Development and Validation of a Quality System for Community Pharmacy Practice

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Dedicated to my family and partner for their continuous support and encouragement.

Abstract

Quality performance instruments focusing on different service aspects are developed for community pharmacy practice. This study aimed to design, validate, and implement a community pharmacy quality framework (CPQF) and standard operating procedure (SOP) templates covering quality aspects. It also aimed to test the feasibility of implementing the developed quality system. The methodology involved: (1) a literature review to identify the main quality aspects in community pharmacy practice, (2) design of the CPQF and SOPs through Maltese Legislation and published global pharmacy practice standards, (3) validation of the documentation through a focus group, (4) thematic analysis, (5) design and validation of a Feasibility Questionnaire and (6) questionnaire dissemination to 14 community pharmacies identified through stratified random sampling. Data analysis was undertaken and the Friedman Test and Kruskal Wallis Test were applied. The literature analysis performed led to the determination of quality aspects in relation to community pharmacy practice: (1) Care, (2) Safety, (3) Improvement and (4) Services. The four quality aspects were each subdivided into pertinent sections. Four SOPs related to these quality aspects were designed. Five main findings were noted from the Feasibility Questionnaire (N=14): (1) eight participants strongly agree and five agree that the quality system designed can help standardise quality aspects in community pharmacy practice in Malta, (2) eight participants strongly agree and six agree that the SOPs cover all aspects checked within an inspection, (3) nine participants strongly agree and four agree that they will pass the inspection when using these SOPs, (4) A significant difference between the mean rating scores of the statements within the Layout ($p=0.013$) and Use ($p=0.006$) section was noted. There was no significant difference between the mean rating scores within the Applicability ($p=0.146$) section, (5) The mean rating scores vary significantly between the different districts with

regards to CPQF ease of use (p=0.040) and SOP use prior to an inspection (p=0.013). This variability can be attributed to the low scores provided by the Northern Harbour district. The study has delivered a validated Framework and interlinked SOPs for the assessment of quality of community pharmacy services.

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List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CPPQ	Community Pharmacy Patient Questionnaire
CPQF	Community Pharmacy Quality Framework
CPRA	Community Pharmacy Regulatory Audit
CPSQG	Community Pharmacy Services Quality Guidelines
FIP	International Pharmaceutical Federation
IBM	International Business Machines Corporation
ISMP	Institute for Safe Medication Practices
MaPSaF	Manchester Patient Safety Assessment Framework
MMA	Malta Medicines Authority
MSSA®	Medication Safety Self-Assessment®
NHS	National Health Service
PQA	Pharmacy Quality Alliance
PSOPSC™	Pharmacy Survey on Patient Safety Culture™
SAQ	Safety Attitudes Questionnaire
S.L.	Subsidiary Legislation

SOP	Standard Operating Procedure
SPSS	Statistical Package for the Social Sciences
WHO	World Health Organisation

Chapter 1: Introduction

1.1.Assessing Quality in Community Pharmacy

In healthcare, quality portrays a large spectrum of perceptions such as "accreditation and certification, compliance with rules and regulations, meeting established levels, use of modern equipment, efficiency and performing inspections".[1]

Quality within the community pharmacy setting is very dynamic as it incorporates multiple aspects (Halsall *et al.*, 2012). Various instruments have been developed internationally to ensure or better the quality in pharmacies (Azzopardi, 2000; Ashcroft *et al.*, 2005; Halsall *et al.*, 2008; Parker *et al.*, 2008; Ashcroft & Parker 2009; Nordén-Hägg *et al.*, 2010; Scicluna, 2011; Teinilä *et al.*, 2012; Flynn, 2015; Schoenmakers *et al.*, 2015; Shiyanbola & Mort, 2015; Teichert *et al.*, 2016; Attard, 2018; Lawati *et al.*, 2018; Bratkowska *et al.*, 2020; Langaro, 2020; Sepp *et al.*, 2021a; Sepp *et al.*, 2021b).

1.1.1. North America

Numerous quality tools were developed within North America namely the American and Canadian Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® (MSSA®) for community and ambulatory pharmacy[2], The Pharmacy Quality Alliance (PQA) quality indicator measures[3], The Agency for Healthcare Research

[1] International Pharmaceutical Federation (FIP). Quality Care Standards in Community Pharmacy [Internet]. Hillerød (Denmark): FIP; 2005 [cited 2021 Mar 04]. Available from: https://www.fip.org/files/fip/CPS/Quality%20Care%20Standards%20final.pdf

[2] Institute for Safe Medication Practices (ISMP). Medication Safety Self Assessment® for Community/Ambulatory Pharmacy [Internet]. Pennsylvania (United States of America): ISMP; 2017 [cited 2020 Mar 14]. Available from: https://www.ismp.org/assessments/community-ambulatory-pharmacy

[3] Pharmacy Quality Alliance (PQA). PQA Measures Overview [Internet]. Virginia (United States of America: PQA; 2021 [cited 2022 Mar 22]. Available from: https://www.pqaalliance.org/assets/Measures/PQA_Measures_Overview.pdf

and Quality (AHRQ) Pharmacy Survey on Patient Safety Culture™ (PSOPSC™)[4] and the adapted Canadian Safety Attitudes Questionnaire (SAQ) (Colla *et al.*, 2005; Sexton *et al.*, 2006).

1.1.1.1.United States

The ISMP MSSA® for community and ambulatory pharmacy[2] (Colla *et al.*, 2005; Halsall *et al.*, 2008) was created to identify the importance of distinguishing all forms of practices related to safety within a pharmacy setting (Teinilä *et al.*, 2012). The use of the MSSA® decreases patient harm regarding medicines, from the preparation to the dispensing aspect. This assessment helps the pharmacy to perform risk evaluation over a period of time.[2] Development of the ISMP instrument involved a thorough literature review related to medication errors and the capability to decrease such errors. According to the ISMP, any statements found in this self-assessment are present to show pharmacists what the ideal situation should be. This encourages pharmacies to reach a high level of safety with regards to medication errors (Halsall *et al.*, 2008).

The PQA developed three different types of measures related to monitoring and performing measures and quality indicators for improvement. The general domains of the measures encompass medication safety, adherence to therapy, appropriate use of

[2] Institute for Safe Medication Practices (ISMP). Medication Safety Self Assessment® for Community/Ambulatory Pharmacy [Internet]. Pennsylvania (United States of America): ISMP; 2017 [cited 2020 Mar 14]. Available from: https://www.ismp.org/assessments/community-ambulatory-pharmacy

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

medication and management of medication.[3] Shiyanbola & Mort (2015) performed a focus group and developed a questionnaire as a tool to assess patients' perception to the PQA quality measures with regards to choosing a community pharmacy. The tool developed by Shiyanbola & Mort (2015) showed that patients would not change their community pharmacy based on quality measures, however, the quality indicators might influence the general selection.

The AHRQ developed a Survey on Patient Safety Culture™ program in 2001.[5] The original survey was developed for hospital use. The AHRQ further developed surveys to be used in Medical Offices, Nursing Homes, Community Pharmacy and Ambulatory Surgery Centres. The PSOPSC™ released in 2012 [5] consists of 36 items which measure 11 factors associated with the culture of patient safety (Aboneh *et al.*, 2016; Aboneh *et al.*, 2020). These factors include "physical space and environment, teamwork, staff training and skills, communication openness, patient counseling, staffing work pressure and pace, communication about prescriptions across shifts, communication about mistakes, response to mistakes, organizational learning – continuous improvement, overall perceptions of patient safety". [4] The AHRQ performed a pilot study with 55 community pharmacies across the United States (Aboneh *et al.*, 2016; Aboneh *et al.*, 2020). Aboneh *et al.* (2016) assessed the survey factors defined by the AHRQ by sending out the survey to 543 pharmacies in the United States. The confirmatory factor analysis

[3] Pharmacy Quality Alliance (PQA). PQA Measures Overview [Internet]. Virginia (United States of America: PQA; 2021 [cited 2022 Mar 22]. Available from: https://www.pqaalliance.org/assets/Measures/PQA_Measures_Overview.pdf

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

[5] Agency for Healthcare Research and Quality (AHRQ). About SOPS [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/about/index.html

performed showed that the original structure was inadequate with the exploratory factor analysis showing that the ideal structure includes 27 items and four factors. These factors include "safety related communication, staff training and work environment, organizational response to safety events and staffing work pressure and pace" (Aboneh *et al*., 2016). Aboneh *et al.* (2016) showed that the original AHRQ survey model does not reflect the community pharmacy setting.

1.1.1.2. Canada

The Canadian ISMP adapted the MSSA® from the ISMP of the United States of America.[2] This tool aims to create a sense of awareness with regards to distinguishable characteristics related to medication safety in the pharmacy. The Canadian MSSA® is used as a safety and quality improvement tool whilst providing ways of improvement evaluation as time passes by. [6] The instrument is used by the pharmacy staff as a form of self-assessment through a questionnaire (Halsall *et al.,* 2008).

Kong *et al.* (2020) made use of the SAQ (Colla *et al.*, 2005; Sexton *et al.*, 2006) that was adapted by Nordén-Hägg *et al.* (2010) for use in Sweden. The same six factors and 40 items were kept in the SAQ distributed to pharmacists and pharmacy technicians in Saskatchewan. The SAQ was re-distributed in 2021. The factors that scored the highest in both years included teamwork and safety culture. Despite the global coronavirus

[2] Institute for Safe Medication Practices (ISMP). Medication Safety Self Assessment® for Community/Ambulatory Pharmacy [Internet]. Pennsylvania (United States of America): ISMP; 2017 [cited 2020 Mar 14]. Available from: https://www.ismp.org/assessments/community-ambulatory-pharmacy

[6] Institution for Safe Medication Practices (ISMP) Canada. Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy™ [Internet]. Ontario (Canada): ISMP Canada; 2020 [cited 2020 Mar 12]. Available from: https://www.ismp-canada.org/amssa/index.htm

pandemic, the scores obtained in 2021 were similar or better than those obtained in 2018. It was noted that the score for Stress Recognition was lower in 2021. [7]

1.1.2. Europe

Quality instruments from European countries like Malta, the United Kingdom, the Netherlands, Finland, Sweden, and Estonia were identified and discussed.

1.1.2.1.Malta

Azzopardi (2000) developed internal and external validation instruments for community pharmacy practice (Table 1.1).

Table 1.1: The Internal and External Validation Tools

Internal Validation Tools	External Validation Tools
1. "The Setting of the Community Pharmacy 2. Dispensing of Prescription 3. Responding to Symptoms 4. Communicating with the Patient 5. Equipment and Professional Services Available in a Community Pharmacy" (Azzopardi, 2000)	1. "Consumer Services Tool 2. Health Professionals Tool" (Azzopardi, 2000)

[7] Institution for Safe Medication Practices (ISMP) Canada. An Assessment of Safety Culture in Saskatchewan Community Pharmacies 2021 Edition [Internet]. Ontario (Canada): ISMP Canada; 2021 [cited 2023 Jan 30]. Available from: https://saskpharm.ca/document/8674/SK_SAQ_ Report_Final_20210902.pdf

The purpose of the internal validation tools is to look at professionalism in the service and care provided regarding medicine dispensing and symptom response in a community pharmacy setting. The instrument was developed by observing the services provided by community pharmacists (Halsall *et al*., 2008).

The external validation tools look at what the views of customers and allied health care professionals (that are not pharmacists) are regarding how effective the pharmacy is in patient care. The instrument was developed in a similar way to the internal tools, with the difference being that interviews were also performed. In the Consumer Services Tool, the consumers are questioned on the type of service they provided, their overall satisfaction and the service provided by the staff and community pharmacist. In the Health Care Professionals Tool, allied health care professionals are asked about their satisfaction of the pharmacy services, whether they utilise the pharmacy as a space to consult with pharmacists regarding their patients' drug treatments and their overall perception of pharmacists as health care professionals (Halsall *et al*., 2008).

Scicluna (2011) updated the internal and external validation tools as per newer guidelines and knowledge gap identification. Clinical governance was added as the sixth internal validation tool due to the evolvement of this topic in pharmacy. A website including such tools was developed in the process (Scicluna, 2011). Flynn (2015) further updated the validation tools in place without identifying new tools.

Attard (2018) designed a Community Pharmacy Regulatory Audit (CPRA) tool by analysing previously performed CPRA reports by the Malta Medicines Authority (MMA)

and performing interviews with community pharmacists. The tool includes seven main sections, one of which is a checklist designed around Maltese legislation and regulations. The main sections within the checklist include "standard operating procedures, storage of medicinal products, locum register and the pharmacist, daily medicine dispensing register, dangerous drug register, cupboard and stock takes, extemporaneous preparations, the premises, and miscellaneous items" (Attard, 2018).

Langaro (2020) designed a self-audit protocol consisting of two self-audits, (1) Pharmacist Competencies and (2) Regulatory. The Pharmacist Competencies Self-Audit was designed to identify the competency of pharmacists with regards to the good pharmacy practice guidelines. The Regulatory Self-Audit includes the updated version of the CPRA designed by Attard (2018). The main updates include an increase in the number of questions and the option to perform the CPRA as a pharmacist and not just as an auditor.

1.1.2.2.United Kingdom

Various quality tools are used within the United Kingdom, namely the Community Pharmacy Contractual Framework[8], the Community Pharmacy Assurance Framework[9], the Maturity Matrix for Community Pharmacy (Halsall *et al.,* 2008), the Manchester Patient Safety Assessment Framework (MaPSaF) (Aschroft *et al.,* 2005), the Patient

[8] Pharmaceutical Services Negotiating Committee (PSNC). Community Pharmacy Contractual Framework [Internet]. Date not applicable [cited 2022 Mar 23]. Available from: https://psnc.org.uk/contract-it/the-pharmacy-contract/

[9] National Health Service (NHS) Business Service Authority. Community Pharmacy Assurance Framework (CPAF) [Internet]. Newcastle (United Kingdom): NHS Business Service Authority; 2020 [cited 2020 Mar 14]. Available from: https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/community-pharmacy-assurance-framework-cpaf

Safety Climate Questionnaire (Ashcroft & Parker, 2009) and the Community Pharmacy Patient Questionnaire (CPPQ).[10]

The Community Pharmacy Contractual Framework[8] was developed by the National Health Service (NHS) in deliberation with pharmacists and primary care trusts (Halsall *et al*., 2008). The framework consists of three types of community pharmacy services, these being "essential services"[8], "advanced services"[8], and "locally commissioned services".[8] Part of this framework encompasses contract monitoring.[11]

The Community Pharmacy Assurance Framework [9] was developed as part of the NHS contract monitoring procedure. It is done yearly to comply with the contract for community pharmacies. All pharmacies are obliged to fill in the screening questionnaire, the results of which are published on the NHS business service authority portal. Visits are scheduled according to the score obtained in the questionnaire. Clinical governance is mainly addressed in this tool. This assessment aims to monitor pharmacies and their conformity to the regulations within the Community Pharmacy Contractual Framework.[8]

[8] Pharmaceutical Services Negotiating Committee (PSNC). Community Pharmacy Contractual Framework [Internet]. Date not applicable [cited 2022 Mar 23]. Available from: https://psnc.org.uk/contract-it/the-pharmacy-contract/

[9] National Health Service (NHS) Business Service Authority. Community Pharmacy Assurance Framework (CPAF) [Internet]. Newcastle (United Kingdom): NHS Business Service Authority; 2020 [cited 2020 Mar 14]. Available from: https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/community-pharmacy-assurance-framework-cpaf

[10] Pharmaceutical Services Negotiating Committee (PSNC). Patient Satisfaction Survey [Internet]. London (United Kingdom): PSNC; 2021 [cited 2022 Mar 22]. Available from: https://psnc.org.uk/contract-it/essential-service-clinical-governance/cppq/

[11] Pharmaceutical Services Negotiating Committee (PSNC). Contract Monitoring [Internet]. London (United Kingdom): PSNC; 2021 [cited 2022 Mar 23]. Available from: https://psnc.org.uk/contract-it/the-pharmacy-contract/contract-monitoring/

The Maturity Matrix for Community Pharmacy aims to provide the opportunity for pharmacies to record any practice profiles in order to compare the information with other pharmacies. Development of this tool involved the assessment of the original tool which was designed for general practice. It is an instrument used for quality-improvement (Halsall *et al*., 2008).

The MaPSaF was developed to be used in primary care facilities to help identify any progress made regarding patient safety. The instrument was constructed to aid NHS institutions. The MaPSaF is based on Westrum's theory about how establishments process any information (Westrum, 2004). This was further elaborated through other studies and applied to safety. Five safety culture levels were obtained: "pathological, reactive, calculative, proactive, and generative" (Ashcroft *et al.*, 2005; Kirk *et al.*, 2007; Phipps *et al.*, 2018). Different studies state that the tool measures eight (Ashcroft *et al.*, 2005; Phipps *et al.*, 2018), or nine (Kirk *et al.*, 2007; Parker *et al.*, 2008; Parker, 2009; Lawati *et al.*, 2018) dimensions related to safety within a primary care setting including "overall commitment to quality and safety; incident causation and reporting; investigation of patient safety incidents; learning from patient safety incidents; communication about safety issues; staff management and safety issues; education and training about safety; team working around safety issues" (Phipps *et al.*, 2018). Ashcroft *et al*. (2005) adapted the framework to community pharmacy by creating a focus group with pharmacists practising in the community setting. Review of the original framework exhibited the possibility of adapting this framework to the community pharmacy profession. Phipps *et al.* (2018) characterised the levels of safety culture organisation according to a community pharmacy setting. The pathological level is when the pharmacist refuses to use an incident as a learning opportunity unless enforced by a pharmacy inspector. The

reactive level is when there is little if any learning only related to the inconvenience experienced. The calculative level is when there are some processes in place to support learning which is limited to local improvements and not shared across the organisation. The proactive level is when a learning tradition is present within the pharmacy and systems about sharing what one has learnt like audits and reflection are available. The generative level is when there is commitment to distribute knowledge and information throughout the organisation and improvements occur without an incident occurring (Phipps *et al.*, 2018). Phipps *et al.* (2018) carried out improvement workshops whilst using the MaPSaF in ten community pharmacies. A behavioural change framework was designed following a follow up focus group. This study concluded that it is crucial to create an environment that supports improvement within the pharmacy and for teams to be ready to engage in improvement activities (Phipps *et al.*, 2018).

The Patient Safety Climate Questionnaire (Colla *et al.,* 2005; Halsall *et al*., 2008; Ashcroft & Parker, 2009) aims to monitor the safety climate inside a community pharmacy. It was adapted from the MaPSaF. The scores obtained from the questionnaire aid pharmacists in identifying any shortcomings within the pharmacy (Halsall *et al.*, 2008). It measures the agreement of statements based on different themes: "commitment to patient safety, communication in the pharmacy, staffing and management, education and training about safety, team working, perceptions of the causes of incidents, incident reporting, investigating incidents and learning following an incident" (Ashcroft & Parker, 2009).

The CPPQ[10] aims to obtain patients' criticism regarding the services provided in the pharmacy. This leads to the identification of any areas that require improvement. British pharmacies are encouraged to utilise this questionnaire to identify any weaknesses present within their ongoing systems. The CPPQ was developed due to the need for a new contractual framework for pharmacy practice in the United Kingdom. This questionnaire measures the stakeholder's views allowing for a full view of quality within the pharmacy (Halsall *et al.*, 2008). Bratkowska *et al.* (2020) adapted the CPPQ used in the United Kingdom to the Polish community pharmacy setting. The study evaluated the satisfaction of patients with the services provided within Polish pharmacy chains and independent pharmacies using the CPPQ.[10]

1.1.2.3.Netherlands

In 2008, the Dutch Health Care Transparency Programme developed a set of quality indicators for the Netherlands. The quality indicators validity was assessed using an Indicator Assessment Framework (Schoenmakers *et al.,* 2015; Teichert *et al.,* 2016). Schoenmakers *et al.* (2015) performed an expert panel to assess the current 52 quality indicators by applying the criteria of the Indicator Assessment Framework. Teichert *et al.* (2016) designed and disseminated a quality indicator Survey Tool to all Dutch pharmacies. The quality indicators were divided into ten main categories related to follow-ups, training, counselling, quality management, general compounding, care continuation, risk management, dispensing, patient communication and main logistics (Teichert *et al.,* 2016).

[10] Pharmaceutical Services Negotiating Committee (PSNC). Patient Satisfaction Survey [Internet]. London (United Kingdom): PSNC; 2021 [cited 2022 Mar 22]. Available from: https://psnc.org.uk/contract-it/essential-service-clinical-governance/cppq/

1.1.2.4.Finland

Teinilä *et al.* (2012) adapted the ISMP MSSA® for community and ambulatory pharmacy[2] (Colla *et al.*, 2005; Halsall *et al.*, 2008) for community pharmacy practice in Finland. Due to differences in Finnish and American legislations and regulations the MSSA® was adjusted accordingly. The adjustments were made following a three phase Delphi questionnaire. This tool was piloted within Finnish pharmacies with another questionnaire to further refine the tool to the Finnish community pharmacy setting (Teinilä *et al.*, 2012).

1.1.2.5.Sweden

Nordén-Hägg *et al.* (2010) adapted the SAQ (Colla *et al.*, 2005; Sexton *et al.*, 2006) to be used in Swedish community pharmacy. The SAQ was previously used to explore relationships between the culture of safety in primary care and the final patient outcome. Nordén-Hägg *et al.* (2010) distributed a 40 item SAQ to all Swedish pharmacies to help them map out their safety culture. The SAQ is composed of six factors: teamwork, safety, management perceptions, stress recognition, job satisfaction and general labour conditions (Nordén-Hägg *et al.*, 2010; Nordén-Hägg *et al.*, 2012). The six factors are framed in a generic way with changes only including references to the different setting (Nordén-Hägg *et al.*, 2010; Nordén-Hägg *et al.*, 2012).

[2] Institute for Safe Medication Practices (ISMP). Medication Safety Self Assessment® for Community/Ambulatory Pharmacy [Internet]. Pennsylvania (United States of America): ISMP; 2017 [cited 2020 Mar 14]. Available from: https://www.ismp.org/assessments/community-ambulatory-pharmacy

1.1.2.6.Estonia

In 2012, the Estonian Community Pharmacy Services Quality Guidelines (CPSQG) were developed. The Estonian guidelines were further updated in 2016 and 2021. The CPSQG were designed to compose the general principles of community pharmacy service quality and to identify service evaluation criteria. Ten main chapters with information related to counselling, health promotion, provision of services, medicine handling, premises, management, professional development, communication, legislation, and ethics are present within the CPSQG. The guidelines include more than 100 different quality indicators. Three voluntary based self-evaluations were performed in 2014, 2016 and 2019. A self-assessment tool was designed and distributed among the Estonian pharmacies (Sepp *et al.,* 2021a; Sepp *et al.,* 2021b).

1.1.3. Australia

The Quality Care in Pharmacy Program was designed and implemented in 1997 by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia (Halsall *et al.,* 2008; Alhusein & Watson, 2019). The Quality Care in Pharmacy Program provides a framework for pharmacies to deliver a professional service which is safe, consistent and of a high quality. It is based on the Australian Standard 85000:2017 which describe a quality management system within pharmacies.[12] This quality assurance program accredits a community pharmacy based on an on-site assessment, with re-accreditation performed every two years. The most recent update was in 2020.[13] The Quality Care 2020 led to the introduction of five quality domains, these being: "Pharmacy Management and

[12] Quality Care Pharmacy Program (QCPP). What is QCPP [Internet]. Australia: QCPP; 2022 [cited 2022 Mar 21]. Available from: https://www.qcpp.com/about-qcpp/what-is-qcpp

[13] The Pharmacy Guild of Australia. Quality Care 2020 [Internet]. Australia: The Pharmacy Guild of Australia; 2019 [cited 2022 Mar 21]. Available from: https://www.guild.org.au/news-events/news/forefront/v09n15/quality-care-2020

Governance, Consumer Centred Care, Human Resources, Premises, Infrastructure and Stock, and Pharmacy Services" [14]

Community pharmacies are provided with a preparation checklist prior to the official assessment period. Pharmacies are required to provide evidence of compliance across relevant high-risk areas within seven days. Up to 21 days after performing the assessment, the pharmacy receives corrective actions which must be addressed and amended immediately to obtain accreditation. The three main categories include non-conformance which is of major risk, remedial action required which is of moderate risk and observation which is of low risk. [15]

1.1.4. Asia

The AHRQ validated PSOPSC™ [4] was used within community pharmacies in Malaysia (Sivanandy *et al.*, 2016), Kuwait (Alsaleh *et al.*, 2018), Abu Dhabi (Alslubi & El-Dahiyat, 2019), Qatar (Owusu *et al.*, 2020), Saudi Arabia (Almalki *et al.*, 2021), Iraq (Jasim & Jamal, 2021) and Lebanon (Radwan & Salameh, 2023).

