Jacobs et al, 2018; Milosavljevic et al,2018; Ramachandran et al, 2021). Furthermore, the maintenance of a high-quality service requires professionals to plan for improvement, participate in evidence-based quality improvement interventions and quality indicators, and participate in training for continuous professional development.[1]

Mirzaei et al (2019) developed a survey intended to obtain information on customer perceptions of the quality of the pharmacy service. The qualities included in the survey were based on previous studies, theories, and qualitative interviews. The quality of pharmaceutical service was linked to interpersonal quality, including the pharmacist-patient relationship, interaction, and accessibility, technical quality, such as health outcomes, expertise, advice and trust, environment quality, including setting, atmosphere and cleanliness, and administrative quality, including timeliness, organisational efficiency, and support services.

1.3. Quality improvement as a pathway to optimise pharmaceutical care service

Quality improvement is the consistent effort to maintain the level of care, to improve the health and well-being of the patient and to drive professional development. Effective change should be an inherent part of a healthcare professional's job to allow for improvement. These changes come about because of new research data, knowledge of the present circumstances, performance measurement, plans for change and implementation of planned changes (Schoenmakers et al, 2015; Alhusein et al, 2019; Latif et al, 2021; Ramachandran et al, 2021).

The ever-changing healthcare system requires quality to be accurately measured and evaluated to plan for quality improvement. Quality systems and quality improvement measures are a growing priority in many countries that aim to obtain reliable information on the quality of care being provided at different levels. These measures are essential to evaluate current service provision and to improve transparency and accountability (Schoenmakers et al, 2015; Alhusein et al, 2019; Dubbai et al, 2019; Latif et al, 2021, Sepp et al, 2021). Measuring the quality of pharmaceutical care is complex as services are difficult to define and quantify (Dubbai et al, 2019). The Donabedian framework (2005) is an established conceptual framework utilised to assess the quality of healthcare and services. The framework consists of three main measures namely structure, process, and outcomes (Donabedian 2005; Moullin et al, 2013; Alhusein et al, 2019; Urick et al, 2019; Ramachandran et al, 2021).

Patient outcomes, patient feedback, clinical goals, or feedback from healthcare professionals are often used as quantifiable measures of pharmaceutical care (Grew et al, 2019; Mirzaei et al, 2019; Ramachandran et al, 2021). A local study by Parnis (2020) evaluated the local pharmaceutical service by obtaining feedback from patients. Parnis (2020), in agreement with previous local studies by Wirth et al (2011), Vella et al (2015) and Mohamed (2018), found that Maltese consumers have a positive attitude towards pharmaceutical services and that participants were satisfied with the pharmacist's role within the community, with the majority utilising the services provided. Parnis (2020) linked positive attitudes and beliefs towards professional service and advice with positive treatment outcomes.

Duxbury and Fisher (2022)[3], on behalf of the UK NHS, through Ipsos group, carried out an assessment of public perception towards community pharmacies in the UK. The study reported that the majority of patients felt they were treated with respect, the pharmacy building was well maintained, and patients acquired what was required from the pharmacy. Patients confirmed receiving good pharmacist advice and were comfortable being referred to a community pharmacy for services such as smoking cessation, minor ailments assessment and weight loss. The report noted that there is a reduced level of awareness and confidence in pharmacist-led extended services, and this may be overcome by further clinical training of pharmacists and public promotion. Other studies which evaluated public perception of community pharmacy demonstrated similar findings (Merks et al, 2016; Hindi et al, 2018; Policarpo et al, 2019; El-Kholy et al, 2022; Hikaka et al, 2023).

[3] Duxbury K, Fisher K. Public perceptions of community pharmacy | Ipsos [Internet]. Public Perceptions of Community Pharmacy. NHSE; 2022 [cited 2023 Jun 7]. Available from: https://www.ipsos.com/en-uk/public-perceptions-community-pharmacy

These results show one marker within the quality chasm. While collecting and utilising patient feedback to evaluate an intervention or service may be a fast and easy method to collect data, using patient feedback as a sole data collection method has its limitations due to issues related to validity and reliability (Berger et al, 2020; Parnis, 2020).

Standardised quality indicators are performance measurements that are validated by adequate evidence and/or consensus to measure and improve the quality of service provision. Standardised quality indicators, such as self-assessment tools, are measures to assess overall performance, monitor outcomes of interventions and changes in quality, and encourage professional growth. Lack of standardised quality indicators may lead to inconsistencies in the quality of pharmacy services provided (Watson and Skea, 2018; Alhusein et al, 2019; Dubbai et al, 2019; Fonseca et al, 2021). A standardised quality indicator allows the community pharmacy personnel to effectively analyse one's performance, reflect on shortcomings and plan for improvement. A standardised quality tool allows for resilience to the dynamic scenario of the healthcare system (Thomas et al, 2015). This empowers the community pharmacy team to optimise their pharmaceutical service, proactively strive to achieve set goals, strengthen inter-professional relationships, and enhance patient-centred care services, irrelevant of increasing workload and pressures (Fonseca et al, 2021).

Quality indicators often focus on the legal and regulatory requirements, however, the pharmacist’s role in the management of patient health and optimisation of medication use, demands qualities that exceed the basic legal requirements (Watson and Skea, 2018; Sepp et al, 2021). For such quality tools to be reliable, they must be evidence-based, tested

for validity, feasible, sustainable, and financially supported (Schoenmakers et al, 2015; Latif et al, 2021).

1.4. International quality standards

The International Pharmaceutical Federation (FIP) developed a standard on 'Good pharmacy practice in community and hospital pharmacy settings' in 1992. In 1997, this standard was updated according to recommendations from the WHO expert committee and the FIP council. The FIP/WHO Good Pharmacy Practice (GPP)[4] joint standard was published in 1999. WHO meetings on the role of pharmacists in 1997 and 1998, reiterated the role of the pharmacist in self-care and self-medication and advocated for the change in pharmacy curricula to reflect the modified role of the pharmacist. The FIP/WHO developed an updated GPP guideline, 'Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standard for Quality of Pharmacy Services' in 2011.[2]

These standards encouraged countries to invest in good-quality pharmacy practice and to develop national quality standards and indicators (Alhusein et al, 2019; Latif et al, 2020; Sepp et al, 2021). The present study focused on quality programs from the United Kingdom (UK), Australia and the United States of America (USA) due to their developments in quality measures for community pharmacy. The focus on patient-centred pharmaceutical care drives changes in policy for the expansion of the community pharmacist scope of practice.

[4] WHO. Good Pharmacy Practice in Community and Hospital Pharmacy Settings; World Health Organization (WHO) Technical Report Series, No. 885, Annex 7; [Internet] Geneva, Switzerland;1999. [cited 2023 Jun 7]. Available online: https://www.who.int/publications/i/item/WHO_TRS_885

1.4.1. UK: National Health Service pharmacy quality scheme

The UK National Health Service (NHS) introduced the Pharmacy Quality Scheme[5] as part of the Community Pharmacy Contractual Framework in 2016. Through this scheme, pharmacy contractors declare their performance yearly via a point system that is allocated to each criterion and are paid according to the number of points attained. The scheme rewards community pharmacies that meet quality and gateway criteria related to clinical effectiveness, patient safety and patient experience. Registered pharmacists and front-facing pharmacy personnel are obliged to participate in training seminars to educate and support their participation in the criterion campaigns previously outlined.

The quality and gateway criteria outline a list of new pharmaceutical services, reporting requirements, training requirements and campaign participation expected to be carried out in community pharmacies. The quality domain of the Pharmacy Quality Scheme 2022/2023 incorporates the need to perform risk review updates, clinical services training, and participate in domestic abuse prevention campaigns. The quality domains focus on respiratory conditions and optimisation of treatment, weight management services, antimicrobial stewardship, palliative and end-of-life care. Each year the NHS provides a different set of criteria with the aim to expand the pharmaceutical services available in community pharmacies. The criteria focus mainly on ensuring that regular training is performed, expanding the pharmaceutical services and participating in campaigns.[5]

[5] NHS. Pharmacy Quality Scheme Guidance 2022/2023 [internet]. NHS England; 2022 [cited 2023 Jun 8]. Available from: https://www.england.nhs.uk/wp-content/uploads/2021/09/B2051-pqs-pharmacy-quality-scheme-guidance-22-23.pdf

The NHS quality scheme establishes a new set of criteria expected by community pharmacies on a yearly basis, with the aim of increasing the number of pharmaceutical services. It focuses on the provision of extended pharmaceutical services; however, it fails to confirm the fundamental quality requirements of the community pharmacy service. Jacobs et al (2018) criticised UK's 2005 NHS contractual framework for offering remuneration based on the services provided. This has led to an increase in workload and increased the risk of incentivising the service quantity provided over quality of the service. The study suggests remuneration of pharmaceutical services based on process and outcome quality measures to maintain high quality (Jacobs et al, 2018).

1.4.2. Australia: Pharmaceutical Society of Australia quality standards

The Pharmacy Guild of Australia developed the Quality Care Pharmacy Program (QCPP) in 1997 and the updated Quality Care 2020 in consultation with the Pharmaceutical Society of Australia (PSA).[6] This is a quality assurance program which supports and develops guidance for community pharmacies. The program rewards accreditation to pharmacies that meet the quality and safety criteria and requests a reassessment every two years. To-date, 94% of pharmacies in Australia have received QCPP accreditation.

The PSA is a professional pharmacy organisation focusing on excellent pharmaceutical care by optimising the expertise of the pharmacist to address healthcare needs. The

[6] Pharmacy Guild of Australia. What is QCPP? [Internet]. 2022 [cited 2023 Jun 8] . Available from: https://www.qcpp.com/about-qcpp/what-is-qcpp

Professional Practice Standards[7] and the National Competency Standards[8] by PSA were developed to ensure ethical, professional practice and define the expected quality and competency standards required for effective pharmacy practice. The practice standard is divided into four streams consisting of a total of sixteen standards. Each standard consists of a background and scope, a diagram depicting an overview of the criteria, and a list of criteria together with the actions required to attain such standards. The four streams are 'Foundations of Practice', 'Providing Health Information', 'Providing Therapeutic Goods', and 'Delivering Professional Services'. The national competency standard consists of six domains outlining twenty-six standards of competencies and a self-assessment tool. The five domains are professionalism and ethics, communication and collaboration, medicines management and patient care, leadership and management and education and research. The self-assessment tool is linked to the national competency standards framework and is divided into the same domains and standards. The self-assessment tool is utilised as a reflective tool to identify their needs for continuous professional development.

Jackson and Urick (2019) criticised Australia's current pharmacy payment model and noted that for a pharmacy to be recognised as a valuable asset within the healthcare system, performance-based payment models must be incorporated within the community pharmacy remuneration. The traditional fee-for-service plan is currently in place together with the enhanced service payment plans. The enhanced service plan rewards pharmacists who perform quality-improvement services such as medication reviews and preparation

[7] Pharmaceutical Society of Australia. Professional Practice Standards [Internet]. Pharmaceutical Society of Australia; 2017 [cited 2023 Jun 7]. Available from: https://www.psa.org.au/practice-support-industry/professional-practice-standards/.
[8] Pharmaceutical Society of Australia. National Competency Standards [Internet]. Pharmaceutical Society of Australia; 2016 [cited 2023 Jun 7]. Available from: https://www.psa.org.au/practice-support-industry/national-competency-standards/

of medicines in dose administration aids. This was the initial step towards value-based payment models however, most payment still relies on the volume of medicines dispensed rather than the level of quality of care provided. The study proposed that the performance-based payment models should be specifically developed for Australian community pharmacies and initially based only on 'adherence' as the performance measure. This is based on the assumption that high-quality pharmaceutical care results in a higher percentage of adherence and thus improved patient outcomes. This may then be developed into more robust payment models such as the ones utilised in the USA (Jackson and Urick, 2019).

1.4.3. USA: Pharmacy Quality Alliance quality measures

The USA has many agencies and organisations related to healthcare research, quality and safety of medication use (Ross et al, 2013). The Agency for Healthcare Research and Quality (AHRQ) is a lead federal agency on the safety and quality of healthcare. The AHRQ invests in research on the scenario of the health system and how to improve it, develops training modules for professionals to put the study conclusions into practice and develops surveys and tools for policymakers to assess outcomes of the implemented changes.[9] The Centres for Medicare and Medicaid Innovations develop, validate and fund innovative care models which focus on improving care whilst reducing costs through the optimisation of Medicare and Medicaid beneficiaries (Ross et al, 2013). These care models are not specific to pharmaceutical care and may result in a lack of transparency when applied to community pharmacies.

[9] Agency for Healthcare Research and Quality. About AHRQ. [Internet] 2014 [Updated July 2022; cited 2023 Jun7]. Available from: https://www.ahrq.gov/cpi/about/profile/index.html

In 2006, the USA Pharmacy Quality Alliance[10] (PQA) non-profit organisation was established to develop performance measures and quality improvement indicators to improve medication use and quality of care in community pharmacies. There are three types of PQA measures: 'Performance Measures', 'Monitoring Measures', and 'Quality Improvement Indicators'. Performance measures are utilised to evaluate healthcare operations and outcomes, monitoring measures encourage appropriate documentation and reporting for monitoring purposes and quality improvement indicators evaluate the improvement from baseline. The PQA measures were developed to be utilised for the purpose of quality improvement, benchmarking and value-based pharmacy models following increasing interest in quality performance measures and new requirements listed in the 2022 Medicare Part D fact sheet (Mossialos et al, 2015).

Pharmacies are not incentivised by the government to perform extended patient-centred services, however, more than half of all US Medicare Part D Plan (Drug coverage plans) include a performance assessment and are reimbursed by health insurers for medication therapy management (MTM) services such as medication reviews and telephone follow-ups (Mossialos et al, 2015; Urick et al, 2019; Mercadante et al, 2020). The 2022 Medicare Part D (drug coverage) requires pharmacies to disclose the performance measures used to evaluate the quality of pharmaceutical care. This requirement allowed healthcare payers to improve their understanding of the pharmacy performance level being declared and increase transparency.[11] As a result, there is a growing interest in evaluating the value and performance of community pharmacies.

