Risk-Based Analysis Of The Pharmacy Of Your Choice Scheme

Submitted in partial fulfilment
of the requirements of the
Degree of Master of Pharmacy

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Dedicated to my parents,

for their endless love, support and encouragement

Abstract

Background

The dispensing process may be at risk of error if proper guidelines are not adhered to since dispensing is a complex process and not just supplying the medication according to the patient's prescription.

Objective

To identify risk factors in dispensing, evaluate pharmaceutical dispensing processes and establish the best practice for dispensing Pharmacy Of Your Choice medicines.

Design

A survey data sheet, pharmacist questionnaire and time-motion study form were developed and validated to identify risk factors in dispensing Pharmacy Of Your Choice medicines and to evaluate pharmaceutical dispensing processes. In Malta, an island with an area of 316km^2, there are 201 community pharmacies which provide Pharmacy Of Your Choice services. Pharmacy Of Your Choice prescriptions being dispensed were observed through visits in 40 community pharmacies and recorded via survey data sheets. Pharmacists ranked risks according to their probability of occurrence and severity of consequences using a Likert scale from 1 (lowest score) to 5 (highest score) via a questionnaire. Risk was calculated by multiplying probability of occurrence with severity of consequences, giving a risk priority number of 1 to 25. A standard operating procedure for dispensing Pharmacy Of Your Choice medicines was developed and pharmacists' perception recorded after implementation in 10 pharmacies via an evaluation questionnaire.

Setting

Community pharmacies

Main outcome measures

Establishment of risk mitigation strategies and a standard operating procedure

Results

The risks with the highest scores were illegible prescriptions (risk priority number = 13.6) and incorrect prescriptions (risk priority number = 12.0). All participating pharmacists stated that they deal with customers individually (N = 40). All 10 pharmacists participating in the SOP implementation stated that the standard operating procedure represents the content clearly and concisely, while nine agreed that it is useful. Nine pharmacists agreed that the changes made during COVID-19 were effective to limit contamination, eight stated that they created new risks and seven agreed to permanently going paperless.

Conclusions

The processes identified as having the highest risk were illegible prescriptions and incorrect prescriptions. Individual attention to customers was identified as being the best mitigation factor to risk occurrence. This demonstrates a good feature of Maltese pharmacy practice. Using a risk-based approach to evaluate pharmacy practices is time-consuming, but identifies high-risk processes to the patient and allows for a greater understanding of the nature and occurrence of dispensing errors.

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List of Abbreviations

ALARP	As Low As Reasonably Practicable
ARMS	Aviation Risk Management Solutions
CEO	Chief Executive Officer
CMPH	Committee for Medicinal Products for Human Use
COVID-19	Coronavirus Disease 2019
DDA	Dangerous Drug of Abuse
EMA PRAC	European Medicines Agency Pharmacovigilance Risk Assessment Committee
ET	Event Tree
FDA	Food and Drug Administration
FONA	Faults or Near Accidents
FT	Fault Tree
GP	General Practitioner
GRTU	Malta National Chamber for Small and Medium Enterprises
ICH	International Conference on Harmonisation
ISO	International Organisation of Standardisation
MAA	Marketing Authorisation Application
MCoP	Malta Chamber of Pharmacists
MDH	Mater Dei Hospital
MHRA	Medicines and Healthcare Products Regulatory Agency

MMA	Malta Medicines Authority
N/A	Not Applicable
NRLS	National Reporting and Learning System
POM	Prescription Only Medicine
POYC	Pharmacy of Your Choice
PQ	Pharmacist Questionnaire
RMP	Risk Management Plan
RPN	Risk Priority Number
SALAD	Sound-Alike Look-Alike Drugs
SAMOC	Sir Anthony Mamo Oncology Centre
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SMS	Safety Management System
SOP	Standard Operating Procedure
UREC	University Research Ethics Committee

Chapter 1

Literature Review

1.1 What is Risk?

Traditional decision-making models describe risk as being a variation or impact in expected outcomes and their probability of occurrence (Mohammed and Youssef, 2017). Risk can be described mathematically as the probability of loss or gain of value, multiplied by its respective magnitude or the severity of its impact (Jaafari, 2007).

The English Oxford Dictionary defines risk as "a situation involving exposure to danger, or the possibility that something unpleasant or unwelcome will happen".[1] Risk can be seen as relating to the probability of the indeterminate future and equal to the expected damage.

The word 'risk' is usually used in a negative connotation as it implies the exposure of danger to an individual, for example the risk of death. Risk is a probability, which measures the likelihood of an event taking place, not necessarily implying that a harmful event will take place, for instance the risk of pregnancy, which is most often regarded as a positive outcome (Khattab et al, 2007).

A more accurate definition of risk is the uncertainty of an event taking place or a deviation from the expected result, leading to either a positive or a negative outcome (Šotić and Rajtić, 2015). For risk to be addressed directly and safety problems considered with reference to the risk involved, previous investigations on objectives, context, hazard and susceptibility must be carried out.

[1] Oxford English Dictionary. Risk [Internet]. Oxford: Oxford University Press; 2000 [updated 2010 Jun; cited 2021 Aug 7]. Available from: http://www.oed.com.ejournals.um.edu.mt/view/Entry/166306?rskey=EkHBcH&result=1#eid

1.2 Types of Risks

Risks can either be inherent or residual. Inherent risks are incidental and cannot be avoided, i.e. they occur naturally in the business before any precautions for mitigating them can be taken. Such risks negatively affect the profitability. Residual risks are those that persist, even after the necessary precautions are taken.[2]

Enterprises, such as financial, infrastructure, petroleum, information technology and pharmaceutical industries, face general risks which can be categorised into three groups:

i. *Intangible risk*: A risk which has absolute certainty of occurring but remains undetected due to poor risk recognition (Hamdani et al, 2018)

ii. *Relationship risk*: A risk which results due to unsuccessful collaboration and coordination between the departments involved, such as engineering, commerce, procurement, manufacture and maintenance[3]

iii. *Process-engagement risk*: A risk which occurs due to practice of unsuccessful operational processes, resulting in decreased valuable factors, such as the productivity of experienced personnel, profitability, status, service, quality and brand value[2]

1.3 Risk Management

The purpose of risk management is to recognise and minimise potential risks holistically while simultaneously encouraging room for improvement in performance (Shad et al, 2019). Risk management is strongly associated with policy and its evaluation,

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[2] Curtis P, Carey M. Risk Assessment in Practice Report [Internet]. US: Deloitte and Touche LLP. Committee of Sponsoring Organisation of the Treadway Commission (COSO); 2012 [cited on 2021 Aug 7]. Available from: https://www.coso.org/Documents/COSO-ERM-Risk-Assessment-in-Practice-Thought-Paper-October-2012.pdf

[3] Mobley RK. What is Risk Management? [Internet]. US: Life Cycle Engineering; 2011 [cited 2021 Aug 7]. Available from: https://reliabilityweb.com/articles/entry/what_is_risk_management/

not excluding the development of guidelines and efficient utilisation of resources to minimise negative effects accompanying the identified risks, following risk assessment and prioritisation (Aven, 2016).

The risk management cycle must be continuously updated by implementing newer strategies to manage risks, based on any changes in laws and regulations at the time. Amendments in accordance to regulatory changes will keep institutions up-to-date with current regulatory expectations. Proper risk management involves the control of future risk-involved events and their possibly damaging impact, if not dealt with immediately.[4]

Ideal risk management plans strategically follow a ranking process whereby risks with the greatest probability and severity are handled first, prior to other risks with a lower probability and severity (Vatanpour et al, 2015). In actual practice, this process can be a challenge since risks can be categorised with a high probability of occurrence and a low severity of consequences, or vice-versa. Such risks can often be mishandled (Kamath et al, 2012).

In the European Union, a risk management plan (RMP) is required to be included with the Marketing Authorisation Application (MAA) of a proposed drug.[5] The RMP must include information about the safety profile of the pharmaceutical product in the context of the risk-benefit ratio, plans of pharmacovigilance measures to identify the risks and strategies for risk mitigation, as well as an assessment of their effectiveness (Baldrick and Reeve, 2015).

[4] Stanleigh M. Risk Management: The What, Why and How. The Management Compass Newsletter [Internet]. US: Business Improvement Architects; 2016 Issue Mar 29 [cited on 2021 Aug 7]. Available from: https://bia.ca/risk-management-the-what-why-and-how/

[5] European Medicines Agency (EMA). Risk Management Plans [Internet]. Amsterdam: European Medicines Agency; 2021 [cited 2021 Aug 25]. Available from: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management/risk-management-plans

The European Medicines Agency Pharmacovigilance Risk Assessment Committee (EMA PRAC) assigns a reporter to review and assess the RMP. A report will then be submitted to the Committee for Medicinal Products for Human Use (CMPH). The CMPH will then scrutinise the application and express their final opinion on the approval of the dossier (Trivedi et al, 2016).

1.3.1 Risk Management Principles and Guidelines

As indicated by the International Organisation for Standardisation (ISO) in ISO 31000 entitled 'Risk Management Guidelines', effective risk management systems should implement certain principles, such as the following: guarantee productive decision-making, be systematic and structured, take into account human factors, allow basis to be on the best available information at the time, ensure adequate updating if laws and regulations change, be flexible, be transparent and inclusive, address uncertainty, be an integral part of the organisational process, and be responsive to change.[6]

To produce an effective risk management plan and benefit from proper levels of risk mitigation, one must select the appropriate measure controls to quantify each risk and any implementation selected must be approved by the correct board of management. For instance, the EMA PRAC has the authority to decide whether or not the submitted MAA and RMP of a proposed drug acquires approval for marketing in the EU member states. According to ISO 27000, this is a measure of risk mitigation control as part of the risk treatment plan that should follow the risk assessment phase.[7]

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[6] International Organisation for Standardisation. ISO 31000:2018. Risk Management Guidelines [Internet]. Geneva: ISO; 2018 [cited 2021 Aug 7]. Available from: https://www.iso.org/standard/65694.html

[7] International Organisation for Standardisation. ISO 27000:2018. Information technology, Security techniques, Information security management systems, Overview and Vocabulary [Internet]. Geneva: ISO; 2018. [cited 2021 Aug 7]. Available from: https://www.iso.org/standard/73906.html

Ideal risk management should reduce excessive resource expenses; however, a common problem in risk management is the rationing of funds, since those being used for risk management could have been disbursed on other profitable operations, which may be seen as opportunity loss (Xu et al, 2017).

1.3.2 Approaches to Risk Management

Risk management of an organisation can be addressed by incorporating the following three different forms of risk management methods, which improve its safety perspectives:[8]

i. *Reactive risk management*: This approach waits for the incident having a negative impact to happen before any actions are taken to prevent its reoccurrence (Gonzalez-Granadillo et al, 2017). Incident analysis after a medication error has occurred is a form of reactive risk management in the pharmaceutical system (Hudson and Guchelaar, 2003)

ii. *Proactive risk management*: This approach involves taking actions addressing the identified risk before an incident due to that risk takes place, preventing its initial occurrence (Gonzalez-Granadillo et al, 2017). A proactive risk management in pharmacy can be to encourage pharmacists to actively participate in reviewing pharmacy policies and procedures to ensure that they comply with state practices and standards of care[9]

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[8] Federal Aviation Administration. Safety Management System [Internet]. Washington, DC: US Department of Transportation; 2016 [updated 2016 Jul; cited 2021 Aug 7]. Available from: https://www.faa.gov/about/initiatives/sms/

[9] Healthcare Providers Service Organisation (HPSO). Risk Management Self-Assessment Checklist for Pharmacists [Internet]. Washington, PA: 2013 [cited 2021 Aug 7]. Available from: http://www.hpso.com/Documents/Risk%20Education/individuals/Claim-Reports/Pharmacist/Risk-Control-Self-Assessment-Checklist-Spotlight.pdf

iii. *Predictive risk management*: This approach attempts to predict potential future risks by analysing current operational techniques and identifying areas of concern in hypothetical situations (Snooks et al, 2019). Predictive risk management is used in healthcare to estimate individual patients' risk scores and identify those at high risk of being unexpectedly admitted to hospital urgently to establish strategies to reduce the number of avoidable emergency admissions (Snooks et al, 2019)

1.4 Quality Risk Management Process

According to the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, 2021), quality risk management is a "systematic process for the assessment, control, communication and review of risks of medicinal products."[10] This robust process incorporates all the elements relating to a particular risk and combines them to ensure that the organisation's developments run as smoothly as possible (Giannakis and Papadopoulos, 2016). Figure 1.1 demonstrates an outline of a risk management process.

Risk management begins with the identification of a potential risk and its possible negative impacts on the organisation, followed by the selection of a risk management leader and necessary resources for decision-making (Sax and Andersen, 2018).