Alsaleh *et al.* (2018) and Owusu *et al.* (2020) adapted the questionnaire by including more questions regarding professional characteristics and demographics. The 11 factors were

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

[14] Quality Care Pharmacy Program (QCPP). Preparing For Your Assessment [Internet]. Australia: QCPP; 2020 [cited 2022 Mar 21]. Available from: https://www.qcpp.com/assessment/preparing-for-your-assessment

[15] Quality Care Pharmacy Program (QCPP). Quality Care 2020 Assessments [Internet]. Australia: QCPP; 2020 [cited 2022 Mar 21]. Available from: https://www.qcpp.com/assessment/quality-care-2020-assessments

not altered. Sivanandy *et al.* (2016) noted a positive response rate of 67% for the culture of patient safety while Alsubi & El-Dahiyat (2019) obtained a 74.7% positive response rate. These results were higher than that obtained for the PSOPSC™ [4] used in a hospital setting in Taiwan (Chen & Li, 2010) and in Chinese hospital pharmacies (Jia *et al.*, 2014). Alsaleh *et al.* (2018) noted that the greatest positive response rate was obtained for the teamwork, continuous improvement, and patient counselling domains. Owusu *et al.* (2020) and Radwan & Salameh (2023) noted that in their individual studies, the highest positive responses were seen within the teamwork and patient counselling domains. Owusu *et al.* (2020) noted that staffing and work pressure within the pharmacy requires improvement due to the low scores obtained. This result was also seen in the original AHRQ pilot study and the studies by Jia *et al.* (2014), Sivanandy *et al.* (2016), Alsaleh *et al.* (2018), Alsubi & El-Dahiyat (2019), Almalki *et al.* (2021) and Jasim & Jamal (2021).

1.2.Aims and Objectives

The aims of the study were to design, validate, and implement a community pharmacy quality framework (CPQF) and standard operating procedure (SOP) templates covering the quality with respect to care, safety, services, and improvement. It aims to test the feasibility of implementing the quality system developed through an expert group.

The objectives of the study were:

(1) Identify quality systems in different countries across the world which apply to community pharmacy practice.

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

(2) Develop and validate a quality system by creating SOPs and a framework system.

(3) Testing the feasibility of implementation of the quality system developed through an expert group and by disseminating in community pharmacies in Malta.

Chapter 2: Methodology

2.1.Research Design and Overview

The flow diagram seen in Figure 2.1 depicts the design of the study. The methodology was divided into two distinct phases. The first phase of the study consisted of qualitative research techniques. A literature review was performed to identify quality aspects in community pharmacy practice. The CPQF and four SOPs were designed and validated through a focus group. Following a thematic analysis, the CPQF and SOPs were adjusted according to the recommendations put forward by the members. The second phase of the study consisted of quantitative research techniques wherein a Feasibility Questionnaire was designed, validated, and disseminated. Statistical analysis of the Feasibility Questionnaire results was undertaken.

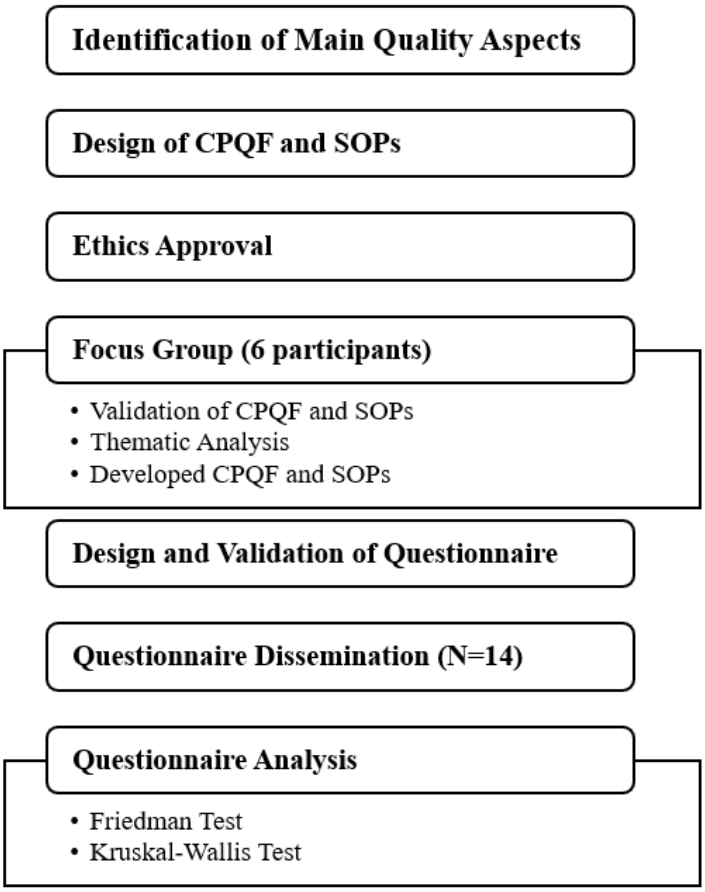

Figure 2.1: Flow Diagram Depicting the Study Design.

2.2.Literature Review

A thorough literature review was performed to identify the main quality aspects in community pharmacy practice. Journal articles were sourced from electronic databases including PubMed, Google Scholar, and Hybrid Discovery, the University of Malta search getaway. Key words used for the research of relevant journal articles included: *community pharmacy standards, patient care, patient safety, quality improvement, quality in community pharmacy, quality indicators, quality instrument, quality framework, quality standards, quality tools, quality.* In addition to this search, reference lists from the retrieved articles were examined for potential studies. Student dissertations were sourced from Hybrid Discovery and the University of Malta's Institutional Repository.

The undergraduate and postgraduate dissertations by Azzopardi (2000), Scicluna (2012), Flynn (2015), Attard (2018) and Langaro (2020) were reviewed. Pharmacy practice standards from the following sources were reviewed: the WHO, FIP, The NHS of England, The Pharmaceutical Society of Australia, The ISMP and The Public Health of England.

Relevant Maltese legislation including Subsidiary Legislations (S.L.) and Chapters related to pharmacy practice were reviewed. Table 2.1 depicts the number and name of each legislation used.

Table 2.1: Maltese Legislation.

Maltese Legislation	Name
Chapter 464	Health Care Professionals Act [16]
Chapter 458	Medicines Act [17]
S.L. 31.18	Drugs (Control) Regulations [18]
S.L. 101.02	Internal Control of Dangerous Drugs Rules [19]
S.L. 458.16	Pharmacy Licence Regulations [20]
S.L. 458.32	Medicinal Products (Advertising) Regulations [21]
S.L. 458.49	Prescription and Dispensing Requirements Rules [22]
S.L. 458.52	Dispensing of Medicinal Products (Foundation for Social Welfare Services) Rules [23]

[16] Ministry for Justice, Culture and Local Government. Chapter 464 Health Care Professionals Act [Internet]. Valletta (Malta): The Ministry; 2003 [cited 2021 Mar 18]. Available from: https://legislation.mt/eli/cap/464/eng/pdf

[17] Ministry for Justice, Culture and Local Government. Chapter 458 Medicines Act [Internet]. Valletta (Malta): The Ministry; 2003 [cited 2021 Mar 18]. Available from: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1

[18] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 31.18 Drugs (Control) Regulations [Internet]. Valletta (Malta): The Ministry; 1985 [cited 2020 Dec 22]. Available from: https://legislation.mt/eli/sl/31.18/eng/pdf

[19] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 101.02 Internal Control of Dangerous Drugs Rules [Internet]. Valletta (Malta): The Ministry; 1939 [cited 2020 Dec 22] Available from: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=9261

[20] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.16 Pharmacy Licence Regulations [Internet]. Valletta (Malta): The Ministry; 2007 [cited 2021 Mar 09]. Available from: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11256&l=1

[21] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.32 Medicinal Products (Advertising) Regulations [Internet]. Valletta (Malta): The Ministry; 2005 [cited 2021 Aug 21]. Available from: https://legislation.mt/eli/sl/458.32/eng/pdf

[22] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.49 Prescription and Dispensing Requirements Rules [Internet]. Valletta (Malta): The Ministry; 2006 [cited 2020 Dec 22] Available from: https://legislation.mt/eli/sl/458.49/eng/pdf

[23] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 458.52 Dispensing of Medicinal Products (Foundation for Social Welfare Services) Rules [Internet]. Valletta (Malta): The Ministry; 2008 [cited 2020 Dec 22] Available from: https://legislation.mt/eli/sl/458.52/eng/pdf

2.3.Design and Structure of the CPQF and SOPs

The framework was designed to include five main sections (Appendix 1). The first section was an introductory section which briefly described the research project and the importance of exerting professional judgement when using the documentation. The other four sections represented the four quality aspects identified during the literature review.

One table for each quality aspect was presented. The general layout included two table columns; the quality aspect sub-sections were included within one column while the relevant statements were included in the other column. Each quality aspect section included declarative statements rather than imperative statements to act as a guide thus allowing pharmacists to exert their professional judgement according to the scenario they are in. The relevant references were included at the back of the document.

Four SOPs were designed (Appendix 2) according to the quality aspects described within the CPQF. Each SOP included the purpose and scope, general definitions of certain words included in the SOP, the individuals responsible for following the SOP, Health and Safety Requirements, the Procedure, References and Appendices. A section entitled reason for revisions was included even though the procedure was new.

All statements within the procedure section were subdivided according to the sub-sections specified within the CPQF. Each SOP was given an SOP Code and SOP Title in order to distinguish between them.

2.4.Ethics Approval

Following the design of the CPQF and SOPs, ethics approval was sought from the Faculty Research Ethics Committee of the Faculty of Medicine and Surgery. The submitted documentation included the CPQF, Focus Group Questions, Focus Group Information Letter (English), Feasibility Questionnaire, Pharmacy Information Letter (English), Research Proposal, Research Protocol, University Research Ethics Committee Form, and the Curriculum Vitale of the Researcher.

The research project was granted ethics approval through the reference number: 8909_27052021 (Appendix 3). The application was filed for record and audit purposes as no issues were identified in the self-assessment.

2.5.Focus Group

Purposive recruitment was used to identify the individuals taking part in the group. Two community pharmacists, two pharmacists working at the MMA, two academic pharmacists, two healthcare professionals and two lay people were selected. The ten respondents were individually contacted via electronic mail and provided with an engagement letter explaining the research project. A consent form was given to each participant. Upon agreement, a date was chosen depending on the participants' availabilities. Six respondents attended the session. The focus group was executed in a semi-structured form wherein guide questions were used to initiate a discussion between the members. The focus group took place on an online videoconferencing platform.

The session was divided into four parts. During the first part, the interviewer described the purpose of the focus group and the planned session layout. The participants were instructed to introduce themselves to each other prior to commencing the next part. In part two, the participants were asked to express their thoughts regarding the concept of having a quality framework for community pharmacy practice. In part three, the participants were asked about each quality aspect within the CPQF and their relevant SOP. In the final part, the participants were asked to discuss the general presentation of the documents and their viability and feasibility within a community pharmacy setting.

The emic perspective (Hennink, 2014) of the participants was obtained by recording the discussion and transcribing the dialogue. Before recording the session, the participants were asked for their consent and given the option to withdraw themselves from the group. The interviewer demonstrated reflexivity to avoid influencing the discussion in any way. The discourse was analysed by considering any group dynamics present (Hennink, 2014; Roller & Lavrakas, 2015).

2.6.Qualitative Analysis

A stepwise thematic analysis was performed in order to code the qualitative data obtained from the focus group. The themes selected were related to the general topics discussed during the focus group. The transcript was analysed thoroughly for the presence of sub-themes. Each sub-theme was reviewed to ensure the ideal fit within the thematic analysis (Braun & Clarke, 2006; Lauri, 2019).

Any recommendations put forward by the focus group members were used to adjust the CPQF and the SOPs accordingly. The focus group was utilised as a form of validation of the documentation.

2.7.Development and Validation of the Feasibility Questionnaire

A Feasibility Questionnaire directed towards community pharmacists was developed (Appendix 4). The demographics collected from this questionnaire included the pharmacy locality, pharmacy district and the duration of time using the documentation in days. The questionnaire consisted of three sections with regards to the CPQF and SOPs:

(1) Layout

(2) Use

(3) Applicability

Each section comprised of closed ended statements with a 5-point Likert scale. The layout section was designed to understand whether the CPQF and SOPs covered the majority of quality aspects present in a community pharmacy setting, their ease of use, whether their wording allows for professional judgement to take place and whether the majority of aspects checked in a MMA inspection are present. Twelve closed ended and two open ended questions were included within the Feasibility Questionnaire. The open-ended questions were worded in a way to only be answered if the pharmacist answering the questionnaire disagreed or strongly disagreed with a statement in order to obtain more information. The use section (four closed ended questions) was designed to understand whether pharmacists believe that the CPQF and SOPs can be a useful reference tool within a pharmacy setting. The applicability section (six closed ended questions) was designed to understand whether pharmacists would make use of such documentation prior

to a MMA inspection. All closed ended questions present within the Feasibility Questionnaire were compulsory.

The Feasibility Questionnaire was validated by the focus group members that attended the session. A questionnaire was forwarded to each participant via electronic mail. The face and content validity performed led to the introduction of two open ended questions within the layout section. The original demographics collected were modified to exclude the name of the community pharmacy and the name of the managing pharmacist for confidentiality purposes. Other minor changes obtained through the validation process were considered.

2.8.Dissemination of the Feasibility Questionnaire

Stratified random sampling was used to identify the pharmacies that will test the feasibility of the CPQF and SOPs. Three pharmacies from each of the five districts in Malta were randomly selected using a random generator.

Each managing pharmacist was individually contacted and provided with an information letter explaining the research project along with a consent form. Upon agreement, the managing pharmacist was provided with a soft copy of the CPQF and of each SOP via electronic mail. A few hard copies of the documentation were kept in hand in case the pharmacist preferred hard over soft copies. The managing pharmacist was instructed to self-administer a hard copy of the Feasibility Questionnaire within 14 days of obtaining and utilising the CPQF and SOPs to assess the effectiveness of the templates within a

community pharmacy setting. After the 14 days the pharmacists were followed up with a reminder by means of a telephone call. All self-administered questionnaires were collected personally by the researcher. The questionnaire data was inputted into Microsoft Excel to analyse accordingly.

2.9.Quantitative Analysis

Descriptive statistics of the data collected from the Feasibility Questionnaire were obtained using Microsoft Excel. International Business Machines Corporation (IBM) Statistical Package for the Social Sciences (SPSS) version 24 was used for statistical analysis of the Feasibility Questionnaire data. The pharmacy districts were coded numerically in order to be inputted into SPSS: Southern Harbour = 1; Northern Harbour = 2; Southeastern = 3; Western = 4; Northern = 5. The Likert Scale data was coded numerically as follows: Strongly Disagree = 0; Disagree = 1; Neutral = 2; Agree = 3; Strongly Agree = 4. The mean rating scores for each statement were obtained through SPSS. This was calculated by taking an average of the numerical Likert Scale data described above, wherein a mean rating score greater than three indicates agreement and one less than two indicates disagreement.

Two statistical tests were performed using SPSS, the Friedman Test and the Kruskal-Wallis Test. The Friedman Test was utilised to provide a comparison between the mean rating scores of similar statements within the questionnaire sections of ‘Layout’, ‘Use’ and ‘Applicability’. The Kruskal-Wallis Test was utilised to provide a comparison for the mean rating scores obtained for each statement between the five Maltese districts. A 0.05 level of significance was considered for each test.

2.10. Dissemination

An abstract was submitted to the FIP Brisbane 2023 Conference. The abstract of the study was accepted as a poster presentation.

Chapter 3: Results

3.1. CPQF Characterisation

The literature analysis performed led to the determination of four quality aspects in relation to community pharmacy practice as depicted in Figure 3.1. Each quality aspect was further subdivided into pertinent sections.

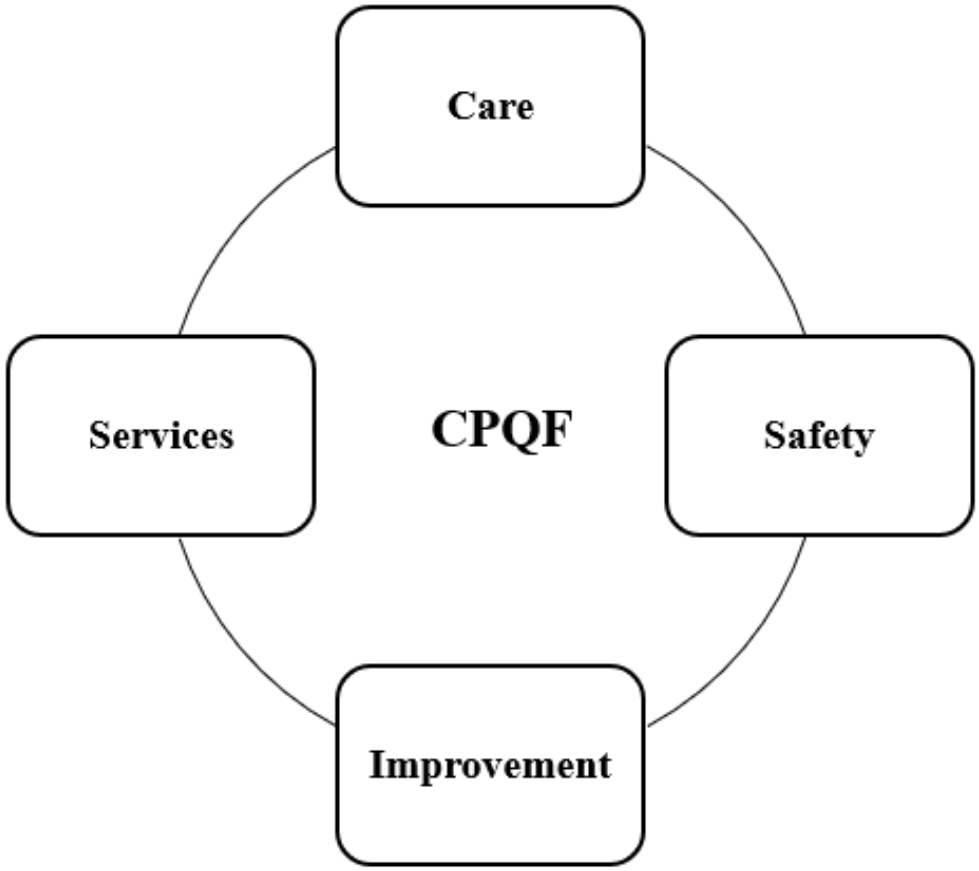

Figure 3.1: The CPQF Quality Aspects

3.1.1. Quality of Care

The care quality aspect was characterised into six sections (Figure 3.2).

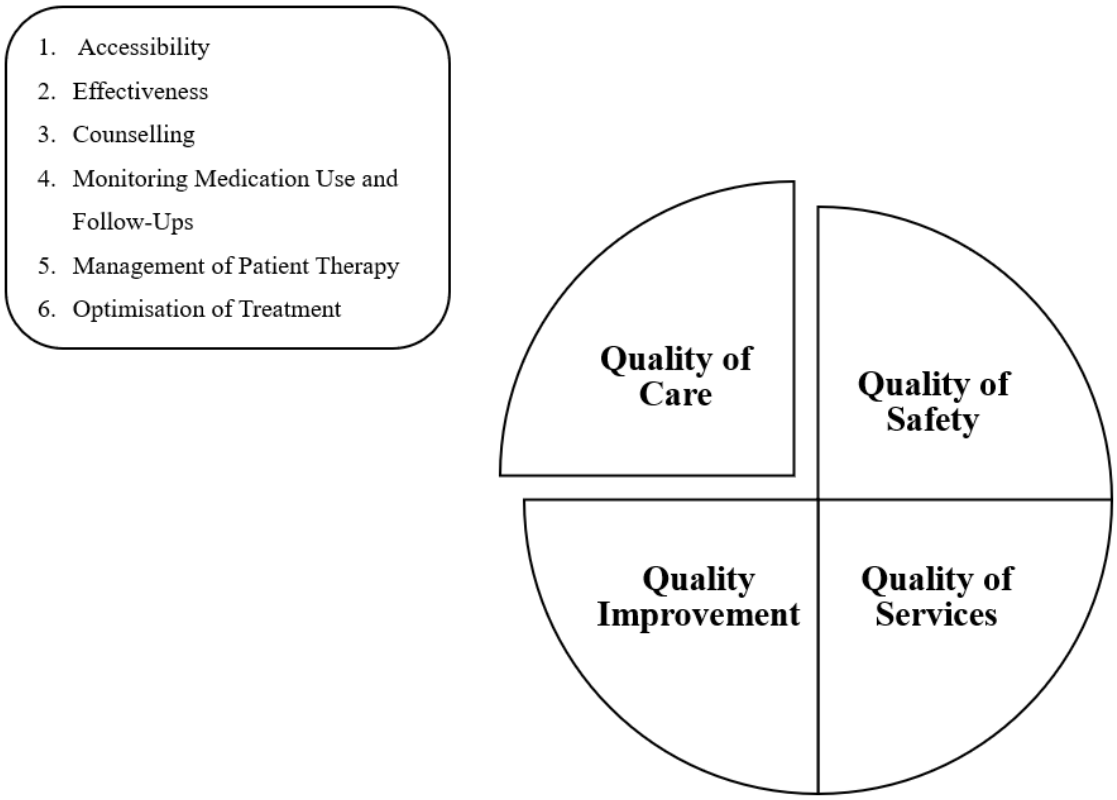

Figure 3.2: Quality of Care Sections

The 'Accessibility' section includes statements to describe the accessibility of pharmacists to their patients, substitution of branded medication to generic medication and management of drug shortages. The 'Effectiveness' section includes statements to describe the dispensing of medications in an effective, economical, rational, safe, and efficacious way. The 'Counselling' section includes statements to describe patient empowerment in self-care and patient advice including, how to use a medicinal device, use of a medication with food, timing of medication and side effects. The 'Monitoring Medication Use and Follow-Up' section includes statements to describe monitoring patients purchasing non-prescription medications for inappropriate reasons and to

identify needs for follow-ups especially for high risk patients. The 'Management of Patient Therapy' section includes statements to describe the importance of providing patients with all the necessary information regarding their health, patient autonomy, and patient referral when the patients' care is beyond the pharmacists' ability. The 'Optimisation of Treatment' section includes statements to describe the use of medication charts or pill boxes to optimise adherence.

3.1.2. Quality of Safety

The safety quality aspect was characterised into eight sections (Figure 3.3).