[10] Pharmacy Quality Alliance. PQA Measures Overview [Internet] 2022 [Updated April 2022; cited 2023 Jun 7]. Available from: https://www.pqaalliance.org/pqa-measures

[11] CMS. Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) Fact Sheet. [Internet] Baltimore 2021. [cited 2023 Jun 7]. Available from: https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet

1.5. Local quality performance indicators

On a national level, Azzopardi (2000) developed validation tools to assess the quality of service provision and to evaluate the role of the pharmacist in the community pharmacy. Five internal validation tools and two external validation tools were developed. In the internal validation tools, the pharmacy setting and the tasks undertaken by the pharmacist such as dispensing and counselling are evaluated by the pharmacist to assess the service provision and the impact of the pharmacist on patient outcomes. The external validation tools evaluate the significance given to the community pharmacist by patients and other healthcare professionals. A characteristic of this quality system is with regard to pharmacist intervention for minor symptoms and self-care recommendations. The validation tool has been updated by Buttigieg (2006), Scicluna et al (2012) and Flynn (2017).

Community pharmacies in Malta are assessed by the national regulatory body, the Malta Medicines Authority, through community pharmacy regulatory audits (CPRAs). CPRAs evaluate local community pharmacies from a regulatory and competence perspective. Attard (2018) updated the CPRA tool so as to be more patient-focused rather than compliance and conformance-focused. Langaro (2020) developed a regulatory checklist and designed a self-audit tool to assess pharmacist competencies and regulatory conformity prior to CPRAs.

1.6. A shift to value-based payment models

Whilst evaluating quality, healthcare ecosystems are expected to reflect on sustainability which includes economic considerations. The context of sustainability is in itself an essential element of ensuring quality since, if the healthcare setting is not economically stable then the quality of the service may be jeopardised (Hermansyah et al, 2018; Jacobs et al, 2018; Fonseca et al, 2021; Richard et al, 2021). In the USA, healthcare is associated with the highest expenditure and low quality of care and this led to the shift towards value-based plans to enhance patient care while reducing healthcare costs. Although delayed, this shift is being applied to community pharmacies where payment models are linked to quality metrics (Urick et al, 2019; Richard et al 2021)

Traditional pharmacy payment models pay pharmacies a fixed fee for every service provided and prescription dispensed. Performance-based payment models reward pharmacies, withhold payment or penalise pharmacies based on the results of the performance-based measures, such as patient outcomes, and clinical services provided (Pringle et al, 2016; Urick et al, 2019; Hincapie et al, 2021; Richard et al, 2021). The 'Electronic Quality Improvement Platform for Plans and Pharmacies (EQuIPP) is an IT system utilised by US healthcare plans to extract data on claims of prescription plans and computes quality measures of pharmacies (Urick et al, 2019; Richard et al, 2021).

New healthcare delivery systems and quality performance measures are being developed and assessed in the UK, USA and Australia to identify the optimal performance-based payment model. This is an important step in the shift towards more patient-centric community pharmacy services (Mossialos et al, 2015; Pringle et al, 2016; Mercadante et

al, 2020). Performance and quality measures, such as the PQA measures and the tool being developed in the present study, provide a benchmark to assess performance, pharmacy services, patient outcomes and patient satisfaction.

Mercadante et al (2020) proposed four payment models which may overcome challenges of the traditional payment models which depend on dispensing practices and sale of medicinal products. These include the pharmacist attached to primary care physician offices model, transparency payment model, accountable care organisation plus patent model and pharmacist network model. Mercadante et al (2020) and Richard et al (2021) noted that a formal analysis should be carried out to assess the different payment models and performance analysis to confirm the outcomes, ensure a positive impact of performance-based models and encourage pharmacies to participate. Increasing access to measures, appropriate electronic data collection systems, training and increasing the workforce were some of the recommendations of the study by Richard et al (2021), to encourage payers, pharmacies and patients to implement performance-based pharmacy payment models. These models allow pharmacists to focus on pharmaceutical care services rather than traditional dispensing practices.

Mossialos et al (2015) reviewed the role of the pharmacist in six countries: England, Scotland, Australia, Canada, USA and the Netherlands. The study found that England and Scotland are leading with respect to utilising pharmacists at their best capacity, taking advantage of their knowledge, expertise, location and availability. Policymakers in both countries have rewarded pharmacists for their extended responsibilities through a fee-for-service model. Mossialos et al (2015) found that Canada's reimbursement model varies across provinces and Australia offers compensation for medication reviews in five main

areas; diabetes, respiratory disease, cardiovascular disease, mental health conditions and health promotion. The remuneration system in the Netherlands mainly focuses on dispensing services and does not encourage provision of patient-centred services.

1.7. Rationale for the research

The development and implementation of a self-assessment tool which analyses pharmaceutical professional services from a quality perspective is a concept that addresses a gap between the available legal and regulatory measures and the additional quality standards required for a professional service. The provision of a high-quality pharmaceutical service is perceived as an imperative element within a professional pharmacy setting. Considering the ever-changing healthcare system and the dynamic pharmacist role within the community, quality improvement measures such as self-assessment tools, training, and financial incentives should be available to maintain high-quality community pharmacy services.

A pharmacist is ethically and legally bound to provide a safe and effective service and this is ensured through the national regulatory authority and the legal and ethical framework, which together with the pharmacist's education, offer the basis of pharmacy practice. This study focuses on the qualities required for a high-quality professional service, such qualities exceed the basic regulatory and competency requirements explored in previous studies (Attard, 2018; Langaro, 2020). Considering the aforementioned quality standards and incentives on an international scale, and the healthcare strategy established for Malta, this research study lays the foundation for the implementation of a quality assurance mechanism that is both evidence-based and practical. The availability

of a self-assessment tool will be an asset for all community pharmacists who aim to improve and maintain the provision of high-quality pharmacy services.

1.8. Aim and Objectives

The study aimed to answer the following research question: Can a self-assessment tool adequately evaluate the quality of clinical community pharmacy service provision?

The aim of this study was to develop, validate and evaluate a self-assessment tool for clinical community pharmacy services.

The objectives were to:

1. Analyse established quality standards and pharmacy services outcomes requirements
2. Develop and psychometrically evaluate a self-assessment tool for clinical community pharmacy services
3. Evaluate the practicality of the self-assessment tool

Chapter 2

Methodology

2.1. Overview

The methodology involved a review to evaluate established quality standards, development of the self-assessment tool for community pharmacy services, content validation, reliability testing, and criterion validation, and implementation of the self-assessment tool (Figure 2.1).

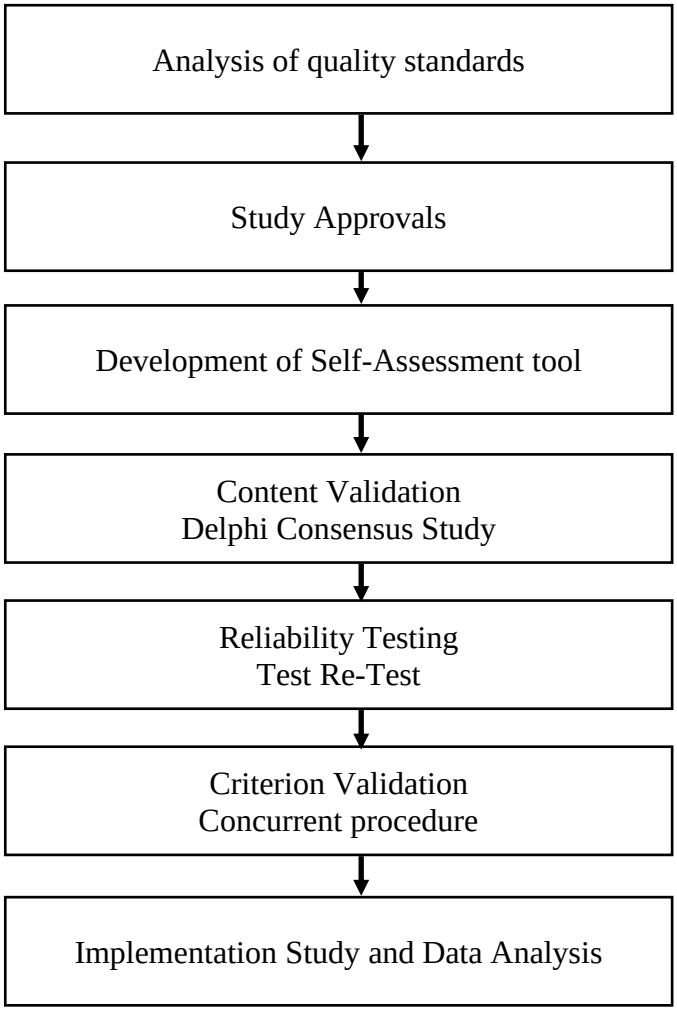


Figure 2.1: Research methodology flowchart

2.2. Research design

A mixed-method approach was employed in this study. A qualitative research approach was used for the development of the self-assessment tool. Established community pharmacy quality measures were identified and analysed, and a literature review was carried out. A self-assessment tool for community pharmacists was developed based on the identified quality dimensions from the review. A quantitative approach was adopted for the psychometric evaluation and implementation study of the self-assessment tool.

2.3. Setting and Approvals

The research was carried out in retail community pharmacies in Malta. The research was registered with the University of Malta, Faculty of Medicine and Surgery Research Ethics Committee (Appendix 1). Permission from the Pharmaceutical Society of Australia (PSA) was granted to use the Professional Practice Standards (version 5, 2017)[7] as the gold standard for the study (Appendix 1).

2.4. Development of the self-assessment tool

A literature search was conducted using PubMed® and *Hydi* focusing on studies published in the last ten years. The objective was to identify instruments which evaluate the quality of pharmaceutical care in community pharmacies. The keywords and phrases for the literature search included; 'community pharmacy services', 'quality', 'quality indicators', 'quality measures', 'quality standards', 'risk', 'pharmacy practice', 'patient-centred care', 'clinical pharmacist role', 'self-assessment', 'GPP', and 'Good Pharmacy Practice'. Websites of international non-governmental organisations, competent authorities and governmental institutions pertaining to quality standards and quality schemes were reviewed. Established quality programs of community pharmacy services were explored to identify the required quality standards, and quality indicators used to assess the level of quality and to learn about quality schemes employed to encourage the high-quality provision of pharmaceutical services.

Following an in-depth review of the currently available quality programs, three international quality schemes were identified, including the UK NHS pharmacy quality scheme[5], the quality programs developed by the Pharmaceutical Society of Australia[7,8], and performance measures developed by the US Pharmacy Quality Alliance[10]. The local validation tool for community pharmacy services developed in 2000 was evaluated (Azzopardi, 2000). The quality programs were reviewed in terms of the scope of the program, the specific or general focus, types of quality criteria outlined, how performance is measured, incentives and linked payment schemes and whether the program is voluntary.

These quality programs were used as a guideline to develop the self-assessment tool. A list of 250 statements outlining the key quality criteria for community pharmacy services was developed. These statements were reviewed in terms of applicability, terminology, and construction by the researcher. The statements covering the same topic or role were grouped into sets such as effective communication, acting respectfully, and empowering patients. The sets were further grouped into domains according to the quality concept e.g. Patient Care and Medicine Management.

2.5. Content validation

A Delphi consensus study was performed to establish content validity. The Delphi technique is an internationally recognised validation study that aims to reach a conclusion based on a consensus between expert opinions. Nine participants selected by convenience sampling accepted the invitation to participate in the Delphi Consensus study. The expert panel included two quality pharmacists, one international quality pharmacist, two community pharmacists, a general practitioner, a nurse, and two lay persons.

The statements outlining quality criteria were presented in sets, together with a rating box for participants to rate the clarity, relevance, and comprehensiveness using a Likert scale from 1 (Poor) to 5 (Excellent). Participants were encouraged to forward feedback and recommendations in the text box. A general consensus of 7 out of 9 participants (80%) and an acceptance threshold of a mean rating score ≥4.5, were established prior to the initiation of the Delphi consensus study.

The self-assessment tool was disseminated to all participants who accepted to participate and signed the consent form. The expert panel were asked to revert within two weeks. The ratings and feedback were collated in Microsoft Excel®. Statements with ratings of 3 or less were highlighted and revised in accordance with the feedback received. A mean rating score for each set of statements was calculated. The updated self-assessment tool was sent to the expert panel for round II of the Delphi Consensus study. The expert panel members were asked to rate and forward feedback on the updated content of the self-assessment tool within two weeks. A general consensus was reached, and the content of the developed self-assessment tool was validated (Appendix 2)

2.6. Reliability testing

The reliability of the tool was analysed using the test-retest reliability procedure to ensure that the results generated from the self-assessment tool are representative and fixed over time. The test-retest reliability procedure involved ten pharmacies selected by convenience sampling. The self-assessment tool was disseminated and the participants were asked to perform the self-assessment tool twice, two weeks apart. SPSS® was used to analyse the results. Cronbach's Alpha was applied to determine the correlation between the results of the two-time points and to measure the internal consistency. Cronbach's alpha is a coefficient of reliability and a value greater than 0.6 indicates good reliability.

2.7. Criterion validation

Criterion validation was established using the concurrent validity procedure to verify that the developed self-assessment tool adequately measures the result of interest. This validation procedure aimed to demonstrate that the results of the self-assessment tool being developed correlate to the results of other established quality assessment tools. The procedure required ten pharmacies, selected by convenience sampling, to complete the self-assessment tool being developed in the present study and the gold standard. The Pharmaceutical Society of Australia (PSA) self-assessment tool[8] was identified as the gold standard for the criterion validation phase.