[10] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf

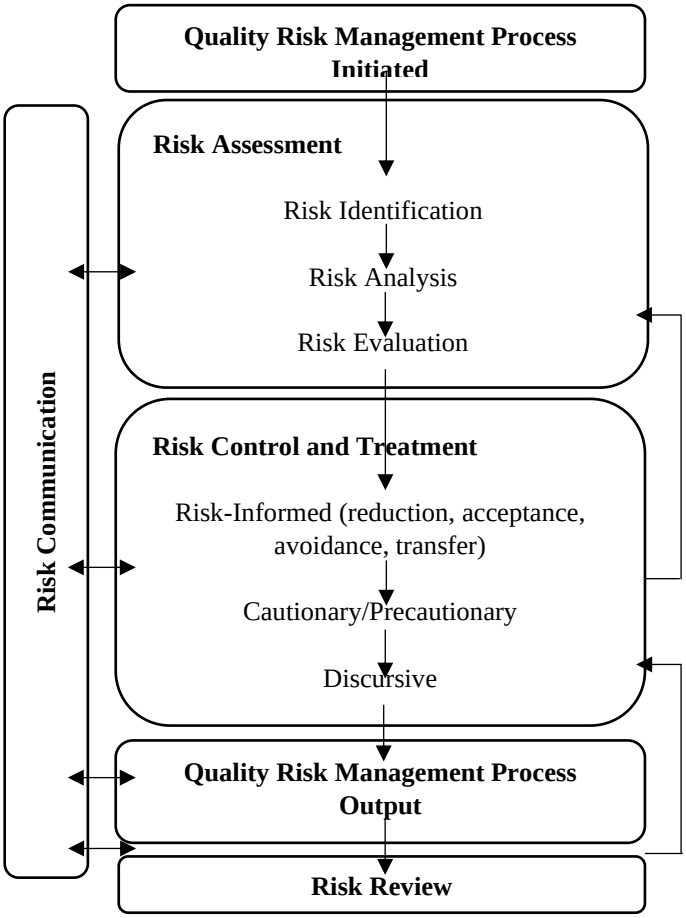

Figure 1.1 - Risk management process (adapted: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf)

1.4.1 Risk Assessment

Risk assessment is seen as the initial phase of risk management and consists of risk identification and analysis of the exposure to these risks (Sax and Anderson, 2018). Methods used to assess risks can be either of the following:

i. *Intuitive*, such as asking for generic advice from expert groups co-ordinated by the EMA during research and development of a drug prior to MAA submission (Trivedi et al, 2016)
ii. *Inductive*, such as checklists to aid pharmaceutical professionals in assessing and updating current practices to ensure patient safety (for example, the Risk Management Self-Assessment Checklist for Pharmacists established by HPSO)[11]
iii. *Deductive*, such as accident investigations via the development of Standard Operating Procedures for incident reporting and documentation)[12]

1.4.1.1 Risk Identification

Risk identification allows for more advanced development in risk management since risks are identified to provide a clearer understanding of their nature and potential negative effects (Giannakis and Papadopoulos, 2016). This process involves obtaining information about developing events prior to documentation of the risks to obtain better awareness on the potential safety consequences associated with the risks identified (Sax and Anderson, 2018). Risk identification is crucial in the RMP since it deals with the

[11] Healthcare Providers Service Organisation (HPSO). Risk Management Self-Assessment Checklist for Pharmacists [Internet]. Washington, PA: 2013 [cited 2021 Aug 7]. Available from: http://www.hpso.com/Documents/Risk%20Education/individuals/Claim-Reports/Pharmacist/Risk-Control-Self-Assessment-Checklist-Spotlight.pdf

[12] Choudhary A. SOP for Incident Reporting and Investigation [Internet]. US: Pharmaceutical Guidelines; 2010 [cited 2021 Aug 7]. Available from: https://www.pharmaguideline.com/2010/02/sop-for-incident-reporting-and-investigation.html

safety specification of the proposed drug, including a synopsis of the identified risks to characterise its safety profile (Trivedi et al, 2016).

1.4.1.2 Risk Analysis

Risks are ranked according to the probability of occurrence and severity of consequences (Mohammed and Youssef, 2017). This systematic qualitative and quantitative study allows for the identification of root causes, potential consequences and routes the risks involved may take (Vilko and Hallikas, 2012). Risk analysis is the tool that helps to measure risks and determine the most appropriate and effective risk mitigation strategies to adopt (Haas, 2016).

Risk analysis may also involve simultaneous use of correlation analysis and controlled experiments to identify patterns in the occurrence of risks, which are useful in risk treatment to handle more than one risk at once (Giannakis and Papadopoulos, 2016).

A method used in risk analysis is the Bow-Tie method, which allows for a quick qualitative evaluation of risk assessment (Cacciabue and Oddone, 2017; Aust and Pons, 2019). In the aviation domain, the Aviation Risk Management Solutions (ARMS) is strongly correlated to the Bow-Tie method, as it allows for the application of a Safety Management System (SMS). This describes the steps taken before initiating high-risk processes, including safety checks and strategies for handling urgent situations (Cacciabue and Oddone, 2017).

The Bow-Tie method diagram considers different and detailed methods, including Fault Trees (FTs) and Event Trees (ETs) analyses to assess risk (Cacciabue and Oddone, 2017; Cui et al, 2018). As shown in Figure 1.2 where the Bow-Tie method can be seen as divided into two parts, this method is initiated by the hazard, causing the business upset, followed by the top event, which is the moment in time before the damage is done (Book,

2012). On the left of the diagram, one can find the identified threats and the preventative controls taken (FT), while on the right, there are the consequences arising from the undesired event (ET), depending on the activities to stop further development of the harm caused (Hudson and Guchelaar, 2003). The Bow-Tie method has been described to provide a "best of both worlds" with respect to the hazards and consequences of an incident as it is able to establish a relationship between the two by incorporating both FTs and ETs analyses (Delvosalle et al, 2006; Cui et al 2018).

Hudson and Guchelaar (2003) stated that, in a pharmaceutical setting, harmful events consist of "wrong patient, wrong diagnosis, wrong medicine, wrong formulation, wrong route of administration, wrong technique, wrong dose, wrong time and wrong delivery." This presents the basic structure for differentiating between different failure routes, analysing their probabilities and identifying barriers to prevent or mitigate consequences, which in turn allows for the identification of barriers that failed and those that continued to work successfully, in the case of near misses (Hudson and Guchelaar, 2003).

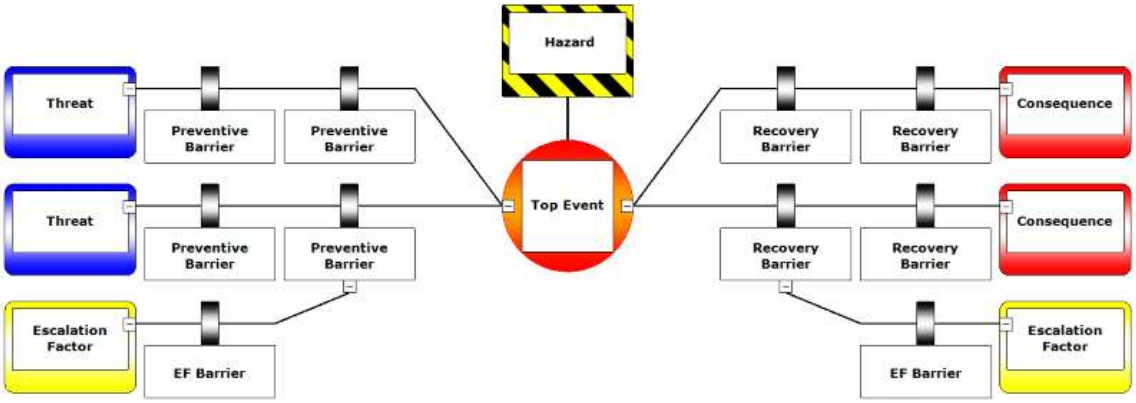

Figure 1.2 – Schematic bow-tie diagram with prevention and recovery barriers (reproduced from: Aust J, Pons D. Bowtie Methodology for Risk Analysis of Visual Borescope Inspection during Aircraft Engine Maintenance. Aerospace. 2019; 6 (110): 1-30)

1.4.1.3 Risk Evaluation

In risk evaluation, knowledge obtained from risk assessment is used to establish a summary judgement on the risks involved (Aven, 2016). Risk evaluation considers the strength of the evidence of the probability and the severity of the risks identified.[13]

A risk matrix provides a structured approach which plots the potential effect of an occurrence according to the probability and severity (Gray et al, 2018). The measure of a risk for a class of events is calculated by multiplying the probability of incidence with the severity of the consequences, which are both calculated on a 1 to 5 scale (Guerra Bretaña et al, 2016; Rezaei et al, 2018; Xiao et al, 2011). Risks are then evaluated using a risk matrix, as shown in figure 1.3, which can be described both as a qualitative and a quantitative tool, since risks are ranked using real numbers along two ordinal ranking scales (Vatanpour et al, 2015). This will form the basis for allocating resources to implement risk mitigation strategies.

Risk prioritisation in a risk matrix is visualised by allocating colours to the risk categories, which are the cells in the matrix, where the greater the exposure to the risk, the higher the priority assigned to it (Vatanpour et al, 2015). Columns in a risk matrix classify the severity of outcomes in ascension (Gray et al, 2018). Low-risk categories are usually indicated in green (such risks are tolerated), medium-risk categories in yellow, high-risk categories in orange, while extreme-risk categories in red (such risks are unacceptable). Medium-risk and high-risk categories are an in-between stage of the two extremes. Such risks usually require monitoring, but probability and severity are

[13] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf

controlled As Low As Reasonably Practicable (ALARP) since the cost involved in minimising the risks even further would be grossly disproportionate to the benefits gained (Roberts, 2018).

Risk matrices are used in risk modelling in the pharmaceutical industry as they strengthen the approach to limit the frequency of occurrence of risks and control the overall damage to the industry. This is crucial since the Food and Drug Administration (FDA) and the pharmaceutical industry must agree on every phase of the system lifecycle, the latter involving the identification and prioritisation of threat levels of potential hazards via iterative systems developed and maintained by the pharmaceutical industry (Adis, 2007).

	Likelihood				
Consequence	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Figure 1.3 – General risk matrix (reproduced from: National Health Service (NHS). Risk Management Strategy Version 5.0 [Internet]. UK: NHS; 2012 [updated 2015 Sept; cited 2021 Aug 7]. Available from: https://www.ouh.nhs.uk/about/trust-board/2015/november/documents/TB2015.136a-appendix.pdf)

1.4.2 Risk Control and Treatment Strategies

Risk control involves the decision-making required to decrease risk to an adequate level or to accept it. The effort put in this stage reflects the significance and the magnitude of the risk to ensure an optimal level of risk control.[14]

The following are the three major strategies used to manage risk, where the most suitable approach would be a combination of all three strategies (Asselt and Renn, 2011):

i. *Risk-based approach*: This approach involves activities of risk reduction, acceptance, avoidance and transfer, depending on the type and nature of the risk (Aven, 2016):
    a. Risk reduction involves any attempt to prevent risks through the minimisation of the probability and severity (Giannakis and Papadopoulos, 2016)
    b. Risk acceptance involves the recognition, approval and adaptation to the consequences of risks (Hamdani et al, 2018). When risk cannot be eliminated completely, it is reduced to an acceptable level.[15] Risk acceptance is used when the actual cost of other risk-mitigation strategies is higher than the total cost of the damage caused by the risk, or when any other strategies implemented have failed (Hamdani et al, 2018). This strategy is mostly effective for small risks that do not pose any significant threat[16]

[14] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf

[15] Institute for Research for Safety and Security at Work and The Commission for Safety and Security at Work in Quebec. Machine safety: Prevention of Mechanical Hazards. [Internet]. Quebec, Canada: Author; 2009 [cited 2021 Aug 7]. Available from: http://www.irsst.qc.ca/media/documents/pubirsst/rg-597-pref-tcont-intr.pdf?i=0&redirected=1

[16] International Organisation for Standardisation. ISO 31000:2018. Risk Management Guidelines [Internet]. Geneva: ISO; 2018 [cited 2021 Aug 7]. Available from: https://www.iso.org/standard/65694.html

c. Risk avoidance involves the elimination of activities prone to causing an increased exposure to the risks, or the involvement of alternative activities to preserve valuable assets (Hamdani et al, 2018)

d. Risk transfer involves the shifting of risk from one party to another via co-operation with suppliers to obtain risk pooling, which is a method used by insurance companies to protect against natural disasters. By sharing mutual risks, multiple parties of collective responsibility cover themselves and their valuable assets against loss (Arthmar and McLure, 2016)

ii. *Precaution-based approach*: This approach aims to develop alternative strategies, safety factors and emergency management conditions, as well as to recognise risk precursors (Aven, 2016)

iii. *Discourse-based approach*: This is a method used to enhance accountability and obtain a common understanding of the risks by reducing their probability of occurrence and the involvement of affected personnel by risk communication (Asselt and Renn, 2011)

The risk-based and precaution-based approaches are created by industries that consider safety as a critical issue, such as aviation and healthcare systems (Lyons et al, 2004). Examples of such strategies include analysis that take into consideration the root causes, effects of the consequences, operability studies and human errors. These involve either the investigation of a process, such as dispensing a pharmaceutical product, and the identification of the instances prone to failure, or the examination of an error, such as dispensing or prescription errors, and the recognition of activities resulting in that event (Phipps et al, 2011).

A discourse-based approach can also prove to be a suitable strategy to undertake since it allows risk in pharmacy practice to be viewed from different perspectives

(McLaughlin, 2007). In a UK study, the discourse-based approach was used in the pharmaceutical setting, where the perspectives of patients and general practitioners were investigated for the most appropriate treatment for hypertension. The study resulted in the identification of two groups greatly contrasting in their views on what was considered the most appropriate treatment (Morecroft et al, 2005).

1.4.3 Risk Communication

Risk communication can take place at any stage in the risk management process since decision-makers can share information on risks and their management, which includes information on the nature, existence, probability, severity, detectability and control of the risks. Risk communication occurs among different parties, including the industry, the patient and the regulatory authority.[17]

The FDA is able to reduce the probability of risks occurring by communicating with pharmaceutical companies to develop medication guides containing drug information for patients, especially for high-risk drugs, and patient information leaflets (PILs), which are pre-printed drug information materials written by the wholesaler for educational purposes (Lee et al, 2008).

1.4.4 Risk Review

Risk review ensures that risk management remains a continuous process to safeguard the organisation from encountering hazardous events.[18] This stage involves ongoing monitoring and reviewing of effects of management strategies adopted. Risk

[17] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf

[18] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guidelines: Quality Risk Management (Q9) [Internet]. Geneva: ICH; 2005 [cited 2021 Aug 7]. Available from: https://database.ich.org/sites/default/files/Q9%20Guideline.pdf

review reduces impulsive decision-making in emergencies since problems can be predicted and, as a result, solutions can be proposed at an earlier stage (Wu and Blackhurst, 2009).

In pharmacy practice, risk review establishes the need for an improved awareness on the quality of medicinal products during distribution, which initiates further studies to improve risk management in the supply chain (Kumar and Jha, 2018).

1.5 Risk Management in Different Industries

Risk management was primarily introduced in industries involving error-prone activities, such as the aviation industry. The concept of risk management is to analyse the processes involved and their interaction with each other to identify and eliminate organisational, technical and social vulnerabilities (Shad et al, 2019).