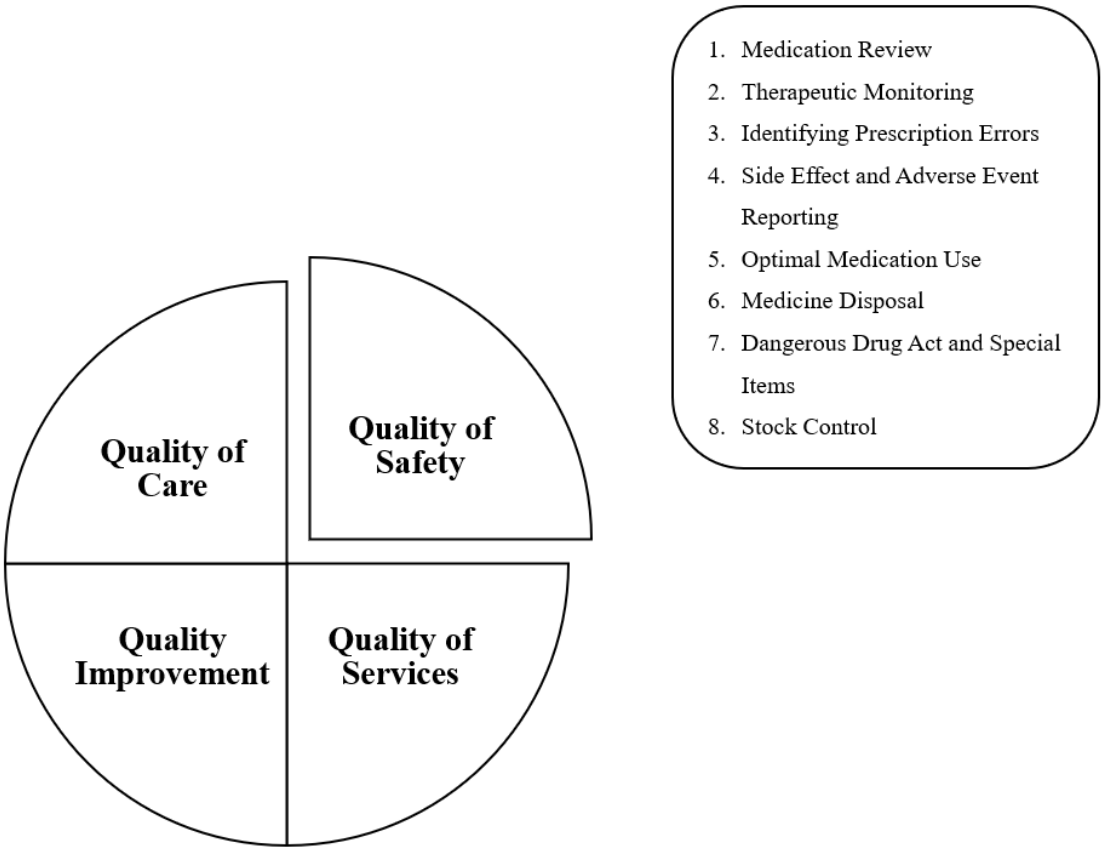

Figure 3.3: Quality of Safety Sections

The ‘Medication Review’ section includes statements to describe contraindications to treatment, adverse drug reactions, polypharmacy and deprescribing and physician referral upon identification of issues in the patient care plan. The ‘Therapeutic Monitoring’ section includes a statement to describe use of point of care testing to recommend alterations in treatment to prescriber. The ‘Identifying Prescription Errors’ section includes statements to describe adequate hand over between shifts to minimise errors and verifying errors noted with the prescriber. The ‘Side Effect and Adverse Event Reporting’ section includes statements to describe adverse event reporting to the MMA, patient side effect reporting to the MMA and development of internal systems to monitor errors and misuse as a means of discussion between staff. The ‘Optimal Medication Use’ section includes statements to describe use of appropriate measuring or medical devices to measure or take a dose of medication. The ‘Medicine Disposal’ section includes statements to describe the importance of patient awareness on incorrect medicine disposal. The ‘Dangerous Drug Act and Special Items’ section includes statements to describe the dangerous drug registers and their format, storage and dispensing of dangerous drugs, stock takes of dangerous drugs, postage of green prescriptions to the relevant authorities and stoma, and catheter care. The ‘Stock Control’ section includes statements to describe temperature registers, temperature descriptions according to medicinal packaging, thermometer calibration, storage of medication with look-a-like packaging, systematic storage systems, expiry date monitoring and stock rotation, discontinued or recalled medications, decommissioning medicinal products as per the falsified medicines directive and pest control.

3.1.3. Quality Improvement

The improvement quality aspect was characterised into three sections (Figure 3.4).

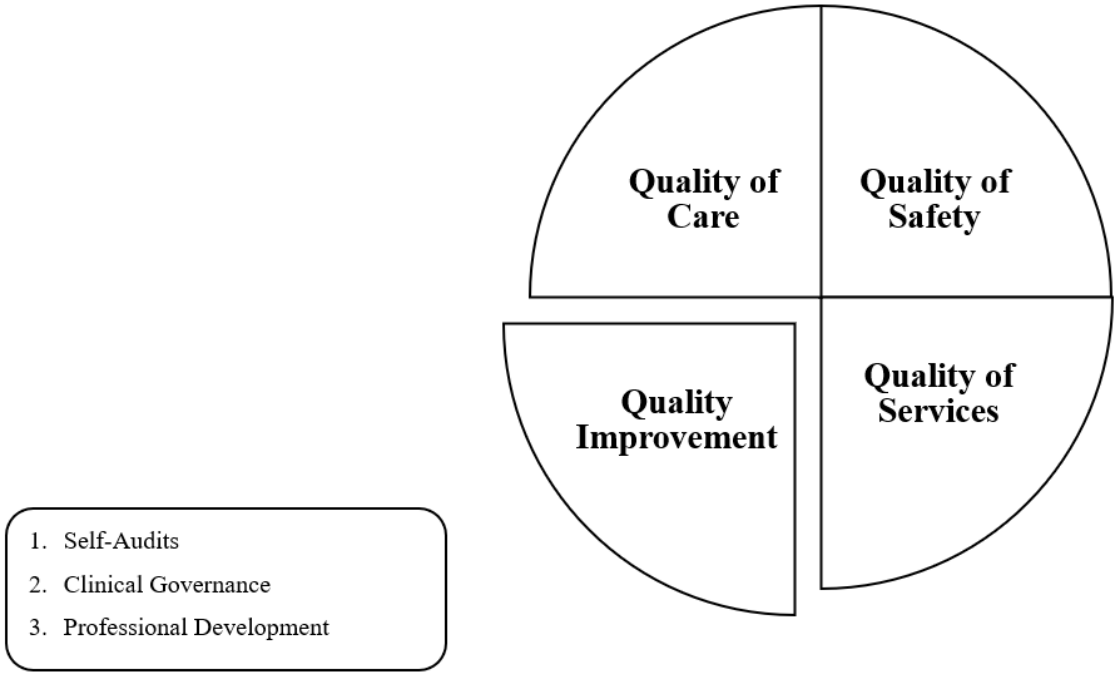

Figure 3.4: Quality Improvement Sections

The ‘Self-Audits’ section includes statements to describe the use of the CPRA tool and what an audit within a community pharmacy should cover. The ‘Clinical Governance’ section includes statements to describe the use of systems to enhance patient health outcomes. The ‘Professional Development’ section includes statements to describe continuous education, maintaining and improving professional competency, and the importance of training of staff.

3.1.4. Quality of Services

The services quality aspect was characterised into four sections (Figure 3.5).

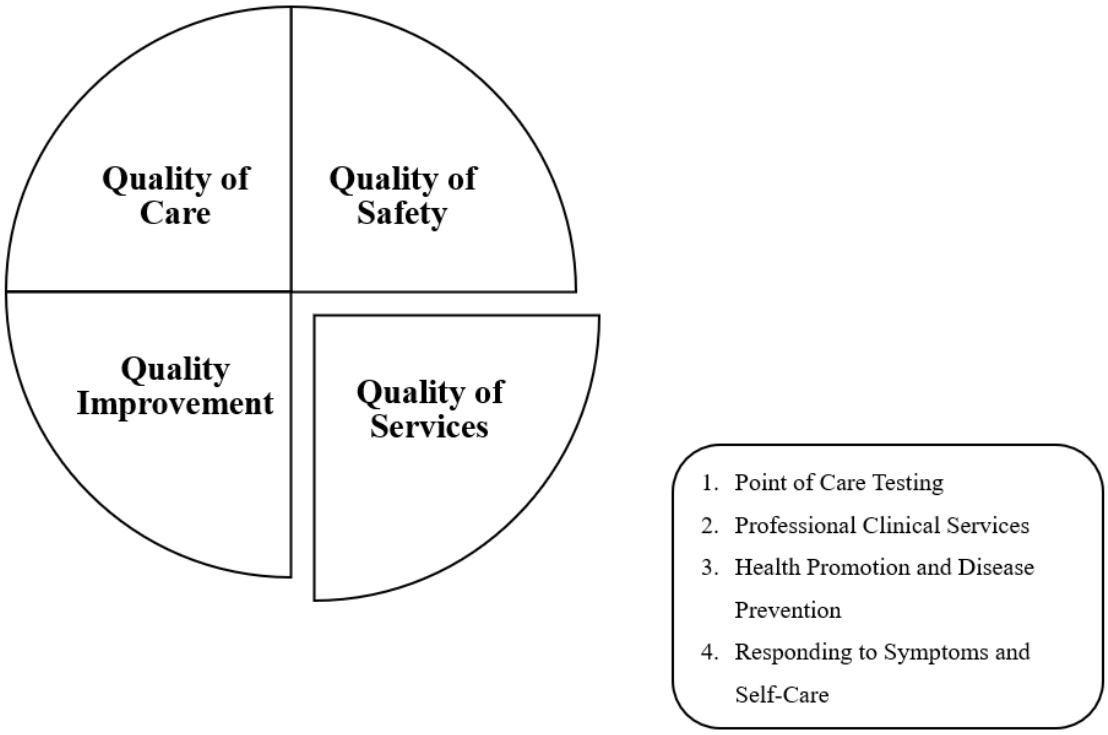

Figure 3.5: Quality of Services Sections

The 'Point of Care Testing' section includes statements to describe staff training about point of care tests, counselling after carrying out point of care tests, setting procedures on how to handle needle stick injuries, calibration of devices and documentation sheets for each point of care test. The 'Professional Clinical Services' section includes statements to describe cleaning equipment between use, ensuring presence of appropriate equipment for extemporaneous preparations, labelling extemporaneous preparations, appropriate dispensing with partially dispensed, repeat and non-repeat prescriptions, dispensing register contents and use, validity of repeat prescriptions and prescriptions containing an anti-bacterial agent, handling a prescribers verbal instructions by a telephone call, re-

checking prior to dispensing and delivery services using the schemes offered by the government. The 'Health Promotion and Disease Prevention' section includes statements to describe participation in health campaigns, providing lifestyle advice, basing materials provided within the pharmacy on scientific evidence, ensuring that prescription only medications and narcotics are not promoted and patient awareness of chronic diseases. The 'Responding to Symptoms and Self-Care' section includes statements that describe the process pharmacists should follow when responding to a patients' symptoms, including familiarisation with the patient, obtaining their medical and treatment history, elaboration of symptoms and referral if appropriate.

3.2.SOP Characterisation

Four SOP's related to the quality aspects discussed in the CPQF were designed. The SOP code and title are as follows:

(1) QUALITY-01: Quality of Care

(2) QUALITY-02: Quality of Safety

(3) QUALITY-03: Quality Improvement

(4) QUALITY-04: Quality of Services

3.3.CPQF and SOP Validation

The CPQF and SOPs were adjusted according to suggestions put forward by the focus group members. Table 3.1 depicts the six major changes made to the documents.

Table 3.1: Changes to the CPQF and SOPs

Quality Aspect	CPQF or SOP	Change
Quality of Care	CPQF and SOP	Words like 'convince' were changed to 'advise' thus switching the pharmacist approach from a policing one to advisory one.
	CPQF and SOP	Statements regarding drug shortages were included.
Quality of Safety	CPQF and SOP	Statements regarding anti-tampering devices and decommissioning medicinal products were included.
	SOP	Two flow charts were introduced within the quality of safety SOP: how to dispense a dangerous drug and how to report an adverse drug reaction to the MMA.
	SOP	The Adverse Drug Reaction and Medication Error Report Form were included as an appendix.
Quality of Services	CPQF and SOP	Statements regarding delivery services offered by the government were included.

3.4.Focus Group Members Perception

The first emerging theme from the thematic analysis performed was related to the Framework Concept. It consisted of five main sub-themes: Accountability, Safeguarding the Profession, Standardisation, Harmonisation and Revisions. The sub-themes and the relevant quotations from the focus group are depicted in Table 3.2.

Table 3.2: Quotations from the focus group depicting the framework concept theme and its relevant sub-themes.

Theme 1: Framework Concept	
Sub-Theme	**Extract From the Focus Group Discussion**
Accountability	"The more accountable that the pharmacists are at an individual and holistic level the better it is for the profession."
Safeguarding the Profession	"In harmonising the way that professionals conduct their work we would help the professionals adhere to procedures and safeguard their roles and always be aware of their responsibilities and duties to themselves, to the profession and to their patient."
Standardisation	"Having such a framework will standardise the practice. It will harmonise the procedures and I think this is very important so that all of us are doing the same thing."
Harmonisation	"There are different professionals working within the pharmacy….sometimes there are individuals that find adhering to the different SOPs difficult or daunting, so having these operations in place would help not just the professional to have this harmonisation in the practice but also for the development of the professional to become more accountable and professional in their role."
Revisions	"I think there needs to be a deadline in the far future to outline if the SOPs are still current and following all the regulations." "I agree that maybe it has to be revised before other SOPs are because it is a new process in a way so you don't know if it is working or not in how it is standardised or not."

The second emerging theme from the focus group analysis was related to Care. It consisted of four main sub-themes: Medicine Stock Management, Advise, Empowerment and Equity. The sub-themes and their relevant quotations from the focus group are depicted in Table 3.3.

Table 3.3: Quotations from the focus group depicting the care theme and its relevant sub-themes.

Theme 2: Care	
Sub-Theme	**Extract From the Focus Group Discussion**
Medicine Stock Management	"When the pharmacist finds a patient that needs a particular medication and that medication is out of stock, what can be done, where does the pharmacist stop himself at the moment and other tools that can be provided."
Advise	"Advise is nicer in this context. To go away from a policing role to an advisory role."
Empowerment	"We are moving onto empowering the patients by making them take charge of their own care…rather than imposing on them we are teaching them to take charge of their health in a direct way."
Equity	"Pharmacists can discuss generic substitutions irrelevant of financial abilities…..if I know that the patient is living on a pension that comment would become even more important, but I think that its irrespective of that."

The third emerging theme from the focus group analysis was related to Safety. It consisted of one main sub-theme: Prescription Errors. The sub-theme and its relevant quotation from the focus group are depicted in Table 3.4.

Table 3.4: Quotation from the focus group depicting the safety theme and its relevant sub-theme.

Theme 3: Safety	
Sub-Theme	**Extract From the Focus Group Discussion**
Prescription Errors	"Adopt a strategy being using by another country or another institution on how prescription errors can be minimised."

The fourth emerging theme from the focus group analysis was related to Improvement. It consisted of one main sub-theme: Compulsory Training. The sub-theme and its relevant quotation from the focus group are depicted in Table 3.5.

Table 3.5: Quotation from the focus group depicting the improvement theme and its relevant sub-theme.

Theme 4: Improvement	
Sub-Theme	**Extract From the Focus Group Discussion**
Compulsory Training	"If not compulsory it should be incentivised, in particular as science is changing every day and we have new knowledge which is coming out every day."

The fifth emerging theme from the focus group analysis was related to Services. It consisted of two main sub-themes: Recommendations Versus Advertisements and Delivery Services. The sub-themes and their relevant quotations from the focus group are depicted in Table 3.6.

Table 3.6: Quotations from the focus group depicting the services theme and its relevant sub-themes.

Theme 5: Services	
Sub-Theme	**Extract From the Focus Group Discussion**
Recommendations Versus Advertisements	"You can promote Nurofen®, but you can't promote a prescription only medicine, you can also promote cosmeceuticals" "If you are recommending a lifestyle modification or a service, you are recommending it and not advertising it. This can be a bit of a troublesome comment."
Delivery Services	"Delivery services can be introduced in the SOP….from a regulatory perspective we are seeing a lot of missing knowledge about it." "I think most pharmacies are understaffed and unable to do these deliveries."

The sixth and final emerging theme from the focus group analysis was related to Presentation and Dissemination. It consisted of one main sub-theme: Diagrammatic Representation. The sub-theme and its relevant quotations from the focus group are depicted in Table 3.7.

Table 3.7: Quotations from the focus group depicting the presentation and dissemination theme and its relevant sub-theme.

Theme 6: Presentation and Dissemination	
Sub-Theme	**Extract From the Focus Group Discussion**
Diagrammatic Representation	"You can just print the flow chart and put it somewhere in the pharmacy." "Lately we're seeing that in Malta we have a shortage of pharmacists and a lot of foreigners are coming to Malta to work as pharmacists. Sometimes some pharmacists won't manage to find a managing pharmacist to manage a pharmacy. So, I think that having detailed steps like how to dispense against a white prescription, green prescription."

3.5.CPQF and SOP Layout

Fourteen valid questionnaires were collected from the managing pharmacists working in the participating community pharmacies. The data obtained from the questionnaire was not normally distributed as it was skewed to the left. A significant difference between the mean rating scores of the statements within the layout section of the questionnaire was noted (Friedman Test, $p=0.013$). This implies that scores obtained vary between statements.

Six separate statements were used to ask participants about their opinion regarding whether the documentation is clear and thorough, well structured, and easy to use and follow.

The majority of participants (n=12) agree or strongly agree that the CPQF (mean rating score: 3.36) and SOPs (mean rating score: 3.29) are clear and thorough. Eleven participants agree or strongly agree that the CPQF is well structured (mean rating score: 3.21) and easy to use and follow (mean rating score: 2.93). All participants agree or strongly agree that the SOPs are well structured (mean rating score: 3.50) and easy to use and follow (mean rating score: 3.43). Figures 3.6 and 3.7 display the pharmacist perception about the CPQF and SOP layout.

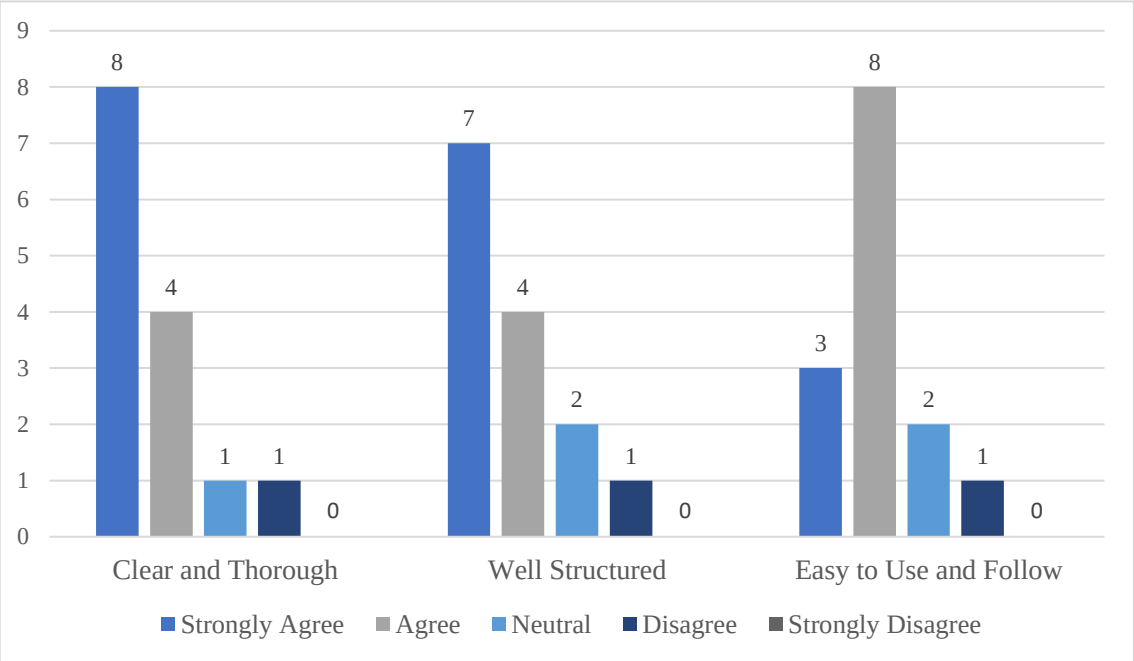

Figure 3.6: Pharmacist perception of CPQF layout with regards to whether the CPQF is clear and thorough, well structured and easy to use and follow (N=14).

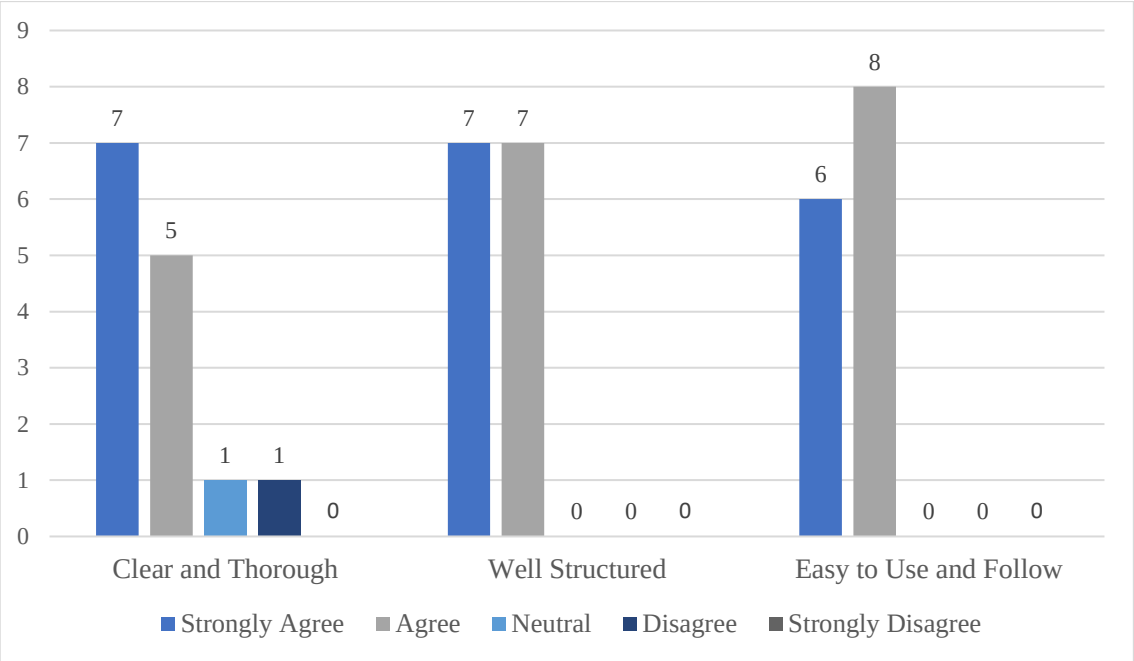

Figure 3.7: Pharmacist perception of SOP layout with regards to whether the SOPs are clear and thorough, well structured and easy to use and follow (N=14).

The CPQF ease of use statement obtained the lowest mean rating score within the layout section of the questionnaire. The mean rating scores of this statement vary significantly between the different districts (Kruskal-Wallis Test, p=0.040): Southern harbour, Northern harbour, Southeastern, Western and Northern. This is attributed to the low scores provided by the Northern Harbour district as depicted in Table 3.8. The remaining statements within the layout section have mean rating scores that vary marginally between the different districts as the p-values are greater than 0.05.

Table 3.8: CPQF ease of use mean rating scores according to the district.

		Mean Rating Score	p-value
The CPQF structure is easy to use and follow.	Southern harbour	3.33	0.040
	Northern harbour	1.67	
	Southeastern	3.00	
	Western	3.00	
	Northern	3.67	

The majority of participants agree or strongly agree that both the CPQF (mean rating score: 3.50) and SOPs (mean rating score: 3.21) cover the main quality aspects present within a community pharmacy setting. Eight participants strongly agree and six participants agree that the SOPs created cover the majority of aspects checked during a MMA inspection (mean rating score: 3.57). This statement obtained the highest mean rating score from the layout section of the questionnaire. Figure 3.8 displays the pharmacist perception of whether the documentation covers the main quality aspects in a pharmacy.

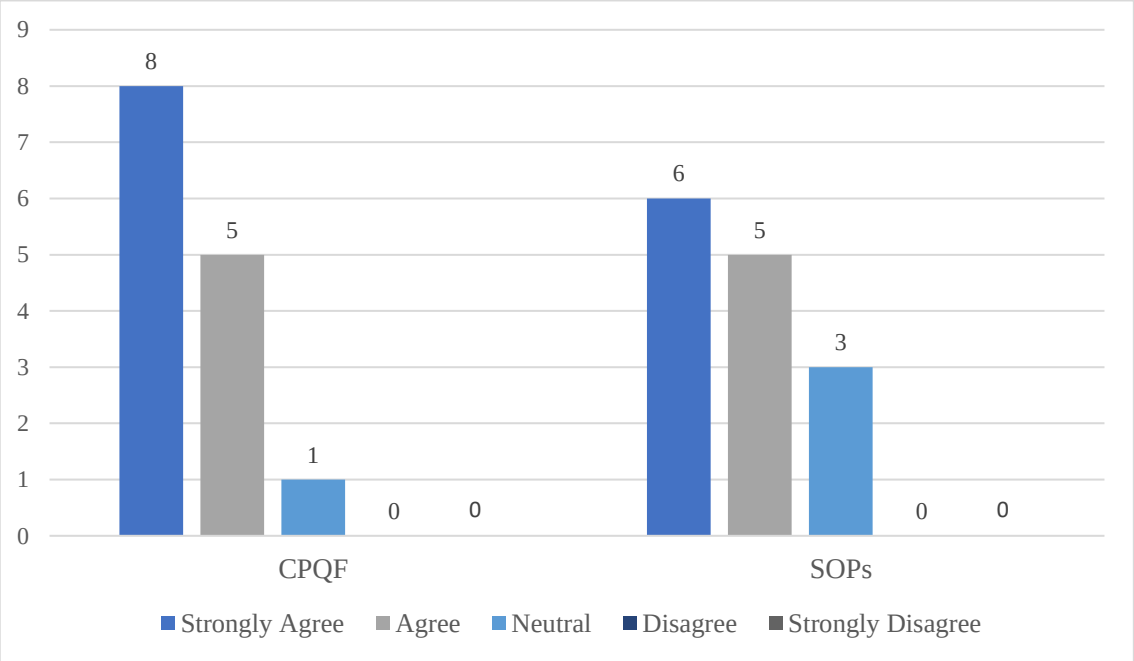

Figure 3.8: Pharmacist perception of whether the CPQF and SOPs cover the main quality aspects in a community pharmacy setting (N=14).