The self-assessment tool and the gold standard were disseminated to the ten participants who had agreed to participate and signed the consent form. The participants were asked to perform both self-assessment tools within five days of each other. The results of the self-assessment tool (test) being developed, and the results of the gold standard quality assessment tool (criterion) were collected and SPSS® was used to analyse the results. The paired Sample t-test was used to analyse statistical differences between the results of the developed self-assessment tool and the gold standard. A p-value greater than 0.05 indicated that there were no statistically significant differences between the mean scores of both self-assessment tools. The scores during the criterion validation test were converted according to Table 2.1for statistical analysis purposes.

Table 2.1: Scoring of developed self-assessment tool versus gold standard

	Self- assessment tool being developed in this study	**Gold standard (PSA self-assessment tool)**
Scores	5 - Excellent	0 - Development is not required
	4 - Very Good	
	3 - Good	1 - Development is required for future scope
	2 - Fair	
	1- Poor	2 - Development is required for current scope

The corresponding relation between the self-assessment tool being developed and the gold standard was according to Table 2.2.

Table 2.2: Domains of developed self-assessment tool versus gold standard

	Self-Assessment Tool being developed in present study		**Gold Standard (PSA self- assessment tool)**
1	Professional practice	1	Professionalism and Ethics
2	Patient care and Medicine management	3	Medicine Management and Patient Care
3	Dispensing practices and counseling	2	Communication and Collaboration
4	Collaboration with health care professionals and colleagues		
5	Training and professional development	5	Education and Research
6	Management of stock and pharmacy environment	4	Leadership and Management
7	Quality assurance and quality management		

2.8. Implementation study

The objective of the implementation study was to evaluate use of the tool by pharmacists and to assess practicality and applicability. The participating pharmacies were chosen by convenience sampling based on the first 30 pharmacies that confirmed participation following an invitation email. The self-assessment tool was distributed to participating pharmacies together with a feedback questionnaire. The participants were asked to first perform the self-assessment tool followed by the feedback questionnaire.

The feedback questionnaire included two multiple-choice grids and a feedback box where participants could forward feedback and recommendations. The first grid asked the participant to rate the clarity, relevance, comprehensiveness, practicality, and applicability of the developed self-assessment tool. The second grid asked the participants to rate their likeliness to perform the self-assessment tool, to participate in training to improve the pharmaceutical service and to identify the need and plan for training of pharmacy personnel (Appendix 3). Descriptive statistics were performed using Microsoft® Excel and SPSS® and presented as frequencies and percentages. The demographics, position of the pharmacist and years of experience were computed to describe the respondents. The chi-square test was carried out to determine if there were significant associations between the variable and the years of pharmacist experience, and the variables and position of the pharmacist within the pharmacy (managing or locum pharmacist). The variables were clarity, relevance, comprehensiveness, practicality, and applicability.

Chapter 3

Results

3.1. Quality standards evaluated

The review of the quality standards was focused on local validation tools for community pharmacies (Azzopardi, 2000), UK NHS Pharmacy Quality Scheme[5], USA PQA Measures[10] and Australian professional practice and competency standards[7,8] (Table 3.1). The UK NHS Pharmacy Quality Scheme and USA PQA Measures deal with specific conditions, medication groups and campaigns. Although the quality measures from Malta and Australia outline the general quality criteria for community pharmacy, both have sections which are more specific. The local validation tools deal with specific patient symptoms presented at the pharmacy and evaluate pharmacist intervention for the specific symptom. The Australian professional practice and competency standards include criteria on specific pharmaceutical services such as screening and risk assessment service and vaccination service. The assessment type varies between all quality measures.

The local validation tools utilise a score system for the internal validation, where each criterion within the checklist corresponds to a score. The UK NHS Pharmacy Quality Scheme requires pharmacies to present proof of services provided, number of referrals and training performed. The USA PQA Measures utilises prescription data and pharmacy claims on the number of services performed and interventions carried out to optimise patient treatment. The Australian professional practice is a self-reflection tool with no means of assessment and the National competency standard is linked to a self-assessment tool which assesses solely the need for further development. This review confirmed the need for a quality measure which reflects the general quality criteria applicable to all community pharmacies worldwide. Furthermore, the need for an assessment tool with a quantifiable quality score was realised.

Table 3.1: Quality standards reviewed

	Validation Tool for Community Pharmacies (Azzopardi, 2000)	UK NHS: Pharmacy Quality Scheme[6] 2022/2023	USA: PQA Measures[10] 2022/2023	Australia: PSA Standards[8] 2016/2017
Country	Malta	UK	USA	Australia
Scope	Utilised by pharmacists to assess impact of pharmaceutical service	To support the NHS Long Term Plan and incentivise quality improvement	Standardised criteria to assess and improve quality of care	Ccomprehensive criteria outlining expected standard
Measures assessed	Validation tool incorporates internal and external validation. Internal Validation tackles setting of community pharmacy, dispensing procedure, responding to symptoms, communication with patient, equipment and professional services and clinical governance. External validation is performed by patients and healthcare professionals.	Scheme outlines several quality criteria required by each participating pharmacy. Criteria are linked to training level requirements, risk reviews and action plans for new services, active participation in campaigns and pharmaceutical services, identifying high risk patients and referrals for further review. Domains include risk management and safeguarding, respiratory, healthy living support, prevention and addressing unwarranted variation in care.	42 PQA measures divided into 3 types: performance measures, monitoring measures and quality improvement indicators. Only performance measures may be utilised for assessment of performance. Performance measures consist of 4 domains: adherence of chronic medications, appropriate medication use, medication safety and medication therapy management. PQA also published measures related to opioids and speciality medications.	Practice standard consists of 16 main standards outlining foundations of practice, providing therapeutic goods, providing health information, delivering professional services and collaborative care. The national competency standard and linked self-assessment include 5 domains: Professionalism and ethics, communication and collaboration, medicines management and patient care, leadership and management, education and research.
Criteria type	General	Specific	Specific	General
Measurement	Internal validation tools outline a checklist of activities expected by a pharmacist when performing a number of services. Each criterion within the checklist is linked to a score. In external validation tool, patients and healthcare professionals rate the pharmacist.	Participating pharmacies are asked to declare that they have met the quality criteria by reporting that required training has been completed, risk reviews and action plans are in place to undertake the service/campaign/referral outlined in the quality criterion and note number of patients positively impacted.	Adherence, prescription claims, drug-drug interactions, appropriate medications prescribed and appropriate monitoring are assessed when evaluating prescription data, medication management services are assessed based on number of reviews performed and interventions carried out to resolve medication problems.	Professional practice standards may be utilised as a reflection tool to ensure uniformity and high-quality service. National competency standard includes a self-assessment tool utilised to identify needs for continuous professional development.
Incentives and Payment schemes	No incentives or payment schemes linked to performance measures.	Scheme rewards pharmacies who meet criteria according to point-system.	Utilised by healthcare payers to evaluate the performance of pharmacy and to identify training requirements.	Standards are applied for continuous professional development.
Assessment type	Voluntary assessment of pharmacy service	Voluntary quality report sent to NHS	Mandatory only when requested by healthcare payers/ government payers	Voluntary self-assessment to plan for continuous professional development

3.2. Structure of the developed self-assessment tool

The developed self-assessment tool (Appendix 2) consists of 7 domains of 27 sets of statements outlining quality criteria, with a total of 105 statements (Table 3.2).

Table 3.2: Self-assessment tool domain titles and criteria outlined

Domain number	Domain	Criteria outlined
1	**Professional practice**	Professional role, regulatory requirements, ethical requirements, professional autonomy, privacy, and confidentiality
2	**Patient care and medicine management**	Effective communication, act respectfully, empower patients, medication management, patient-centered medication review, promote health and well-being
3	**Dispensing practices and counseling**	Gather patient information, evidence-based and relevant patient advice, dispensing of medication, compounding of medicines
4	**Collaboration with health care professionals and colleagues**	Effective inter-professional communication, support healthcare professionals and research, collaboration with colleagues
5	**Training and professional development**	Pharmaceutical professional requirements, lifelong learning and continuous professional development, leadership
6	**Management of stock and pharmacy environment**	Physical environment of the pharmacy, pharmacy infrastructure, stock management
7	**Quality assurance and quality management**	Risk management, quality management

The performance assessment section consists of a list of statements outlining the quality criteria and a Likert scale. A Likert scale of 1 (Poor) to 5 (Excellent) was the chosen method for the participant to rate performance for each statement. The rating system allows the pharmacist to quantify the quality standard score, evaluate the professional service being provided and detect weaknesses. The self-reflection section consists of the quality standard scores of each role described in the domain and text boxes for the pharmacist to note the strengths, weaknesses and plans for improvement.

3.3. Content validation results

For each criterion, the mean rating obtained for clarity, relevance and comprehensiveness is tabulated in Table 3.3. The mean rating score for clarity of the statements was 4.62 (range 4.11 - 4.89) with 21 out of 27 sets of statements obtaining a mean rating score greater than 4.5. With regard to clarity, the panel noted the use of long sentences, repetitiveness, and vague statements and recommended having statements with one main focal point. The statements were rephrased and shortened resulting in more concise and direct criteria. The mean rating score for relevance of the statements was 4.72 (range 4.00-5.00) with 25 out of 27 criteria obtaining a mean rating score of greater 4.5. The panel questioned the link of some criteria to pharmaceutical care hence some criteria were rephrased to focus on more relevant qualities. The mean rating score for comprehensiveness of the statements was 4.59 (range 4.11 - 4.89) with 20 out of 27 criteria obtaining a mean rating score greater than 4.5. The expert panel recommended the addition of pharmaceutical activities relevant to the domains, such as handling and returning unused medication, dangerous drug act, hazardous and sharps items.

Table 3.3: Delphi study round I rating scores

Domain	Quality Criteria	Rating [Clarity]	Rating [Relevance]	Rating [Comprehensiveness]
1 Professional practice	1.1 Professional role	4.78	4.89	4.67
	1.2 Regulatory requirements	4.56	4.67	**4.33**
	1.3 Ethical requirements	4.89	5.00	4.89
	1.4 Professional autonomy	4.89	5.00	4.67
	1.5 Privacy and confidentiality	4.89	4.89	4.89
2 Patient care and Medicine management	2.1 Effective communication	4.56	4.67	4.56
	2.2 Act respectfully	4.56	4.78	4.67
	2.3 Empower patients	4.78	4.78	4.67
	2.4 Medication management	**4.33**	4.89	4.67
	2.5 Patient review	4.56	4.88	**4.44**
	2.6 Promote health and well-being	4.78	4.78	4.67
3 Dispensing practices and counseling	3.1 Gather patient information	4.88	4.89	4.78
	3.2 Patient advice	4.56	**4.33**	4.56
	3.3 Dispensing of medication	**4.44**	4.56	4.56
	3.4 Long-term medication	4.78	4.89	4.78
	3.5 Compounding of medicines	**4.44**	4.56	4.56
4 Collaboration with health care professionals and colleagues	4.1 Inter- professional communication	**4.22**	4.67	**4.44**
	4.2 Support healthcare professionals and research	4.56	4.56	4.56
	4.3 Collaboration with colleagues	4.67	4.78	4.56
5 Training and professional development	5.1 Pharmaceutical professional requirements	**4.33**	4.67	**4.33**
	5.2 Lifelong learning and continuous professional development	4.89	4.67	4.67
6 Management of stock and pharmacy environment	6.1 Physical environment	4.67	4.89	4.75
	6.2 Pharmacy ambience	**4.11**	**4.00**	**4.11**
	6.3 Stock management	4.56	4.78	**4.44**
7 Quality assurance and quality management	7.1 Leadership	4.56	4.78	**4.44**
	7.2 Risk management	4.63	4.56	4.67
	7.3 Quality management	4.67	4.78	4.67
Self-reflection section		4.67	4.67	4.56
Mean rating score		**4.62**	**4.72**	**4.59**

The rating scores of round II of the Delphi study were analysed. The mean rating score for clarity of the statements improved to 4.73 (range 4.56 - 4.89), the relevance score improved to 4.77 (range 4.56-4.89) and the comprehensiveness score improved to 4.76 (range 4.67 -5.00). All criteria attained a mean score greater than the pre-established acceptance threshold of 4.5 (Table 3.4). Minor grammatical and punctuation revisions were made in accordance with the feedback received. The general consensus (8 out of 9 participants in agreement) and the acceptance threshold (a mean score of 4.5 or more) established prior to the start of the content validation were achieved. The Delphi consensus study was finalised and the content of the self-assessment tool was validated (Appendix 2).

3.4. Reliability testing results

Cronbach's alpha is 0.991, which indicates a high level of internal consistency of the tool.