Risk is universal and miscellaneous in all industries, resulting in the demand for appropriate risk management. A code of ethics must be endorsed, which focuses on risk evaluation and mitigation by the professional on behalf of the client, patient, public or society.[19] Any business entity can be threatened by financial, strategic, environmental, compliance and operational risks; however, human error is still considered as the biggest risk (Kádárova and Durkáčová, 2012; Kim et al, 2019). Examples of human error include overload, poor training, lack of competence or knowledge, communication deficiencies and documentation errors.

Business or enterprise risk management handles risk by quantifying its exposure, measuring the cost and benefits of risk management, using information technology

[19] The Institute of Internal Auditors for North America (IIA). Mandatory Guidance: Code of Ethics [Internet]. US: IIA; 2016 [cited 2021 Aug 7]. Available from: https://na.theiia.org/standards-guidance/mandatory-guidance/pages/code-of-ethics.aspx

systems to facilitate the process and training personnel to guide clients (Rosenbloom et al, 2008; Sax and Andersen, 2018).

1.5.1 Aviation

The US National Transportation Safety Board (2019) stated that, since aviation involves complex processes, it results in an increased demand for requirements to ensure maximal safety, 'man and machine' interactions, co-operation among personnel and professional competence. Risk management in aviation involves continuous reporting of errors. For example, the US National Transportation Safety Board investigated 412 and 350 aviation transportation fatalities in 2016 and 2017, respectively.[20] Based on their findings, the board recommends risk mitigation strategies to prevent future accidents.

Risk management systems of aviation companies are characterized by high and robust safety and quality levels due to the occurrence of dangerous consequences should an incident occur as a result of a risk (Wittimer et al, 2011; Kapur et al, 2015).

Risk management approaches in airline industries can be influenced by flawed airline industry structure, complex business environment, labour, nature of airline operations and external risks (Misiura, 2015). The aviation industry is extensively controlled, and compliance to risk management strategies greatly influences their effectiveness (Adler and Gellman, 2012). This compliance to the regulatory framework affects greatly the risk management in the aviation industry (Leloudas, 2003).

[20] The National Transportation Safety Board (NTSB). Data and Stats 2016-2017 US Transportation Fatalities [Internet]. Washington, DC: NTSB; 2019 [cited 2021 Aug 7]. Available from: https://www.ntsb.gov/investigations/data/Pages/Data_Stats.aspx

The Department of Primary Industries in New South Wales follows three main risk mitigation strategies, which are:[21]

i. "Do not accept unnecessary risk"
ii. "Accept risk only when the potential benefits outweigh the potential cost"
iii. "Risk decisions are made at the appropriate management level within the Department"

The aviation and healthcare industries are similar in the sense that they both involve complex processes, and require maximal safety in their procedures. In both industries, the human is regarded as the service provider and any errors have serious, even fatal, consequences (Kapur et al, 2015).

1.5.2 Pharmacy Practice

Risks concerning patients in community pharmacies and in hospitals include those leading to near misses and dispensing errors (Aronson, 2009; Kapur et al, 2015). The availability of risk management systems and skilled professionals reduce the risk of providing poor quality care to patients and the possibility of adverse health outcomes in the incidence of a harmful event.[22]

Risks having the greatest probability of occurring and severity of consequences must be identified and, by carefully considering the factors that may cause harm to patients using pharmacy services, steps to reduce risk can be established. For instance,

[21] The New South Wales Department of Primary Industries (NSW DPI). Procedure: Aviation Risk Assessment and Management Processes [Internet]. Australia: NSW DPI; 2012 [updated 2012 May 31; cited 2021 Aug 7]. Available from: http://www.dpi.nsw.gov.au/__data/assets/pdf_file/0011/434729/risk-assessment-and-management-process.pdf

[22] General Pharmaceutical Council (GPhC). Focus on Risk Management in Pharmacy [Internet]. UK: GPhC; 2016 [cited 2021 Aug 7]. Available from: https://www.pharmacyregulation.org/regulate/article/focus-risk-management-pharmacy

causes for the risk of dispensing the wrong medication to the patient include the inability of the pharmacists to differentiate among sound-alike look-alike drugs (SALAD), illegible handwriting of the prescription by the physician or being unaware of drug-drug interactions before dispensing (Aronson, 2009; O'Donnell and Vogenberg, 2014).

Pharmacy-related risks in the hospital setting include patient pharmaceutical care and dispensing, drug compounding, IV drug administration, nutrition and drug management. Medication errors are the primary cause of injury in healthcare systems; thus, risk identification is a crucial first step in the prevention of harmful events relating to drug use (Castro Vida et al, 2017; Pourrain et al, 2018).

Risk management strategies adopted by the professionals involved include the evaluation of workplace practices that may result in unacceptable dispensing errors, reporting any poor or outdated policies and protocols, advising patients on potential side-effects and educating them on actions that should be taken in such an event, as well as ensuring that prescription drug packages contain all relevant information.[23]

1.6 Medication Errors

Medication errors can be classified as a type of extrinsic toxicity, which refers to medication errors due to drug mishandling by healthcare professionals or patients (Van Den Bemt and Egberts, 2007). The National Coordinating Council defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or

[23] Healthcare Providers Service Organisation (HPSO). Risk Management Self-Assessment Checklist for Pharmacists [Internet]. Washington, PA: 2013 [cited 2021 Aug 7]. Available from: http://www.hpso.com/Documents/Risk%20Education/individuals/Claim-Reports/Pharmacist/Risk-Control-Self-Assessment-Checklist-Spotlight.pdf

patient harm while the medication is in the control of the healthcare professional, patient or consumer."[24]

The main medication errors in medicinal patient care can be classified into prescribing, prescription, transcription, dispensing, administration and 'across settings' errors (Van Den Bemt and Egberts, 2007; Cheung et al, 2009; Mekonnen et al, 2018).

Medication errors in the community pharmacy setting usually happen in the stages of prescribing and dispensing, i.e. the areas which are classified as the major processes in medication use (Aldhwaihi et al, 2016). In fact, in England and Wales, out of the 526,379 medication errors reported to the National Reporting and Learning System (NRLS) between 2005 and 2010, 16.54% occurred during dispensing while 18.45% occurred during prescribing (Cousins et al, 2011).

The occurrence of medication errors can be understood by the medication use process, an example of which is shown in Figure 1.4 (Aldhwaihi et al, 2016). The pharmacist is involved in all five stages.

[24] National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). What is a Medication Error? [Internet]. US: NCC MERP; 2019 [cited 2021 Aug 7]. Available from: https://www.nccmerp.org/about-medication-errors

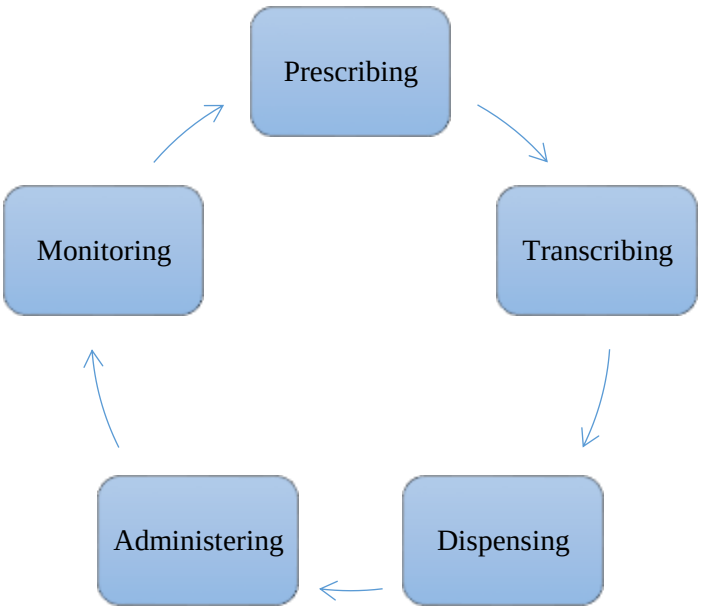

Figure 1.4 – Cycle of the process of medication use (adapted: Bubalo J, Warden BA, Wiegel JJ, Nishida T, Handel E, Svoboda LM, et al. Does applying technology throughout the medication use process improve patient safety with antineoplastic? Journal of Oncology Pharmacy Practice. 2013; 20 (6): 445-60).

1.6.1 Dispensing Errors

A dispensing error in community pharmacy practice can be defined as an error which is detected after the patient has left the pharmacy along with their medication (Szeinbach et al, 2007; James et al, 2009; Al-Arifi, 2013) or an accidental deviation from a written prescription (Cheung et al, 2009; James et al, 2009). Dispensing errors, although preventable, are the most predominant medicinal errors (Bobb et al, 2004; Perwitasari et al, 2010; Stojković et al, 2017; Bourne et al, 2018). Table 1.1 displays the categories in which errors in dispensing can be classified into.

Studies from the UK (Ashcroft et al, 2005; Franklin and O'Grady, 2007) demonstrate a high rate of errors in dispensing in pharmacies ranging from 0.04% (Ashcroft et al, 2005) to 24% (Allan et al, 1995) of dispensed items. This widespread difference may be partly attributable to the differences in the study methodologies (Franklin et al, 2014). A study conducted in the USA observed four dispensing errors with every 250 prescriptions observed daily in 50 pharmacies (Flynn et al, 2003), while a study in India observed an overall rate of dispensing errors of 1.29% (Thomas et al, 2011).

Table 1.1 – Categories of dispensing errors (reproduced from: Cheung KC, Bouvy ML, De Smet PAGM. Medication Errors: The Importance of Safe Dispensing. British Journal of Clinical Pharmacology. 2009; 67 (6): 676-80).

Dispensing medicine for the wrong patient
Dispensing the wrong medicine
Dispensing the wrong drug strength
Dispensing at the wrong time
Dispensing the wrong quantity
Dispensing the wrong dosage form
Dispensing an expired or almost expired medicine
Omission (failure to dispense)
Dispensing an incorrectly compounded medicine
Dispensing with the wrong information on the label ▪ Incorrect patient name ▪ Incorrect drug name ▪ Incorrect drug strength ▪ Incorrect instruction (including incorrect dosage) ▪ Incorrect drug quantity ▪ Incorrect dosage form ▪ Incorrect expiry date ▪ Omission of additional warning(s) ▪ Incorrect pharmacy address ▪ Other labelling errors
Dispensing with the wrong verbal advice to the patient or representative

1.7 The Dispensing Process

The dispensing process includes all the stages involved when the patient enters the pharmacy presenting a prescription to the point where the patient leaves the pharmacy (Kelly, 2012). The process of dispensing can be divided into the following major stages, where errors can arise at any stage (James et al, 2009):

i. Validate the prescription upon receiving it by confirming name, age, sex, residence and ID number of the patient to ensure that the correct patient receives the correct medication (Azzopardi, 2000; Kelly, 2012)

ii. Read, understand and interpret any abbreviations on the prescription. The pharmacist must also make sure that the medication is to be used by the patient for the right indications and that it is prescribed at the right dose for the patient, calculate correctly the quantity of medication to be issued, and identify any common drug-drug interactions (Azzopardi, 2000; Spivey, 2012)

iii. Prepare and label items for issue, which is an important process of self-assessment after the prescription has been clearly understood and correct calculations have been performed (Spivey, 2012)

iv. Re-check that the medication's identity, dose and quantity to be dispensed conforms with the prescription. This final check is ideally performed by another competent staff member, who should look at the prescription before looking at the dispensed medication (James et al, 2009)

v. Document the actions taken, by retaining the prescription or by recording the details of the medicine dispensed before returning the prescription to the patient, to be able to regulate medicine stock in the dispensary (Spivey, 2012)

vi. Issue medicine to the patient with clear instructions and advice on when to take the medicine, how to take it and how to store it, both in a written format (either handwritten or on a printed label) and verbally (Azzopardi, 2000; Spivey, 2012)

vii. Confirm that the patient has fully understood the information that has been conveyed by asking the patient about any queries that he/she might have, as well as ask them to repeat back the instructions given (Azzopardi, 2000)

1.8 The Role of the Pharmacist in Reducing Dispensing Errors

Dispensing prescriptions is one of the main activities of a community pharmacist, involving both cognitive and manual steps that should be followed to reduce risks in dispensing, which may increase the demand for a more rigorous process of medical care and drug therapy (Al-Arifi, 2014). Dispensing errors may be attributable to the high medication volumes, where even a low chance of error may result in several dispensing errors (Cina et al, 2006; Stojković et al, 2017).

Medication use and drug therapy have always been related to several risks, where most of the time, the benefits outweigh the risks (Kaufmann et al, 2015). It is important for the patient to be informed about both the benefits and the possible risks of the drug therapy. Community pharmacists can contribute to the reduction of risks with medication use by increasing information flow about drug use and detecting medication problems, where any recommendations for changes in drug therapy or monitoring of response to drug therapy should be documented (Strojković et al, 2017). Community pharmacists participating in the dispensing process can detect harmful prescribing errors, the latter of which may be a source for a dispensing error (Al-Arifi, 2014).

One disadvantage of medication errors is the accountability of healthcare professionals, particularly physicians. The role of the pharmacist in such situations is to

detect and correct errors that can occur in the medication use process, including adequate patient education and counselling in order to ensure safe and effective medicine use (Mangino, 2004; Strojković et al, 2017).

1.9 The Importance of Safe Dispensing

Medication errors, including errors occurring during the dispensing process, can cause significant consequences regarding the safety of the patient, bringing out the importance of repeated use of good dispensing procedures which, if incorrectly performed, can cause in patient mortality or hospitalisation (Elden and Ismail, 2016). Even though most dispensing errors are identified by pharmacists before dispensing, those that remain undetected can cause serious patient harm and may also prove to be fatal (James et al, 2009). It is for this reason that the reviewing of data by competent pharmacists is of such importance to decrease the risk of dispensing errors.

1.10 Factors contributing to Dispensing Errors

Factors contributing to dispensing errors can be identified by root-cause analysis or via surveys directed towards community pharmacists to measure pharmacists' opinions and perceptions on such errors. In a UK study (Beso et al, 2005) in which pharmacists were surveyed via semi-structured interviews, a total of 106 possible causes for dispensing errors were included, in which the most common ones were high dispensing volume (21%), lack of competent personnel (12%), deadlines (11%), pharmacist fatigue (11%), interruptions during dispensing such as by telephone calls or the customers themselves (9.4%), and SALADs (8.5%).