Five participants strongly agree, six agree, two are neutral and one disagrees with the statement 'The SOPs are able to be modified according to the needs of the pharmacy' (mean rating score: 3.07). When asked whether the structure of the CPQF and SOPs allows for fluidity within the community pharmacy setting, the majority of participants agreed (n=6) or strongly agreed (n=6) while two provided a neutral response (mean rating

score: 3.29). The mean rating scores of the perception of pharmacists regarding modification of the quality system documentation can be seen in Figure 3.9.

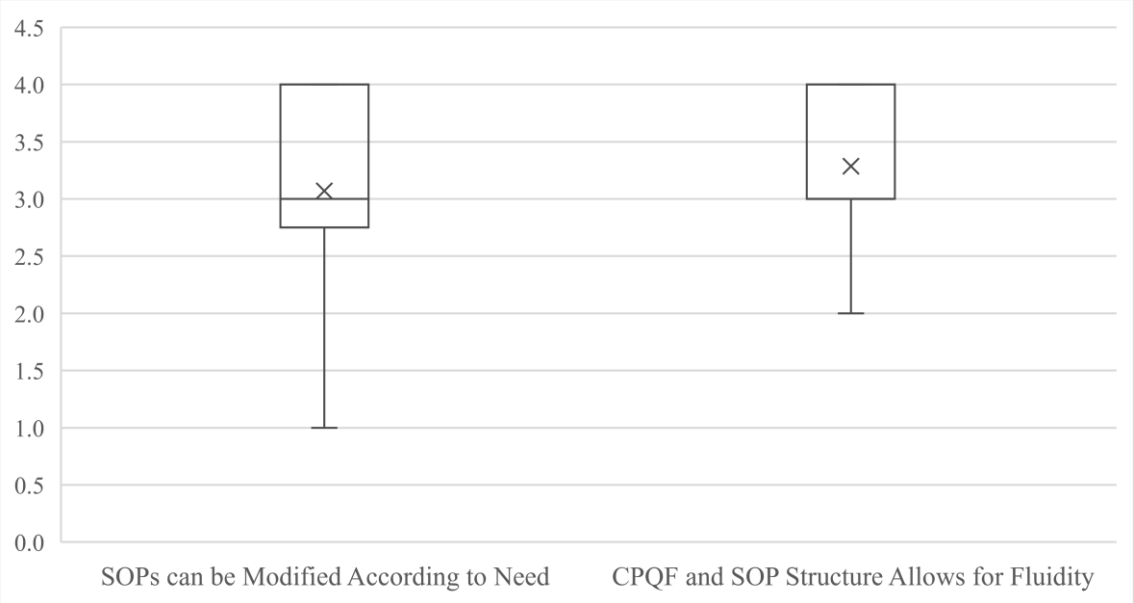

Figure 3.9: The mean rating scores for statements related to SOP modifications and quality system structure allowing for fluidity (N=14).

The majority of the participants agree (n=8) or strongly agree (n=4) that the wording of the CPQF and SOPs allows pharmacists to exert their professional judgement upon use (mean rating score: 3.14).

3.6.CPQF and SOP Use

A significant difference between the mean rating scores of the statements within the use section of the questionnaire was noted (Friedman Test, p=0.006). This implies that scores obtained vary between statements. The statements within the use section of the questionnaire had mean rating scores that vary marginally between the different districts as the p-values are greater than 0.05.

The majority of participants agree or strongly agree that the SOPs are relevant to the needs of the pharmacy (mean rating score: 3.43) and that the information provided within each SOP is useful within a community pharmacy setting (mean rating score: 3.43). Figure 3.10 depicts the pharmacist perception about SOP relevancy and usefulness.

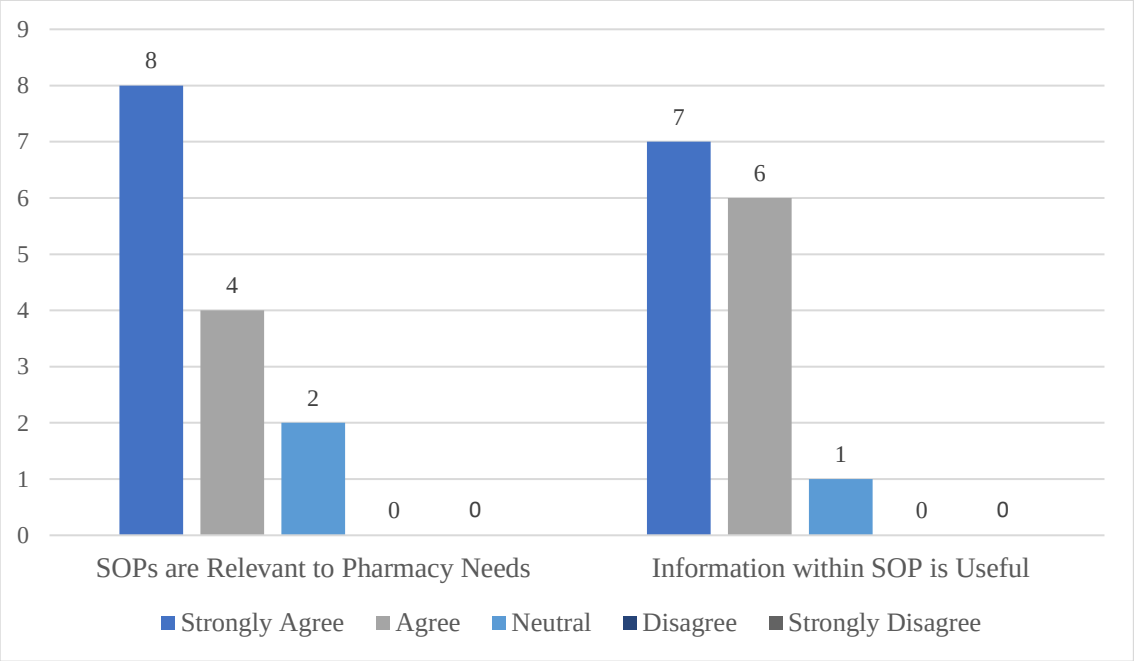

Figure 3.10: Pharmacist perception regarding SOP relevancy to pharmacy needs and presence of useful information (N=14).

Mixed results were obtained for the statement 'the SOPs can be used daily within the pharmacy'. Four participants strongly agree, four agree, three provided a neutral response and three disagree with this statement. The mean rating score obtained (2.64) for this statement was the lowest score across all the statements within the questionnaire. The majority of participants agree (n=7) or strongly agree (n=4) that the CPQF and SOPs are a useful reference when tackling issues encountered within the pharmacy (mean rating score: 3.00). Two provided a neutral response while one disagreed with this statement. Figure 3.11 depicts the mean rating scores for both statements in the form of a box and whisker plot.

Figure 3.11: The mean rating scores for statements related to the CPQF and SOP use within a community pharmacy setting (N=14).

3.7.CPQF and SOP Applicability

There was no significant difference between the mean rating scores of the statements within the applicability section of the Feasibility Questionnaire (Friedman Test, p=0.146). Most participants (n=12 agree or strongly agree) stated that they would make use of the CPQF and SOPs (mean rating score: 3.21) and would recommend their use (n=12 agree or strongly agree) within Maltese community pharmacies (mean rating score: 3.29). A mean rating score of 3.43 was obtained for the statement 'the CPQF and SOPs are useful as a template quality system in Maltese community pharmacies' showing that the majority of participants agreed or strongly agreed. Figure 3.12 depicts the results obtained for this statement.

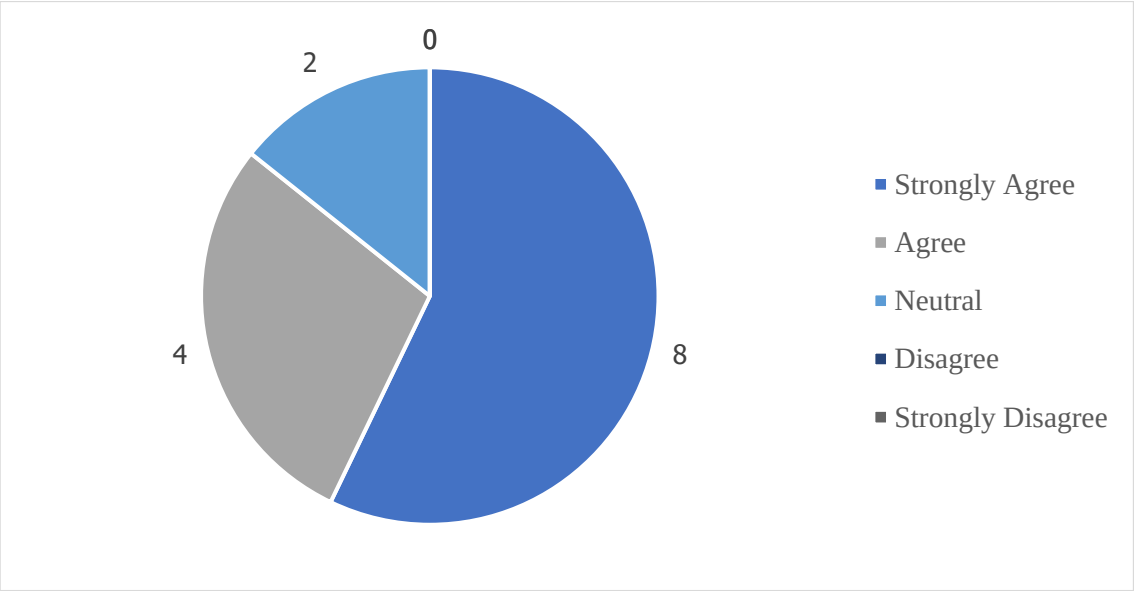

Figure 3.12: Pharmacist perception for the statement 'the CPQF and SOPs are useful as a template quality system in Maltese community pharmacies' (N=14).

Almost all participants (n=13) believe that the CPQF and SOPs can be used as a tool to standardise quality aspects within Maltese community pharmacies as a mean rating score of 3.50 was obtained.

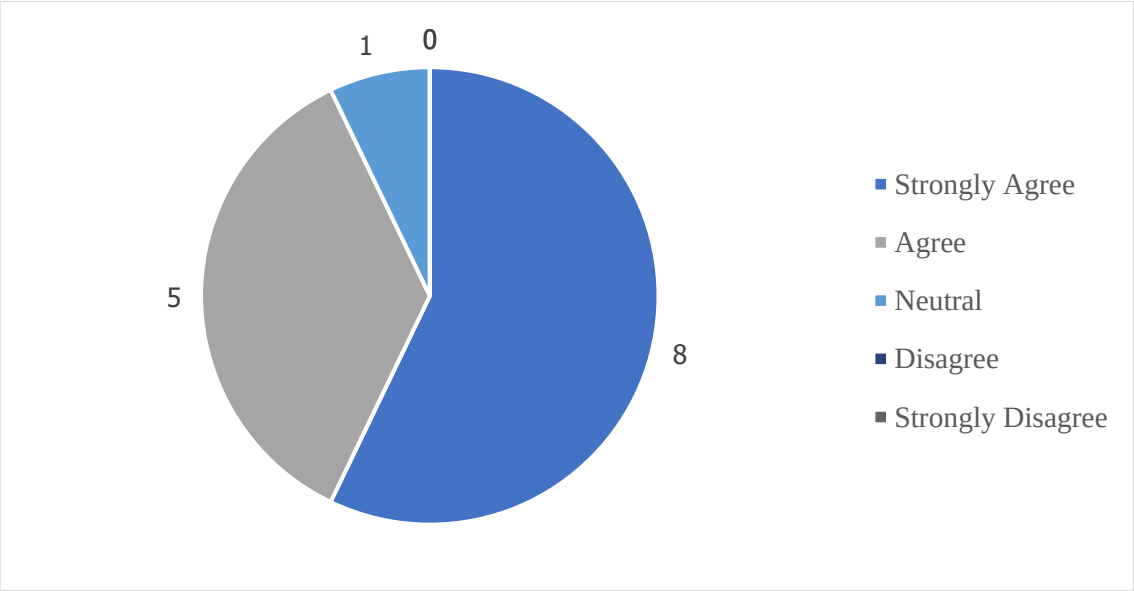

Figure 3.13: Pharmacist perception for the statement 'I think that the CPQF and SOPs would help standardise quality aspects within community pharmacies in Malta (N=14).

Two statements within the applicability section were related to MMA Inspections as depicted in Figure 3.14. The highest mean rating scores (3.57) within the Feasibility questionnaire were obtained for both statements related to inspections. The majority of participants (n=13) would make use of the SOPs prior to a MMA inspection and believe that they would pass the inspection when making use of this quality system.

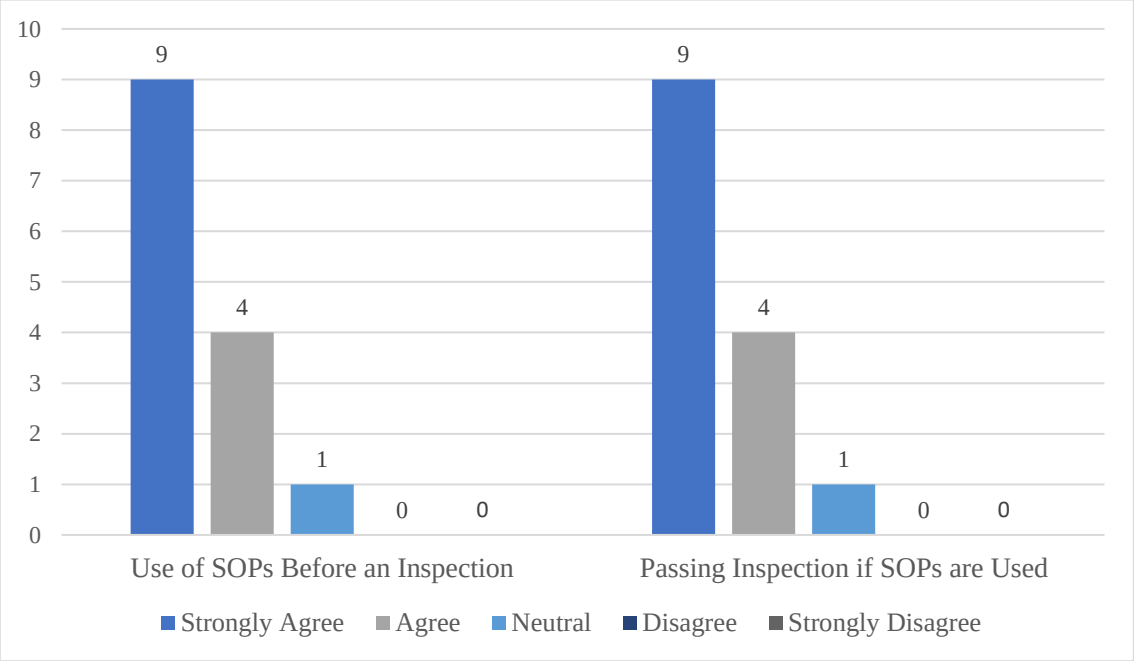

Figure 3.14: Pharmacist perception of two statements related to SOP use and the MMA Inspections (N=14).

The mean rating scores of the statement related to use of the SOPs prior to an inspection vary significantly between the different districts (Kruskal-Wallis Test, p=0.013): Southern harbour, Northern harbour, Southeastern, Western and Northern. This is attributed to the low scores provided by the Northern Harbour district as depicted in Table 3.9. The remaining statements within the applicability section have mean rating scores that vary marginally between the different districts as the p-values are greater than 0.05.

Table 3.9: SOP use before a MMA inspection mean rating scores according to the district.

		Mean Rating Score	p-value
I would make use of these SOPs prior to an inspection from the MMA	Southern harbour	4.00	0.013
	Northern harbour	2.67	
	Southeastern	3.00	
	Western	4.00	
	Northern	4.00	

Chapter 4: Discussion

4.1.Evolvement of Quality Aspects

Quality care standards are present to confirm how effective pharmacists are in terms of intervening in patient care. They present processes which aid pharmacists in improving their morale with regards to the services they provide. These standards help in monitoring all kinds of services provided by the pharmacy.[1] This links the care aspect with the services aspect with respect to pharmaceutical quality. Campbell *et al.* (2000) state that accessibility and effectiveness are the two main quality of care principles. A focus group performed by Halsall *et al.* (2012) further defines healthcare quality into accessibility, effectiveness, and any positive perceptions obtained from the experience. Two issues related to patient accessibility to medication were discussed in the focus group. These include medication shortages and medication prices. Medication shortages occur due to procurement and regulatory complications (Phuong *et al.*, 2019). Currently, there is a lack of literature regarding medicine shortage management (Omer *et al.*, 2021). The introduction of a management system for medication shortages was a point of discussion within the focus group. Statements related to such shortages were included in order to further improve patient accessibility. Healthcare systems should ensure that a patient has the access to medicines which are safe and efficacious at affordable prices. Substitution of a generic medication leads to cost-savings for the patient (Chong *et al.*, 2011; Rischatsch *et al.*, 2013). In mature healthcare systems, pharmacists and general practitioners tend to dispense or prescribe generics regardless of the patients' socioeconomic background (Toverud *et al.*, 2015). These factors portray the aspect of equity within the community pharmacy as described during the focus group.

[1] International Pharmaceutical Federation (FIP). Quality Care Standards in Community Pharmacy [Internet]. Hillerød (Denmark): FIP; 2005 [cited 2021 Mar 04]. Available from: https://www.fip.org/files/fip/CPS/Quality%20Care%20Standards%20final.pdf

Pharmacists should play an active role within the patients' care by providing information and guidance on how medications should be taken in a safe and effective manner (Showande & Laniyan, 2022). Medication adherence can be improved through patient counselling and management of patient therapy (Schroeder *et al.*, 2016). Patient medication counselling is attributed to the pharmaceutical care aspect which targets patient treatment optimisation (Showande & Laniyan, 2022). The advisory role of a pharmacist was a point of discussion within the focus group. A focus group member stated that pharmacists are to advise patients rather than convince them. In this aspect, there is the shift of the pharmacist taking an advisory role rather than a policing role which is commonly observed in community pharmacy. This links with patient empowerment. Healthcare professionals within the primary care sector involve patients in the decision-making process by empowering them (Swartwout *et al.*, 2016; Langaro, 2020). Patient empowerment allows pharmacists to collaborate with the patient and help them obtain relevant information. The outcome of such empowerment is having a patient that can manage their condition better whilst making their own informed decisions on the condition (Bailo *et al.*, 2019). This concept is focused on the patients' autonomy (Werbrouck *et al.*, 2018) as was discussed within the focus group. A number of guidelines and studies included counselling as a quality indicator. Differences were noted in characterisation of counselling within quality when compared to this study which associated counselling with a form of quality of care. The Estonian CPQSG included counselling with the service aspect of quality (Sepp *et al.*, 2021a; Sepp *et al.*, 2021b) which contrasts with the AHRQ PSOPSC™ [4] which included patient counselling within the safety aspect (Aboneh *et al.*, 2016; Aboneh *et al.*, 2020). The Dutch Health Care

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

Transparency Programme included counselling as a general quality indicator without further defining the indicator into a quality aspect (Teichert *et al.,* 2016).

A means to assure quality care standards of the appropriate safety is by following certain quality processes within the service provision. Pharmacists are required to provide their patients with the safest care possible. Safety in pharmacotherapy is approached through medication safety and drug safety. Drug safety involves the harm to benefit ratio with regards to adverse drug reactions. Medication safety involves the management and prevention of medication errors. The WHO describes three main concepts in patient safety breaches. These include polypharmacy, transitions in care and high-risk situations.[24] Prevention or adjustment of medication errors is undertaken through medication reviews. In this study, medication reviews were viewed from an aspect of safety due to harm that can be caused from medication errors. This is in contrast to other studies which view a medication review as a service or an interventional aspect (Rose *et al.*, 2020; Varas-Doval *et al.*, 2020). A system to reduce medication errors from the dispensing perspective should be set in place (Chen *et al.*, 2005; de las Mercedes Martínez Sánchez, 2013; Samsiah *et al.*, 2016; Cabri *et al.*, 2021). Focus group members suggested the initiation of such a system with flow charts for ease of use. The lack of these systems led to the introduction of key points within the CPQF like interacting with the prescriber regarding the error and ensuring proper handover between shifts to prevent dispensing errors.

[24] International Pharmaceutical Federation (FIP). Patient Safety – pharmacists' role in "medication without harm" [Internet]. The Hague (The Netherlands): FIP; 2020 [cited 2021 Feb 16]. Available from: https://www.fip.org/file/4757

Initiatives for patient safety and quality improvement have been targeted at lowering medication errors. A Canadian study showed that most significant adverse events are not related to medication errors (Hohl *et al.*, 2018). The adverse event section of the framework was discussed in the focus group. This led to the introduction of the adverse event reporting form within the SOP appendix. A Canadian study showed that adverse event reporting from clinicians can be less than 5% even when mandatory reporting is required (Hohl *et al.*, 2018). This highlights the importance of including side effect and adverse event reporting as part of the safety quality aspect.

Improper medication disposal poses a risk for the environment, the health and wellbeing of living things and possibly humans if medication is kept at home and ingested rather than being disposed of (Alshehri & Banjar, 2022; Kumari *et al.*, 2022). As presented in this study, pharmacists should increase awareness of this issue whilst offering the service of safe medicine disposal. Medicine Disposal can also be linked with stock control and management. Adequate stock rotation minimises stock expiry and decreases medication waste generated (Alhomoud, 2020; Chong *et al.*, 2022). Stock control is vital and encompasses multiple aspects related to safety. Factors related to stock management include temperature monitoring and medication storage. Inappropriate temperatures reduce the efficacy of medication (Crichton, 2004) possibly leading to compromised patient safety. Medication storage is linked with dispensing errors. Medication stored with inappropriate storage systems and in a cluttered environment increase the frequency of dispensing errors (Grissinger, 2012).

Quality improvement is important in enhancing patient and medication safety practices.[24] It is used to promote effectiveness, the experience of the patient and the safety of the patient (Latif *et al.*, 2021). Clinical governance has been identified as a key mechanism for improving health care safety, quality, and effectiveness. [25] It is set in place to ensure that pharmacies discuss patient care with the patient, perform risk management, deliver information, encourage professional development, and perform audits (Halsall *et al.*, 2008). Clinical self-audits are a means of measuring and improving care, sustaining improvement, and ensuring the best practice measures (Newby *et al.*, 2008). They allow pharmacists to reflect on how they handle patient management, making audits an active form of continuous education rather than a passive one. Science is continuously transforming due to new advancements (Wheeler *et al.*, 2018; Batista *et al.*, 2022). Pharmacists should aim to improve their knowledge to guarantee the appropriate quality of care and safety for their patients (van Huyssteen *et al.*, 2020). Implementing continuing professional development schemes is important to maintain professional competence (Batista *et al.*, 2022). Compulsory training was discussed between the focus group members wherein two different healthcare professionals mentioned requirements in their profession and in another country. The AHRQ PSOPSC™ [4] included training of pharmaceutical staff as part of the aspect of safety rather than as a means to improve quality within the community pharmacy setting. The MaPSaF described by Phipps *et al.* (2018) included education and training about safety within a safety framework while also being viewed through an improvement aspect.