Table 3.4: Delphi study round II rating scores

Domain	Question Number	Rating [Clarity]	Rating [Relevance]	Rating [Comprehensiveness]
1 Professional practice	1.1 Professional role	4.78	4.78	4.89
	1.2 Regulatory requirements	4.67	4.56	4.67
	1.3 Ethical requirements	4.67	4.78	4.67
	1.4 Professional autonomy	4.67	4.89	4.78
	1.5 Privacy and confidentiality	4.78	4.89	4.78
2 Patient care and Medicine management	2.1 Effective communication	4.78	4.78	4.78
	2.2 Act respectfully	4.56	4.89	4.89
	2.3 Empower patients	4.78	4.89	4.78
	2.4 Medication management	4.78	4.89	4.89
	2.5 Patient review	4.56	4.78	4.67
	2.6 Promote health and well-being	4.67	4.67	4.78
3 Dispensing practices and counseling	3.1 Gather patient information	4.78	4.78	4.78
	3.2 Patient advice	4.56	4.56	4.56
	3.3 Dispensing of medication	4.78	4.78	4.67
	3.4 Dispensing of Chronic medication	4.78	4.89	4.89
	3.5 Compounding of medicines	4.78	4.78	4.56
4 Collaboration with health care professionals and colleagues	4.1 Inter- professional communication	4.78	4.78	4.78
	4.2 Support healthcare professionals and research	4.67	4.89	4.56
	4.3 Collaboration with colleagues	4.89	4.78	4.78
5 Training and professional development	5.1 Pharmaceutical professional requirements	4.56	4.78	4.67
	5.2 Lifelong learning and continuous professional development	4.78	4.56	4.89
6 Management of stock and pharmacy environment	6.1 Physical environment	4.78	4.78	4.78
	6.2 Pharmacy ambience	4.56	4.67	4.67
	6.3 Stock management	4.89	4.67	4.89
7 Quality assurance and quality management	7.1 Leadership	4.89	4.89	5.00
	7.2 Risk management	4.56	4.78	4.78
	7.3 Quality management	4.78	4.67	4.67
Self-reflection		4.78	4.78	4.89
	Mean Score	**4.73**	**4.77**	**4.76**

3.5. Criterion validation results

Domain 1, 2 and 3 of the gold standard and the correlated domains of the self-assessment tool being developed (Domains 1, 2, 3 and 4) show significant differences between the mean scores since the corresponding p-value of these statements is less than 0.05 (Table 3.5). The alternate hypothesis is accepted for these domains indicating low criterion validity. Domain 4 and Domain 5 of the gold standard and the correlated Domain 5, 6 and 7 of the developed self-assessment tool have a p-value that exceeds 0.05 level of significance, confirming criterion validity.

Table 3.5: Criterion validation: Paired sample t-test

Self-Assessment Tool being developed in present study	**Gold Standard Self-Assessment Tool**	**p value** **Paired sample t-test**
1 Professional practice	1 Professionalism and Ethics	0.001*
2 Patient care and Medicine management	3 Medicine Management and Patient Care	0.008*
3 Dispensing practices and counseling	2 Communication and Collaboration	0.016*
4 Collaboration with health care professionals and colleagues		
5 Training and professional development	5 Education and Research	0.119
6 Management of stock and pharmacy environment	4 Leadership and Management	0.075
7 Quality assurance and quality management		

*p<0.05 statistically significant

Cohen's d test and Hedge's g test were utilised to analyse the extent of the differences between the mean scores of domains 1,2,3 and 4 of the developed self-assessment tool and the corresponding domains of the gold standard (domains 1,2 and 3) (Table 3.6). A large Cohen's d (> 0.8) and Hedge's g (> 0.8) indicates a large effect between the mean

scores of the two self-assessment tools, while a small Cohen's d (<0.2) and Hedge's g (<0.2) indicates a small difference, although significant, between the mean scores of the self-assessment tools. Hedge's g is a more reliable measure when dealing with small sample sizes.

Table 3.6: Criterion validation: Cohen's d test and Hedge's g test

Self-Assessment Tool being developed	Gold Standard Self-Assessment Tool	Cohen's d	Hedge's g	Effect
1 Professional practice	1Professionalism and Ethics	0.389	0.425	Small
3 Dispensing practices and counseling	2 Communication and Collaboration	0.486	0.531	Medium
4 Collaboration with health care professionals and colleagues				
2 Patient care and Medicine management	3 Medicine Management and Patient Care	0.613	0.671	Medium

3.6. Implementation study results

Thirty pharmacies participated in the implementation study by performing the self-assessment tool and completing the feedback questionnaire. The participating pharmacies were predominantly from the Northern Harbour district (Figure 3.1). This is representative of the distribution of pharmacies in Malta, since the Northern Harbour District holds the highest number of pharmacies, with 82 out of 226 pharmacies located in the district. One participant did not disclose the location of the pharmacy where he/she practices.

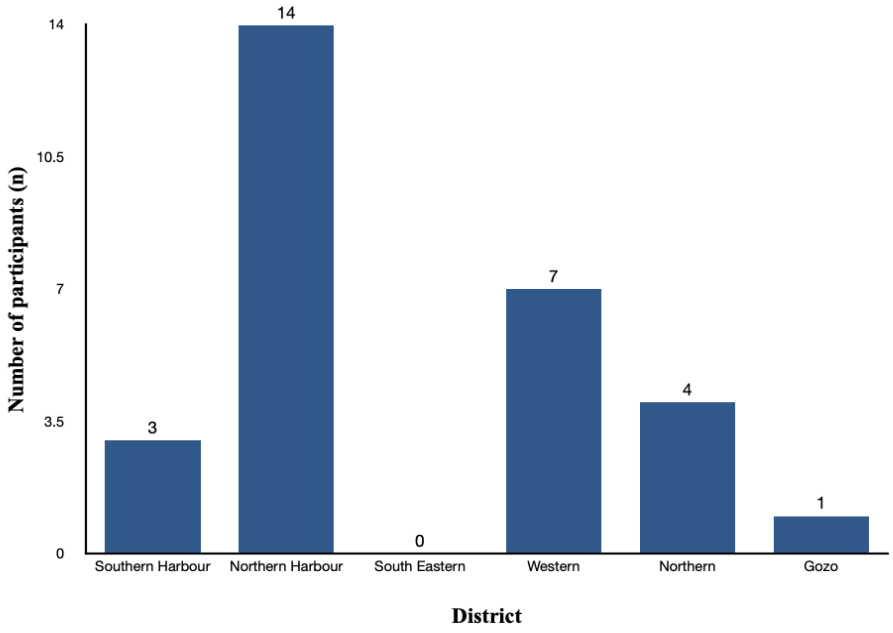


Figure 3.1: Location of the participating pharmacies (n=29)

Most respondents (n=18) were managing pharmacists while the remaining respondents (n=12) were locum pharmacists. Most of the respondents have between 0 to 5 years of working experience as pharmacists (n=19), 3 respondents had 6-10 years of experience, 4 respondents had 11-20 years of experience and 4 respondents had 20 years or more of experience. The majority of the pharmacists (n=26) have been working in the current pharmacy for 5 years or less.

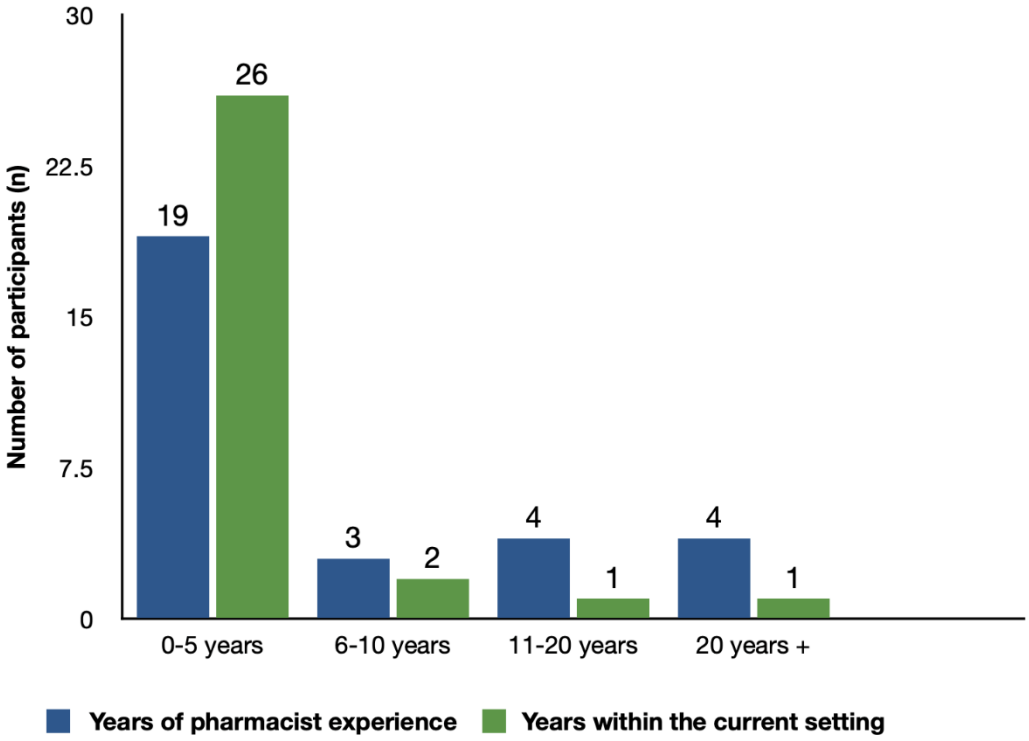


Figure 3.2: Years of experience as a pharmacist and within the current setting (N=30)

3.6.1. Application of tool

The pharmacists participating in the implementation study (N=30) completed the self-assessment tool. The self-reflection section required pharmacists to reflect on the quality score obtained and to note the strengths, weaknesses, and plan for improvement (Table 3.7).

Table 3.7: Results of application of the self-assessment tool

Domain	Mean Rating Score	Plan for improvement
1 Professional practice	4.52	- Review patients with polypharmacy - Preempt medication shortages and order more accordingly to ensure continuous availability of treatment - Ensure all staff is aware of roles and responsibilities and work within set role - Review requirements of storage and disposal of medicines - Identify problems prior to occurring - Set clear boundaries with patients and colleagues - Dedicate more time to update myself on literature, guidelines and prescribing trends - Improve communication skills
2 Patient care and Medicine management	4.13	- Ensure follow-up with patients when required - Collaborate more with other health care professionals - Perform medication reviews - Engage more with clients and actively participate in optimising treatment - Discuss medication related issues with other healthcare workers - Utilise social media platform for health campaigns
3 Dispensing practices and counseling	4.4	- Thoroughly review changes in chronic treatment and contact prescribing doctor when unclear - Read and update myself on counseling and health information
4 Collaboration with health care professionals and colleagues	4.3	- Continually work on inter-professional relationships - Contribute to research, professional and personal growth - Be more diligent when delegating tasks to pharmacy staff to reduce errors - Encourage pharmacy staff to forward feedback - Dedicate more time to follow-up
5 Training and professional development	4.36	- Encourage transparency - Attend CPD courses when available - Improve organisation skills - Devise standard operating procedures - Develop and implement measures of double-checking and reviews to minimise errors
6 Management of stock and pharmacy environment	4.53	- Develop a computerised system to monitor stock - Develop a document with a list of medications expiring in the year to come - Check for expiries regularly - Monitor closely and actively work to foresee the need of the pharmacy
7 Quality assurance and quality management	4.32	- Seek FMD training - Continue to perform quality indicators and identify shortcomings in order to improve - Regularly visit company SOPs - Develop a risk management plan

3.6.2. Feedback from pharmacies

The thirty participating pharmacies rated the clarity, relevance, comprehensiveness, practicality, and applicability of the self-assessment tool. The majority of participants rated the variables as 'very good' or 'excellent' and none of the participants gave a rating score of 'very poor' (Table 3.8).

Table 3.8: Results from the implementation study feedback questionnaire (N=30)

Variables rated	Very Poor	Poor	Acceptable	Very Good	Excellent
	Number of Participants				
Clarity	0	2	5	11	12
Relevance	0	0	4	15	11
Comprehensiveness	0	1	5	13	11
Practicality	0	2	7	12	9
Applicability	0	1	8	11	10

For each variable, the pharmacist rating was correlated to the position of the pharmacist (locum or managing pharmacist). There were no statistically significant association between the position of the pharmacist and the rating score ($p>0.05$). Te pharmacist rating of each variable was also correlated to the years of experience as a pharmacist. There were no statistically significant association between the number of years working as a pharmacist and the pharmacist's rating ($p>0.05$).

Twenty out of thirty participants are ‘likely’ or ‘very likely’ to perform quality indicators while 2 participants noted that it is ‘very unlikely’ that they perform the self-assessment tool (Table 3.9). There was a greater number of participants (n=25) who were willing to participate in training to improve their pharmaceutical care. When asked about the likelihood of planning training for the pharmacy personnel, 21 pharmacists rated ‘likely’ or ‘very likely’.

Table 3.9: Likeliness to plan and perform quality indicators and training (N=30)

Participant likeliness to:	Very Unlikely	Unlikely	Neutral	Likely	Very likely
	Number of Participants				
Perform quality indicators such as this self-assessment tool to assess the quality of service	2	0	8	17	3
Participate in training to improve the service	1	0	4	16	9
Identify and plan training for all the pharmacy staff	0	1	8	13	8

The participant's likeliness ratings were correlated to the position of the pharmacist (locum or managing pharmacist). There were no statistically significant association between the position of the pharmacist and their likeliness perform quality indicators and plan and participate in training ($p>0.05$). Moreover, the participant's likeliness ratings were also correlated to the years of experience as a pharmacist. There were no statistically significant association between the number of years working as a pharmacist and the likeliness to perform quality indicators and plan and participate in training ($p>0.05$).

These results confirm that pharmacists understand the importance of quality in pharmaceutical care and are willing to take responsibility by performing quality indicators and participating in training for themselves and all the pharmaceutical personnel.

Out of the 10 respondents who gave feedback and recommendations, 6 commended the comprehensiveness of the self-assessment tool, however, noted that the tool is lengthy to complete. A participant recommended the tool to be available in both electronic and hard copy format. Two participants recommended an introduction with a brief explanation of the aims of the tool, the benefits of such quality indicators and a description of what is required from the pharmacist performing the self-assessment tool. A participant recommended the addition of the title of the domain in the self-reflection section to help the participants recall the subject being reflected on. Another participant recommended the self-reflection section be amalgamated into one section at the end of the self-assessment tool to be able to rate performance through the domains and provide an overall analysis of the strengths, weaknesses, and improvement plan.

Chapter 4

Discussion

4.1. Impact and application of the self-assessment tool

The community pharmacy sector has evolved to provide more patient-focused services to support the growing healthcare demands. Community pharmacists are continuously seeking to improve the quality of care and broaden the services provided while maintaining safety and efficiency (Hindi et al, 2017; Costa et al; 2017; Dubbai et al, 2019, Chagas et al, 2022). High-quality healthcare requires professional healthcare workers who have up-to-date knowledge, receive regular training and are motivated (Jackson et al, 2019).