In other studies (Peterson et al, 1999; Knudsen et al, 2007; Teinila et al, 2008; Al-Arifi, 2013; Stojković et al, 2017), the occurrence of dispensing errors was attributable to other factors as well, including illegible handwriting of physicians, distractions due to

broadcasting devices, discrepancies in details between original prescription and repeat form, job dissatisfaction, participation in dispensing by pharmacy salespersons, layout of dispensary and shelves, design of computer dispensing software, insufficient resources (e.g. equipment or reference books), lack of privacy when dispensing and insufficient time to talk to the patient or the patient's representative (e.g. customers in a hurry, customers with multiple prescriptions and talkative customers).

1.11 Detection and Reduction of Dispensing Errors

Several methods can be used to identify dispensing errors, where those most commonly used in quantitative research analysis include pharmacist self-recording of their own dispensing activities, observation studies performed by an external observer or covert standardised patients visiting the pharmacy (Azzopardi, 2000; Franklin et al, 2009; James et al, 2009; Trap et al, 2010; Stojković et al, 2017).

Several dispensing error risk minimisation strategies have been implemented in community pharmacies, one commonly advocated approach being the introduction of information technology, including electronic prescriptions to community pharmacies for dispensing (Franklin et al, 2009; Franklin et al, 2014). In a US study (Maviglia et al, 2007), the implementation of a bar-code system decreased the rate of dispensing errors from 0.19% to 0.07%, resulting in a positive financial outcome on the healthcare organisation investment. Elden and Ismail (2016) state that error detection through proper management and effective reporting allows for the identification of medication errors and encourages safe practices.

1.12 The Pharmacy of Your Choice Scheme

The Pharmacy of Your Choice (POYC) scheme was introduced as a pilot project in December 2007 with the aim of enabling patients who fall under the Government's

legislation of Schedule V and Schedule II to be entitled to free pharmaceutical medications, which can be collected at their preferred and most convenient pharmacy of their choice. This scheme was implemented to minimise the long queues at Government dispensaries and allows the patient to build a relationship with their pharmacist, who will become more familiar with the patient's conditions and treatment.[25] The progress of the patient's conditions can be effectively monitored, and any adverse reactions can be reported immediately and with greater confidence, ensuring optimal pharmaceutical care.[26]

1.12.1 Entitlement to Free Medicine

Entitlement to free medication in Malta through the public health sector not forming part of the Government hospital, i.e. out-patients, is based on social solidarity. This entitlement occurs via a system based on disease-linked criteria by means of the Social Security Act Cap 318 Article 23 and its amendment, Act No. I of 2012, as well as the Fifth Schedule of this Act. Patients with from chronic conditions fall under Schedule V (Yellow Card), while those with limited income fall under Schedule II (Pink Card). Pink card holders are only entitled to a limited number of medicines, which are specifically marked as pink card positive on the Government Formulary List.[27]

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[25] Ministry for Health. Annual Report 2018 [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2018 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/CommMentalHealth/Documents/Annual%20Report%202018.pdf

[26] Said M. POYC Scheme reaches 33% of Malta's population. The Business Observer (Issue 74). 2017 May 25; Sect. A: 16 (col. 1)

[27] Ministry for Health. Pharmacy Of Your Choice: Medicines Approval Section [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2019 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/360%C2%B0-One-Stop-Shop-Service-Concept/Medicines-Approval/Introduction.aspx

1.12.2 Collection of Free Medicine and Requirements

Since 2007, patients are able to choose their dispensing pharmacist by registering themselves in a pharmacy of their own choice and one that is most suited for their individual needs.[28] Before the POYC Scheme was implemented, patients and their carers/representatives had to collect their medicines from the Government dispensaries distributed in Malta, according to their town of residence. However, the past system did not offer the patient direct contact with a pharmacist, resulting in a lack of development of a patient-pharmacist relationship (Briffa Rizzo, 2010).

To be able to collect their medicines from their local pharmacy, patients are required to present the following documents to the pharmacist on duty:

i. A valid prescription for free drugs (white form), or prescription for controlled drugs (green form), if applicable, correctly filled in and signed by the appropriate physician
ii. Schedule II (pink) and/or Schedule V (yellow) Entitlement card/s
iii. Control card for controlled drugs (white card) duly-filled by the medical practitioner, if applicable
iv. Any relevant permits including DH 75, DH 1034, DH 1020, CPSU, MDH 145, SLH 145, also known as "To Whom It May Concern" notes which lists the medications that accompanies the entitlement card with a "treatment as prescribed" clause

[28] Ministry for Health. Annual Report 2018 [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2018 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/CommMentalHealth/Documents/Annual%20Report%202018.pdf

v. Patient's ID card, as well as the ID card of the person who collects the medication from the pharmacy on the patient's behalf, if applicable[29]

Patients may also possess a POYC membership or scheme card, which replaced the paper-based patient voucher in 2017 and remains valid for three years.[30] However, the POYC Unit is no longer issuing or replacing these cards, thus, the system will eventually migrate to the use of the patient's ID card number and date of birth exclusively.[31]

White prescription forms are used for the duration of treatment not exceeding two months, while green prescription forms are used for the duration of treatment not exceeding one month. Medications cannot by dispensed in the case of an incomplete or incorrect prescription.

1.12.3 Risk in the Pharmacy of Your Choice Scheme

The main risks involved in this system include workload, time constraints due to added administrative work, necessary computer software upgrades and maintenance of adequate medicine stock levels.[32] The use of an IT system and the issue that a huge volume of patients is benefiting from this scheme may increase risk levels of dispensing

[29] Ministry for Health. The Pharmacy Of Your Choice National Scheme [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2019 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/Poyc-scheme.aspx

[30] Times of Malta. 40,000 POYC cards already delivered [Internet]. 2017 Apr 29 [cited 2021 Aug 7]; National. Available from: https://timesofmalta.com/articles/view/40000-poyc-cards-already-delivered.646586#cta_ comments

[31] Ministry for Health. Frequently Asked Questions [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2019 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/Schedule%20V/Frequently-Asked-Questions.aspx

[32] Vella A. The Research Spot: POYC. The Pharmacy Department Review [Internet]. Valletta: University of Malta; 2010; 1 (7) [cited 2021 Aug 7]. Available from: https://www.um.edu.mt/library/oar/bitstream/123456789/48845/1/Issue_7.pdf

and processing errors, as well as the risk of suffering an increase in overtime costs as more pharmacy employees are working longer hours.[33]

1.12.4 The Impact of Coronavirus Disease 2019

The worldwide pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), also known as Coronavirus disease 2019 (COVID-19), has caused 4,265,903 deaths as of 7th August 2021.[34] This has impacted the standard procedure followed by Maltese community pharmacists to prepare and dispense POYC medicines to patients in a way that some temporary changes had to be made in order to curb the rise in contamination from COVID-19 whilst also serving patients appropriately.

1.13 Rationale for the Study

Risk can be defined as the uncertainty of an undesired event taking place (Jaafari, 2007). The dispensing process is at risk of error if proper dispensing guidelines are not adhered to since it is a complex process than merely supplying the medication on the patient's prescription (Kelly, 2012). Errors in dispensing by pharmacists, being one main cause of preventable adverse effects, may ultimately lead to patient harm (Perwitasari et al, 2010).

Focus groups are an effective way to identify the priorities of participants and obtain understandings on their reasoning, discussion and argument, as well as validation of any research methods used (Azzopardi, 2010). This qualitative research method

[33] National Audit Office. Performance Audit: An Analysis of the Pharmacy of Your Choice Scheme [Internet]. Valletta: National Audit Office; 2012 [cited 2021 Aug 7]. Available from: http://nao.gov.mt/loadfile/4bd31498-d5ae-4261-bce2-60e7206d4a40

[34] World Health Organisation (WHO). WHO Coronavirus Disease (COVID-19) Dashboard [Internet]. Geneva: WHO; 2020 [cited 2021 Aug 7]. Available from: https://covid19.who.int/

captures a full range of views as it allows linguistic freedom of expression amongst pharmaceutical professionals (Brown et al, 2006).

Observation studies are an effective way to determine how the pharmacist in the community pharmacy setting responds to the process of dispensing a prescription to a patient or their representative (Azzopardi, 2000). This can be effectively done by an external observer documenting the pharmacists' activities via a designed survey data collection sheet.

Questionnaires allow the researcher to reach a large sample size of the population easily and economically, as well as provide both qualitative and quantitative data via open-ended and close-ended questions, respectively (Azzopardi, 2010). In addition, questionnaires prove to be less time-consuming than interviews and allow the researcher to obtain statistical information from the data collected.

Time-motion studies allow the researcher to obtain detailed quantitative data, with regards to duration and movements, via the observation of a specific task performed. In addition, it allows the determination of the factors affecting the workflow of the task with the aim of improving efficiency (Lopetegui et al, 2014).

Classification of pharmaceutical dispensing processes using a risk-based approach, i.e. involving the steps of risk identification, analysis and evaluation, and determining interventions for risk mitigation, helps to identify and establish best practices in the dispensing process in community pharmacy practice (Stelzenmüller et al, 2018). By classifying pharmaceutical dispensing processes, one can determine high-ranked processes, i.e. with a high urgency to be controlled first, ultimately producing an adequate action list of recommendations to follow so as to improve the process of prescription

dispensing (Azzopardi, 2000). Two-dimensional risk matrices can also prove to be helpful in assessing the pharmaceutical dispensing processes.

Standard operating procedures (SOPs) are detailed written instructions intended to document one or more procedures involved in a routine task, and are used by companies to continuously ensure uniformity and quality in the performance. SOPs can also be used to establish company policies, government regulations, as well as best practices.[35] SOPs may prove to be effective in community pharmacies since such documents ensure that Good Pharmacy Practice is constantly observed, while also defining the personnel responsible to carry out the task (Grima, 2012). The influence of an SOP in community pharmacies can be determined by implementing it, then assessing the pharmacists' perception via an evaluation questionnaire. SOPs are useful in guiding pharmacists on how to carry out certain standard procedures systematically, particularly when locums or pharmacists employed on a part-time basis are involved.

This study aids to answer questions regarding what types of risks are involved in dispensing prescriptions in community pharmacy practice, under what circumstances they occur, what the possible consequences are, how likely they are to occur, how severe the consequences are and whether they are controlled effectively or if further action is required. In addition, it also helps to attain a better understanding on risk-causing actions in prescription and POYC medication dispensing in community pharmacy practice and to learn to appreciate and improve the risk management processes in community pharmacy practice.

[35] European Medicines Agency (EMA). Policies and Procedures [Internet]. Amsterdam: European Medicines Agency; 2020 [cited 2021 Aug 7]. Available from: https://www.ema.europa.eu/en/about-us/how-we-work/governance-documents/policies-procedures

1.14 Aim and Objectives

The aims of this research are to:

i. Identify risk factors contributing to the occurrence of dispensing errors
ii. Evaluate the pharmaceutical dispensing processes using a risk-based approach
iii. Identify interventions for risk mitigation
iv. Establish the best practice that presents the least risk for dispensing POYC medicines

A mixed method approach, including qualitative and quantitative research methods, is adopted for this study. The objectives are:

i. Identification of the system followed in dispensing POYC medicines, as well as the risks, possible causes and consequences involved in the system via a small-scale observation study in community pharmacies
ii. Development of data collection documents (community pharmacy survey data sheet, questionnaire directed towards community pharmacists and time-motion study form) to identify dispensing risks and risk mitigation strategies
iii. Organisation of expert focus groups to validate the list of risks, causes and consequences involved in dispensing POYC medicines, as well as the data collection documents, to identify experts' opinions on the risks involved in the system followed when preparing and dispensing POYC medicines identified through observation studies
iv. Pilot study in four community pharmacies, selected by convenience sampling to evaluate the feasibility of the community pharmacy survey data sheet for dispensing prescriptions and improve the study design prior to conducting the full-scale research
v. Conduction of full-scale observation studies in community pharmacies in Malta

vi. Development and validation by a focus group of a standard operating procedure for the preparation and dispensing of POYC medicines

vii. Development of an evaluation questionnaire to be given to participating community pharmacists to gather their perception on the SOP after two weeks of implementation

viii. Pilot study in one community pharmacy selected by convenience sampling to test for feasibility of the procedure

ix. Implementation of the SOP on a full-scale in five community pharmacies selected by convenience sampling from the pharmacies selected previously for observation studies.

Chapter 2

Methodology

2.1 Study Design

The study was divided into five phases. Phase 1 of the study consisted of a small-scale observation study to reveal the processes involved in dispensing Pharmacy Of Your Choice (POYC) medicines, from which the risks involved in the system followed were identified and validated by an expert focus group. Phase 2 involved the development of the data collection documents, whose feasibility was tested in a pilot study following validation by a second focus group prior to being used in the full-scale observation studies. Phase 3 consisted of obtaining Ethics approval before research on a larger scale commenced. Phase 4 involved the conduction of the full-scale observation studies in community pharmacies. The results of the observation studies were coded and statistically analysed. Phase 5, which is the final stage of the study, involved the development and validation, by an expert group, of a standard operating procedure (SOP) for the preparation and dispensing of POYC medicines. A small-scale observation study identified the temporary changes made to the system of preparing and dispensing POYC medicines due to COVID-19 to limit the spread of the disease. An evaluation questionnaire was also developed, which was used to gather the participating pharmacists' perception on the SOP after two weeks of implementation. A pilot study was conducted prior to the full-scale implementation to test the feasibility of the procedure. Figure 2.1 summarises the procedure followed for the development of the study.