[4] Agency for Healthcare Research and Quality (AHRQ). Community Pharmacy Survey on Patient Safety Culture [Internet]. Maryland (United States of America): AHRQ; 2023 [cited 2023 Jan 28]. Available from: https://www.ahrq.gov/sops/surveys/pharmacy/index.html

[24] International Pharmaceutical Federation (FIP). Patient Safety – pharmacists' role in "medication without harm" [Internet]. The Hague (The Netherlands): FIP; 2020 [cited 2021 Feb 16]. Available from: https://www.fip.org/file/4757

[25] Pharmaceutical Society of Australia (PSA). Clinical Governance Principles for Pharmacy Services [Internet]. Deakin West (Australia): PSA; 2018 [cited 2023 Jul 23]. Available from: https://my.psa.org.au/s/article/Clinical-Governance-Principles-for-Pharmacy-Services

Process mapping is utilised to support quality improvement aspects. This procedure helps the pharmacist improve their understanding of certain complex systems (Antonacci *et al.*, 2021). An example of process mapping is the use of flow charts. Focus group suggestions included the introduction of flow charts to help foreign pharmacists understand Maltese procedures related to the dispensing of dangerous drugs.

The quality of services provided by a pharmacy is of utmost importance. A vital service offered by community pharmacies are point of care tests. These tests provide pharmacists with the opportunity to further engage themselves in care management and monitoring (Kehrer & James, 2016). The WHO and FIP joint good pharmacy practice guidelines state that pharmacists are required to promote the health and well-being of the patient.[26] This can be done by participating in local health campaigns[16], providing patients with evidence-based advice[27,28], and increasing awareness on chronic diseases.[28] Health promotion was further defined as a service quality guideline by the Estonian CPSQG (Sepp *et al.*, 2021a; Sepp *et al.*, 2021b) as depicted in the framework of this study.

Professional clinical services include drug dispensing which when performed in a proper manner will improve the patients' quality of life, whilst providing them with treatment

[16] Ministry for Justice, Culture and Local Government. Chapter 464 Health Care Professionals Act [Internet]. Valletta (Malta): The Ministry; 2003 [cited 2021 Mar 18]. Available from: https://legislation.mt/eli/cap/464/eng/pdf

[26] International Pharmaceutical Federation (FIP) and World Health Organisation (WHO). Good Pharmacy Practice [Internet]. The Hague (The Netherlands) and Geneva (Switzerland): FIP and WHO; 2011 [cited 2021 Mar 18]. Available from: https://www.fip.org/files/fip/WHO/GPP%20guidelines%20FIP%20publication_final.pdf

[27] Pharmaceutical Society of Australia (PSA). Professional Practice Standards Version 5 [Internet]. Australia: PSA; 2017 [cited 2021 Feb 23]. Available from: https://my.psa.org.au/s/article/Professional-Practice-Standards

[28] Public Health England. Healthy Living Pharmacy Level 1 Quality Criteria - Assessment of Compliance Healthy Living Pharmacy (HLP) Level 1 [Internet]. London (United Kingdom): Public Health England; 2016 [cited 2021 Feb 20]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/743128/HLP-quality-criteria-and-self-assessement-process.pdf

which is safe and effective (Pizetta *et al.*, 2021; Cerqueira-Santos *et al.*, 2022). The drug dispensing process includes the legal aspect of having valid prescriptions (Cerqueira-Santos *et al.*, 2022). The professional clinical service aspect links with the service of responding to a patients' symptoms and self-care. Pharmacists are able to act as intermediaries between the patient and the doctor by being the first point of contact and responding to the patients' presenting symptoms (Ilardo & Speciale, 2020). Pharmacists should follow a process when responding to a patients' symptoms by firstly obtaining the appropriate information from the patient (Mikhael *et al.*, 2022). This study included the general process as described by Scicluna (2011) and Scicluna *et al.* (2012).

Other relevant services include delivery services of pharmaceutical products. The pandemic brought about the need to decrease stress on healthcare services (Abu-Farha *et al.*, 2022; Kavanagh *et al.*, 2022). In some countries, delivery services were introduced to reduce the risk of patients with comorbidities (Peláez Bejarano *et al.*, 2021; Mash *et al.*, 2022). A focus group member mentioned that from the regulatory perspective information about delivery services is lacking. Another member stated that pharmacies tend to be understaffed and since the pharmacist should be doing the medicine delivery it is unfeasible. Apart from feasibility, one should note that delivery services hinder the counselling aspect of the profession (Abu-Farha *et al.*, 2022).

Presently, direct to consumer advertising is only permissible for over-the-counter medication. Such promotions improve patient autonomy and awareness whilst leading to safety concerns (Chaar & Kwong, 2010). A concern brought forward in the focus group

was related to recommending versus advertising. A lifestyle modification or a service should be recommended rather than advertised.

The presence of four different quality aspects within this study makes it more robust when compared to other frameworks available which target one quality aspect. The advantage of having such divisions is that it allows for more appropriate characterisation. This was further confirmed when mean rating scores of 3.5 and 3.21 were obtained when pharmacists answering the Feasibility Questionnaire were asked whether the CPQF and SOPs cover the main quality aspects in community pharmacy practice.

The care, safety, improvement, and services aspects are interlinked in multiple scenarios and are deemed to be closely interconnected within a pharmacy setting. The connection allows pharmacists to deliver high quality healthcare through a cohesive approach whilst optimising the patients' health outcomes.

4.2.Framework and SOP Concept and Feasibility

Standardisation and harmonisation, two of the main key words identified in the focus group analysis are vital to safeguard the pharmacist profession and the patient. Developing documents such as the CPQF and SOPs is a step forward towards the improvement and harmonisation of quality within the community pharmacy setting (Sepp *et al.*, 2021b). As discussed in the focus group, frameworks like the CPQF standardise the general practice whilst harmonising complex procedures. Such standards help improve the profession due to the greater accountability required. Lack of accountability within the pharmacy profession affects collaborations with other healthcare workers and

leads to conflicts within the primary care setting (Brown *et al.*, 2011; Taylor *et al.*, 2020). A key point put forward in the focus group was that accountability is linked with safeguarding and improving the views of the pharmacy profession. The quality system designed is useful in standardising quality aspects in relation to the Maltese scenario. This was highlighted in the Feasibility Questionnaire as eight participants strongly agree and five agree that the CPQF and SOPs can potentially standardise quality aspects.

When considering feasibility of using the CPQF and SOPs, one should firstly consider the feasibility of using the layout presented. The results obtained noted that with regards to ease of use the participants preferred the layout of the SOPs (mean rating score: 3.43) rather than the CPQF (mean rating score: 2.93). The low score obtained for the CPQF ease of use statement is attributed to the low scores provided by the Northern Harbour district which skewed the final result. The other four districts obtained mean rating scores of three or higher meaning that the majority of participants in those districts stated they agree or strongly agree that the CPQF layout makes it easy to use and follow. The result obtained is likely related to the presence of a general procedure and flow charts which make SOPs more accessible leading to increased efficiency and compliance (Amare, 2012).

The importance of exerting professional or clinical judgement when using the SOPs and CPQF was emphasised within the documentation. The majority of pharmacists answering the questionnaire agree (n=8) or strongly agree (n=4) that the wording of the documentation allowed them to exert their own professional judgement in situations they were placed in. A British study by Saxby *et al.* (2017) found that most pharmacists (93%

agree or strongly agree) tend to rely on their own professional judgement rather than using an assigned tool. Saxby *et al.* (2017) noted that use of their tool increased the confidence of the pharmacist when predicting patient acuity levels however professional judgement ultimately overrides the prediction. The ability of a pharmacist to exert their own professional judgement benefits the patient and increases favourable outcomes (Roche & Kelliher, 2014). Apart from allowing for professional judgement to take place, the documentation should be modified according to pharmacy needs within reason. The participants agreed or strongly agreed that the documentation allows for fluidity (n=12) within the pharmacy and is able to be modified (n=11).

The results obtained noted that the SOPs are not feasible to be used on a daily basis being that only eight participants agreed or strongly agreed that they can be used as such. This statement obtained the lowest mean rating score throughout the full questionnaire. Pharmacists noted that the documentation is a more relevant reference when tackling issues (n=11 agree or strongly agree) or prior to a MMA inspection (n=13 agree or strongly agree). The only disagreement with use prior to an MMA inspection was noted from the Northern Harbour district. These results suggest that periodic review of the SOPs rather than daily review is more feasible within the hectic pharmacy setting.

The documentation designed bridges the gap between the legislative aspect of pharmacy practice, the general code of conduct of a pharmacist and principles which enhance the quality of the health care service provided to the patient. By using these SOPs pharmacists are complying with the law whilst solidifying the best practices and demonstrating ethical conduct.

4.3.Study Limitations

A possible limitation includes an insufficient number of research sources. More study frameworks and guidelines from healthcare organisations could have been reviewed and included in the CPQF and SOPs.

Limitations were encountered within the validation process of this study. Six out of ten participants joined the focus group session. This is attributed to the period of time when the validation was carried out. Most participants had multiple commitments during the summer months making it difficult to find a suitable date for all participants. The ideal scenario would have been that the participants were contacted months prior to the focus group session to find a date were more participants could have attended.

The CPQF and SOPs were validated by only one community pharmacist as a member of a diverse focus group. The presence of more community pharmacists within the focus group would have led to more discussions, revisions and recommendations related to the documents being that the use of this quality system is targeted for pharmacy use.

A small sample size was used for the questionnaire distribution. Small sample sizes do not represent the general population leading to limited generalisability, reduced statistical power, increased variability, and a greater probability of finding significant outliers.

4.4.Recommendations for Future Studies

Further studies include assessing the feasibility of using the CPQF and SOPs on a larger scale. A proposed distribution consists of fifteen pharmacies from each district in the Maltese Islands. Inclusion of the sixth district 'Gozo and Comino' should be considered to have a better sample representation.

Small changes to SOPs should be compiled and adapted within the SOP when periodic revisions are performed. These revisions should be executed on a regular basis (Barbé *et al.*, 2016). Frameworks and guidelines from scientific organisations are constantly being updated making revisions of the documentation vital in order to bring each SOP up to date. The focus group members brought forward the point that these periodic revisions normally occur every two years. It was recommended to perform such revisions prior to the two-year mark since it is a relatively new procedure.

Proposition of minor SOPs for each of the four developed SOPs to further define certain important processes in more detail than what is already specified in the documentation would be ideal. Examples include specific SOPs about managing medicine shortages and the specific process of carrying out an in-depth medication review.

SOP digitalisation should be considered as a future study. This process is beneficial as one can track the SOP version history easily allowing for an audit trail. SOP updates can be performed in a quicker manner with the authorised personnel receiving updates immediately. SOP dissemination is quicker and undisturbed allowing for increased efficiency. Part of the digitalisation procedure would include signature and access

monitoring to assess who is making use of the documentation, the time of access and the frequency of use. User authentication would be implemented to ensure that only authorised personnel have access to the data.

4.5.Conclusion

The study has delivered a validated Framework and interlinked SOPs for the assessment of quality of community pharmacy services. The design and use of SOP's related to community pharmacy quality can aid in maintaining a certain level of standards. Each SOP can be adjusted according to the needs of the pharmacy. Pharmacists are to exert their professional judgement according to the scenario they are in, meaning that the majority of statements present within the documentation can be altered accordingly.

The quality system obtained can be utilised prior to a MMA Inspection to ensure that the pharmacy is up to the ideal standard. The developed system is a step forward in the standardisation and harmonisation of quality within a pharmacy setting thus allowing for consistency in the service provided to the patient whilst ensuring safety of the patient and of the pharmacy profession.

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List of Publications and Abstracts

Abstract presented at 2023 FIP Brisbane Conference.

Development and Validation of a Quality System for Community Pharmacy Practice

Background Information

Quality performance instruments focusing on different service aspects are developed for community pharmacy practice.

Purpose

To design, validate, and test the feasibility of a community pharmacy quality framework (CPQF) and standard operating procedures (SOP) covering quality aspects.

Method

A literature review was performed to identify quality aspects in community pharmacy practice. The CPQF and SOPs were designed and based on Maltese Legislation, published global pharmacy practice standards and undergraduate and postgraduate dissertations. The documentation developed was validated through a focus group. A stepwise thematic analysis was performed to code the qualitative data obtained. The documentation was adjusted according to recommendations put forward. A feasibility questionnaire consisting of closed ended statements with a 5-point Likert scale, along with two open ended questions was designed and validated by the focus group members. Stratified random sampling was used to identify pharmacies to test the feasibility of the SOPs. Three pharmacies from each of the five districts in Malta were randomly selected. The selected

pharmacies self-administered the feasibility questionnaire after using the SOPs for two weeks.

Results

The literature analysis performed led to the determination of quality aspects in relation to community pharmacy practice: Care, Safety, Improvement and Services. The quality aspects were each subdivided into pertinent sections. The care aspect was characterised into: 1) accessibility, 2) effectiveness, 3) counselling, 4) monitoring medication use and follow-up, 5) management of patient therapy and 6) optimisation of treatment. The safety aspect was characterised into: 1) medication review, 2) therapeutic monitoring, 3) identifying prescription errors, 4) side effect and adverse event reporting, 5) optimal medication use, 6) medicine disposal, 7) dangerous drug act and special items and 8) stock control. The improvement aspect was characterised into: 1) self-audits, 2) clinical governance, and 3) professional development. The services aspect was characterised into: 1) point of care testing, 2) professional clinical services, 3) health promotion and disease prevention and 4) responding to symptoms and self-care. The thematic analysis led to the identification of six general themes: 1) Framework concept theme incorporates accountability, safeguarding the profession, standardisation, harmonisation, and revisions. 2) Care theme incorporates medicine stock management, advise, empowerment, equity. 3) Safety theme incorporates prescription errors. 4) Improvement theme incorporates compulsory training. 5) Services theme incorporates recommendations versus advertisements and delivery services. 6) Presentation and dissemination theme incorporates diagrammatic representation. Three main findings were noted from the feasibility questionnaire (N=14): 1) 57% strongly agree and 36% agree that the quality system designed can help standardise quality aspects in community pharmacy practice in Malta, 2) 57% strongly agree and 43% agree that the SOPs cover

all aspects checked within a MMA Inspection, 3) 64% strongly agree and 29% agree that they will pass an inspection when using these SOPs.

Conclusion

The study has delivered a validated Framework and interlinked SOPs for the assessment of quality of community pharmacy services. This a step forward in the standardisation and harmonisation of quality within community pharmacies.

Appendices

Appendix 1: The Community Pharmacy Quality Framework

The Community Pharmacy Quality Framework

The Community Pharmacy Quality Framework

The research project entitled Quality Systems in Community Pharmacy aims to design a quality system that can be utilised within community pharmacies present on the Maltese Islands. A thorough literature review led to the identification of the four major quality aspects present in community pharmacies, these being, the quality of care, safety, improvement, and services.

The community pharmacy quality framework (CPQF) explores these quality aspects in detail whilst incorporating standards, guidelines, regulations, and local legislation. Figure 1 shows the relevant sections and subsections of the CPQF. Four standard operating procedure (SOP) templates for each quality aspect present within the CPQF are also designed and validated. The CPQF and SOP's are guides that can be utilised within community pharmacies. Pharmacists are to exert their professional judgement according to the scenario they are in meaning that the majority of statements present within the CPQF and SOP's can be altered accordingly.

Figure 1: The General Layout of the CPQF

1. Quality of Care	
1.1 Accessibility	Pharmacists are to be readily available for any patient that enters the pharmacy.[1]
	Pharmacists shall understand the healthcare system and be able to explain the complexity of the system to any patient seeking advice.[2]
	Pharmacists can discuss the availability of generic medication for originator products.[1]
	Pharmacists can be more accessible to their patient by altering how they communicate with the patient according to their level of education, age, and character.[3]
	Pharmacists can substitute a branded medication with a generic medication if the branded product is out of stock. This is only relevant if the generic medication has the same dosage form and strength. If a different strength is available, the pharmacist must ensure that the prescribed dose can be made up prior to dispensing it.[4]
	Pharmacists should try to obtain medications through different wholesale dealers when there is a drug shortage.[4]
	Pharmacists are to inform any attending physicians of current drug shortages in order to prevent patients' from panicking.[4]
1.2 Effectiveness	Pharmacists shall ensure that the medicines dispensed are effective.[1]
	Pharmacists are to promote dispensing and prescribing which is both economical and rational.[1]

	The pharmacy service is relevant to the patient, it shall be defined clearly and is communicated effectively to the involved parties.[1]
	Pharmacists are to supply, prepare, test, store, distribute and dispense medicines in a safe and efficacious way.[5]
	Pharmacists shall make sure that the right medication is dispensed to the right patient. The medication should be in both the right dose and dosage form for the patient. Pharmacists should ensure that the patient is empowered to take the medication at the right time and frequency.[6]
1.3 Counselling	Pharmacists can verbally advise the patient about any medication information along with providing written information for future reference.[6]
	Pharmacists are to advise patients to take the medication dispensed in an appropriate manner.[6]
	Pharmacists are to educate patients on correct medication use, side effects, interactions with food and even adverse reactions.[6]
	Pharmacists are to take the patient's history and ensure that the patient made the appropriate self-diagnosis before dispensing any medication.[6]
	Pharmacists are to support patients in self-care for appropriate self-diagnoses, in the use of non-prescription medications and the appropriate time for physician referall.[6]
	Pharmacists are to demonstrate how to use medical devices in an accurate and effective way. Pharmacists shall ensure that the patient understands how to use the device in a proper manner.[6]

	Pharmacists can opt to repeat any main advisory points given to the patient or ask the patient to repeat the advice themselves to ensure the maximum benefit is attained.[3]
	Pharmacists are to discuss the timing of medication with the patients and adjust the timing according to the patients' lifestyle and the presence of certain medication in the current regimen.[3]
	Pharmacists are to ensure that the patient is aware of any food items that should not be taken with the medication or should be avoided.[3]
	Pharmacists are to provide the patients with valid reasons as to why certain counselling remarks are being stated.[3]
1.4 Monitoring Medication Use and Follow-Ups	Pharmacists are to monitor patients in order to identify whether the services used and the drugs taken are being optimised.[7]
	Follow-ups with patients that visit a pharmacy regularly can be performed. During the follow-up, the pharmacist can assess patients' adherence to medication, identify any problems related to adherence and address any issues that are being encountered.[8]
	Pharmacists shall recognise whether high risk patients require a follow up or need to be referred to a physician.[7]
	Pharmacy owners shall ensure that the pharmacy has a designated area to council patients regarding their medication usage.[9]
	Pharmacists are to monitor regular patients getting non-prescription medication for inappropriate reasons. Pharmacists shall ensure that these patients are responding well to their self-care medication.[7]

1.5 Management of Patient Therapy	Pharmacists shall identify and help the patient manage and prioritise their health problems.[1]
	Pharmacists are to provide the patient with all the medicine, illness, and health related information to allow the patient to participate in the process of designing a medication care plan.[9]
	Pharmacists can communicate with the other healthcare providers involved in the patients care to prevent any medication errors from occurring.[9]
	Pharmacists shall refer any patient coming to the pharmacy with certain health concerns to the appropriate physician.[9]
	Pharmacists shall identify when the patient's care is outside their abilities and should refer them to an appropriate physician.[7]
1.6 Optimisation of Treatment	Pharmacists can suggest the use of pill boxes, medication calendars or medication charts to help improve the patients' adherence and thus optimise the treatment.[8]
	Pharmacists shall council the patient and consult with other healthcare professionals to guarantee that the patient is receiving advice which is in accordance with their health goals thus optimising their health outcomes.[7]

2. Quality of Safety	
2.1 Medication Review	Pharmacists are to be vigilant in identifying medicinal products that are contraindicated or are posing risks which exceed the benefits.[1]
	Pharmacists shall identify the patients' information by asking any relevant questions in order to eliminate the risk of possible allergies and adverse drug reactions.[1]
	Pharmacists can collaborate with other healthcare professionals in order to have a certain level of confidence and trust in the pharmacotherapy chosen for the patient.[1]
	Pharmacists can perform medication reviews with elderly patients to identify the presence of unsuitable medications. Deprescribing certain medication could be a step forward in resolving the issue of polypharmacy.[6]
	Pharmacists shall address medication problems that arise after a medication review is performed. These issues are to be discussed with other healthcare professionals.[7]
	Pharmacists can report any issues identified in the patients care plan to the patients main physician. This is mainly important if a change in behaviour is observed.[7]
	Pharmacists can ensure that the medication is still suitable for the needs of the patient by identifying if any changes in health status or regimen have occurred. This can be ideal if the patient comes to the pharmacy with a repeat prescription.[3]

2.2 Therapeutic Monitoring	Pharmacists can monitor the patients' therapy by performing point-of care tests. Recommendations to alter any medications according to the results obtained can be made and are to be discussed with both the patient and care providers to ensure collaborative patient care.[6]
2.3 Identifying Prescription Errors	Pharmacists are to prevent the patient from getting harmed from any medicinal product.[1]
	Pharmacists are to promote an environment within their community pharmacy that identifies, evaluates, and acts on prescription errors.[6]
	Pharmacists are to ensure that a proper handover between shifts occurs in order to reduce prescription errors due to the presence of multiple staff. [6]
	Pharmacists are to call the prescriber if the prescription is illegible, an error was present or there is lack of information such as the dose, and dosage regimen. [10]
2.4 Side Effect and Adverse Event Reporting	Pharmacists can create an internal system to obtain feedback about any errors, adverse events, medication misuse and abuse occurring at the pharmacy. Such a system can promote a discussion between the pharmacists and pharmacy staff.[1]
	Pharmacists shall report any adverse reactions they discover at the pharmacy to the competent authority, being the Malta Medicines Authority.[5]
	Pharmacists can check what adverse reactions are being reported in the European Union through the following website 'www.adrreports.eu'. [11]

	Pharmacists can encourage patients to report their own side effects using the 'patient side-effect online form' designed by the competent authority present in Malta which is the Malta Medicines Authority. [11]
2.5 Optimal Medication Use	Pharmacists are to help patients using medical devices to dispense their medications e.g., pen injectors, by showing them how to take the appropriate dose.[12]
	Pharmacists are to suggest appropriate measuring devices like a dropper or oral syringe when dispensing an oral liquid medicinal product in order to accurately measure the prescribed dose.[12]
2.6 Medicine Disposal	Pharmacists are to make patients aware of the hazards posed by disposing medical waste incorrectly.[1]
	Pharmacists can offer a pharmacy service whereby collection of expired or unwanted medications can take place, to promote safe medication disposal.[6]
2.7 DDA's and Special Items	Pharmacists are to follow the legal requirements for dispensing drugs listed within the Dangerous Drugs Act (DDA).[13]
	The drugs listed within this act are required to be kept under lock and key and should only be accessed by authorised technical staff under the direction of the pharmacist. It is the responsibility of pharmacists to take measures to prevent any theft and diverse stock.[13]
	Managing pharmacists should ensure that Dangerous Drugs are subject to the same storage and dispensing conditions as with other medication.[14]
	Pharmacists should keep records of any registers, prescriptions, or documents for not less than two years.[13]

	Pharmacists are to have a Dangerous Drug sales register and a Dangerous Drug purchases register for both pharmacy and POYC stock.[15, 16]
	Pharmacists are to ensure that the Dangerous Drug register has the following format: date of dispensing, name, medicine quantity, dosage form, medicine strength, prescriber name, prescriber registration number, date, prescription number.[16]
	Pharmacists are duty bound to request a legal document of the person when dispensing a prescription. If someone is collecting medications on another person's behalf, legal documents of both individuals are to be requested.[13, 15]
	The managing pharmacist is required to send the Superintendent of Public Health an envelope with the prescriptions dispensed in the pharmacy. This should be sent on the first day of every month.[13, 15]
	Pharmacists should ensure that each green prescription is used only once.[15]
	Pharmacists should ensure that an urgent prescription does not exceed a supply of more than seven days.[15]
	Pharmacists should be aware of the fact that the Control Card used for Dangerous Drugs is only valid for one year from the date of issue.[15]
	Pharmacists are to perform a stock take of Dangerous Drugs on a yearly basis. This is to be sent to the Malta Medicines Authority.[16]
	Pharmacists are encouraged to perform regular stock takes of the DDA cupboard.[16]