Assessing quality is imperative to drive quality improvement. Learning from the experience of other countries and the experience of healthcare workers ensures a better understanding of the barriers to high-quality services and aids in the proposal of effective solutions (Jackson et al, 2019). The present study focused on the evaluation of quality measures available locally, and internationally, in the UK, USA and Australia. The UK[5] and USA[9] quality measures assessed are specific to chronic conditions, patient groups, treatment adherence or specific health campaigns. The Australian PSA professional practice[7] and national competency standard[8] describe both generalised domains, such as professionalism and patient care, and more specific domains such as vaccination services and screening services. Moreover, not all domains of the PSA national competency standard self-assessment tool are universally applicable to all practising community pharmacists since some domains outline criteria intended for leadership roles, planning and conducting training, and participating in research. The PSA professional practice standard is solely a self-reflective tool which does not include a method of assessment, and the PSA self-assessment tool mainly assesses whether there is need for development

and whether the need for development is required for current scope of practice or future scope of practice. This tool is utilised to identify continuous professional development needs. The available local validation tools consist of internal and external validation (Azzopardi et al, 2000). The tools assess the general criteria required for regulatory conformity and focus on specific criteria assessing the pharmacist's interventions in the management of minor symptoms, such as headache and indigestion, and self-care recommendations. The self-audit tool developed by Langaro (2020) focuses on the competency and regulatory requirements assessed during community pharmacy regulatory audits.

Considering the available quality measures (Azzopardi, 2000; Langaro et al, 2020) [5,7,8,9] the development of a new self-assessment tool, that is universally applicable to all community pharmacists in different countries and outlines the fundamental quality requirements for community pharmacy, was required. The developed self-assessment tool addresses a gap in the availability of a quality measure which focuses on the generalised quality requirements for community pharmacies. The tool focuses on the quality criteria which is overlooked in community pharmacy regulatory audit. While regulatory conformity is key for a professional service, a high-quality service is not guaranteed with compliance to regulatory requirements. Moreover, through the developed self-assessment tool, this study presents a quality measure for community pharmacy services which results in a quantifiable quality score, together with descriptive data on the strengths, weaknesses, and plan for improvement.

The developed self-assessment tool has multiple applications to ensure high-quality pharmaceutical care. With the increasing pressure to provide an equitable, sustainable, high quality and efficient health service, the expansion of community pharmacy services to improve access to healthcare has been recognised worldwide. The expansion of the pharmacist's role within the community pharmacy has led to increased need to assess, monitor, and improve the quality of community pharmacy services (Hermansyah et al, 2018; Jacobs et al, 2018; Fonseca et al, 2021; Richard et al, 2021). The self-assessment tool developed in this study covers the fundamental quality requirements for all community pharmacies, and it may be utilised by different countries as a quality measure to ensure the maintenance of a high quality community pharmacy services.

The implementation study confirmed that pharmacists are eager to perform quality indicators and, plan and carry out training to improve the quality of service provision irrelevant of the years of pharmacy experience and the position within the pharmacy (managing or locum pharmacist). Pertaining to this, the developed tool allows the community pharmacist to analyse oneself, the team and the pharmacy's overall performance. The self-assessment tool may be utilised as a benchmark for the quality criteria expected by all pharmacists practising within a pharmacy. Managing pharmacists may request that all practicing pharmacists in the pharmacy perform this self-assessment tool to ensure seamless care and optimal pharmaceutical service at all times irrelevant of the model of practice. The self-assessment tool allows the identification of inconsistencies and shortcomings in the service provision and identification of specific training requirements.

The self-assessment tool may be used for external audits by researchers, managers and policymakers as a means of instigating discussions on quality. The tool's widespread applicability allows the simultaneous assessment of the community pharmacy services of different countries. By performing the developed tool, the community pharmacist is given the opportunity to assess the service he/she is providing and evaluate it against the benchmark for a high-quality service. The self-reflection section allows one to reflect on the present scenario and the barriers experienced. Results from the self-assessment tool allows stakeholders to better understand the global performance, identify barriers and implement interventions aimed to support the community pharmacy team and to improve the pharmaceutical service.

Notwithstanding the small sample size of the study's implementation study, data was generated from the self-assessment tool on the community pharmacists' quality of pharmaceutical care and perception towards quality measures. Even though most pharmacies rated their performance 'good' or better in the majority of the quality criteria, there were still a number of weaknesses listed and each pharmacist provided a detailed plan for improvement. This attests to the desire for continuous improvement.

Healthcare and medicine are very dynamic and from the implementation study, one could clearly note the struggle to juggle the day-to-day pharmacist role with continuously educating oneself with updated evidence-based information. Pharmacy journals and mobile apps such as 'Medscape'[12] are easily accessible tools for reliable information and guidelines on diseases, medicine, and treatment pathways. Financing access to these

[12] WebMD. Medscape App. [Internet] 2020. [updated 2020 December; cited 2023 Jun 7] Available from: www.medscape.com/public/medscapeapp. Accessed 7 Jun 2023.

mobile apps and journals incentivises pharmacists to use these reliable and peer-reviewed sources to guide decision-making and update on evidence-based practices.

Pharmacists recognised their role in optimising treatment plans, counselling on proper medication use and following up on changes in treatment plans, however, time constraints and patient waiting times were noted as limitations. The 'Pharmacist-Led Medication Use Review (MUR) Service in POYC' is being provided through the national health service for patients receiving chronic medication. Such initiatives encourage pharmacists to broaden their pharmaceutical service and incorporate these services into their daily tasks.

Pharmacists noted the need to improve organisational skills to aid in ordering and inventory management and dealing with short-dated and expired stock. In light of the shortages in medication, stock management has been imperative to ensure continuity of care and access to medication. A robust IT point-of-care system supports the pharmacist in identifying trends in pharmaceutical sales and predicting the needs of the community (Jacobs et al, 2018). Implementing measures for stock monitoring, such as developing a document with a list of medications expiring within the same year, allows for adequately managing stock and reducing wastage.

High workloads and lack of time are two limitations noted by community pharmacists in the implementation study. Pharmacy owners are encouraged to invest in building a stronger workforce to support the pharmacist's role in providing adequate patient-centered pharmaceutical care. A stronger workforce requires appropriate training, basic knowledge of medication use and supervision. Whilst the pharmacist remains the responsible person for all pharmaceutical practices within the community pharmacy,

motivated personnel with appropriate training would encourage more delegation of work and support the pharmacist in providing high-quality pharmaceutical services (Jacobs et al, 2018; Carter et al, 2021). Implementing quality measures and broadening the pharmaceutical service must incorporate appropriate training and education to ensure each stakeholder understands the aim, procedure, and outcomes.

There are several barriers to quality measures which may challenge their implementation. The different stakeholders mainly; the pharmacy owner, the government, the pharmacist, and the patient have conflicting interests (Newlands et al, 2018). When implementing an intervention, one must observe the interests of all stakeholders to ensure a fruitful collaboration. The implementation of quality interventions will need to be linked to incentives to ensure pharmacy and patient engagement.

The current scenario is that the community pharmacy income remains heavily dependent on product sales, and this discourages pharmacy owners to invest in extended pharmaceutical services due to the lack of direct financial benefits (Mossialos et al, 2015; Pringle et al, 2016). Community pharmacy is generally focused on the number of product sales over the level of quality of care. Financial incentives and accreditation systems are utilised internationally as quality reward structures employed to ensure high-quality services (Urick et al, 2019; Mercadante et al, 2020; Richard et al 2021). The introduction and optimisation of governmental funding for extended pharmaceutical services would incentivise pharmacy owners and pharmacists to focus on the provision of extended pharmaceutical services. The developed tool may be utilised as a benchmark for high-quality professional service and applied for financial incentives with the aim to encourage

pharmacy stakeholders and pharmacists to invest in the expansion of pharmaceutical services.

The implementation of quality indicators depends on the pharmacy management's culture and infrastructure. Quality indicators are only effective if the results are discussed and analysed to drive change. To ensure a successful implementation of quality measures, pharmacy management, leaders and owners must be flexible, encourage change and support innovative ideas. The culture and attitude of an organisation and/or management of a pharmacy influence the personnel's outlook towards quality improvement measures and change (Jacobs et al, 2018). Clearly outlined roles and responsibilities, standard operating procedures and regular training enhance the pharmacy team's knowledge and confidence in the service being provided and thus inspires preparedness for change. Pharmacy structural factors such as a high-level IT system allow for data collection and evaluation of quality and performance metrics. The pharmacy management has a responsibility to provide the required training and infrastructure to support the maintenance of a high-quality service.

Standard operating procedures, key performance indicators and risk management plans were also mentioned in the implementation study as a means to improve the quality of services. Dedicated management and leadership skills are important to achieve set goals, build resilience to change and maintain high-quality performance. Continuous professional development was recognised by all participating pharmacies as an important aspect of a professional. Previous studies have confirmed the importance of continuous professional development to advance the role of the pharmacist and drive towards patient-centred care and high-quality services (Jacobs et al, 2018; Schindel et al, 2019).

The developed tool may be applied as a resource for the training of new personnel and continuous professional development of pharmacists. Personnel may be asked to perform the self-assessment tool annually to set goals, identify training requirements and plan for improvement. This allows the pharmacist to be held accountable for professional service provision and professional development. From a pharmacy management perspective, the self-assessment tool yields data on the personnel's needs in terms of resources and training.

National strategies focused on quality, such as the 'National Health System Strategy for Malta 2023-2030'[13], should be the basis for continuous quality improvement. A strong strategy allows all healthcare stakeholders, from leaders to service providers, to be in agreement and to plan, develop and implement interventions to improve quality. A better understanding of the current scenario and demands of healthcare is important to identify the needs and barriers to high-quality care. Applying healthcare quality strategies to the role of the pharmacy and pharmaceutical services, in light of the current scenario, would guide local healthcare professionals towards improving their service provision.

A standardised quality measure for community pharmacy services strengthens patients' and other health care professionals' trust in the pharmacist and community pharmacy services. Quality measures affirm the value of the pharmacist within the healthcare team and encourage patients to utilise community pharmacy services, thus reducing the load from primary-care settings and hospitals (Watson and Skea, 2018; Jackson et al, 2019).

[13] National Health Strategy. National Health System Strategy for Malta 2023-2030. [Internet] 2022. Available from: https://health.gov.mt/publications/a-national-health-systems-strategy-for-malta-2023-2030-investing-successfully-for-a-healthy-future/. Accessed 7 Jun 2023.

High-quality services improve health outcomes and reduce drug-related problems (Alhusein et al, 2019; Badro et al, 2020).

4.2. Strengths and Limitations

This was the first quality-focused self-assessment tool for community pharmacy developed and psychometrically evaluated locally. The tool is practical and comprehensive and has widespread applications. The tool outlines the professional quality requirements of community pharmacy services and may be used as a quality indicator to assess community pharmacy services, for internal audits, and for training and data collection purposes. The self-assessment tool has a universal application as it incorporates the fundamental quality requirements for community pharmacies.

Content validation was undertaken in a two-round Delphi- Consensus study involving a 9-member expert panel. Reliability of the tool was assessed using the test-retest method, with a Cronbach's Alpha of 0.991 indicating good reliability. Criterion validation yielded results that varied between different domains. The results generated from Domains 1 to 4 of the developed self-assessment tool showed significant differences from the results of the gold standard ($p<0.05$). This may be due to differences in the structures of the two tools where one asks the pharmacist to rate the performance while the other tool asks the pharmacist to identify whether there is a need for immediate or future intervention or if no intervention is required. Moreover, the criteria outlined in the two tools did not completely correlate thus establishing criterion validation was difficult. For domains 5, 6 and 7 criterion validation was established ($p>0.05$).

A limitation of the study was that participants were selected by convenience sampling throughout the study, which has a high risk of researcher bias. For the implementation study, the number of participants was low and thus insufficient for generalisation of results. The participation of a larger number of community pharmacies may have yielded more data on the current quality scenario in community pharmacies and feedback on the self-assessment tool. Selection of pharmacies by random stratified sampling would have improved the geographical distribution of participating pharmacies.

4.3. Recommendations for further studies

Widespread implementation of the self-assessment tool would be an excellent data collection method to evaluate the quality scenario of community pharmacy services. More representative data would be utilised to recognise gaps in undergraduate education and to identify professional development requirements for qualified pharmacists. Furthermore, community pharmacy quality-related studies are required to initiate the discussion on the drive towards more patient-focused pharmaceutical care. Further studies may investigate the impact of the developed self-assessment tool towards improved trust in the community pharmacist.

Further studies to evaluate the standpoint of stakeholders such as pharmacy owners, governmental entities, and policymakers regarding quality measures in community pharmacy services is imperative. These stakeholders have the capacity to drive the

implementation of quality improvement programs by investing, incentivising and financially supporting quality interventions.

Further studies focused on quality-related rewards for community pharmacy services may help to identify a method of incentivising pharmacy owners and pharmacy personnel to improve and maintain the quality of care provision. The self-assessment tool covers the general quality criteria of community pharmacy services. Other tools may be developed which focus on specific services such as point-of-care testing, medication reviews and other extended services.

The self-assessment tool may be implemented in other countries to assess the global applicability and feasibility. The self-assessment tool developed in this study focuses on the generalised quality criteria pertaining to all community pharmacies. Currently available self-assessment tools are mostly focused on criteria related to specific pharmaceutical services, conditions, or medications, highlighting the need for quality related measures focused on the fundamental quality criteria such the one developed in this study.