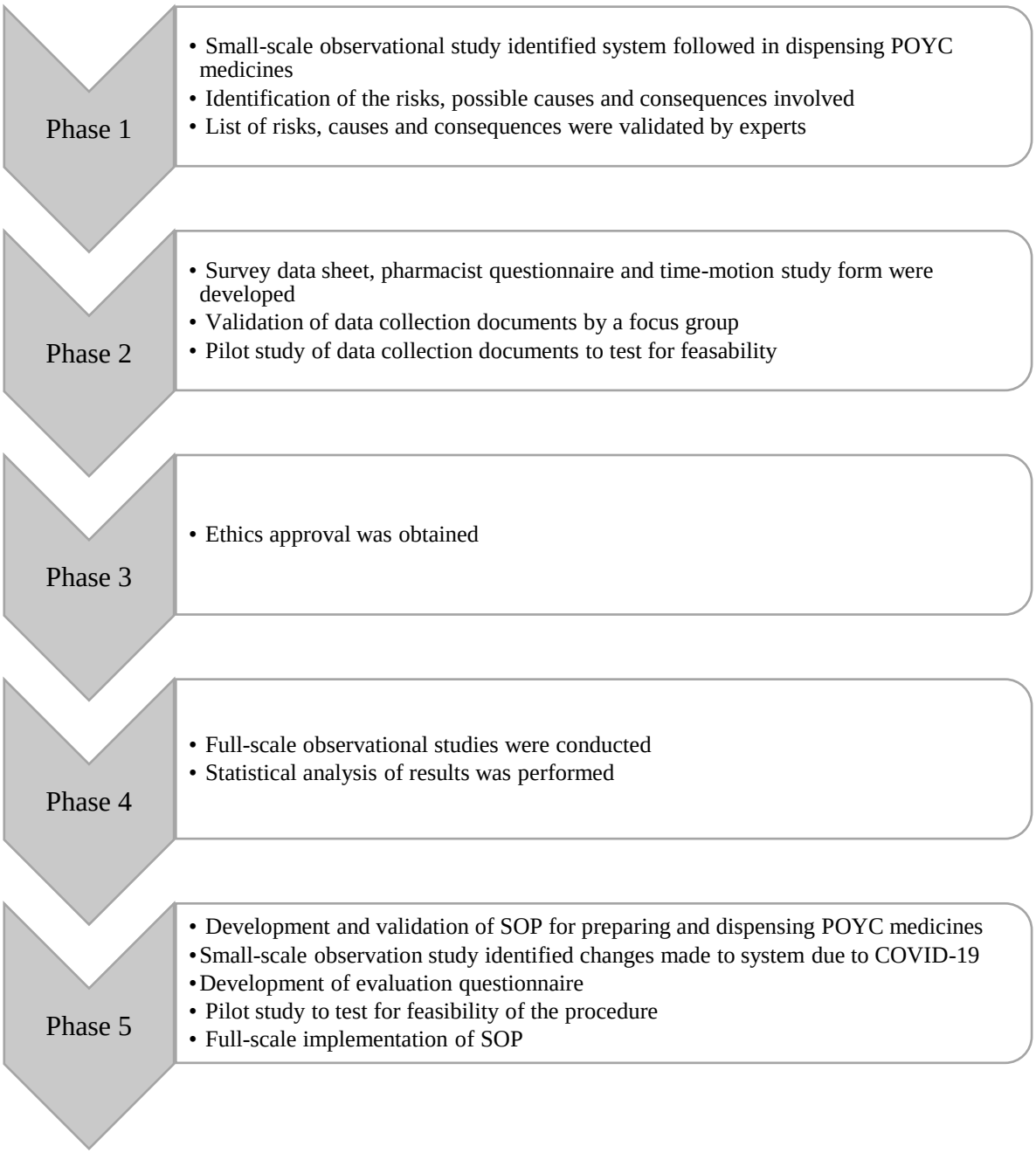

Figure 2.1 – Steps used in methodology

2.2 Identification of Dispensing Processes and Risks

The processes performed by the community pharmacist in order to prepare and dispense the POYC prescriptions were identified via a small-scale observation study, which was performed in four community pharmacies (three independent pharmacies and one pharmacy belonging to a group of pharmacies) selected by convenience sampling. The process of preparing and dispensing POYC prescriptions was observed and a flow chart representing all the steps involved in the dispensing process was developed.

The risks associated with the system followed by the community pharmacist to prepare and dispense POYC prescriptions were identified. These risks were documented along with their possible causes and effects. Expert group A was then consulted to obtain their opinion regarding the risks involved in the system followed when preparing and dispensing POYC medicines.

2.3 Development of Data Collection Documents

The data collection documents to be used in the conduction of full-scale observation studies in community pharmacies were developed in phase 2 of the study. The data collection documents include the survey data sheet, the questionnaire directed towards the community pharmacist on duty during the observation study and the time-motion study form. A pilot study was performed in the same four community pharmacies which were involved in the first small-scale observation study. The data collection documents were validated by focus group B prior to being tested for their feasibility.

2.3.1 Community Pharmacy Survey Data Sheet

The community pharmacy survey data sheet was developed with reference to a research carried out by Azzopardi (2000). Azzopardi developed and implemented internal validation tools for community pharmacy, including those to be used in dispensing a

prescription and communicating with the patient, to produce a sustainable pharmaceutical care service.

The community pharmacy survey data sheet (Appendix 1) was composed of 27 processes involved in the procedure followed in dispensing POYC medicines in the form of multiple-choice questions. The researcher observed whether the dispensing processes were performed or not during the observation studies by ticking 'Yes' or 'No', respectively. Alternatively, 'Not Applicable' (N/A) was marked in case the action was not applicable in the particular dispensing process. A remarks section was also included for each question for any additional comments. One survey data sheet was used for each prescription being dispensed.

2.3.2 Pharmacist Questionnaire

The pharmacist questionnaire (PQ) was adapted from Peterson et al (1999) and Stojković (2017) and was used to evaluate pharmacists' perception and practices of dispensing POYC medicines, as well as to establish the probability of occurrence and severity of patient harm of the risks involved in dispensing POYC medicines. Other similar studies were considered and referred to when developing the PQ (Allan et al, 1995; Szeinbach et al, 2007; Teinila et al, 2008; Thomas et al, 2011).

The PQ (Appendix 1) included a combination of both open-ended and close-ended questions. A total of 64 close-ended questions and eight open-ended questions were included in the PQ. The close-ended questions were multiple-choice in which respondents could choose the most suitable answer from the list provided, being either a value on a five-point Likert-scale or a categorical value. In the case of the categorical value, then the respondent's opinion falls in one particular class. The Likert scale is the most commonly used psychometric scale for self-reporting, where the respondent indicates the most

appropriate point on a scale of one to five to represent their opinion (Wakita et al, 2012). The Likert scale used for this study ranged from one to five, where one represented the lowest score and five represented the highest score.

2.3.2.1 Structure of Pharmacist Questionnaire

The PQ was developed for the community pharmacists on duty during the observation study. The questionnaire was divided into three different sections:

i. *Section I:* Demographic Data

Demographic information included the pharmacist's age, gender, status as a pharmacist, years of professional experience, time spent dispensing POYC medicines per week and time spent performing each process involved in dispensing a prescription, as well as information on the pharmacy including whether the pharmacy is pharmacist-owned and the type of community pharmacy. This section consisted of eight questions, the last one being further sub-divided into five.

ii. *Section II:* Risks Involved in Dispensing POYC Medicines

This section regards the possible risks involved in the system followed when dispensing POYC medicines and consisted of a total of nine questions: two containing an identical list of eighteen risks using a Likert scale (one for probability and one for severity), two multiple-choice questions and five open-ended questions. Pharmacists were asked to rank the risks involved in dispensing POYC medicines according to their probability of occurrence and their severity of potential patient harm, should the risks occur using a Likert scale from one to five. Pharmacists were also asked to state any other risks that were not mentioned, their possible causes and consequences, as well as whether and how they were being mitigated, or why if they were not being mitigated.

iii. *Section III:* Risk Perception and Risk Mitigation

This section regards the pharmacist's perception of the risks involved in dispensing POYC medicines and their mitigation strategies. It consisted of a total of five questions: one sub-divided into 17 multiple-choice questions, another two multiple-choice questions and two open-ended questions. Pharmacists were asked to state whether strategies to mitigate risk are performed at the pharmacy, as well as to state any other risk mitigation strategies that were not mentioned and any improvements that can be implemented by the POYC Unit.

2.3.3 Time-Motion Study Form

The time-motion study form (Appendix 1) was developed in order to record the time taken for the community pharmacist on duty to prepare the POYC prescription to be dispensed to the patient. The number of minutes recorded included the time taken to contact the POYC Unit, or whoever must be contacted in case of a POYC or patient-related problem in the patient's documents (respectively), selecting the medicine(s) and quantity to be prescribed, scanning the POYC card, recording medicine(s) on the IT system, writing the patient's name and ID number/patient number on the paper bag, printing and signing the labels, and filling in the control card (if applicable). The time-motion study was performed in three community pharmacies which were selected by random sampling from the pharmacies already chosen for the observation studies.

The time-motion study form was developed to record the number of medicines, type of prescription and time in minutes to prepare the POYC prescription to be dispensed for five prescriptions. The first five prescriptions at the start of the observation study were taken into consideration. The time of day during the observation was also recorded and a comments section was included for any additional remarks.

2.4 Development of Standard Operating Procedure

An SOP titled 'Preparation and Dispensing of POYC Medicines' was written in the format adapted from a previous local study (Briffa, 2011). The templates of other SOPs were referred to when developing this SOP.[36, 37, 38]

The developed SOP contains the following titles:

i. **Objective** (aim of the SOP)

ii. **Scope** (to whom the SOP applies)

iii. **Responsibilities** (the persons responsible in each stage of the procedure)

iv. **Definitions** (any technical words that need to be described)

v. **Procedure** (steps required to perform the activity of the SOP)

vi. **Precautions** (any safety measures undertaken when performing the procedure)

vii. **Process flow chart** (graphical representation of the procedure)

viii. **References** (list of published material used to compile the SOP)

ix. **Appendices** (contains other information and related documents of the SOP)

x. **Revision History** (amendments made each time a new version of SOP is issued)[39]

[36] Duca D. Management of Standard Operating Procedures at the University of Malta [Internet]. 2020 [cited 2021 Aug 7]. Available from: https://www.um.edu.mt/operatingprocedures/doc/UNI-001-01

[37] Shoemake C. Procedures for Dealing with Arising Complaints [Internet]. 2018 [cited 2021 Aug 7]. Available from: https://spizjara.org/wp-content/uploads/2018/02/sop-dealing-with-complaints-malta-chamber-of-pharmacists_final-1-1.pdf

[38] Castellani F. Preparation and Updates of EPAR Summaries by Product-Related Information to the Network Service [Internet]. 2014 [cited 2021 Aug 7]. Available from: https://www.ema.europa.eu/en/documents/sop/standard-operating-procedure-preparation-updates-european-public-assessment-report-summaries-product_en.pdf

[39] United States Environmental Protection Agency. Guidance for Preparing Standard Operating Procedures (SOPs) [Internet]. Washington: USEPA Office of Environmental Information; 2007 [cited 2021 Aug 7]. Available from: https://www.epa.gov/sites/production/files/2015-06/documents/g6-final.pdf

Microsoft® Office Word 2016 (Microsoft Corporation, Redmond, Washington) was used to write the SOP. The SOP (Appendix 2) was written using font style Calibri (Body) with font size 12 and text was aligned to a justified manner. All headings were written in bold and 1.5 line spacing was used.

Each page contains the same header:

<table>
<tr><td rowspan="3">Pharmacy
Logo</td><td>Name of Pharmacy, Locality
License No.</td><td rowspan="2">SOP No.:
SOP/PDM/001</td></tr>
<tr><td>Standard Operating Procedure</td></tr>
<tr><td>Preparation and Dispensing of Pharmacy Of Your Choice Medicines</td><td>Version: 01</td></tr>
</table>

This contains the pharmacy logo, the name and locality of the pharmacy, the license number, the name of the SOP, the SOP number and the version number. The SOP number is unique and consists of the term ‘SOP’ followed by three letters, three digits, the version number and a title (Grima, 2012).

Each page contains the same footer, which contains the page number in the format ‘Page X of 11’. A dotted line was included under the page number where the authorised person is to sign each page of the SOP in a unique colour, depending if it is the original SOP or a copy.

The first page of the SOP contains the table of contents, the type of document (whether the SOP is the original, authorised or reading copy) and the authorisation box. The table of contents will aid the reader to find the subject needed and the corresponding pages. The authorisation box consists of the names and signatures of the author, approver and reviewer of the SOP. The date in which the document was issued and the date the document should be reviewed were also included. The date reviewed is usually 2-3 years, depending on the pharmacy. The SOP may have to be revised earlier than the review date due to some changes. In this case, the document must be re-evaluated. If it is superseded

by any other document, it should be included. The authorisation box included was as follows:

Written by:	Emily Magro	Signature/Date:	**SOP No.:** **SOP/PMD/001**
Reviewed by:		Signature/Date:	Date issued:
Approved by:	Managing Pharmacist	Signature/Date:	Date reviewed:

Simple bulleted steps following a numbered list were used the describe the procedure of the SOP, while hierarchical steps were used to describe the definitions and precautions of the SOP. A branching flow chart, which consists of subdivisions that connect to different areas of the procedure shown by graphic symbols, was used to make the procedure easier to follow (Briffa, 2011).

The appendices included a 'Read and Understood Form' and a 'Points of Distribution' table. The 'Read and Understood Form' consists of a table having full name, signature and date as headers. This table is used by the pharmacists who deal with the SOP, which they have to date and sign as a conformation. The 'Points of Distribution' table contains place of distribution, name, signature and date and headers. This table shows where a copy of the SOP was placed in the workplace. This will help in locating and replacing the SOP copies in the event of an SOP amendment or review (Briffa, 2011).

2.5 Identification of Changes Made to System due to COVID-19

The temporary changes made to the system of preparing and dispensing POYC medicines were identified via a small-scale observation study, which was performed in two community pharmacies (one independent pharmacy and one pharmacy belonging to

a group of pharmacies) selected by convenience sampling. The process of preparing and dispensing POYC prescriptions was observed and the changes made to the standard procedure were noted.

2.6 Development of Evaluation Questionnaire

The evaluation questionnaire was adapted from Freitas et al (2016) and was used to assess the pharmacists' perception and gather suggestions for improvements regarding the SOP developed, which describes the procedure for the preparation and dispensing of POYC medicines.

The evaluation questionnaire (Appendix 2) is directed towards community pharmacists participating in the implementation of the SOP. This questionnaire was divided into three sections: Section I, which contains questions intended to gather demographic information of the participant, including age, gender, status as a pharmacist, years of professional experience and hours per week spent dispensing POYC medicines, Section II, which contains questions intended to obtain information on the evaluation of the SOP, and Section III, which contains questions regarding the temporary changes made to the system followed in preparing and dispensing POYC medicines to patients due to COVID-19.