	Pharmacists are to store any expired Dangerous Drugs in a specific area of the DDA cupboard and not next to the other stock.[16]
	Pharmacists can provide product application services to patients with a colostomy, ileostomy, or a urostomy. Stoma care can also be discussed with the patient.[17]
	Pharmacists can provide catheter care and information to patients with a catheter.[18]
2.8 Stock Control	The procurement, handling, and storage of medicinal products shall ensure that the products safety, quality, and efficacy is maintained. Pharmacists are to ensure that systems to safeguard this are set in place. If these steps are not performed in an appropriate manner a breach of safety can occur by the time the medication is dispensed.[6]
	Pharmacies are required to have a register for the temperature within the pharmacy, the stores and even the refrigerator. Medicinal products found in the pharmacy should be preserved from any form of humidity and excess heat or cold.[19]
	Pharmacists should store stock according to the temperatures stated on the medicinal packaging. - Frozen: at -20°C - At 2-8°C: store in a refrigerator - Cool: store at 8-15°C - At room temperature: store at 15-25°C.[20]
	Pharmacists are to measure, record and review the minimum and maximum temperature of the refrigerator where both pharmacy and POYC stock is stored.[16, 21]

	Pharmacists are to measure, record and review the minimum and maximum temperature of the dispensary and any other area where both pharmacy and POYC stock is stored.[16, 21]
	Pharmacists must ensure that the thermometers used to check the temperature in the pharmacy are calibrated on a yearly basis.[16]
	Medications having look-a-like packaging or similar names should ideally be stored in different areas to decrease the likelihood of dispensing errors.[12]
	Pharmacies are to have methods in place in order to regularly review the stock present. [12]
	Pharmacy stock is to be stored carefully and appropriately. Storage areas should not be cluttered as this increases the chance of prescription errors. [12]
	A systematic storage system like an alphabetical system should be employed to make the retrieval of drugs easier and to reduce the risk of errors. [12]
	The stock can be stored according to the generic name or brand name with no distinction of dosage forms. [12]
	An adequate area for unpacking new stock which is received is necessary to reduce the mixing of products. [12]
	Pharmacists are to ensure that their stock is stored according to the expiry date with the product having the shortest expiry date in front and the product with the longest expiry date at the back. This prevents pharmacists from dispensing expired medicines. [12]

	Pharmacists and pharmacy staff are to store expired medicinal products in a separate area of the pharmacy. They must be clearly labelled to avoid any confusion.[16]
	Systems to ensure that expiry date monitoring is undertaken are to be set in place. [12]
	Medications like insulin can be stored in separate containers in the refrigerator in order to easily distinguish the different types. [12]
	Stock which has been discontinued or recalled should immediately be removed from the other stock. This is also the case for expired medications. [12]
	Pharmacists are to confirm the authenticity of the medicinal products' unique identifier code, verify the anti-tampering device identity and decommission the code as per the falsified medicines directive. This can be performed by scanning the unique identifier code.[22,23]
	Pharmacists can open a medicinal product having a unique identifier code and supply only a part of the product. The medicinal product has to be verified and decommissioned as per the falsified medicines directive. [22-23]
	Pharmacists are to ensure that pest control is performed on an annual basis. [16]

3. Quality Improvement	
3.1 Self-Audits	Pharmacists can carry out audits for the services being provided within the premises.[24]
	Pharmacists can make use of the community pharmacy regulatory audit tool to perform internal self-audits prior to an inspection from the Malta Medicines Authority.[16]
	Pharmacists are to ensure that the audit covers the following features: medicinal product storage conditions, SOP's, registers, stock take of the Dangerous Drugs, the condition of the premises, waste disposal and equipment related to making extemporaneous preparation.[16]
3.2 Clinical Governance	A clinical governance lead can be present in a pharmacy. Pharmacies can apply certain clinical governance concepts to their services. Examples include making use of standard operating procedures, professional development, performing self-audits, evaluating the satisfaction of patients, applying risk management strategies, educating staff on any incidents that occur and recording and reporting.[25]
	Pharmacists are to produce and utilise community pharmacy systems that are effective and efficient. All elements in a pharmacy shall be organised into suitable systems. These systems are to be optimised to allow for better patient health outcomes.[7]
	Pharmacies are to perform appropriate risk analyses before applying any system or service.[7]

3.3 Professional Development	Pharmacists are to engage in continuous education meetings along with regularly reviewing relevant pharmacy journals to further develop their professional career.[3]
	Pharmacists should be colleagues and work together in order to improve the pharmacy services offered.[1]
	Pharmacists are to be responsible for maintaining their professional competency. Self-monitoring to ensure that pharmacists abide by the standards present is to be performed regularly.[1]
	Education of the staff is important to minimise medication errors. The competency of the staff is to be regularly assessed and if it is not satisfied training should take place.[6]
	Pharmacists and pharmacy staff should learn to support patients in a non-judgemental way in order to help patients reach any health goals they have.[26]
	Pharmacists and pharmacy staff should be able to assess their own knowledge and abilities in order to improve their professional skills.[7]
	Pharmacy owners are to support their staff by setting certain goals in order to reach the professional level they require. [7]
	Pharmacists are to keep a copy of a formulary like the British National Formulary and an updated edition of the Maltese pharmacy legislation within the pharmacy.[3]

4. Quality of Services	
4.1 Point of Care Testing	Pharmacists are to train their staff accordingly in order to ensure that the devices are used efficiently and effectively by following standard operating procedures set in place. Training should include the interpretation of results obtained and test limitations.[27]
	Specific areas of the pharmacy designated for conducting such tests and for disposing of any biological waste are to be present.[27]
	Pharmacists are to provide the patient with any relevant information obtained from the point of care test and deliver adequate counselling within a private area of the pharmacy.[27]
	Pharmacists are to inform chronically ill patients of when a follow-up of the test is required.[27]
	Pharmacists should ensure that the patient has consented to the point of care test being carried out. Pharmacists should obtain permission from the patient before disseminating the results obtained in the point of care test to a physician. If the permission is not granted, pharmacists are to refer the patient to a physician.[27]
	Procedures to handle needlestick injuries or the spillage of medicinal waste are to be set in place.[27]
	Pharmacists are to ensure that weighing scales are calibrated in a proper manner before use.[3]
	Pharmacists are to ensure that any point of care equipment is checked frequently to ensure their accuracy.[3]

	Pharmacists are to have a documentation sheet for each point of care test. Such documentation sheets can be utilised to list the patients information, date, and result.[3]
	Pharmacists are to ensure that any point of care tests including blood and urine test strips along with pregnancy tests are checked frequently and stored appropriately.[3]
4.2 Professional Clinical Services	Pharmacists are to ensure that any dispensing equipment such as tablet counting aids are kept in a clean environment and are cleaned in between uses.[3]
	If extemporaneous preparations are prepared in the pharmacy, the pharmacist must ensure that the appropriate equipment is present and kept clean. [16, 21]
	If extemporaneous preparations are prepared in the pharmacy, the pharmacist should label the preparation with the expiry date which is four weeks. [16, 21]
	Pharmacists are not to dispense a medicinal product more than once with the same prescription unless the medication was partially dispensed or it is a repeat prescription. Pharmacists should clearly indicate the word 'dispensed' next to the appropriate medication, with the quantity and the date. Apart from this information, pharmacists should also include their registration number, their signature, and a stamp of the pharmacy.[28]
	Pharmacists are to keep a record of any medicines dispensed with a repeat prescription or partially dispensed prescriptions. In their register, pharmacists are to list the date, the name, quantity,

	medicinal product, prescriber name and registration number, prescription date and the date when the prescription was received. These should also be satisfied if the pharmacy keeps computerised records. In that case, the record should be printed each day the pharmacy is open.[28]
	If the prescription is an eprescription, pharmacists are to ensure that the eprescription was delivered by an official system.[13]
	Pharmacists are not to dispense medicinal products without a prescription unless the competent authority states that these medications do not require a prescription to be dispensed.[28]
	Verbal instructions by a telephone call are not to be accepted unless the pharmacist is sure that the prescriber is authorised to give such instructions and cannot issue a prescription due to an emergency. The prescriber is to give the pharmacist a prescription within 48 hours. An entry shall be made in a register. This is not applicable to Dangerous Drugs.[28]
	Pharmacists are not to dispense a prescription only medication if the prescription is more than 6 months old. This does not apply to repeat prescriptions.[28]
	Pharmacists should only dispense antibacterial agents up to 10 days after the prescription was issued.[28]
	Pharmacists are to re-check the medicinal product dispensed with that written on the prescription to avoid any potential errors.[3]

	Pharmacists can opt to participate in the 70+ domiciliary delivery scheme where the pharmacist delivers the patients' medications from the POYC scheme to their front door.[29]
	If pharmacists opt to participate in the 70+ domiciliary delivery scheme they are to offer the application to the patient within the pharmacy and inform the patient that in order for them to register they need to be 70 years and over, or else have mobility issues. Patients with mobility issues are to have an identification card provided by the National Commission for Persons with Disability.[29]
4.3 Health Promotion and Disease Prevention	Pharmacists are to promote the health and well-being of the patient.[1]
	Pharmacists are encouraged to contribute to any national or local health campaigns.[5]
	Pharmacists and pharmacy staff are to provide patients with evidence based healthy lifestyle advice along with information that is relevant to the local health scenario.[26]
	Pharmacists and pharmacy staff shall ensure that any materials such as over the counter medication, services, cosmetics, and lifestyle modifications being recommended within the pharmacy are based on scientific evidence. [7]
	Pharmacists are to ensure that prescription only medication and narcotics are not suggested or promoted to patients within a pharmacy setting. Suggestions include adverts, leaflets, and posters.[30]

	Pharmacists are encouraged to recognise any emerging health requirements within the local scenario. They can create resources to address these emerging requirements.[7]
	Pharmacists are to make patients more aware of chronic diseases, recommend strategies for disease prevention and suggest health plans.[7]
4.4 Responding to Symptoms and Self-Care	Prior to responding to a patient's symptoms, pharmacists can try to familiarise themselves with the patient's main characteristics, treatment history, past medical history, and the presence of any allergies.[3]
	Prior to responding to a patient's symptoms, pharmacists are to ask the patient to further elaborate on the symptom severity and duration. Pharmacists are to ask whether there is a scenario that improves or worsens the symptoms and if there are any other symptoms that are occurring.[3]
	Pharmacists are to assess the patient's presenting symptoms thoroughly prior to dispensing any over the counter medication.[3]
	Pharmacists are to refer the patient to their physician if the presenting symptom requires referral.[3]
	When responding to symptoms, pharmacists can offer the patient any additional information which is relevant to the presenting symptom.[3]
	Pharmacists can offer to design leaflets regarding self-care.[3]

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Appendix 2: The Four Standard Operating Procedures

Standard Operating Procedure

SOP Code: QUALITY-01

SOP Title: Quality of Care

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SOP Number **QUALITY-01**	SOP Title **Quality Of Care**

1. Purpose and Scope

1.1. This Standard Operating Procedure (SOP) describes the 'Quality of Care' within a Community Pharmacy setting.

1.2. This SOP applies to pharmacists, managing pharmacists, locum pharmacists and pharmacy staff working in a Community Pharmacy setting within Malta and Gozo.

2. Definitions

2.1. ***Generic Medication:*** a medication that is developed in the same way as a previously authorised medication. The authorisation is granted based on the safety and efficacy of the originator medication. The generic medication can be marketed after the originator products' ten-year exclusivity period has expired. [1]

2.2. ***High Risk Patient:*** a high cost and high need patient based on pharmaceutical care aspects. [2]

2.3. ***Medical Device:*** a regulated instrument which is utilised for medical purposes. [3]

2.4. ***Non-Prescription Medication:*** a medicinal product that can be purchased with or without a prescription signed by a medical doctor.

2.5. ***Originator Product:*** a medication that was authorised and marketed originally based on its safety, efficacy, and quality. It is the first medication worldwide containing such active pharmaceutical ingredients. [4]

2.6. ***Prescription Medication:*** a medicinal product that can only be purchased upon the presentation of a prescription signed by a medical doctor.

2.7. ***Regimen:*** a treatment plan given by the prescriber which would specify the treatment duration, the dose, and the schedule. [5]

2.8. ***Self-care:*** when an individual is able to maintain and promote their health and well-being, prevent the occurrence of diseases, and handle any illnesses without the help of a healthcare professional. [6]

2.9. ***Self-medication:*** when an individual takes any herbal preparation, home remedies or active pharmaceutical ingredients for a condition without consulting a healthcare professional. [7]

3. Responsibilities

3.1. Individuals working within the Community Pharmacy are responsible for following this SOP, including:

i. The Managing Pharmacist

ii. Other Pharmacists and Locum Pharmacists

iii. Pharmacy Staff such as Sales Assistants

4. Health and Safety Requirements

4.1. Health and safety requirements are not applicable for the following SOP.

5. Procedure

5.1. ***Accessibility***

5.1.1. Pharmacists are to be readily available for any patient that enters the pharmacy. [8]

5.1.2. Pharmacists shall understand the healthcare system and be able to explain the complexity of the system to any patient seeking advice. [9]

5.1.3. Pharmacists can discuss the availability of generic medication for originator products. [8]

5.1.4. Pharmacists can be more accessible to their patient by altering how they communicate with the patient according to their level of education, age, and character. [10]

5.1.5. Pharmacists can substitute a branded medication with a generic medication. This is only relevant if the generic medication has the same dosage form and strength. If a different strength is available, the pharmacist must ensure that the prescribed dose can be made up prior to dispensing it. [11]

5.1.6. Pharmacists should try to obtain medications through different wholesale dealers when there is a drug shortage. [11]

5.1.7. Pharmacists are to inform any attending physicians of current drug shortages in order to prevent patients' from panicking. [11]

5.2.***Effectiveness***

5.2.1. Pharmacists shall ensure that the medicines dispensed are effective. [8]

5.2.2. Pharmacists are to promote dispensing and prescribing which is both economical and rational. [8]

5.2.3. The pharmacy service is relevant to the patient, it shall be defined clearly and is communicated effectively to the involved parties. [8]

5.2.4. Pharmacists are to supply, prepare, test, store, distribute and dispense medicines in a safe and efficacious way. [12]

5.2.5. Pharmacists shall make sure that the right medication is dispensed to the right patient. The medication should be in both the right dose and dosage form for

the patient. Pharmacists should ensure that the patient is empowered to take the medication at the right time and frequency. [13]

5.3.***Counselling***

5.3.1. Pharmacists can verbally advise the patient about any medication information along with providing written information for future reference. [13]

5.3.2. Pharmacists are to advise patients to take the medication dispensed in an appropriate manner. [13]

5.3.3. Pharmacists are to educate patients on correct medication use, side effects, interactions with food and even adverse reactions. [13]

5.3.4. Pharmacists are to take the patient's history and ensure that the patient made the appropriate self-diagnosis before dispensing any medication. [13]

5.3.5. Pharmacists are to support patients in self-care for appropriate self-diagnoses, in the use of non-prescription medications and the appropriate time for physician referral. [13]

5.3.6. Pharmacists are to demonstrate how to use medical devices in an accurate and effective way. Pharmacists shall ensure that the patient understands how to use the device in a proper manner. [13]

5.3.7. Pharmacists can opt to repeat any main advisory points given to the patient or ask the patient to repeat the advice themselves to ensure the maximum benefit is attained. [10]

5.3.8. Pharmacists are to discuss the timing of medication with the patients and adjust the timing according to the patients' lifestyle and the presence of certain medication in the current regimen. [10]

5.3.9. Pharmacists are to ensure that the patient is aware of any food items that should not be taken with the medication or should be avoided. [10]

5.3.10. Pharmacists are to provide the patients with valid reasons as to why certain counselling remarks are being stated. [10]

5.4.***Monitoring Medication Use and Follow-Ups***

5.4.1. Pharmacists are to monitor patients in order to identify whether the services used and the drugs taken are being optimised. [14]

5.4.2. Follow-ups with patients that visit a pharmacy regularly can be performed. During the follow-up, the pharmacist can assess patients' adherence to medication, identify any problems related to adherence and address any issues that are being encountered. [15]

5.4.3. Pharmacists shall recognise whether high risk patients require a follow up or need to be referred to a physician. [14]

5.4.4. Pharmacy owners shall ensure that the pharmacy has a designated area to council patients regarding their medication usage. [16]

5.4.5. Pharmacists are to monitor regular patients getting non-prescription medication for inappropriate reasons. Pharmacists shall ensure that these patients are responding well to their self-care medication. [14]

5.5.***Management of Patient Therapy***

5.5.1. Pharmacists shall identify and help the patient manage and prioritise their health problems. [8]

5.5.2. Pharmacists are to provide the patient with all the medicine, illness, and health related information to allow the patient to participate in the process of designing a medication care plan. [16]

5.5.3. Pharmacists can communicate with the other healthcare providers involved in the patients care to prevent any medication errors from occurring. [16]

5.5.4. Pharmacists shall refer any patient coming to the pharmacy with certain health concerns to the appropriate physician. [16]

5.5.5. Pharmacists shall identify when the patient's care is outside their abilities and should refer them to an appropriate physician. [14]

5.6.***Optimisation of Treatment***

5.6.1. Pharmacists can suggest the use of pill boxes, medication calendars or medication charts to help improve the patients' adherence and thus optimise the treatment. [15]

5.6.2. Pharmacists shall council the patient and consult with other healthcare professionals to guarantee that the patient is receiving advice which is in accordance with their health goals thus optimising their health outcomes. [14]

6. Reason for Revision

6.1.Not applicable as this is a new SOP.

7. References

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8. Appendix

8.1. Not applicable.

Standard Operating Procedure

SOP Code: QUALITY-02

SOP Title: Quality of Safety

Author: Alessia Stivala

Supervisor: Professor Lilian M. Azzopardi

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1. Purpose and Scope

1.1. This Standard Operating Procedure (SOP) describes the 'Quality of Safety' within a Community Pharmacy setting.

1.2. This SOP applies to pharmacists, managing pharmacists, locum pharmacists and pharmacy staff working in a Community Pharmacy setting within Malta and Gozo.

2. Definitions

2.1. ***Anti-tampering device***: a safety feature which shows whether the medication in question has been tampered with. [1,2]

2.2. ***Brand Name:*** the name of a medication that was authorised and marketed originally based on its safety, efficacy, and quality. It is the first medication worldwide containing such active pharmaceutical ingredients. [3]

2.3. ***Colostomy:*** when an opening within the colon is guided to the side of the abdominal surface. It is utilised to eject the patients faeces. [4]

2.4. ***Competent Authority:*** a medicines regulatory authority which operates within a country present in the European Union. [5]

2.5. ***Decommission:*** this applies to the unique identifier code introduced through the falsified medicines directive. It occurs when the medicinal product has changed its active status within the system to a status which impedes further verification. [1,2]

2.6. ***Deprescribing:*** when a healthcare professional discontinues, withdraws, tapers, or stops a drug the patient is taking. The main aim is to improve the patients' health outcomes and manage the issue of polypharmacy. [6]

2.7. ***Generic Name:*** a medication that is developed in the same way as a previously authorised medication. The authorisation is granted based on the safety and efficacy of the originator medication. The generic medication can be marketed after the originator products' ten-year exclusivity period has expired. [7]

2.8. ***Green Prescription:*** a prescription which is utilised to supply drugs which are classified as narcotics and psychotropics. [8]

2.9. ***Ileostomy:*** when an opening within the ileum is guided to the right side of the abdominal surface. By doing so, the large intestine is either removed, or bypassed in order to create the ileostomy. [4]

2.10. ***Medical Device:*** a regulated instrument which is utilised for medical purposes. [9]

2.11. ***Medication Review:*** A pharmacist reviews the patients medication in a structured way, with the main aim being medication optimisation and improving the patients' health outcomes. Interventions are to be recommended to the patient and drug related issues are to be detected. [10]

2.12. ***Point-of Care Testing:*** laboratory testing which is conducted close to the patient rather than within a laboratory. [11]

2.13. ***Polypharmacy:*** when a patient is taking multiple drugs, or more drugs than the patient medically needs. [12]

2.14. ***Registers:*** the relevant registers are the following: the dangerous drug sales register, the dangerous drug purchases register, the dangerous drug pharmacy of your choice (POYC) sales register, the dangerous drug POYC purchases register, the temperature register, the cleaning records register, the locums register and the daily register.

2.15. ***Stoma:*** when an opening is created during a surgery. [4]

2.16. ***Unique identifier:*** a safety feature which confirms the authenticity of a specific medicinal product box. [1,2]

2.17. ***Urostomy:*** it is formed when the ileal conduit is joined to the ureters in order to allow the passage of urine through an abdominal opening. [4]

3. Responsibilities

3.1. Individuals working within the Community Pharmacy are responsible for following this SOP, including:

i. The Managing Pharmacist

ii. Other Pharmacists and Locum Pharmacists

iii. Pharmacy Staff such as Sales Assistants

4. Health and Safety Requirements

4.1. Health and safety requirements are not applicable for the following SOP.

5. Procedure

5.1. ***Medication Review***

5.1.1. Pharmacists are to be vigilant in identifying medicinal products that are contraindicated or are posing risks which exceed the benefits. [13]

5.1.2. Pharmacists shall identify the patients' information by asking any relevant questions in order to eliminate the risk of possible allergies and adverse drug reactions. [13]

5.1.3. Pharmacists can collaborate with other healthcare professionals in order to have a certain level of confidence and trust in the pharmacotherapy chosen for the patient. [13]

5.1.4. Pharmacists can perform medication reviews with elderly patient to identify the presence of unsuitable medications. Deprescribing certain medication could be a step forward in resolving the issue of polypharmacy. [14]

5.1.5. Pharmacists shall address medication problems that arise after a medication review is performed. These issues are to be discussed with other healthcare professionals. [15]

5.1.6. Pharmacists can report any issues identified in the patients care plan to the patients main physician. This is mainly important if a change in behaviour is observed. [15]

5.1.7. Pharmacists can ensure that the medication is still suitable for the needs of the patient by identifying if any changes in health status or regimen have occurred. This can be ideal if the patient comes to the pharmacy with a repeat prescription. [16]

5.2.***Therapeutic Monitoring***

5.2.1. Pharmacists can monitor the patients' therapy by performing point-of care tests. Recommendations to alter any medications according to the results obtained can be made and are to be discussed with both the patient and care providers to ensure collaborative patient care. [14]

5.3.***Identifying Prescription Errors***

5.3.1. Pharmacists are to prevent the patient from getting harmed from any medicinal product. [13]

5.3.2. Pharmacists are to promote an environment within their community pharmacy that identifies, evaluates, and acts on prescription errors. [14]

5.3.3. Pharmacists are to ensure that a proper handover between shifts occurs in order to reduce prescription errors due to the presence of multiple staff. [14]

5.3.4. Pharmacists are to call the prescriber if the prescription is illegible, an error was present or there is lack of information such as the dose, and dosage regimen. [17]

5.4.***Side Effect and Adverse Event Reporting***

5.4.1. Pharmacists can create an internal system to obtain feedback about any errors, adverse events, medication misuse and abuse occurring at the pharmacy. Such a system can promote a discussion between the pharmacists and pharmacy staff. [13] A similar system is present in Appendix 1 and 2.

5.4.2. Pharmacists are to report any newly discovered side effects and adverse reactions to the competent authority, being the Malta Medicines Authority. [18]

5.4.3. Pharmacists can check what adverse reactions are being reported in the European Union through the following website ‘www.adrreports.eu’. [19]

5.4.4. Pharmacists can encourage patients to report their own side effects using the ‘patient side-effect online form’ designed by the competent authority present in Malta which is the Malta Medicines Authority. [19]

5.5.***Optimal Medicine Use***

5.5.1. Pharmacists are to help patients using medical devices to dispense their medications e.g., pen injectors, by showing them how to take the appropriate dose. [20]

5.5.2. Pharmacists are to suggest appropriate measuring devices like a dropper or oral syringe when dispensing an oral liquid medicinal product in order to accurately measure the prescribed dose. [20]

5.6.***Medicine Disposal***

5.6.1. Pharmacists are to make patients aware of the hazards posed by disposing medical waste incorrectly. [13]

5.6.2. Pharmacists can offer a pharmacy service whereby collection of expired or unwanted medications can take place, to promote safe medication disposal. [14]

5.7.***Dangerous Drug Act (DDA) and Special Items***

5.7.1. Pharmacists are to follow the legal requirements for dispensing drugs listed within the DDA. [21] The dispensing procedure is described in Appendix 3.