4.4. Conclusion

The quality-focused self-assessment tool developed in this study addresses a gap between the available legal and regulatory measures and the additional quality standards required for a high-quality community pharmacy service. The psychometrically evaluated self-assessment tool may adequately evaluate the quality of community pharmacy services and may drive the shift towards more patient-centered pharmaceutical care. The developed self-assessment tool has widespread applications and is internationally applicable to community pharmacies as it outlines fundamental quality requirements.

Through the self-assessment tool for community pharmacies, one aims to improve the provision of pharmaceutical care by educating the pharmacist on the expected quality standards, empowering the pharmacist to reflect on service provision, self-identify shortcomings, and support plans for improvement.

The tool contributes to enhancing pharmacist professionalism, accountability, confidence, and resilience. Results from the study evidence the need for standardised quality-related measures and confirm the community pharmacist's desire for continuous professional improvement. As a result, pharmaceutical stakeholders are encouraged to support the implementation of quality-assurance tools, such as the developed self-assessment tool.

References

Alhusein N, Watson MC. Quality indicators and community pharmacy services: A scoping review. International Journal of Pharmacy Practice. 2019;27(6):490–500. doi:10.1111/ijpp.12561

Attard A. Patient-centred regulatory audits in community pharmacy [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2018.

Azzopardi LM. Validation instruments for community pharmacy. New York: Pharmaceutical Products Press; 2000.

Badro D, Sacre H, Hallit S, Amhaz A, Salameh P. Good pharmacy practice assessment among community pharmacies in Lebanon. Pharmacy Practice. 2020;18(1):1745. doi:10.18549/PharmPract.2020.1.1745

Bartlett A, Pace J, Arora A, Penm J. Self-reflection and peer-assessments effect on pharmacy students ʾperformance at simulated counselling sessions. Pharmacy (Basel). 2022;11(1):5. doi:10.3390/pharmacy11010005

Berger S, Saut AM, Berssaneti FT. Using patient feedback to drive quality improvement in hospitals: a qualitative study. British Medical Journal Open. 2020;10(10):e037641. doi:10.1136/bmjopen-2020-037641

Buttigieg F. Community pharmacy quality programmes [project]. Msida (Malta): Department of Pharmacy University of Malta; 2006.

Carter S, Ng R, El-Den S, Schneider C. Low perceived service quality in community pharmacy is associated with poor medication adherence. Patient Education and Counseling Journal. 2021;104(2):387-394. doi:10.1016/j.pec.2020.07.009

Chagas MO, de Mendonça Lima T, Rebustini F, et al. Instruments to assess the role of the clinical pharmacist: a systematic review. Systematic reviews. 2022;11(1):175. doi:10.1186/s13643-022-02031-1

Chagas MO, de Mendonça Lima T, Souza Santos TS, et al. An instrument to assess the role of Clinical Pharmacists in community pharmacies: Evidence for the validity of content and construct. Research in Social and Administrative Pharmacy. 2023;19(2):308–15. doi: 10.1016/j.sapharm.2022.10.001

Costa F, Scullin C, Al-Taani G, Hawwa A, Anderson C, Bezverhni Z. Provision of pharmaceutical care by community pharmacists across Europe: Is it developing and spreading? Journal of Evaluation in Clinical Practice. 2017;23(6):1336-1347. doi:10.1111/jep.12783

Donabedian A. Evaluating the quality of medical care. Milbank Quarterly. 2005;83(4):691–729. doi:10.1111/j.1468-0009.2005.00397.x

Dubbai H, Adelstein B-A, Taylor S, Shulruf B. Definition of professionalism and tools for assessing professionalism in Pharmacy Practice: A systematic review. Journal of Educational Evaluation for Health Professions. 2019;16:22. doi: 10.3352/jeehp.2019.16.22

El-Kholy AA, Abdelaal K, Alqhtani H, Abdel-Wahab BA, Abdel-Latif MM. Publics ' perceptions of community pharmacists and satisfaction with pharmacy services in Al-Madinah City, Saudi Arabia: A Cross-Sectional Study. Medicina. 2022;58(3):432. doi:10.3390/medicina58030432

Flynn H. Development of a self-evaluation validation process for community pharmacy [dissertation]. Msida (Malta): Department of Pharmacy University of Malta; 2017.

Fonseca J, Violette R, Houle SKD, Dolovich L, McCarthy LM, Waite NM. Helping unlock better care using Quality Improvement Science in community pharmacies – an implementation method. Research in Social and Administrative Pharmacy. 2021;17(3):572–7. doi:10.1016/j.sapharm.2020.05.006

Grew B, Schneider CR, Mirzaei A, Carter SR. Validation of a questionnaire for consumers' perception of service quality in community pharmacy. Research in Social and Administrative Pharmacy. 2019;15(6):673-681. doi:10.1016/j.sapharm.2018.08.008

Hefny Mohamed Y. Public Perception and Expectations of Pharmacy Services [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2018.

Hermansyah A, Sainsbury E, Krass I. Multiple policy approaches in improving community pharmacy practice: the case in Indonesia. BMC Health Service Research. 2018;18(1):449. doi:10.1186/s12913-018-3258-8

Hikaka J, Haua R, Parore N, McIntosh B, Anderson A, Pewhairangi K, et al. Designing for health equity: A mixed method study exploring community experiences and perceptions of pharmacists' role in minor ailment care. Research in Social and Administrative Pharmacy. 2023;19(4):643–52. doi:10.1016/j.sapharm.2022.12.011

Hincapie AL, Alyami F, Alrasheed M, et al. Continuous quality improvement regulations for community pharmacy practice in the United States. Journal of the American Pharmacists Association (2003). 2022;62(1):285. doi:10.1016/j.japh.2021.02.008

Hindi AMK, Schafheutle EI, Jacobs S. Patient and public perspectives of community pharmacies in the United Kingdom: A systematic review. Health Expectations. 2018;21(2):409–428. doi:10.1111/hex.12639

Ilardo ML, Speciale A. The community pharmacist: Perceived barriers and patient-centred care communication. International Journal of Environmental Research and Public Health. 2020;17(2):536. doi:10.3390/ijerph17020536

Jackson J, Urick B. Performance-based pharmacy payment models: the case for change. Australian Health Review. 2019;43:502–507. doi: 10.1071/AH18201

Jacobs S, Fegan T, Bradley F, Halsall D, Hann M, Schafheutle EI. How do organisational configuration and context influence the quantity and quality of NHS services provided by English community pharmacies? A qualitative investigation. PLoS One. 2018;13(9):e0204304. doi:10.1371/journal.pone.0204304

Kruijtbosch M, Göttgens-Jansen W, Floor-Schreudering A, van Leeuwen E, Bouvy ML. Moral dilemmas reflect professional core values of pharmacists in community pharmacy. International Journal of Pharmacy Practice. 2018;27(2):140–8. doi:10.1111/ijpp.12490

Langaro M. Innovative regulatory framework in community pharmacy [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2020.

Latif A, Gulzar N, Gohil S, Ansong T. Quality improvement in community pharmacy: a qualitative investigation of the impact of a postgraduate quality improvement educational module on pharmacists understanding and practice. The International Journal of Pharmacy Practice. 2021;29(1):84-89. doi:10.1111/ijpp.12663

Latif A, Gulzar N, Lowe F, Ansong T, Gohil S. Engaging community pharmacists in Quality Improvement (QI): A qualitative case study of a partnership between a Higher Education Institute and local pharmaceutical committees. British Medical Journal Open Quality. 2021;10(1):e001047. doi:10.1136/bmjoq-2020-001047

Lias N, Lindholm T, Pohjanoksa-Mäntylä M, Westerholm A, Airaksinen M. Developing and piloting a self-assessment tool for medication review competence of practicing pharmacists based on nationally set competence criteria. BMC Health Services Research. 2021;21(1):1274. doi:10.1186/s12913-021-07291-6

Mercadante AR, Yokota M, Hwang A, Hata M, Law AV. Choosing evolution over extinction: Integrating Direct Patient Care Services and value-based payment models into the community-based pharmacy setting. Pharmacy. 2020;8(3):128. doi:10.3390/pharmacy8030128

Merks P, Świeczkowski D, Jaguszewski MJ. Patients ʾperception of pharmaceutical services available in a community pharmacy among patients living in a rural area of the United Kingdom. Pharmacy Practice. 2016;14(3):774. doi:10.18549/PharmPract.2016.03.774

Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 2018;26(5):387-397. doi:10.1111/ijpp.12462

Mirzaei A, Carter SR, Chen JY, Rittsteuer C, Schneider CR. Development of a questionnaire to measure consumers' perceptions of service quality in community pharmacies. Research in Social and Administrative Pharmacy. 2019;15(4):346-357. doi:10.1016/j.sapharm.2018.05.005

Mossialos E, Courtin E, Naci H, et al. From "retailers" to health care providers: Transforming the role of community pharmacists in chronic disease management. Health Policy. 2015;119(5):628-639. doi:10.1016/j.healthpol.2015.02.007

Moullin JC, Sabater-Hernández D, Fernandez-Llimos F, Benrimoj SI. Defining professional pharmacy services in Community Pharmacy. Research in Social and Administrative Pharmacy. 2013;9(6):989–95. doi: 10.1016/j.sapharm.2013.02.005.

Newlands RS, Power A, Young L, Watson M. Quality Improvement of community pharmacy services: A prioritisation exercise. International Journal of Pharmacy Practice.2018;26(1):39-48. doi:10.1111/ijpp.12354

Nordin N, Ahmad Hassali, MA, Sarriff A. A global picture of extended pharmacy services, perceptions, and barriers toward its performance: A systematic review. Asian Journal of Pharmaceutical and Clinical Research. 2017;10(11):417. doi: 10.22159/ajpcr.2017.v10i11.19884

Parnis MJ. Attitudes and Beliefs of Patients about Community Pharmacy Services. [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; 2020.

Policarpo V, Romano S, António JHC, Correia TS, Costa S. A new model for pharmacies? Insights from a quantitative study regarding the public's perceptions. 2019; BMC Health Services Research. 2019;19(1):186. doi: 10.1186/s12913-019-3987-3

Pringle JL, Rucker NL, Domann D, Chan C, Tice B, Burns AL. Applying value-based incentive models within community pharmacy practice. American Journal of Pharmacy Benefits. 2016;8(1):22–29

Ramachandran S, Galdo JA, Urick BY, Farley JF. Measuring Health Care Quality: Implications, threats, and opportunities for Clinical Pharmacists. Journal of the American College of clinical pharmacy (JACCP). 2021;4(1):92–100. doi: 10.1002/jac5.1355

Rawy M, Look KA, Amin MEK, Chewning B. Development and validation of a theory-based instrument to predict community pharmacists' intention to provide pharmaceutical care services. Research in Social and Administrative Pharmacy. 2021;17(4):664-676. doi:10.1016/j.sapharm.2020.06.026

Richard C, Urick BY, Pathak S, Jackson J, Livet M. Performance-based pharmacy payment models: Key Components and critical implementation considerations for successful uptake and integration. Journal of Managed Care & Specialty Pharmacy. 2021;27(11):1568–78. doi:10.18553/jmcp.2021.27.11.1568

Ross LA. Quality Improvement in health care. Annals of Pharmacotherapy. 2013;47(9):1206–9. doi: 10.1177/1060028013503128

Schindel TJ, Yuksel N, Breault R, Daniels J, Varnhagen S, Hughes CA. Pharmacists' learning needs in the era of expanding scopes of practice: Evolving practices and changing needs. Research in social & administrative pharmacy. 2019;15(4):448-458. doi:10.1016/j.sapharm.2018.06.013

Schoenmakers TW, Teichert M, Braspenning J, Vunderink L, De Smet PA, Wensing M. Evaluation of quality indicators for Dutch community pharmacies using a comprehensive assessment framework. Journal of Managed Care and Speciality Pharmacy. 2015;21(2):144-152. doi:10.18553/jmcp.2015.21.2.144

Scicluna CA, Azzopardi LM, Serracino-Inglott A. Validation instruments for community pharmacy: An update. 1st ed. Germany: Lambert Academic Publishing; 2012.