The evaluation questionnaire included a combination of both open-ended and close-ended questions. A total of 23 close-ended questions and 10 open-ended questions were included in the questionnaire. The close-ended questions were multiple-choice in which respondents could choose the most suitable answer from a rating scale or the categories provided. In the case of a rating scale, the options were 'yes' (full compliance), 'no' (not compliant) or 'maybe' (partially compliant). In this manner, results obtained by different respondents can be compared without the need of establishing a detailed list of

criteria for each question and each rating.[40] In the case of a categorical value, the respondent's opinion falls in one particular class.

2.7 Validation

The concept of validation may be described as the process carried out to confirm the effectiveness and reproducibility of an instrument intended for analytical application (Azzopardi, 2000). The validation exercise served to obtain experts' opinion and improve data collection tools and analysis of the study prior to performing the research on a full-scale.

2.7.1 Panel Selection for the Validation Process

The list of risks identified from the pilot observation study, along with their possible causes and effects, were validated by expert group A consisting of three community pharmacists, one physician and one official within the top management of the POYC Unit. The flow chart of the system followed in dispensing POYC medicines was validated by the official within the top management of the POYC Unit. The expert panel were asked to scrutinise the list of risks identified, their possible causes and effects, as well as whether they agree with the risks, causes and effects, and whether there are any other risks which were not mentioned or any risks they would omit.

The survey data sheet, the questionnaire directed towards community pharmacists on duty during the observation study and the time-motion study form were validated by focus group B consisting of two community pharmacists, two physicians and one lay person. The informed consent form, which is required to be signed by the managing

[40] McGuire G. Handbook of Humanitarian Health Care Logistics: Designing the Supply Network and Managing the Flows of Information and Health Care Goods in Humanitarian Assistance during Complex Political Emergencies [Internet]. 2nd edition; 2011 [cited 2021 Aug 7]. Available from: http://iaphl.org/wp-content/uploads/2016/05/Handbook-of-Humanitarian-Health-Care-Logistics-MAY-2011.pdf

pharmacists of each randomly-selected community pharmacy should they wish to participate, was validated by the layperson. The informed consent form was also developed together with the data collection documents. The data collection documents were edited according to the recommendations of the expert panel.

After validation, the revised data collection documents were tested for their feasibility via a pilot study in the same four pharmacies involved in the small-scale observation study previously performed. The feasibility of the data collection documents was evaluated to improve the study design prior to conducting the research on a full-scale.

The SOP was validated by focus group C consisting of three community pharmacists and one layperson. The informed consent form for implementing the SOP in community pharmacies (Appendix 2), which is required to be signed by the participating pharmacists, was validated by the layperson. The document was then updated according to the recommendations of the focus group. The feasibility of the procedure involving the implementation of the SOP in community pharmacies was then evaluated via a pilot study in one community pharmacy selected by convenience sampling prior to conducting the study on a full-scale.

2.7.2 Validation Method

Data collection documents were assessed for face and content validity. The term 'content validity', which is of utmost importance in the development of a new instrument, refers to the degree to which the questions are relevant, and representative of, the topics it is designed to cover (Rusticus, 2014).

Each individual involved in the validation panels was contacted and asked if they wished to contribute to the study. All of the individuals chosen were willing to share their personal opinion regarding any improvements which can be made to achieve the best

possible results. A form containing general demographic questions (Appendix 3) was distributed to each individual of every expert or focus group consulted and asked to complete it for statistical purposes.

The group of experts involved in the validation of the list of risks developed were given a copy of this list. Experts were asked to scrutinise the list to obtain constructive criticism that will aid in the development of the data collection documents.

For the validation of the data collection documents, each individual was given a brief overview of the background, aims and objectives of the study (Appendix 3). Copies of the survey data sheet, the PQ and the time-motion study form were distributed to each individual. Each individual was given time to read the documents to be used in the study, after which the questions in table 2.1 were asked to obtain constructive criticism on the documents. For the validation of the SOP, each individual was given a copy of the document.

Table 2.1 – Expert group validation questions (adapted: Xuereb M. Perception of Pharmacists and Patients of the Pharmacy Of Your Choice Scheme in Community Pharmacies [Dissertation]. Valletta: University Of Malta; 2014).

Would you include anything else? If yes, please state any other questions/statements that you think should be included.
Does the sequencing of the questions/sections seem logical?
Does the questionnaire/survey data sheet represent the content?
Is the questionnaire/survey data sheet comprehensive enough to collect all the information needed to address the purpose and goals of the study?
Are all the questions/statements worded in a clear, concise and unambiguous manner? If no, please state which questions/statements are not clear.
Are any of the questions/statements unnecessary, repetitive or inappropriate? If yes, please state which questions/statements are unnecessary, repetitive or inappropriate.
Do you have any other comments or suggestions?

2.8 Implementation Study

The implementation study involves the selection of the community pharmacies to take part in the study by random sampling, as well as the application to obtain Ethics approval prior to conducting the observation studies.

2.8.1 Population Sample and Selection of Pharmacies

Out of the 229 community pharmacies in Malta and Gozo, 220 have implemented the POYC scheme, where 201 are found in Malta and the remaining 19 are found in Gozo.[41] For this study, community pharmacies in Malta were taken into account.

A list of all the community pharmacies providing POYC services in Malta was obtained from the POYC Unit in Gwardamangia. These community pharmacies were categorised into five statistical districts according to their location, as shown in Table 2.2.[42] Eight community pharmacies were chosen from each statistical district by random sampling, which was computer-generated using Microsoft® Excel® 2016 (Microsoft Corporation, Redmond, Washington). Each pharmacy was assigned a random number using the RAND function and were arranged in ascending order, after which the first eight pharmacies were chosen. Random sampling was used to eliminate bias. A total of 40 community pharmacies were included in the study.

The implementation of the SOP involved in phase 5 of the study was conducted in five pharmacies selected by convenience sampling from the 40 pharmacies included in

[41] Ministry for Health. The Pharmacy Of Your Choice National Scheme [Internet]. Valletta: Office of the Deputy Prime Minister and Ministry for Health; 2019 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/Poyc-scheme.aspx

[42] National Statistics Office (NSO). Regional Statistics Malta 2020 Edition [Internet]. Valletta: NSO; 2020 [cited 2021 Aug 7]. Available from: https://nso.gov.mt/en/publicatons/Publications_by_Unit/Documents/02_Regional_Statistics_(Gozo_Office)/2020/Regional_Statistics_Malta-2020%20Edition.pdf

the study. The evaluation questionnaire was given to the participating pharmacists to gather their perception on the SOP after two weeks of implementation.

Table 2.2 – Maltese localities in districts (adapted: National Statistics Office (NSO). Regional Statistics Malta 2020 Edition [Internet]. Valletta: NSO; 2020 [cited 2021 Aug 7]. Available from: https://nso.gov.mt/en/publicatons/Publications_by_Unit/Documents/02_Regional_Statistics_(Gozo_Office)/2020/Regional_Statistics_Malta-2020%20Edition.pdf)

District Number	District Name	Localities
1	Southern Harbour	Cospicua (Bormla); Fgura; Floriana; Ħal Luqa; Ħaż-Żabbar; Kalkara; Marsa; Paola; Santa Luċija; Senglea (L-Isla); Ħal Tarxien; Valletta; Vittoriosa (Birgu); Xgħajra
2	Northern Harbour	Birkirkara/Fleur-de-Lys; Gżira; Ħal Qormi; Ħamrun; Msida; Pembroke; San Ġwann; Santa Venera; St Julian's/Ta' Giorni; Swieqi; Ta' Xbiex; Tal-Pietà; Tas-Sliema
3	South Eastern	Birżebbuġa; Gudja; Ħal Għaxaq; Ħal Kirkop; Ħal Safi; Marsaskala; Marsaxlokk; Mqabba; Qrendi; Żejtun; Żurrieq
4	Western	Ħad-Dingli; Ħal Balzan; Ħal Lija; Ħ'Attard; Ħaż-Żebbuġ; Iklin; Mdina; Mtarfa; Rabat/Baħrija; Siġġiewi
5	Northern	Ħal Għargħur; Mellieħa; Mġarr; Mosta; Naxxar; St Paul's Bay/Bugibba/Qawra

2.8.2 University Research Ethics Committee Approval

Before the observation studies could be carried out in community pharmacies, the University Research Ethics Committee (UREC) approval had to be obtained. Permission, in the form of a 'No Objection Certificate' (Appendix 4), which states that the party does not object against the study to be carried out, was obtained from the Chief Executive Officer (CEO) of the POYC Unit, the Chairperson of the Healthcare section at The Malta National Chamber for Small and Medium Enterprises (GRTU), the President of the Malta Chamber of Pharmacists (MCoP) and the Director for Scientific and Regulatory Operations at the Malta Medicines Authority (MMA).

While these permissions were being obtained, approval from the forty randomly selected pharmacies was obtained in the form of an informed consent form (Appendix 4), which was signed by the managing pharmacist of each respective community pharmacy.

The necessary application form was filled in (Appendix 4) and sent to UREC along with the following documents: community pharmacy survey data sheet, questionnaire directed towards community pharmacists on duty at the time of the observation study, informed consent form, time-motion study form for the preparation of POYC medicines, as well as the project proposal and protocol (Appendix 4).

Once the application was processed, a meeting with the UREC was held to discuss the main points of the study. Approval to carry out the study was obtained during the meeting (Appendix 4).

2.8.3 Observation Studies

Each community pharmacist on duty during the observation study was approached by the researcher and information on the nature of the study was presented orally and in a written form via the informed consent form. Pharmacists were required to sign the informed consent form once they agreed to participate. The questionnaire was handed to the community pharmacist, which they either completed during the observation study or later. If the pharmacist completed the questionnaire at a different time and not during the observation study, the researcher went back to the pharmacy to collect the questionnaire.

The first five POYC prescriptions dispensed by the community pharmacist on duty at the start of the observation study were observed to evaluate the dispensing process and complete the survey data sheet for each prescription dispensed. The observation study in each pharmacy took approximately three hours and was conducted once in each

pharmacy. The researcher went either in the morning (8am – 12pm), in the afternoon (12pm – 4pm) or in the evening (4pm – 7pm onwards) to conduct the observation study, depending on the time of day in which the different pharmacies dispense POYC medicines to patients.

2.8.4 Standard Operating Procedure

The SOP was implemented in five pharmacies. The pharmacists of those pharmacies were approached by the researcher and information on the nature of the SOP implementation study was presented orally and in a written form via the informed consent form. The pharmacists who were willing to participate were asked to sign the informed consent form as form of approval for participation. An evaluation questionnaire was given to the participating pharmacists two weeks following the implementation of the SOP.

2.9 Statistical Analysis

Data was coded using Microsoft® Excel® 2016 (Microsoft Corporation, Redmond, Washington) and statistical analysis was performed using IBM Statistical Package for the Social Sciences® (SPSS) version 23.0 (IBM Corporation, Armonk, New York). The Likert rating scale was used due to the ease with which data can be analysed. It also allows the questionnaire respondents the freedom to give a neutral answer, represented by '3' on the Likert scale.

The Friedman test was used to compare mean rating scores between a number of related risks. These mean rating scores range from one to five, where one corresponds to never, or no harm, and five corresponds to always, or death, relating to probability of occurrence and severity of consequences respectively. This test is a non-parametric alternative to the repeated measures ANOVA test and is used when the normality assumption is not satisfied. The null hypothesis specifies that the mean rating scores

provided to the risks are comparable and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies the converse and is accepted if the p-value is less than the 0.05 criterion. The Mann-Whitney test is used to compare mean durations to carry out processes involved in the supply of POYC medicines between actual observations and those stated by the pharmacists. This test is a non-parametric alternative to the independent samples T-test and is used when the duration distribution does not satisfy the normality assumption. The null hypothesis specifies that the observed mean durations are similar to the mean duration stated by the pharmacists and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the observed mean durations differ significantly from the mean durations stated by the pharmacists and is accepted as the p-value is less than the 0.05 criterion. The Kruskal Wallis test was used to compare mean risk priority scores between independent groups of pharmacists clustered by their years of professional experience (1-10 years, 11-20 years and more than 20 years) and dispensing duration per week (0-10 hours, 11-20 hours and more than 20 hours). This test is a non-parametric alternative to the one-way ANOVA test and is used when the normality assumption is violated. The null hypothesis specifies that mean rating scores vary marginally between the groups of pharmacists and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean risk priority scores vary significantly between the groups of pharmacists and is accepted if the p-value is less than the 0.05 criterion. The Kruskal Wallis test was also used to compare mean scores of data obtained using the survey data sheet and the districts.

These tests were used since most rating score distributions were left skewed and did not satisfy normality assumptions. Moreover, rating scores are ordinal categorical responses and cannot be considered as having a metric scale.

Error bar graphs were also generated, which display the 95% confidence interval of the actual mean rating score provided to a particular risk. Overlapping of two confidence intervals indicates that their mean rating scores are similar and do not vary significantly. Disjointing of two confidence intervals indicates that their mean rating scores differ significantly.

Chapter 3

Results

3.1 System Followed in Dispensing POYC Medicines

The processes involved in dispensing POYC medicines were identified via a small-scale observation study performed in four community pharmacies. Figure 3.1 shows the flowchart which was developed following the observation study to identify the processes performed by the community pharmacist in order to prepare and dispense POYC medicines, from the point when the patient, or patient representative, enters the pharmacy to the point when they leave the pharmacy. The flowchart was produced using draw.io® version 12.5.1 (JGraph Ltd, Zürich, Switzerland).