5.7.2. The drugs listed within this act are required to be kept under lock and key and should only be accessed by authorised technical staff under the direction of the pharmacist. It is the responsibility of pharmacists to take measures to prevent any theft and have diverse stock. [21]

5.7.3. Managing pharmacists should ensure that Dangerous Drugs are subject to the same storage and dispensing conditions as with other medication. [22]

5.7.4. Pharmacists should keep records of any registers, prescriptions, or documents for not less than two years. [21]

5.7.5. Pharmacists are to have a dangerous drug purchases register and a dangerous drug sales register for both pharmacy and POYC stock. [8,23]

5.7.6. Pharmacists are to ensure that the dangerous drug register has the following format: date of dispensing, name, medicine quantity, dosage form, medicine strength, prescriber name, prescriber registration number, date, prescription number. [23]

5.7.7. Pharmacists are duty bound to request a legal document of the person when dispensing a prescription. If someone is collecting medications on another person's behalf, legal documents of both individuals are to be requested. [8,21]

5.7.8. The managing pharmacist is required to send the Superintendent of Public Health an envelope with the prescriptions dispensed in the pharmacy. This should be sent on the first day of every month. [8,21]

5.7.9. Pharmacists should ensure that each green prescription is used only once. [8]

5.7.10. Pharmacists should ensure that an urgent prescription does not exceed a supply of more than seven days. [8]

5.7.11. Pharmacists should be aware of the fact that the Control Card used for Dangerous Drugs is only valid for one year from the date of issue. The validity of the Control Card is to be checked prior to dispensing any medication. [8]

5.7.12. Pharmacists are to perform a stock take of Dangerous Drugs on a yearly basis. This is to be sent to the Malta Medicines Authority. [23]

5.7.13. Pharmacists are encouraged to perform regular stock takes of the DDA cupboard. [21]

5.7.14. Pharmacists are to store any expired Dangerous Drugs in a specific area of the DDA cupboard and not next to the other stock. [23]

5.7.15. Pharmacists can provide product application services to patients with a colostomy, ileostomy or a urostomy. Stoma care can also be discussed with the patient. [24]

5.7.16. Pharmacists can provide catheter care and information to patients with a catheter. [25]

5.8.***Stock Control***

5.8.1. The procurement, handling, and storage of medicinal products shall ensure that the products safety, quality, and efficacy is maintained. Pharmacists are to ensure that systems to safeguard this are set in place. If these steps are not performed in an appropriate manner a breach of safety can occur by the time the medication is dispensed. [14]

5.8.2. Pharmacies are required to have a register for the temperature within the pharmacy, the stores and even the refrigerator. Medicinal products found in the pharmacy should be preserved from any form of humidity and excess heat or cold. [26]

5.8.3. Pharmacists should store stock according to the temperatures stated on the medicinal packaging.

- Frozen: at -20°C
- At 2-8°C: store in a refrigerator
- Cool: store at 8-15°C
- At room temperature: store at 15-25°C. [27]

5.8.4. Pharmacists are to measure, record and review the minimum and maximum temperature of the refrigerator where both pharmacy and POYC stock is stored. [23,28]

5.8.5. Pharmacists are to measure, record and review the minimum and maximum temperature of the dispensary and any other area where both pharmacy and POYC stock is stored. [23,28]

5.8.6. Pharmacists must ensure that the thermometers used to check the temperature in the pharmacy are calibrated on a yearly basis. [23]

5.8.7. Medications having look-a-like packaging or similar names should ideally be stored in different areas to decrease the likelihood of dispensing errors. [20]

5.8.8. Pharmacies are to have methods in place in order to regularly review the stock present.[20]

5.8.9. Pharmacy stock is to be stored carefully and appropriately. Storage areas should not be cluttered as this increases the chance of prescription errors. [20]

5.8.10. A systematic storage system like an alphabetical system should be employed to make the retrieval of drugs easier and to reduce the risk of errors. [20]

5.8.11. The stock can be stored according to the generic name or brand name with no distinction of dosage forms. [20]

5.8.12. An adequate area for unpacking new stock which is received is necessary to reduce the mixing of products. [18]

5.8.13. Pharmacists are to ensure that their stock is stored according to the expiry date with the product having the shortest expiry date in front and the product with the longest expiry date at the back. This prevents pharmacists from dispensing expired medicines. [20]

5.8.14. Pharmacists and pharmacy staff are to store expired medicinal products in a separate area of the pharmacy prior to disposal. They must be clearly labelled to avoid any confusion. [23]

5.8.15. Systems to ensure that expiry date monitoring is undertaken are to be set in place. [20]

5.8.16. Medications like insulin can be stored in separate containers in the refrigerator in order to easily distinguish the different types. [20]

5.8.17. Stock which has been discontinued or recalled should immediately be removed from the other stock. This is also the case for expired medications. [20]

5.8.18. Pharmacists are to confirm the authenticity of the medicinal products' unique identifier code, verify the anti-tampering device identity and decommission the code as per the falsified medicines directive. This can be performed by scanning the unique identifier code. [1,2]

5.8.19. Pharmacists can open a medicinal product having a unique identifier code and supply only a part of the product. The medicinal product has to be verified and decommissioned as per the falsified medicines directive. [1,2]

5.8.20. Pharmacists are to ensure that pest control is performed on an annual basis. [23]

6. Reason for Revision

6.1.Not applicable as this is a new SOP.

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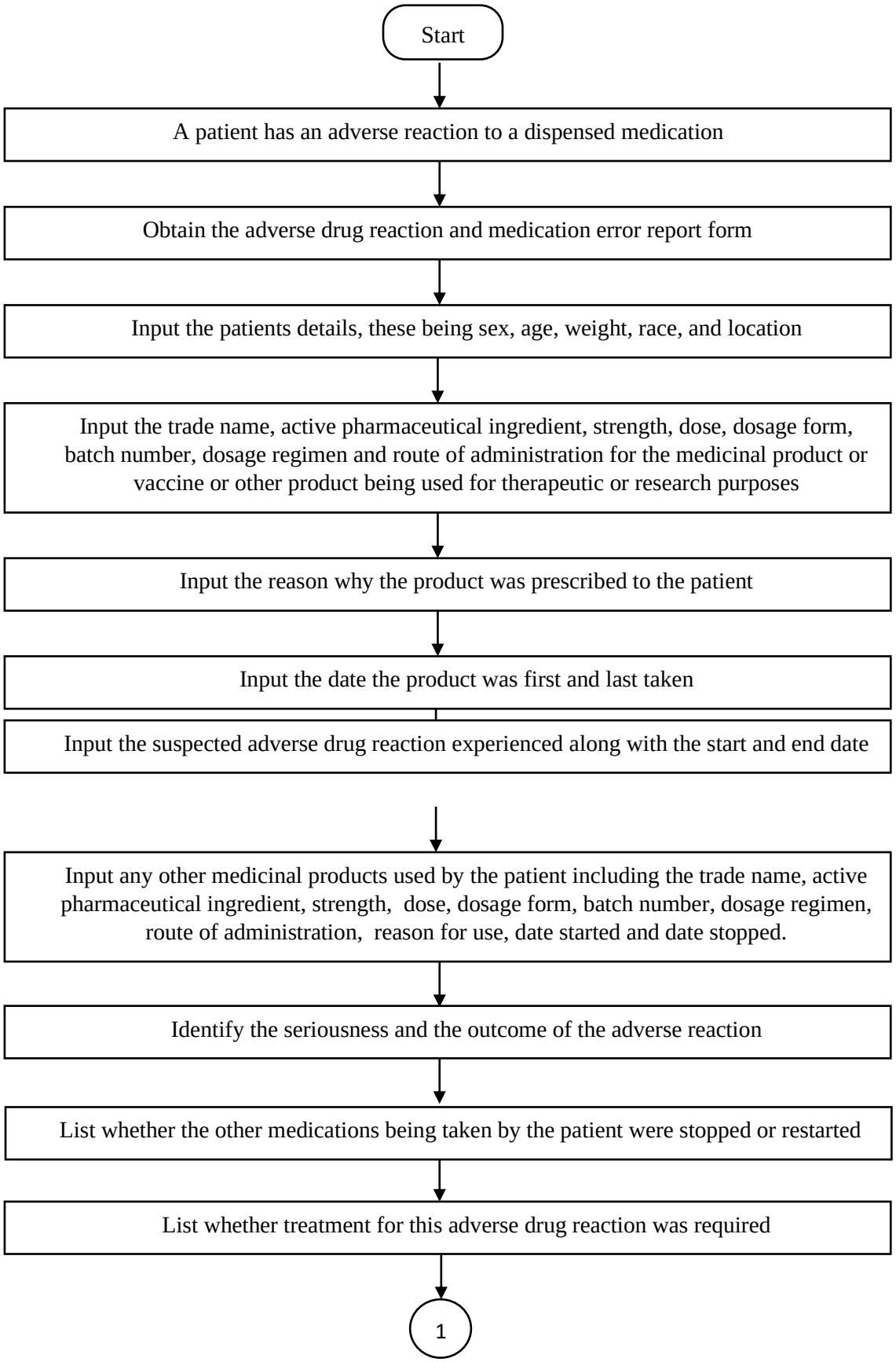
8. Appendix

8.1 Appendix 1: Reporting an Adverse Drug Reaction to the Malta Medicines Authority

8.2 Appendix 2: Adverse Drug Reaction and Medication Error Report Form

8.3 Appendix 3: Dispensing Against a Green Prescription

Appendix 1


Start
A patient has an adverse reaction to a dispensed medication
Obtain the adverse drug reaction and medication error report form
Input the patients details, these being sex, age, weight, race, and location
Input the trade name, active pharmaceutical ingredient, strength, dose, dosage form, batch number, dosage regimen and route of administration for the medicinal product or vaccine or other product being used for therapeutic or research purposes
Input the reason why the product was prescribed to the patient
Input the date the product was first and last taken
Input the suspected adverse drug reaction experienced along with the start and end date
Input any other medicinal products used by the patient including the trade name, active pharmaceutical ingredient, strength, dose, dosage form, batch number, dosage regimen, route of administration, reason for use, date started and date stopped.
Identify the seriousness and the outcome of the adverse reaction
List whether the other medications being taken by the patient were stopped or restarted
List whether treatment for this adverse drug reaction was required
1

Appendix 1 (cont.)

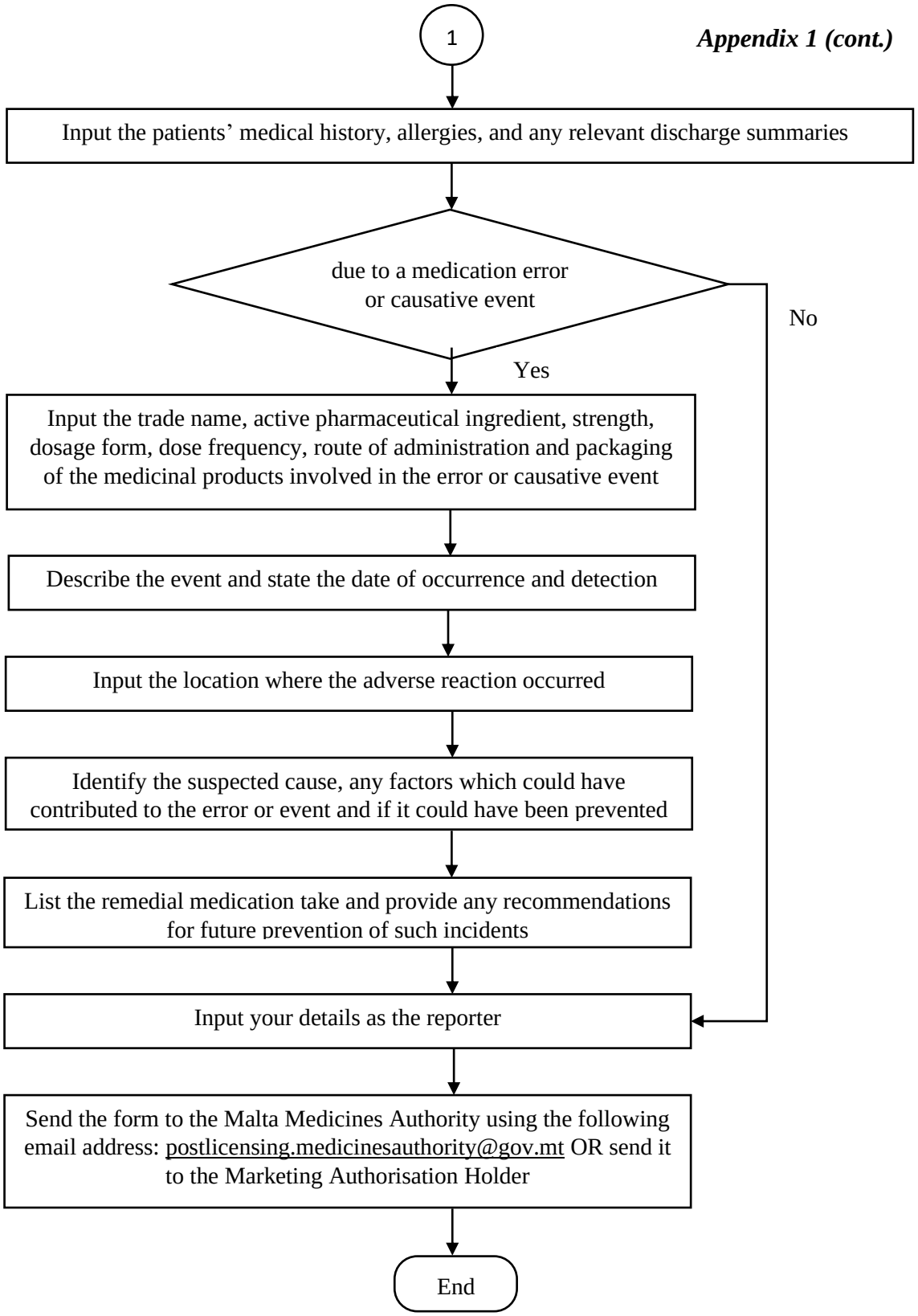


Figure 1: Reporting an Adverse Drug Reaction to the Malta Medicines Authority

Adapted from: Malta Medicines Authority (MMA). Report Side Effects [Internet]. San Gwann (Malta): MMA; 2020 [cited 2021 Aug 21]. Available from: http://www.medicinesauthority.gov.mt /adversedrugreactions?l=1

Appendix 2

ADVERSE DRUG REACTION REPORT FORM

ADVERSE DRUG REACTION AND MEDICATION ERROR REPORT FORM

ALL PATIENT INFORMATION WILL REMAIN CONFIDENTIAL, REPORTER INFORMATION WILL BE DESTROYED

Before you start reporting please check which sections should be filled in
Please complete as much information as possible
Tick boxes where appropriate

Are you reporting an adverse drug reaction?	☐	(fill in sections 1 and 3)
Are you reporting an adverse drug reaction due to a medication error or other causative event (eg occupational exposure, abuse, overdose)?	☐	(fill in sections 1, 2 and 3)
Are you reporting a medication error or other causative event that did not lead to an adverse drug reaction?	☐	(fill in sections 2 and 3)

For a detailed explanation on how to fill in particular sections, please refer to the instructions at the back of the form

SECTION 1: REPORTING ADVERSE DRUG REACTIONS

1.1 PATIENT DETAILS

INITIALS _____ ☐ **MALE** ☐ **FEMALE** **AGE (at time of reaction)** _____ **WEIGHT (in kg, if known)** _____ **RACE** _____ **AREA** _____

1.2 SUSPECTED MEDICINE(S) / VACCINE(S) / BLOOD PRODUCT(S) / CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES
(list the medicine you think caused the side effect)

Trade name, Active ingredient, Strength, Form, Batch no.	Dosage, frequency, route	Prescribed for	Date started dd	Date started mm	Date started yr	Date stopped dd	Date stopped mm	Date stopped yr
Medicine 1								
Medicine 2								
Medicine 3								

1.3 SUSPECTED ADVERSE DRUG REACTION (Describe each side-effect in as much detail as possible)

	Date started dd	Date started mm	Date started yr	Date stopped dd	Date stopped mm	Date stopped yr
ADR 1						
ADR 2						
ADR 3						

1.4 LIST OTHER MEDICINES BEING TAKEN BY THE PATIENT (including over the counter & herbal medicinal products)

Trade name, Active Ingredient	Dosage (amount), frequency (eg: twice a day), route (eg: oral)	Prescribed for	Date started dd	Date started mm	Date started yr	Date stopped dd	Date stopped mm	Date stopped yr

Tick boxes where appropriate

1.5 How serious do you consider this Adverse Drug Reaction?

	ADR 1	ADR 2	ADR 3
Fatal	☐	☐	☐
Life threatening	☐	☐	☐
Caused or prolonged hospitalisation	☐	☐	☐
Birth defect	☐	☐	☐
Caused disability	☐	☐	☐
Other medically significant condition	☐	☐	☐
Not Serious	☐	☐	☐

1.6 Outcome from Adverse Drug Reaction:

	ADR 1	ADR 2	ADR 3
Recovered	☐	☐	☐
Recovering	☐	☐	☐
Symptoms continuing	☐	☐	☐
Long-term effects	☐	☐	☐
Death	☐	☐	☐
Not known	☐	☐	☐

1.7 For this Adverse Drug Reaction(s):

	YES	NO
Suspect medicine 1 was stopped	☐	☐
Suspect medicine 2 was stopped	☐	☐
Suspect medicine 3 was stopped	☐	☐
Was medicine restarted	☐	☐
Manufacturer notified of this ADR	☐	☐
Treatment required for this ADR	☐	☐
If yes, which Is this the first time you reported the ADR	☐	☐

1.8 ADDITIONAL RELEVANT INFORMATION (if known)
(known allergies, test results, medical history, discharge summaries – information may be attached)

☐ Liver disease ☐ Kidney disease	Allergy (please describe):	Pregnancy weeks
Other illnesses (please describe):		

1.9 WAS THIS ADVERSE DRUG REACTION CAUSED BY A MEDICATION ERROR OR OTHER CAUSATIVE EVENT?
☐ **Yes - please fill in section 2 and 3.** ☐ **No - please fill in Section 3 Reporter Details**

PLEASE NOTE THAT FOR ALL REPORTS SECTION 3 MUST BE FILLED IN

FormP010/3version02

ADVERSE DRUG REACTION REPORT FORM

MEDICATION ERROR REPORT FORM

SECTION 2: MEDICATION ERROR REPORTING

IMPORTANT: 'The submission of a report does not constitute an admission that the patient, medical personnel, user facility, importer, distributor, manufacturer or the medicine itself caused or contributed to the event'.

2.1 MEDICINE(S) INVOLVED IN MEDICATION ERROR OR OTHER CAUSATIVE EVENT (EG OCCUPATIONAL EXPOSURE)

	Medicine 1	Medicine 2	Medicine 3
	If the same details were filled in section 1.2, you can leave this section blank		
Medicine Trade Name			
Active Ingredient (substance in a medicine that is biologically active)			
Form (eg: tablets, injection)			
Strength (eg: g, mg, ug)			
Dose frequency, duration, route (eg: 1 tablet, 3 dly, by mouth)			
Type of container (eg blister pack, loose strip or other)			

2.2 DATE OF EVENT

Date event occurred: ___/___/___ Date event was detected: ___/___/___

2.3 DESCRIBE THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT (EG OCCUPATIONAL EXPOSURE) RELATED TO THE MEDICINE

Free Text (eg Wrong route; wrong dose; wrong medicine; other):	**For medication errors – tick the stage the error may have occurred**
	Prescribing ☐
	Dispensing ☐
	Preparation ☐
	Storage ☐
	Distribution ☐
	Administration ☐

2.4 LOCATION WHERE THE EVENT OCCURED

(eg Nursing home, Home, Hospital, Pharmacy, Clinic, Other)

2.5 SUSPECTED CAUSE OF THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RELATED TO THE MEDICINE

2.6 ANY FACTORS CONTRIBUTING TO THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RELATED TO THE MEDICINE

(eg. Omission of meals, concomitant alcohol intake, over exposure to heat and sun, other)

2.7 WAS THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT PREVENTABLE? ☐ Yes ☐ No

2.8 WAS ANY REMEDIAL ACTION RELATED TO THE MEDICINE TAKEN?

☐ Yes (please describe)_____ ☐ No

2.9 RECOMMENDATIONS TO PREVENT REPEAT INCIDENT

2.10 DID THE MEDICATION ERROR OR OTHER CAUSATIVE EVENT RESULT IN AN ADVERSE DRUG REACTION?

☐ **Yes - please fill in section 1.** ☐ **No - please fill in your details below**

SECTION 3: REPORTER DETAILS

Details will be destroyed following transmission to the EU central side effect database Eudravigilance

Type/Circle - doctor/dentist/pharmacist/other healthcare professional/patient
Name:
Address:
Telephone/Mobile:
E-mail address:

Signature _____ **Date** _____

The Medicines Authority thanks you for the time taken to fill in this form. The reporting of Adverse Drug Reactions is an important process whereby Regulatory Authorities can learn more about the medicine and its uses and take appropriate action in order to protect and enhance public health	☐ ***SUPPLY OF ADR REPORT CARDS IS REQUIRED*** ☐ ***INFORMATION ABOUT OTHER ADRs IS REQUIRED***

PLEASE NOTE THAT FOR ALL REPORTS SECTION 3 MUST BE FILLED IN

FormP010/3version02

INSTRUCTIONS FOR REPORTING ADVERSE DRUG REACTIONS AND MEDICATION ERRORS OR OTHER CAUSATIVE EVENT

TERMS AND DEFINITIONS

Definition for Patients/users of medicines (consumers)

Side effects (also referred to as adverse drug reactions or adverse events) are those troublesome effects, symptoms or feelings that show up when you are using a medicine. When medicines are used incorrectly they are more likely to cause a side-effect.

For this reporting system a medication error is an event, related to how medicines were used, which affected or could have potentially affected a patient's safety and caused or had the potential to cause that patient to experience a side-effect.

Definition for Healthcare Professionals

Adverse Drug Reaction (ADR): An ADR is a response to a medicinal product which is noxious and unintended. This includes side effects resulting from the authorised use of a medicinal product at normal doses, medication errors; off-label use and the misuse and abuse of medicinal products.

Medication error: For the scope of this reporting system, medication errors that require reporting to the Medicines Authority are those which are related to the use of medicinal products. The adopted definition of a medication error is: *Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the health-care professional, patient or consumer.* (National Coordinating Council for Medication Error Reporting and Prevention).

Other Causative Events: include occupational exposure, abuse, overdose etc.

Section 1: Side Effect Reporting

1.1 *Patient Details:* Only initials must be used, never the whole name. The identity is kept in strict confidence by the Medicines Authority.

Age at time of event or date of birth: Provide information that is as accurate as possible. Enter the birth date, if known, or the age at the time the side-effect started. For age, indicate time units used (e.g., years, months and days).

Gender: Enter whether male or female. If the side-effect or medication error concerns a congenital anomaly (birth defect) report the gender of the child.

Weight: Indicate whether the weight is in kilograms or any other unit. If the exact weight is unknown, try and make the best estimate.

1.2 *Suspected Medicine(s)/Vaccine(s)/Blood product(s):* For these reports, a suspect medicine is one that you think was associated with the side effect, interaction or medication error. Use the trade name as marketed. If this is unknown, use the active ingredient and the manufacturers name if known.

Dose: Report the strength and form of the medicine in the appropriate units. The frequency of administration and the route of administration should be included in this field e.g. 500mg tablets, twice daily, orally (by mouth). For medication errors involving a wrong dose, write the dose that was used in error.

Prescribed for: Provide the reason (indication) for which the medicine was prescribed as accurately as possible.

Therapy dates: Provide the date when the medicine was started (or best estimate) and the date the medicine was stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g. 6 months) or, if less than 1 day then duration is appropriate e.g. 1 dose or infused over 1 hour.

1.3 *Suspected Adverse Drug Reaction(s):* Describe the side effect in as much detail as possible, including a description of what happened and a summary of all relevant medical information. Example 1-- A hemorrhage from the use of too much anticoagulant (such as heparin) is a side effect caused by treatment.
Example 2 -- The common side effects of cancer treatment including fatigue, nausea, vomiting, decreased blood cell counts, hair loss, and mouth sores are instances of side effects that occur in addition to the desired anticancer effect.

Date of event: Provide the actual or best estimate of the date the side effect first started. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

1.4 *Other Medicines:* Enter all other medicines (herbal, over the counter medicines) that were being used at the time of event but that there is no suspicion of involvement in the event. Be as complete as possible

1.5 *How serious do you consider each Adverse Drug Reaction?:* The seriousness of each Adverse Drug Reaction should be marked in the appropriate box within the table. The following outcomes: fatal, life-threatening, hospitalization, disability, birth defect and medically significant conditions are considered to be serious adverse drug reactions
Fatal – only mark this box if it is suspected that death was an outcome of the reaction to the medication.
Life-threatening – only mark this box if it is suspected that the patient was at substantial risk of dying as a result of the ADR
Hospitalisation - initial/prolonged – only mark this box if there is a suspicion that admission to hospital or prolongation of hospitalisation was a result of the ADR by the medicine.
Disability or Incapacity – only mark this box if the adverse reaction resulted in a disruption of a person's ability to conduct normal life functions.
Birth defect – mark this box if you suspect that exposure to a medicine before conception or during pregnancy may have resulted in an adverse outcome in the child.
Medically significant condition – mark this box when the ADR was a hazard to the patient and may require medical or surgical intervention to prevent further outcomes.
Non serious - mark this box if the consequences of the ADRs were non-serious (ie none of the above).