Sepp K, Cavaco AM, Raal A, Volmer D. Profession Driven Improvement of the quality of pharmacy practice—implementation of Community Pharmacy Services Quality Guidelines in Estonia. Healthcare. 2021;9(7):804. Published 2021 Jun 26. doi:10.3390/healthcare9070804

Son KB, Choi S, Kim D. Public perceptions of the roles and functions of community pharmacies in the era of expanding scopes of Pharmaceutical Practice: A questionnaire survey in South Korea. Health & Social Care in the Community. 2019;27(4):1095–101. doi:10.1111/hsc.12727

Thomas CE, Phipps DL, Ashcroft DM. When procedures meet practice in community pharmacies: Qualitative insights from pharmacists and Pharmacy Support Staff. British Medical Journal Open. 2016;6(6):e010851. doi: 10.1136/bmjopen-2015-010851

Tsuyuki RT, Beahm NP, Okada H, Al Hamarneh YN. Pharmacists as accessible primary health care providers: Review of the evidence. Canadian Pharmacists Journal. 2018;151(1):4-5. doi:10.1177/1715163517745517

Urick BY, Urmie JM. Framework for assessing pharmacy value. Research in Social and Administrative Pharmacy. 2019;15(11):1326–37. doi:10.1016/j.sapharm.2018.12.008

Vella M, Grima M, Wirth F, Attard Pizzuto M, Sammut Bartolo N, Vella J, et al. Consumer perception of community pharmacist extended professional services. Journal of Pharmaceutical Health Services Research. 2015;6(2):91-96. doi: 10.1111/jphs.12094

Vordenberg SE, Hayes L, Hermiz N, Iong SI, Kuhlman K, Lammers M, et al. Older adults ʾunderstanding of hypothetical community pharmacy quality report cards. Journal of the American Pharmacists Association. 2020;60(6):e252-e263. doi:10.1016/j.japh.2020.08.026

Watson MC, Silver K, Watkins R. How does the public conceptualise the quality of care and its measurement in community pharmacies in the UK: A qualitative interview study. British Medical Journal Open. 2019;9(3):e027198. doi:10.1136/bmjopen-2018-027198

Watson MC, Skea ZC. Jugglers and tightrope walkers: The challenge of delivering quality community pharmacy services. PLoS One. 2018 Jul 23;13(7):e0200610.. doi:10.1371/journal.pone.0200610

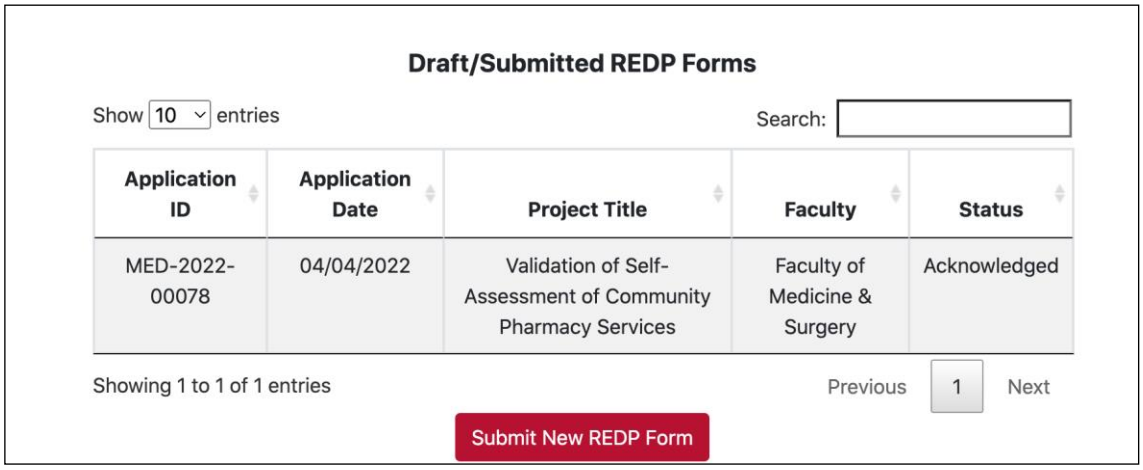
Wirth F, Tabone F, Azzopardi LM, Gauci M, Zarb Adami M, Serracino-Inglott A. Consumer perception of the community pharmacist and community pharmacy services in Malta. Journal of Pharmaceutical Health Services Research. 2011;1(4):189-194. doi: 10.1111/j.1759-8893.2010.00034

Wright DFB, Anakin MG, Duffull SB. Clinical decision-making: An essential skill for 21st-century pharmacy practice. Research in Social and Administrative Pharmacy. 2019;15(5):600–6. doi:10.1016/j.sapharm.2018.08.001

Ylä-Rautio H, Siissalo S, Leikola S. Drug-related problems and pharmacy interventions in non-prescription medication, with a focus on high-risk over-the-counter medications. International Journal of Clinical Pharmacy. 2020;42(2):786–95. doi:10.1007/s11096-020-00984-8

Appendix 1:
Study approvals

Ethics Approval



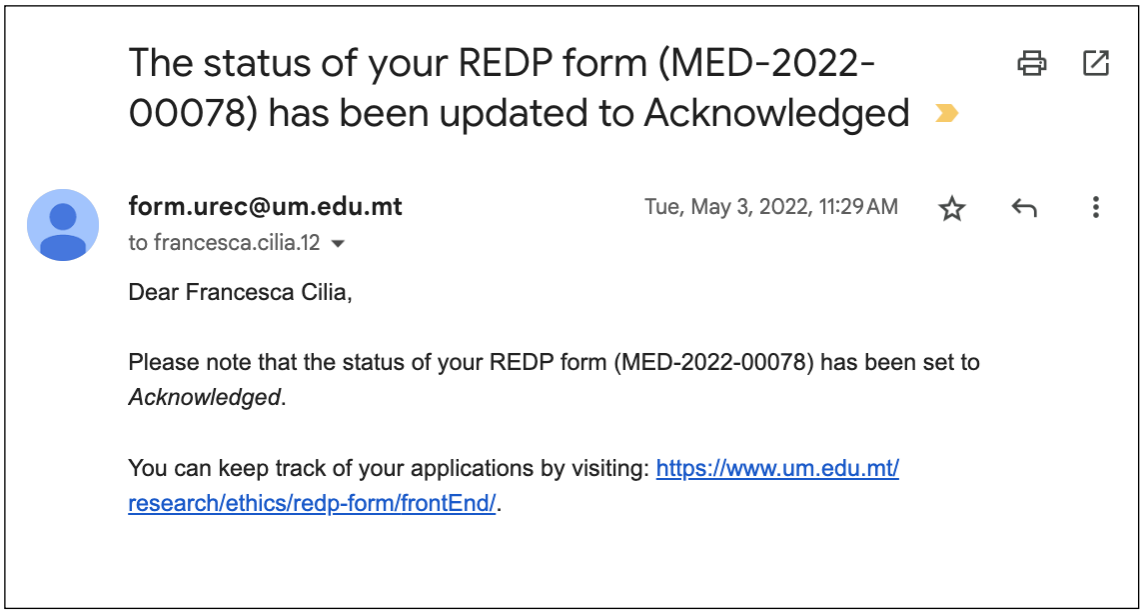
Draft/Submitted REDP Forms

Show 10 entries Search:

Application ID	Application Date	Project Title	Faculty	Status
MED-2022-00078	04/04/2022	Validation of Self-Assessment of Community Pharmacy Services	Faculty of Medicine & Surgery	Acknowledged

Showing 1 to 1 of 1 entries Previous 1 Next

Submit New REDP Form



The status of your REDP form (MED-2022-00078) has been updated to Acknowledged

form.urec@um.edu.mt Tue, May 3, 2022, 11:29 AM

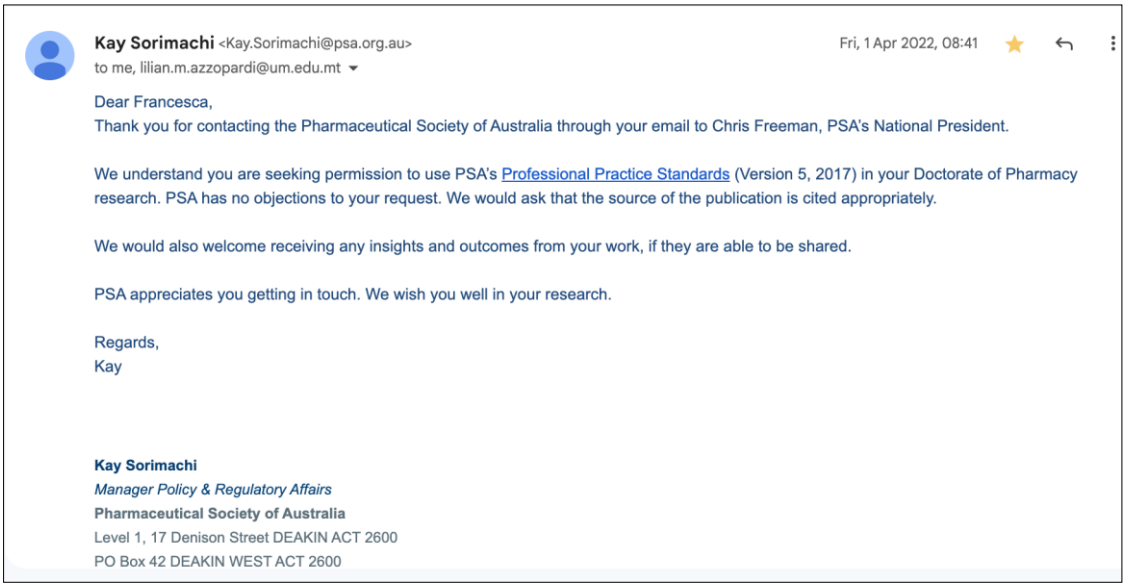
to francesca.cilia.12

Dear Francesca Cilia,

Please note that the status of your REDP form (MED-2022-00078) has been set to *Acknowledged*.

You can keep track of your applications by visiting: https://www.um.edu.mt/research/ethics/redp-form/frontEnd/.

Correspondence with Pharmaceutical Society of Australia
Policy and Regulatory Affairs Manager



Kay Sorimachi <Kay.Sorimachi@psa.org.au> Fri, 1 Apr 2022, 08:41
to me, lilian.m.azzopardi@um.edu.mt

Dear Francesca,
Thank you for contacting the Pharmaceutical Society of Australia through your email to Chris Freeman, PSA's National President.

We understand you are seeking permission to use PSA's Professional Practice Standards (Version 5, 2017) in your Doctorate of Pharmacy research. PSA has no objections to your request. We would ask that the source of the publication is cited appropriately.

We would also welcome receiving any insights and outcomes from your work, if they are able to be shared.

PSA appreciates you getting in touch. We wish you well in your research.

Regards,
Kay

Kay Sorimachi
Manager Policy & Regulatory Affairs
Pharmaceutical Society of Australia
Level 1, 17 Denison Street DEAKIN ACT 2600
PO Box 42 DEAKIN WEST ACT 2600

Appendix 2
Developed Self-Assessment Tool

Domain 1 **Professional Practice**					
1. Professional role	**Poor**	**Fair**	**Good**	**Very Good**	**Excellent**
a. Apply expert knowledge and skills in daily professional practice	1	2	3	4	5
a. Work with commitment, caution, and conscientiousness	1	2	3	4	5
a. Demonstrate accountability and responsibility in daily professional practice	1	2	3	4	5
a. Work in accordance with the principles of the pharmaceutical profession and code of ethics	1	2	3	4	5
Total Points:					
2. Regulatory requirements	**Poor**	**Fair**	**Good**	**Very Good**	**Excellent**
a. Practice in accordance with regulatory frameworks (legislation, guidelines, standards) e.g., temperature monitoring, cleanliness, good documentation, stock management	1	2	3	4	5
b. Periodically carry out assessments to identify shortcomings that could negatively impact the pharmacy's operation	1	2	3	4	5
c. Ensure that standard operating procedures and controls are in place and implemented to reduce the impact of shortcomings	1	2	3	4	5
e. Understand the importance of secure data handling e.g., files placed in a cupboard under lock and key	1	2	3	4	5
Total Points:					

3. Ethical requirements	Poor	Fair	Good	Very Good	Excellent
a. Ensure ethically sound professional practice from all pharmacy personnel	1	2	3	4	5
b. Implement measures to manage ethical issues which may arise	1	2	3	4	5
c. Act with honesty and integrity	1	2	3	4	5
d. Empower and support the patient's decisions when discussing their healthcare plan	1	2	3	4	5
Total Points:					

4. Professional autonomy	Poor	Fair	Good	Very Good	Excellent
a. Practice empathy and compassion with patients and co-workers	1	2	3	4	5
b. Apply appropriate communication skills according to patient characteristics such as age, language, level of intellectuality	1	2	3	4	5
c. Maintain appropriate personal and professional boundaries	1	2	3	4	5
d. Ensure that all patients are treated with dignity and respect irrelevant of age, disability, gender, sexual orientation, beliefs, and race	1	2	3	4	5
Total Points:					

5. Privacy and Confidentiality	Poor	Fair	Good	Very Good	Excellent
a. Respect and protect individual's rights to privacy and confidentiality	1	2	3	4	5
b. Discuss sensitive information with patients in a designated area within the pharmacy	1	2	3	4	5
c. Avoid discussing patient information with other pharmacy personnel unless necessary	1	2	3	4	5
d. Ask for informed consent when discussing patient information with other healthcare professionals, performing point-of-care tests and other pharmaceutical services	1	2	3	4	5
Total Points:					

	1	2	3	4	5	Domain 1 Points
						/100
Strengths						
Weaknesses						
Plan						

Domain 2
Patient care and medicine management

1. Effective communication	Poor	Fair	Good	Very Good	Excellent
a. Use direct and appropriate terminology when speaking to patients, caregivers, and other healthcare professionals	1	2	3	4	5
b. Confirm effectiveness of communication with patients e.g., ask patient to repeat dosage regimen	1	2	3	4	5
c. Refer to caregivers when patient is not understanding advice, with patient's consent as applicable	1	2	3	4	5
d. Recognise when care is outside pharmacist's scope, and refer patient to other appropriate healthcare professionals or healthcare services	1	2	3	4	5

Total Points:

2. Act respectfully	Poor	Fair	Good	Very Good	Excellent
a. Avoid judgmental behavior, verbally and physically, towards a patient	1	2	3	4	5
b. Support and respect rights of patient and caregivers to contribute to decision-making	1	2	3	4	5
c. Promote patient engagement with feedback and follow-up systems	1	2	3	4	5
d. Respectfully decline a medication or a service when deemed dangerous or unnecessary. Explain the reason to the patient and signpost them to a suitable healthcare professional	1	2	3	4	5

Total Points:

3. Empower patients	Poor	Fair	Good	Very Good	Excellent
a. Encourage patient to take responsibility for his/her health care by assisting in development of medication records and health care plans	1	2	3	4	5
b. Recommend and assist use of medication aids such as charts and pillboxes	1	2	3	4	5
c. Facilitate appropriate alternative access to health care services or products in circumstances such as out-of-stock medication	1	2	3	4	5
d. Organise healthcare campaigns and engage patient participation	1	2	3	4	5
Total Points:					

4. Medication management	Poor	Fair	Good	Very Good	Excellent
a. Apply a patient-centered approach to medication management and obtain relevant health and medicines information	1	2	3	4	5
b. Assess medication management needs and prompt patients who require a specific test or review e.g., need for blood tests or need for follow-up	1	2	3	4	5
c. Collaborate with the patient and healthcare team to develop a medication management strategy or plan	1	2	3	4	5
d. Implement medication management strategy or plan e.g., need for follow-up with pharmacist to ensure	1	2	3	4	5
Total Points:					