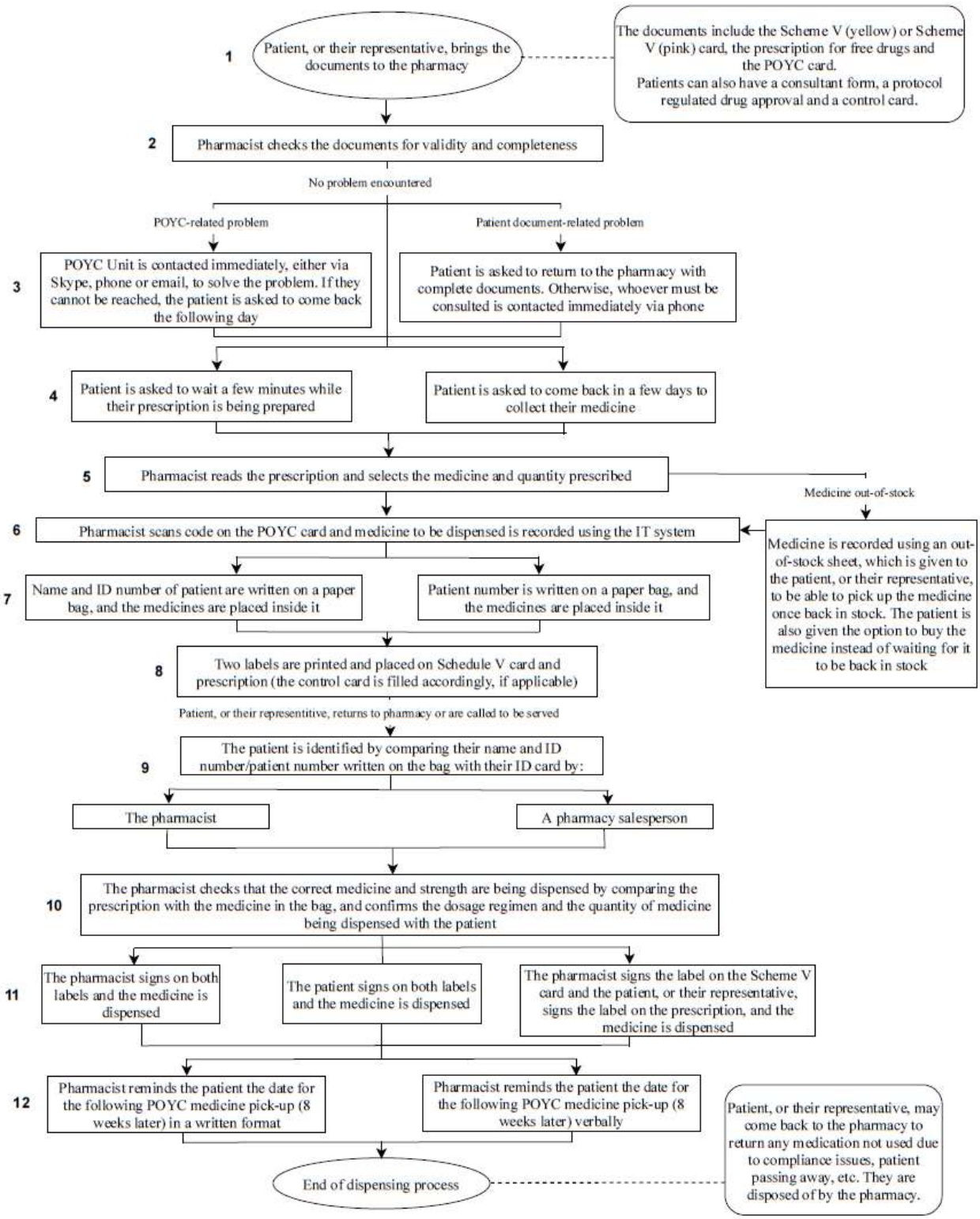

Figure 3.1 – System followed in dispensing POYC medicines

3.2 Contributing Risks

The risks involved in the processes involved in dispensing POYC medicines were identified and summarised in Table 3.1, along with their possible causes and effects.

Table 3.1 – List of risks, causes and effects involved in dispensing POYC medicines

Risk	Possible Causes	Effect
1. Insufficient time for dispensing	• Process is very time-consuming. • Sole pharmacist on duty (which may be a result of lack of funding to pharmacy owners by the Government). • High prescription number. • High medicine volume.	• Patient is not given enough advice on the medicine dispensed. • Any errors remain undetected.
2. Incomplete/invalid patient documents	• Patient does not have all the documents required. • Documents are out-dated. • Discrepancies between entitlement and prescription.	• Delay in dispensing medicine to the patient, since the process to make alterations in Schedule V card is time-consuming.
3. Illegible prescription	• Poor handwriting of physicians.	• The wrong product, dose and/or quantity is dispensed.
4. Inadequate medicine storage	• Sound-Alike/Look-Alike drugs are placed next to each other. • Overcrowding of shelves.	• The wrong product, dose and/or quantity is dispensed.
5. Selection of wrong product, dose and/or quantity of medicine	• Pharmacy salespersons handle the dispensing process. • Medicine to be dispensed is not re-checked against the prescription. • Medicine to be dispensed is not checked by another pharmacist. • Packaging of the same product with different doses are very similar.	• The wrong product, dose and/or quantity is dispensed. • Medicine wastage.
6. Lack of privacy when dispensing	• There is no dedicated space or room for dispensing POYC medicines. • Pharmacist does not talk privately with the patient.	• Patient does not feel safe and does not ask any questions they might have on the medicine dispensed, leading to incorrect administration.
7. Interruptions and distractions	• Pharmacist is interrupted by pharmacy assistants, telephone calls and customers while dispensing POYC medicine. • Pharmacist is distracted by talkative customers and broadcast devices.	• The wrong product, dose and/or quantity is dispensed.
8. Unreliability of IT system	• Discrepancies between patient entitlement on the IT system and the Schedule V card. • Server problems. • Lack of updates and improvements of the IT system, e.g. the IT system does not allow checking of drug interactions and/or contra-indications for each medicine).	• Delay in dispensing medicine to the patient. • Medicine wastage.

Risk	Possible Causes	Effect
9. Incorrect data entry	• Data written in the IT system or control card is not re-checked. • Pharmacy assistants participating in data entry. • Printed labels do not clearly indicate by who they should be signed (e.g. dispensing pharmacist, pharmacist who checked the prescription before dispensing, etc.)	• The wrong quantity is dispensed. • Printed labels are incorrect. • Discrepancies in medicine stock between what is stated by the IT system and the actual stock in the pharmacy. • Medicine wastage.
10. Cluttered work counter	• Work counter is not solely used for dispensing medicine to the patient. • Work counter is not kept tidy, clear and organised.	• An adequate dispensing environment is not provided, possibly leading to undetected errors.
11. Pharmacists/Locums having their own method of preparing and dispensing POYC medications	• Lack of continuity as a result of the different methods of dispensing by different pharmacists/locums working at the pharmacy.	• Disorganised system of dispensing POYC medicines. • Discrepancies in medicine stock between what is stated by the IT system and the actual stock in the pharmacy. • Delay in dispensing medicine to the patient.
12. Stock-taking	• Process is very time-consuming. • Process must be performed too frequently (every 3 months).	• Delay in dispensing medicine to the patient, since no medicines are to be dispensed during stock-taking.
13. Incorrect prescription	• Lack of knowledge on drug-drug interactions by the physician. • Wrong dose prescribed.	• The wrong product, dose and/or quantity is dispensed.
14. Inexperienced pharmacists	• Lack of confidence in correcting physician's prescriptions. • Participation of pharmacy salespersons in dispensing POYC medicines.	• The wrong product, dose and/or quantity is dispensed.
15. Lack of training	• Pharmacists are informed late or not at all on new POYC protocols. • Insufficient educational seminars on dispensing POYC medicines. • Insufficient training for pharmacy technicians in preparing POYC medicines.	• Delay in dispensing medicine to the patient. • Increases stress in the workplace among pharmacists.
16. Limited stock, especially new medicines	• POYC medicines stock not renewed frequently enough.	• Delay in dispensing medicine to the patient. • Less time is dedicated to counsel patients.
17. Inability to reach the POYC Unit	• Limited opening hours of the POYC Unit Call Centre. • Busy operating phone lines make it difficult to get in touch with them. • Inability to reach POYC Unit via Skype.	• Delay in dispensing medicine to the patient.
18. Complicated/Ambiguous POYC protocols	• Protocols can be too complex and/or unclear that they may be open to different interpretations e.g. pharmacists may not be sure whether a certain permit is sufficient or not.	• Delay in dispensing medicine to the patient.

3.2.1 Modifications to List of Risks, Causes and Effects

In risk number 5, the phrase ‘pharmacy salespersons’ was changed to ‘pharmacy assistants’ since the word ‘salespersons’ indicates more that the employees working at the community pharmacy being classified as salespersons possess slight to no experience in a community pharmacy setting, making it more likely that they will select the wrong product, dose and/or quantity of medicine, should they handle the dispensing process.

In risk number 9, another possible cause was added, which was: ‘Printed labels do not clearly indicate by who they should be signed (e.g. dispensing pharmacist, pharmacist who checked the prescription before dispensing, etc.).’ This was added since it was stated that the labels that must be printed and placed on the prescription and the Schedule V card do not clearly show how they should be filled out by the pharmacist and/or patient. This ambiguity may be a cause for incorrect data entry.

Seven other risks, and their relative causes and effects, were added to the list. These were risks number 11 through 18, along with their respective possible causes and effects.

Risk number 11 was added since it was pointed out that it is common for pharmacies to have several locums. This may cause a disruption in the system followed by the particular pharmacy to dispense POYC medicines since different community pharmacists have their own method of preparing and dispensing POYC medicines, each of which is correct but different from one another.

Other risks that were added following validation and that may cause a delay in dispensing POYC medicines to patients are risks numbered 12 and 15 through 18, which are the following, respectively: stock-taking, which was deemed as a very time-consuming and frequent process; lack of training pharmacists both from the pharmacy’s

end in terms of educational seminars and the POYC Unit's end in terms of training regarding new protocols; limited stock (especially new medicines), since it was stated that POYC medicines stock is not renewed frequently enough; inability to reach the POYC Unit due to limited working hours and not enough operating phone lines; and, complicated/ambiguous POYC protocols, which were stated to be too complex and/or unclear sometimes.

Risk number 13 and 14 were added to reflect the professional inexperience both community pharmacists and physicians may have. This may pose a risk to dispense the wrong product, dose and/or quantity to the patient.

3.3 Validation Panel Demographics

Individuals with different competencies were invited to form part of a panel for validation. Representativeness was not assured since selection of experts was made through personal contacts of the investigator and not via random sampling.

For the validation of the list of risks involved in dispensing POYC medicines, a total of four experts were contacted by phone and invited to participate. All the experts recruited agreed to participate in the validation exercise. The group of four experts (three males and one female) comprised of three community pharmacists (one managing pharmacist and two locums employed on a part-time basis) and one physician (who specialises in family medicine and practices privately in two community pharmacies). The experts were part of different age groups, one from each of the following: 21-30 years, 31-40 years, 41-50 years and 51-60 years. Two of the experts have more than 20 years of professional experience, while the remaining two have 1-5 years and 11-15 years of professional experience.

For the validation of the data collection documents developed, a total of five individuals were again contacted by phone and invited to participate. All the individuals recruited agreed to participate in the validation exercise. The members of the validation panel (three males and two females) comprised of two community pharmacists (one managing pharmacist and one locum employed on a part-time basis, both of which participated in the first validation exercise), two physicians (both of which specialise in family medicine, where one practices privately in four clinics/pharmacies and one in two community pharmacies, the latter of which also took part in the first validation exercise) and one layperson (school clerk), the latter of which also validated the informed consent form. The members form part of different age groups, one individual from each of the following age categories: 21-30 years, 31-40 years and 41-50 years, and two individuals forming part of the 51-60 years age category. Two of the individuals have more than 20 years of professional experience, another two have 11-15 years of professional experience, while the remaining individual has 1-5 years of professional experience.

For the validation of the standard operating procedure (SOP) developed, a total of four participants were again contacted by phone and invited to participate. All the individuals recruited agreed to participate in the validation exercise. The members of the validation panel (three females and one male) comprised of three community pharmacists (two managing pharmacist and one locum employed on a part-time basis), and one layperson (school clerk). The layperson also validated the informed consent form for the implementation of the SOP. The members form part of different age groups: one individual aged 21-30 years, two aged 31-40 years and one aged 51-60 years. The community pharmacists have different years of professional experience, one individual from each of the following ranges: 1-5 years, 6-10 years and 11-15 years.

3.4 Selection of Community Pharmacies

Community pharmacies in Malta were divided into the five statistical districts defined as per the National Statistics Office classification. The research was conducted in 40 randomly selected community pharmacies in Malta (eight from each district) and the managing pharmacists were contacted. Of the first 40 randomly selected community pharmacies, 37 agreed to participate in the study while three managing pharmacists were reluctant to participate, either because the managing pharmacists considered no benefit to them from the study or because they were not happy with the presence of an observer at the pharmacy. As a result, three other community pharmacies were selected randomly from the districts where community pharmacies had to be recruited. The 40 managing pharmacists who finally agreed to participate were asked to sign an informed consent form.

Of the 40 community pharmacies selected, 26 were owned by a pharmacist, while the remaining 14 pharmacies were non-pharmacist owned. Twenty-four of the community pharmacies were independent pharmacies, while the remaining 16 pharmacies were one of a group of pharmacies owned by the same owner/s. Figure 3.2 shows the number of pharmacies which make up the group of which those 16 pharmacies form part.