1.6 *Outcome for each Adverse Drug Reaction:* The outcome for each Adverse Drug Reaction reported, should be marked in the related ADR box within the table (eg Adverse Drug Reaction 1 was headache and the outcome was recovered; the Adverse Drug Reaction 2 was rash and the outcome was Symptoms continuing).

1.6 Outcome from Adverse Drug Reaction:

	ADR 1	ADR 2	ADR 3
Recovered	☐	☐	☐
Recovering	☐	☐	☐
Symptoms continuing	☐	☐	☐
Long-term effects	☐	☐	☐
Death	☐	☐	☐
Not known	☐	☐	☐

1.7 *For this Adverse Drug Reaction:* Fill in whether the Suspect medicine(s) indicated in field 1.2 were stopped. *Was medicine restarted*: indicate whether the patient was rechallenged. *Was the manufacturer notified:* Please check the appropriate box depending on whether the Marketing Authorisation Holder; the company that holds a license for the medicine – this information can be found on the box and the patient information leaflet) has been notified. *Treatment required*: indicate whether the adverse drug reaction needed to be treated and if yes, please describe.
Is this an initial report, Please check the appropriate box depending on whether this is the first report of this Adverse Drug Reaction, or whether this report includes additional/follow-up information to a previously submitted report.

1.8 *Additional relevant information:* Provide all appropriate information including medical history, negative test results, differential diagnosis, synopsis of any relevant pathology or further information on the course of events. *If pregnant:* in the case of a pregnancy please specify the number of weeks into the pregnancy at the time the ADR occurred.

1.9 *Was this adverse drug reaction caused by a medication error or other causative event:* Please tick applicable response and follow instructions within the form to report a complete incident report to the Medicines Authority

Section 2: Medication error reporting

A medication error may cause harm (an actual Adverse Drug Reaction) or may have the potential to cause a Adverse Drug Reaction. The Medicines Authority would like to hear about any type of medication error related to medicines, since it can be a source of knowledge on how medicinal products usage can be changed to minimise risk.

2.1 *Medicines involved in medication error or other causative event (eg occupational exposure):* Please provide the trade name as marketed. If this is unknown, use the active substance name with the manufacturers name if known. If the error involves look-alike or sound-alike medicine packaging, include detail on both products.

2.2 *Date of event:* Please indicate to the best of your ability, when the medication error occurred and the date when it was discovered.

2.3 *Describe the medication error or other causative event related to the medicine:* Described the medication error and the events that were related to it, in as much detail as possible, including a description of what happened, how the error was discovered, and who was involved (in a general way without identifying people).

2.4 *Location where the event occurred:* please describe the place where the event (medication error or other cause event) occurred like for example at home or at a pharmacy etc.

2.5 *Suspected cause of medication error or other causative event related to the medicine:* Describe the suspected cause(s) in as much detail as possible. Some examples of suspected causes are sound-alike and look-alike medication or packaging or instructions on dispensing bottles or package etc.

2.6 *Any factors contributing to the medication error or other causative event related to the medicine:* Describe the suspected contributing factor(s) in as much detail as possible (eg. whether there was any omission of meals, concomitant alcohol intake, over exposure to heat and sun etc.)

2.7 *Was the medication error or other causative event preventable?:* Tick the yes or no box in order to give your view on whether the medication error could have been prevented.

2.8 *Was any remedial action related to the medicine taken?:* Tick the yes or no box according to whether any action was taken to prevent the same error from occurring again. If action was taken please describe what this action was.

2.9 *Recommendations to prevent repeat incident:* If no action was taken, you can give your opinion on what remedial action could have been taken. If action was already taken and you would like to add to this, please insert your opinion in this box.

2.10 *Did the medication error or other causative event result in a Adverse Drug Reaction?:* If the medication error resulted in a Adverse Drug Reaction, section 1 on Adverse Drug Reactions should be filled in. If the medication error did not lead to an Adverse Drug Reaction, please fill in section 3 on reporter details.

Section 3.0 Reporter details,

Please provide the name, electronic address and/or mailing address and telephone number. Indicate whether you are a healthcare professional, or consumer/patient by circling the appropriate listing. All reporter information will be destroyed once the ADR is reported to Eudravigilance (a central EU database used by EU regulators to identify risks associated with medicines).

Submit electronically to the Medicines Authority postlicensing.medicinesauthority@gov.mt

Figure 2: Adverse Drug Reaction and Medication Error Report Form

Reproduced from: Malta Medicines Authority (MMA). Report Side Effects [Internet]. San Gwann (Malta): MMA; 2020 [cited 2021 Aug 21]. Available from: http://www.medicinesauthority.gov.mt /adversedrugreactions?l=1

Appendix 3

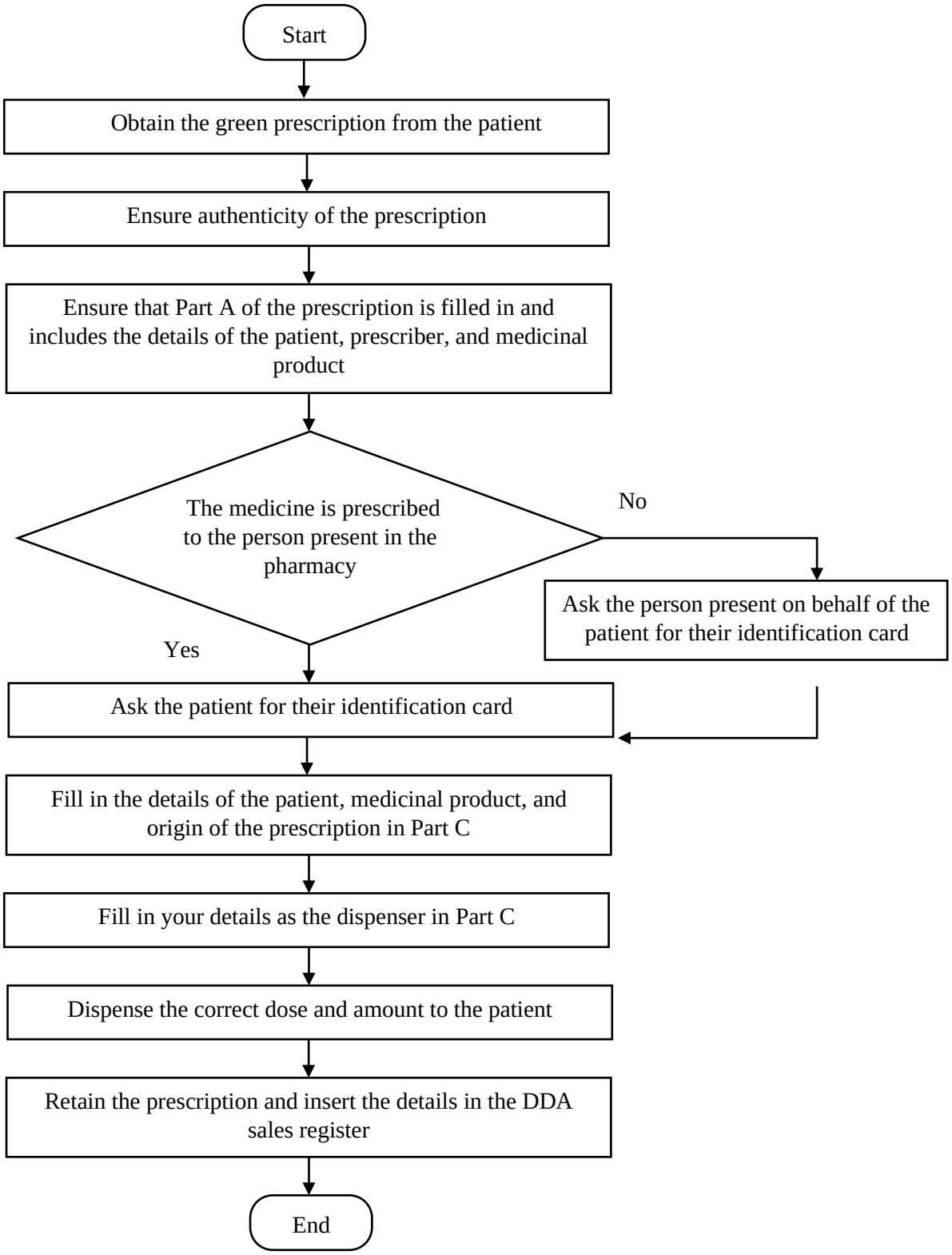


Figure 3: Dispensing Against a Green Prescription

Adapted from: Ministry for Justice, Culture and Local Government. Subsidiary Legislation 101.02 Internal Control of Dangerous Drugs Rules [Internet]. Valletta (Malta): The Ministry; 1939 [cited 2020 Dec 22] Available from: https://legislation.mt/eli/sl/101.2/eng/pdf

Standard Operating Procedure

SOP Code: QUALITY-03

SOP Title: Quality Improvement

Author: Alessia Stivala

Supervisor: Professor Lilian M. Azzopardi

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SOP Number **QUALITY-03**	SOP Title **Quality Improvement**

1. Purpose and Scope

1.1. This Standard Operating Procedure (SOP) describes the 'Quality Improvement' within a Community Pharmacy setting.

1.2. This SOP applies to pharmacists, managing pharmacists, locum pharmacists and pharmacy staff working in a Community Pharmacy setting within Malta and Gozo.

2. Definitions

2.1. ***Clinical Governance:*** a framework used in healthcare organisations to improve service quality and maintain a high standard of care. [1]

2.2. ***Formulary:*** a list of drugs which is continuously updated based on scientific evidence and the judgement of general practitioners and pharmacists. [2]

2.3. ***Risk Assessment:*** a systematic methodology which is used to evaluate and analyse risks present within a working area. [3]

2.4. ***Self-Audit:*** used to identify the major risk areas in order to modify them before an inspection is carried out by the authorities. [4]

3. Responsibilities

3.1. Individuals working within the Community Pharmacy are responsible for following this SOP, including:

i. The Managing Pharmacist

ii. Other Pharmacists and Locum Pharmacists

iii. Pharmacy Staff such as Sales Assistants

4. Health and Safety Requirements

4.1.Health and safety requirements are not applicable for the following SOP.

5. Procedure

5.1.***Self-Audits***

5.1.1. Pharmacists can carry out audits for the services being provided within the premises. [5]

5.1.2. Pharmacists can make use of the community pharmacy regulatory audit tool to perform internal self-audits prior to an inspection from the Malta Medicines Authority. [6]

5.1.3. Pharmacists are to ensure that the audit covers the following features: medicinal product storage conditions, SOP's, registers, stock take of the Dangerous Drugs, the condition of the premises, waste disposal and equipment related to preparing extemporaneous preparations as necessary. [6]

5.2.***Clinical Governance***

5.2.1. A clinical governance lead can be present in a pharmacy. Pharmacies can apply certain clinical governance concepts to their services. Examples include making use of standard operating procedures, professional development, performing self-audits, evaluating the satisfaction of patients, applying risk management strategies, educating staff on any incidents that occur and recording and reporting. [7]

5.2.2. Pharmacists are to produce and utilise community pharmacy systems that are effective and efficient. All elements in a pharmacy shall be organised into

suitable systems. These systems are to be optimised to allow for better patient health outcomes. [8]

5.2.3. Pharmacies are to perform appropriate risk assessments before applying any system or service. [8]

5.3.***Professional Development***

5.3.1. Pharmacists are to engage in continuous education meetings along with regularly reviewing relevant pharmacy journals to further develop their professional career. [9]

5.3.2. Pharmacists should be colleagues and work together in order to improve the pharmacy services offered. [10]

5.3.3. Pharmacists are to be responsible for maintaining their professional competency. Self-monitoring to ensure that pharmacists abide by the standards present is to be performed regularly. [10]

5.3.4. Education of the staff is important to minimise medication errors. The competency of the staff is to be regularly assessed and if it is not satisfied training should take place. [11]

5.3.5. Pharmacists and pharmacy staff should learn to support patients in a non-judgemental way in order to help patients reach any health goals they have. [12]

5.3.6. Pharmacists and pharmacy staff should be able to assess their own knowledge and abilities in order to improve their professional skills. [8]

5.3.7. Pharmacy owners are to support their staff by setting certain goals in order to reach the professional level they require. [8]

5.3.8. Pharmacists are to keep a copy of a formulary like the British National Formulary and an updated edition of the Maltese pharmacy legislation within the pharmacy. [9]

6. Reason for Revision

6.1.Not applicable as this is a new SOP.

7. References

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12. Public Health England. Healthy Living Pharmacy Level 1 Quality Criteria - Assessment of Compliance Healthy Living Pharmacy (HLP) Level 1 [Internet]. London (United Kingdom): Public Health England; 2016 [cited 2021 Feb 20]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads /attachment_data/file/743128/HLP-quality-criteria-and-self-assessement-process.pdf

8. Appendix

8.1. Not applicable.

Standard Operating Procedure

SOP Code: QUALITY-04

SOP Title: Quality of Services

Author: Alessia Stivala

Supervisor: Professor Lilian M. Azzopardi

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1. Purpose and Scope

1.1. This Standard Operating Procedure (SOP) describes the 'Quality of Services' within a Community Pharmacy setting.

1.2. This SOP applies to pharmacists, managing pharmacists, locum pharmacists and pharmacy staff working in a Community Pharmacy setting within Malta and Gozo.

2. Definitions

2.1. ***Biological Waste:*** this includes blood products, blood, human cultures, pathological waste, sharps, and bedding. [1]

2.2. ***Competent Authority:*** a medicines regulatory authority which operates within a country present in the European Union.[2]

2.3. ***Medical Device:*** a regulated instrument which is utilised for medical purposes. [3]

2.4. ***Partially Dispensed Prescription:*** when a medication is partially dispensed due to the pharmacy not having the full quantity. In this case, the pharmacist signs the prescription and states the amount dispensed. [4]

2.5. ***Point-of Care Testing:*** laboratory testing which is conducted close the patient rather than within a laboratory. [5]

2.6. ***Registers:*** the relevant registers are the following: the dangerous drug sales register, the dangerous drug purchases register, the dangerous drug pharmacy of your choice (POYC) sales register, the dangerous drug POYC purchases register, the temperature register, the cleaning records register, the locums register and the daily register.

2.7. ***Repeat Prescription:*** a prescription which is used for a prolonged period of time. The patient is able to use this prescription rather than getting a new prescription every time they go to the pharmacy. [6]

2.8. ***Self-Care:*** when an individual is able to maintain and promote their health and well-being, prevent the occurrence of diseases, and handle any illnesses without the help of a healthcare professional. [7]

2.9. ***Standard Operating Procedure:*** it contains detailed instructions which are used in order to have uniformity in how to perform specific processes. [8]

3. Responsibilities

3.1. Individuals working within the Community Pharmacy are responsible for following this SOP, including:

i. The Managing Pharmacist

ii. Other Pharmacists and Locum Pharmacists

iii. Pharmacy Staff such as Sales Assistants

4. Health and Safety Requirements

4.1. Health and safety requirements are not applicable for the following SOP.

5. Procedure

5.1. ***Point of Care Testing***

5.1.1. Pharmacists are to train their staff accordingly in order to ensure that the devices are used efficiently and effectively by following standard operating procedures set in place. Training should include the interpretation of results obtained and test limitations. [9]

5.1.2. Specific areas of the pharmacy designated for conducting such tests and for disposing of any biological waste are to be present. [9]

5.1.3. Pharmacists are to provide the patient with any relevant information obtained from the point of care test and deliver adequate counselling within a private area of the pharmacy. [9]

5.1.4. Pharmacists are to inform chronically ill patients of when a follow-up of the test is required. [9]

5.1.5. Pharmacists should ensure that the patient has consented to the point of care test being carried out. Pharmacists should obtain permission from the patient before disseminating the results obtained in the point of care test to a physician. If the permission is not granted, pharmacists are to refer the patient to a physician. [9]

5.1.6. Procedures to handle needlestick injuries or the spillage of medicinal waste are to be set in place. [9]

5.1.7. Pharmacists are to ensure that weighing scales are calibrated in a proper manner before use. [10]

5.1.8. Pharmacists are to ensure that any point of care equipment is checked frequently to ensure their accuracy. [10]

5.1.9. Pharmacists are to have a documentation sheet for each point of care test. Such documentation sheets can be utilised to list the patients information, date, and result. [10]

5.1.10. Pharmacists are to ensure that any point of care tests including blood and urine test strips along with pregnancy tests are checked frequently and stored appropriately. [10]

5.2.***Professional Clinical Services***

5.2.1. Pharmacists are to ensure that any dispensing equipment such as tablet counting aids are kept in a clean environment and are cleaned in between uses. [10]

5.2.2. If extemporaneous preparations are prepared in the pharmacy, the pharmacist must ensure that the appropriate equipment is present and kept clean. [11,12]

5.2.3. If extemporaneous preparations are prepared in the pharmacy, the pharmacist should label the preparation with the expiry date which is four weeks. [11,12]

5.2.4. Pharmacists are not to dispense a medicinal product more than once with the same prescription unless the medication was partially dispensed or it is a repeat prescription. Pharmacists should clearly indicate the word ‘dispensed’ next to the appropriate medication, with the quantity and the date. Apart from this information, pharmacists should also include their registration number, their signature, and a stamp of the pharmacy. [13]

5.2.5. Pharmacists are to keep a record of any medicines dispensed with a repeat prescription or partially dispensed prescriptions. In their register, pharmacists are to list the date, the name, quantity, medicinal product, prescriber name and registration number, prescription date and the date when the prescription was received. These should also be satisfied if the pharmacy keeps computerised records. In that case, the record should be printed each day the pharmacy is open. [13]

5.2.6. If the prescription is an eprescription, pharmacists are to ensure that the eprescription was obtained through a legitimate delivery system. [14]

5.2.7. Pharmacists are not to dispense medicinal products without a prescription unless the competent authority states that these medications do not require a prescription to be dispensed. [13]

5.2.8. Verbal instructions by a telephone call are not to be accepted unless the pharmacist is sure that the prescriber is authorised to give such instructions and cannot issue a prescription due to an emergency. The prescriber is to give the pharmacist a prescription within 48 hours. An entry shall be made in a register. This is not applicable to Dangerous Drugs. [13]

5.2.9. Pharmacists are not to dispense a prescription only medication if the prescription is more than 6 months old. This does not apply to repeat prescriptions. [13]

5.2.10. Pharmacists should only dispense antibacterial agents up to 10 days after the prescription was issued. [13]

5.2.11. Pharmacists are to re-check the medicinal product dispensed with that written on the prescription to avoid any potential errors. [10]

5.2.12. Pharmacists can opt to participate in the 70+ domiciliary delivery scheme where the pharmacist delivers the patients' medications from the POYC scheme to their front door. [15]

5.2.13. If pharmacists opt to participate in the 70+ domiciliary delivery scheme they are to offer the application to the patient within the pharmacy and inform the patient that in order for them to register they need to be 70 years and over, or else have mobility issues. Patients with mobility issues are to have an identification card provided by the National Commission for Persons with Disability. [15]

5.3.***Health Promotion and Disease Prevention***

5.3.1. Pharmacists are to promote the health and well-being of the patient. [16]

5.3.2. Pharmacists are encouraged to contribute to any national or local health campaigns. [17]

5.3.3. Pharmacists and pharmacy staff are to provide patients with evidence based healthy lifestyle advice along with information that is relevant to the local health scenario. [18]

5.3.4. Pharmacists and pharmacy staff shall ensure that any materials such as over the counter medication, services, dermo-cosmetics, and lifestyle modifications being recommended within the pharmacy are based on scientific evidence. [19]

5.3.5. Pharmacists are to ensure that prescription only medication and narcotics are not suggested or promoted to patients within a pharmacy setting. Suggestions include adverts, leaflets, and posters. [20]

5.3.6. Pharmacists are encouraged to recognise any emerging health requirements within the local scenario. They can create resources to address these emerging requirements. [19]

5.3.7. Pharmacists are to make patients more aware of risks of chronic diseases, recommend strategies for disease prevention and suggest health plans. [19]

5.4.***Responding to Symptoms and Self-Care***

5.4.1. Prior to responding to a patient's symptoms, pharmacists can try to familiarise themselves with the patient's main characteristics, treatment history, past medical history, and the presence of any allergies. [10]

5.4.2. Prior to responding to a patient's symptoms, pharmacists are to ask the patient to further elaborate on the symptom severity and duration. Pharmacists are to

ask whether there is a scenario that improves or worsens the symptoms and if there are any other symptoms that are occurring. [10]

5.4.3. Pharmacists are to assess the patient's presenting symptoms thoroughly prior to dispensing any over the counter medication. [10]

5.4.4. Pharmacists are to refer the patient to their physician if the presenting symptom requires referral. [10]

5.4.5. When responding to symptoms, pharmacists can offer the patient any additional information which is relevant to the presenting symptom. [10]

5.4.6. Pharmacists can offer to design leaflets regarding self-care. [10]

6. Reason for Revision

6.1.Not applicable as this is a new SOP.

7. References

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8. Appendix

8.1. Not applicable

Appendix 3: Ethics Approval

FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt> 28 May 2021 at 15:24
To: Alessia Stivala <alessia.stivala.18@um.edu.mt>

Dear Ms Stivala,

Your CV and the Protocol and proposal in pdf have been received.

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

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

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

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

Regards,

L-Università ta' Malta

Annalise Mallia Duca | Secretary

Faculty Research Ethics Committee

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

https://www.um.edu.mt/ms/students/researchethic

Appendix 4: The Feasibility Questionnaire

Feasibility Questionnaire

Feasibility Questionnaire

The following questionnaire is to be completed by the managing pharmacist of the pharmacy that utilised the Community Pharmacy Quality Framework (CPQF) and Standard Operating Procedure (SOP) templates.

Pharmacy Locality: _____

Pharmacy District: _____

Duration of time using the CPQF and SOPs (Days): _____

CPQF and SOP Layout

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The CPQF is clear and thorough.	○	○	○	○	○
The CPQF covers main quality aspects present in a community pharmacy setting.	○	○	○	○	○
The CPQF is well structured.	○	○	○	○	○
The CPQF structure is easy to use and follow.	○	○	○	○	○
The SOPs are clear and thorough.	○	○	○	○	○
The SOPs are well structured.	○	○	○	○	○
The SOPs structure is easy to use and follow.	○	○	○	○	○
The four SOPs are sufficient to cover main quality aspects within a community pharmacy setting.	○	○	○	○	○

If you disagree, what other areas do you think the templates should cover?

_____

_____

_____

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The SOPs cover the majority of aspects checked during a Malta Medicines Authority (MMA) inspection.	○	○	○	○	○

If you disagree, what aspects related to the MMA inspection are excluded?

_____

_____

_____

The SOPs are able to be modified according to the needs of the pharmacy.	○	○	○	○	○
The CPQF and SOPs structure allows for fluidity within a community pharmacy setting.	○	○	○	○	○
The wording of the CPQF and SOPs allows for professional judgement to take place	○	○	○	○	○

CPQF and SOP Use

The CPQF and SOPs are useful as a reference when tackling problems encountered within the pharmacy.	○	○	○	○	○

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The SOPs can be used daily within the pharmacy.	○	○	○	○	○
The information present within each SOP is useful.	○	○	○	○	○
The SOPs are relevant to the needs of the pharmacy.	○	○	○	○	○

CPQF and SOP Applicability

The CPQF and SOPs are useful as a template quality system in Maltese community pharmacies.	○	○	○	○	○
I would make use of the CPQF and SOPs.	○	○	○	○	○
I would recommend the use of these SOPs in community pharmacies in Malta.	○	○	○	○	○
I think that the CPQF and SOPs would help standardise quality aspects within community pharmacies in Malta.	○	○	○	○	○
I would make use of these SOPs prior to an inspection from the MMA.	○	○	○	○	○
I think I will pass the MMA inspection if I make use of these SOPs.	○	○	○	○	○

Any further comments:

_____

_____