5. Patient-centred medication review	Poor	Fair	Good	Very Good	Excellent
a. Explain, assess, and confirm patient's understanding of treatment plan and duration of treatment	1	2	3	4	5
b. Review treatment plan ensuring treatment choices are evidence-based and safe	1	2	3	4	5
c. Prompt patient to disclose any therapy related problems and educate on when a patient should speak to the pharmacist or prescribing doctor	1	2	3	4	5
d. Collaborate with the patient, caregivers, and healthcare professionals. e.g., to discuss the treatment plan, in case of a need for follow-up and/or the condition has	1	2	3	4	5
Total Points:					

6. Promote health and well-being	Poor	Fair	Good	Very Good	Excellent
a. Keep well informed on health campaigns and public health initiatives programs to encourage patient participation	1	2	3	4	5
b. Support and actively participate in evidence-based public health intended to maintain and improve health	1	2	3	4	5
c. Promote a healthy diet and exercise as part of patient's overall treatment plan	1	2	3	4	5
d. Support non-pharmacological interventions to prevent and treat health conditions	1	2	3	4	5
Total Points:					

	1	2	3	4	5	6	Domain 2 Points
							/120
Strengths							
Weaknesses							
Plan							

Domain 3
Dispensing practices and counselling

1. Gather patient information	Poor	Fair	Good	Very Good	Excellent
a. Compile information as necessary on current medicines. Prompt patient to disclose all current medicines including chronic medication, non-prescription medication, vitamins, and supplements	1	2	3	4	5
b. When relevant, ask about disease states, pregnancy or lactation, recent medical interventions, smoking and alcohol intake	1	2	3	4	5
c. Prompt disclosure of previous hypersensitivity reactions or adverse drug reactions	1	2	3	4	5
d. Refer to the prescribing doctor, with patient's permission, for further clarifications of patient record and treatment plan hypersensitivity reactions or adverse drug reactions	1	2	3	4	5
Total Points:					
2. Evidence -based and relevant patient advice	**Poor**	**Fair**	**Good**	**Very Good**	**Excellent**
a. Discuss treatment in a patient-centred manner, providing adequate and balanced information to encourage patients to make informed decisions on their treatment plan	1	2	3	4	5
b. Provide preventive healthcare measures for patients and promote behavioural modifications to complement patient's healthcare plan	1	2	3	4	5
c. Apply current, accurate and evidence-based practice principles when contributing to collaborative determination of most appropriate treatment option for patient's healthcare needs and goals	1	2	3	4	5
d. Demonstrate correct and effective use of medical devices and assess and confirm patient's understanding	1	2	3	4	5
Total Points:					

3. Dispensing of medication	Poor	Fair	Good	Very Good	Excellent
a. Minimise misuse, over-use, and under-use of medication through follow-up and referral to prescriber when applicable	1	2	3	4	5
b. Implement processes e.g., Falsified Medicines Directive (FMD) code scanning to ensure optimised and safe dispensing practices and a coordinated team effort	1	2	3	4	5
c. Ensure suitable storage and handling of medicines while in transportation and at the pharmacy	1	2	3	4	5
d. Educate the patient on the safe storage and disposal of medication and medical devices	1	2	3	4	5
Total Points:					

4. Dispensing of medication	Poor	Fair	Good	Very Good	Excellent
a. Ensure that the patients and caregivers are updated with the latest treatment plan to ensure the correct administration of the dispensed medication	1	2	3	4	5
b. Facilitate continuity of care e.g., ensure repeat prescriptions are in order and updated when the patient returns from acute hospital setting or following an appointment with consultant	1	2	3	4	5
c. Prompt patients on next dates for medication collection, appointments with other healthcare professionals, or updating of prescriptions of chronic conditions	1	2	3	4	5
d. Review patient's treatment plans and flag any possible prescribing errors, risk of adverse drug reactions, or need for consultant review	1	2	3	4	5
Total Points:					

5. Compounding of medicines	Poor	Fair	Good	Very Good	Excellent
a. Ensure standard approach to determine required formulation	1	2	3	4	5
b. Ensure availability and maintenance of the required compounding equipment	1	2	3	4	5
c. Complete appropriate documentation, packaging, and labelling	1	2	3	4	5
d. Advice patient on expiry date and storage requirements	1	2	3	4	5
Total Points:					

	1	2	3	4	5	Domain 3 Points
						/100
Strengths						
Weaknesses						
Plan						

Domain 4

Collaborating with colleagues and other healthcare professionals

1. Effective inter-professional communication	Poor	Fair	Good	Very Good	Excellent
a. Effectively communicate across different health care settings to ensure appropriate transition of care	1	2	3	4	5
b. Promote cooperative relationship with other professionals to support multidisciplinary delivery of health care	1	2	3	4	5
c. Respect other professionals' work obligations and cooperate to ensure efficiency	1	2	3	4	5
d. Create culture of accountability and responsibility in all pharmacy personnel by ensuring effective communication trail	1	2	3	4	5
Total Points:					

2. Support healthcare professionals and research	Poor	Fair	Good	Very Good	Excellent
a. Identify gaps in medicines information and request it from relevant sources	1	2	3	4	5
b. Adequately report drug-related problems and adverse events experienced by a patient to the authorities	1	2	3	4	5
c. Support other professionals with queries and request for information	1	2	3	4	5
d. Participate in research	1	2	3	4	5
Total Points:					

3. Collaboration with colleagues	Poor	Fair	Good	Very Good	Excellent
a. Work together to ensure provision of a professional and effective pharmaceutical service	1	2	3	4	5
b. Delegate responsibly and ethically, taking into consideration the individual's competences, training, reliability, and job experience	1	2	3	4	5
c. Monitor work of pharmacy personnel, inform them of any shortcomings and give appropriate training to avoid reoccurrence	1	2	3	4	5
d. Support and facilitate changes in pharmacy setting, procedures, and resources	1	2	3	4	5
Total Points:					

	1	2	3	Domain 4 Points
				/60
Strengths				
Weaknesses				
Plan				

Domain 5
Training and professional development

1. Pharmaceutical professional requirements	Poor	Fair	Good	Very Good	Excellent
a. Practice in accordance with the pharmacy's standard operating procedures (SOPs)	1	2	3	4	5
b. Critically evaluate provision of pharmaceutical care, methodologies adopted and future service requirements	1	2	3	4	5
c. Ensure that set goals of the pharmacy, pharmacy personnel and management are in line with professional expectations	1	2	3	4	5
d. Ensure that employer or other stakeholders' financial incentives are utilised to optimise performance, that they do not cloud one's judgement and that patient's well-being is prioritised	1	2	3	4	5
Total Points:					

2. Lifelong learning and Continuous Professional Development	Poor	Fair	Good	Very Good	Excellent
a. Carry out self-assessment of own knowledge, identify need for training and education to optimise safe and effective pharmaceutical services	1	2	3	4	5
b. Ensure regular training on provision of non-prescription medicines, vitamins, and supplements in accordance with evidence-based guidelines	1	2	3	4	5
c. Actively monitor and carry-out performance appraisal exercises to optimise performance of pharmacy personnel	1	2	3	4	5
d. Foster a culture of lifelong learning and participate in training opportunities	1	2	3	4	5
Total Points:					

3. Leadership	Poor	Fair	Good	Very Good	Excellent
a. Exhibit emotional awareness	1	2	3	4	5
b. Work with self-motivation and an innovative	1	2	3	4	5
c. Encourage and support change, innovative thinking and attaining personal goals	1	2	3	4	5
d. Ensure efficient and effective use of resources	1	2	3	4	5
Total Points:					

	1	2	3	Domain 5 Points
				/60
Strengths				
Weaknesses				
Plan				

Domain 6
Management of stock and Pharmacy environment

1. Physical environment of the pharmacy	Poor	Fair	Good	Very Good	Excellent
a. Optimise pharmaceutical service and pharmacy environment for vulnerable patient groups e.g., wheelchair users or oncology patients ongoing chemotherapy	1	2	3	4	5
b. Ensure infection control measures are in place including the safe disposal of sharps, cytotoxic and hazardous waste	1	2	3	4	5
c. Ensure pharmacy orientation has a good flow, that stock is tidy, clean, and clearly displayed and regular cleaning of pharmacy floor, clinics, and shelves	1	2	3	4	5

Total Points:

2. Pharmacy Infrastructure	Poor	Fair	Good	Very Good	Excellent
a. Maintain a safe pharmacy environment for pharmacy personnel and patients	1	2	3	4	5
b. Ensure the availability of workforce and resources in line with workload and services provided within the pharmacy	1	2	3	4	5
c. Designate an area within the pharmacy for private conversations with patients and play background music to improve privacy	1	2	3	4	5

Total Points:

3. Stock Management	Poor	Fair	Good	Very Good	Excellent
a. Ensure appropriate rotation of stock and maintain a system that ensures timely ordering of stock	1	2	3	4	5
b. Implement a system of stock monitoring, including segregating, returning of expired, damaged, returned and recalled stock	1	2	3	4	5
c. Develop and implement a procedure to ensure safe and appropriate waste management for unused medications, DDAs and sharps	1	2	3	4	5
Total Points:					

	1	2	3	Domain 6 Points
				/45
Strengths				
Weaknesses				
Plan				

Domain 7
Quality Assurance and Quality Management

1. Risk Management	Poor	Fair	Good	Very Good	Excellent
a. Proactively monitor and manage safety risks within pharmacy environment and pharmacy community services e.g., organise appropriate refurbishment to minimise hazards	1	2	3	4	5
b. Evaluate display of prescription and non-prescription medicines and medical devices within pharmacy setting and ensure appropriate advice to minimise risks	1	2	3	4	5
c. Critically analyse and identify potential or existing risks of medication and dispensing errors with pharmacy personnel, and develop accordingly procedures to reduce errors and ensure patient safety	1	2	3	4	5
d. Regularly monitor adherence to procedures and their efficacy in minimising errors	1	2	3	4	5

Total Points:

2. Quality Management	Poor	Fair	Good	Very Good	Excellent
a. Encourage all pharmacy personnel to assess and identify issues in quality of pharmaceutical care	1	2	3	4	5
b. Develop procedures to evaluate, maintain and improve the quality of pharmaceutical care	1	2	3	4	5
c. Monitor and assess the outcomes of interventions and ensure issues are resolved	1	2	3	4	5
d. Yearly calibration of equipment such as point-of-care testing devices and thermometers	1	2	3	4	5

Total Points:

	1	2	Domain 7 Points
			/40
Strengths			
Weaknesses			
Plan			

Appendix 3:
Implementation study feedback questionnaire

Feedback on the self-assessment tool

Rate the following:	Very poor	Poor	Acceptable	Very Good	Excellent
Relevance					
Comprehensiveness					
Clarity					
Practicality					
Applicability					
How likely are you to:	**Very Unlikely**	**Unlikely**	**Neutral**	**Likely**	**Very Likely**
Perform quality indicators such as this self-assessment tool to asses the quality of service					
Participate in training to improve the service					
Identify and plan training for all the pharmacy staff					
Further Feedback on the self-assessment tool:					

Appendix 4:
Dissemination of Results

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

VALIDATION OF SELF-ASSESSMENT OF COMMUNITY PHARMACY SERVICES

Francesca Cilia, Francesca Wirth, Lilian M. Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background information:
Quality improvement measures, such as self-assessment tools, support community pharmacists in evaluating professional service provision and contribute to maintaining the quality of pharmacist professional services.

Purpose:
The objectives were to identify established quality standards and analyse pharmacy services outcomes requirements, develop and validate a self-assessment tool for clinical community pharmacy services, and evaluate the practicality of the self-assessment tool.

Method:
The methodology involved: 1) identification of quality standards for professional community pharmacy services, 2) development of a self-assessment tool for community pharmacists, 3) content validation using a two-round Delphi study with a nine-member expert panel, where a mean score ≥4.5 was used as a threshold for acceptance, 4) reliability testing using the test-retest method performed by 10 pharmacists, 5) criterion validation using the 2017 Professional Practice Standards version 5 of the Pharmaceutical Society of Australia as the gold standard, and 6) implementation of the tool in 30 community pharmacies.

Results:
Quality standards for professional pharmacy services were identified from Australia, Malta, the UK and the USA. The self-assessment tool developed consists of 7 domains namely: 1) professional practice; 2) patient care and medicine management; 3) dispensing practices and counselling; 4) collaboration with health care professionals and colleagues; 5) pharmacist training and professional development; 6) management of stock and pharmacy environment; 7) quality assurance and quality management. The self-assessment tool relies on performance rating using a Likert scale from 1 (Poor) to 5 (Excellent). Each domain consists of a self-reflection section where the pharmacist reflects to highlight strengths, and weaknesses and plan for improvement. Following round I of the Delphi study, statements were amended according to the recommendations and all statements obtained a mean score greater than 4.5 after round II. Reliability testing resulted in a Cronbach's Alpha value of 0.991, indicating high internal consistency. For criterion validation, the paired sample t-test was applied. Domains 1, 2, 3 and 4 resulted in a p-value less than 0.05 implying a significant difference between scores of the tool developed in this study and scores of the gold standard. Criterion validation was established for Domains 5, 6 and 7 ($p > 0.05$). From the implementation study: 30% (n=9) of participants rated the practicality of the tool as 'Excellent,' while 7% (n=2) rated it as 'Poor'; 33% of the participants (n=10) rated the applicability of the tool as 'Excellent', while 3% (n=1) rated it as 'Poor'. Most participants are likely to perform quality indicators (66%), participate in training (84%) and plan for training of pharmacy personnel (70%) to improve the quality of their pharmaceutical service.

Conclusion:
The validated self-assessment tool may be used as a quality indicator for community pharmacies. The tool allows for accountability, continuous improvement and consistency in the provision of quality care and contributes to improved trust in the community pharmacist.

Topic Area:
Community Pharmacy Section