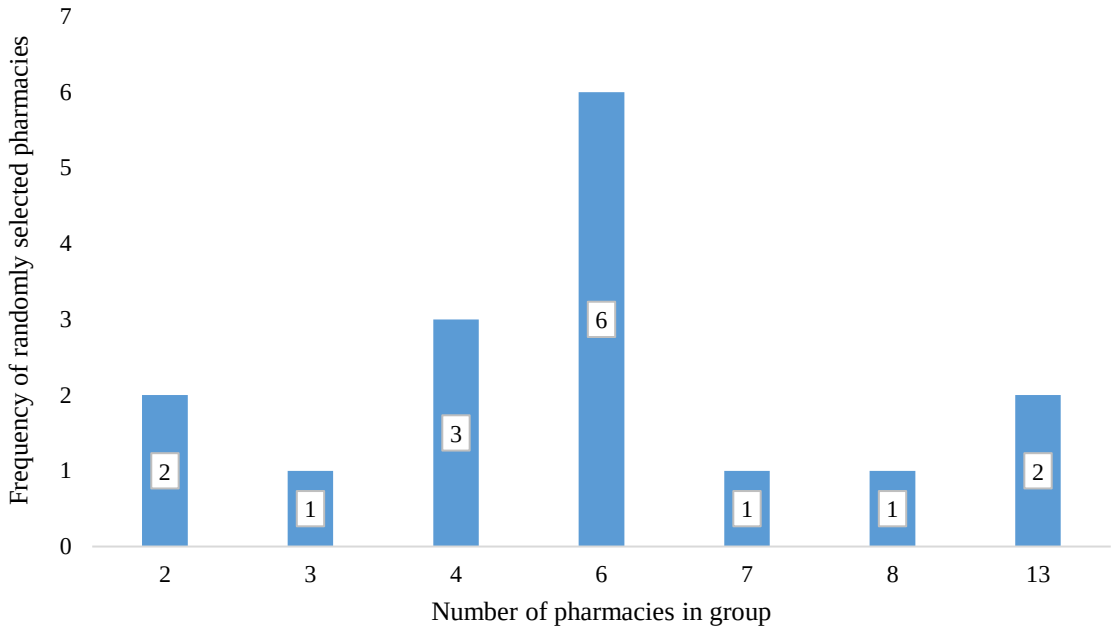

Figure 3.2 – Number of pharmacies in each group owned by the same owner/s of which the randomly selected pharmacies form part

The selected 40 pharmacies were visited by the investigator for one three-hour session. In total, one hundred and twenty hours of observation in pharmacies was performed. The pharmacist on duty during the observation study was observed by the investigator, who stayed in an inconspicuous corner in the pharmacy. Five POYC prescriptions being dispensed were observed in each pharmacy, bringing the total of observed prescriptions being dispensed to 200.

3.5 Community Pharmacy Survey Data Sheet

The community pharmacy survey data sheet is one of the data collection documents developed for the study. This document, which was used by the principal investigator, was validated before being used in the full-scale observation studies.

3.5.1 Modifications to Community Pharmacy Survey Data Sheet

The community pharmacy survey data sheet was modified according to the recommendations given by the members of the panel participating in the validation exercise. Changes in the original community pharmacy survey data sheet included re-wording to improve the flow of the sentence, re-structuring, such as a recommendation to shorten the question, and addition of new questions, such as a recommendation to add whether the prescription being recorded is a new or a repeat prescription (Appendix 5).

Originally, the questions were numbered in Roman numerals. However, it was advised by one individual that Roman numerals can be difficult to read and interpret. As a result, the numbering of the questions was modified to nominal numbers.

Grammatical issues throughout the document were addressed. In addition, a comments section was recommended to be added at the end of the community pharmacy survey data sheet for the investigator to use for any additional qualitative data.

3.5.2 Pharmacy Responses

The observation studies in each community pharmacy were either carried out in the morning (between 8am and 12pm), afternoon (between 12 pm and 4pm) or evening (between 4pm and 7pm onwards). Twenty-nine of the observation studies were carried out in the morning, five were carried out in the afternoon, while six were carried out in the evening.

Out of the 200 dispensed prescriptions observed, twenty-five of them were computer-generated prescriptions, while the rest were hand-written ones. Figure 3.3 shows the number of computer-generated prescriptions found in each statistical district.

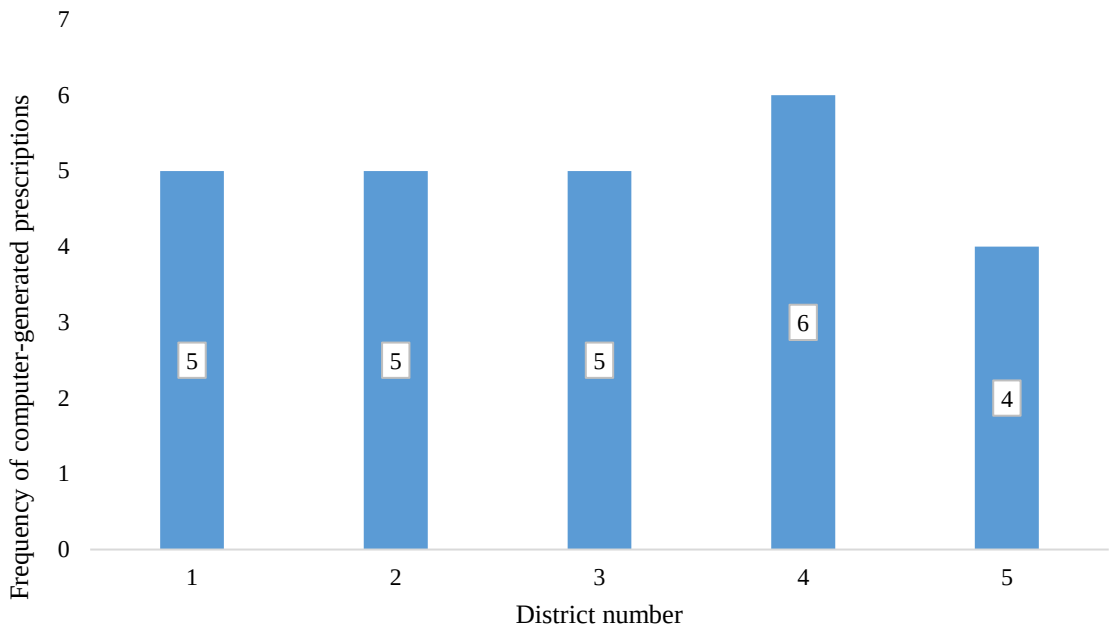

Figure 3.3 – Frequency of computer-generated prescriptions found per district during the observation studies

Figure 3.4 summarises the time taken by pharmacists to perform different processes involved in dispensing POYC medicines with an average of 3 medicines.

In three out of 40 pharmacies (one in each of districts 1, 2 and 3), cases of an illegible prescription were observed. In each of the three pharmacies, one illegible prescription was observed, where the registration number of the physician was hard to read. In each case, the pharmacist on duty managed to determine the illegible handwritten number by trial and error on the POYC IT system.

In two out of 40 pharmacies, both in district 3, the pharmacist on duty verbally confirms the ID number of the patient with that written on the paper bag.

In one pharmacy in district 3, a third label was also placed on the paper bag, apart from the printed labels placed on the prescription and the Schedule V card. All three labels were not signed.

In one observed prescription of one pharmacy in district 3, the pharmacist on duty was on a phone call during the whole dispensing process.

Two out of 40 pharmacies, one in district 1 and one in district 3, made use of a computer programme known as Master Universal, which automatically inputs the medicines, doses, quantity and stock on the POYC IT system. This system, which is able to connect the third-party software of POYC, was developed by pharmacist John Agius and became available for purchase in December 2018. In each pharmacy, labels with patient name, date of the next POYC medicines pick-up and the Data Matrix barcode are printed and placed on the patient file.

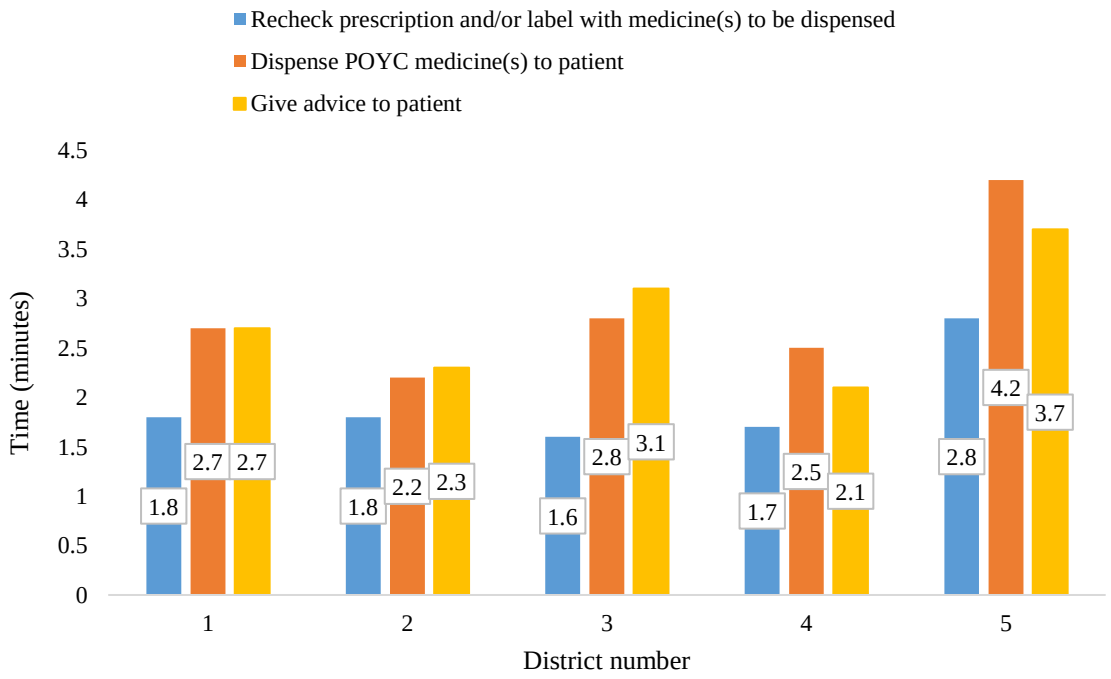

Figure 3.4 – Average time taken in minutes by the pharmacists in each district to perform the different processes involved in dispensing an average of three POYC medicines

3.5.2.1 District 1

The results obtained from the observation studies performed in the eight randomly-selected pharmacies in each district were tabulated (Appendix 1). Out of the 40 prescriptions observed in District 1, thirty-eight were repeat prescriptions while two were new. With regards to the signatures on the printed labels, three out of eight pharmacies had Schedule V signed by the pharmacist and the prescription signed by the patient/patient representative, two pharmacies had both documents signed by the patient/patient representative, one pharmacy had both documents signed by the dispensing pharmacist, one pharmacy had Schedule V signed by both the pharmacist and the patient/patient representative and the prescription signed by the patient/patient representative, and one pharmacy had no signatures on either document.

3.5.2.2 District 2

All of the 40 prescriptions observed in District 2 were repeat prescriptions. With regards to the signatures on the printed labels, three out of eight pharmacies had no signatures on Schedule V and the prescription signed by the patient/patient representative, two pharmacies had no signatures on either document, while the remaining three pharmacies either had both documents signed by both the dispensing pharmacist and the patient/patient representative, both documents signed by the dispensing pharmacist, or both documents signed by the patient/patient representative.

3.5.2.3 District 3

Out of the 40 prescriptions observed in District 3, thirty-eight were repeat prescriptions while two were new. With regards to the signatures on the printed labels, three out of eight pharmacies had no signatures on either document, two pharmacies had

Schedule V signed by both the pharmacist and the patient/patient representative and no signatures on the prescription, while the remaining three pharmacies either had both documents signed by both the dispensing pharmacist and the patient/patient representative, both documents signed by the patient/patient representative, or no signatures on Schedule V and the prescription signed by the patient/patient representative.

3.5.2.4 District 4

All of the 40 prescriptions observed in District 4 were repeat prescriptions. With regards to the signatures on the printed labels, three out of eight pharmacies had no signatures on either document, one pharmacy had Schedule V signed by both the pharmacist and the patient/patient representative and the prescription signed by the patient/patient representative, one pharmacy had Schedule V signed by the pharmacist and the prescription signed by the patient/patient representative, one pharmacy had Schedule V signed by the patient/patient representative and the prescription signed by the pharmacist, one pharmacy had no signatures on Schedule V and the prescription signed by both the pharmacist and patient/patient representative, and one pharmacy had no signatures on Schedule V and the prescription signed by the pharmacist.

3.5.2.5 District 5

Out of the 40 prescriptions observed in District 5, thirty-seven were repeat prescriptions while three were new. With regards to the signatures on the printed labels, three out of eight pharmacies had both documents signed by both the dispensing pharmacist and the patient/patient representative, two pharmacies had no signatures on either document, two pharmacies had no signatures on Schedule V and the prescription signed by the patient/patient representative, and one pharmacy had both documents signed by the patient/patient representative.

3.5.2.6 Overall

The results obtained from the community pharmacy survey data sheets used in all 40 pharmacies were added up to obtain an overall score, as shown in Table 3.3.

Table 3.2 – Overall results obtained from the observation studies performed

Question		Frequency
Type of Prescription	**Repeat**	193
	New	7
1. Patient comes into the pharmacy to collect POYC medicine(s) him/herself.	**Yes**	176
	No	24
	NA	0
2. Patient has more than one comorbidity.	**Yes**	100
	No	100
	NA	0
3. Patient is 60 years old or older (elderly).	**Yes**	104
	No	96
	NA	0
4. Pharmacist deals with the patient, or patient representative.	**Yes**	195
	No	5
	NA	0
5. Pharmacist asks for the patient's ID card for identification by comparing the name and ID card number/patient number with those written on the bag.	**Yes**	35
	No	165
	NA	0
6. Patient documents are checked for completeness and validity.	**Yes**	188
	No	12
	NA	0
7. Pharmacist checks that the medicine(s) listed on Schedule V card correspond(s) to the prescription and/or label.	**Yes**	182
	No	18
	NA	0
8. Pharmacist checks that the medicine(s) listed on Schedule V card correspond(s) to the consultant form, *(if applicable)*.	**Yes**	18
	No	3
	NA	179
9. No problem is identified with the patient documents, or appropriate action is taken to solve the identified problem.	**Yes**	200
	No	0
	NA	0
10. a) Medicine(s) were ready to be collected in a few days after the patient, or patient representative, left the documents at the pharmacy and was asked to come back to collect the medicine(s).	**Yes**	146
	No	0
	NA	0
10. b) Medicine(s) were ready to be collected in a few minutes after the patient, or patient representative, handed the documents to the pharmacist and was asked to wait a few minutes while their prescription was being prepared.	**Yes**	54
	No	0
	NA	0

Question		Frequency
11. Pharmacist compares medicine(s) selected with the prescription and/or label to confirm that the correct product(s), dose and quantity are dispensed.	**Yes**	195
	No	5
	NA	0
12. Pharmacist checks expiration date of the product(s) selected.	**Yes**	9
	No	191
	NA	0
13. The name of the patient was written on the paper bag.	**Yes**	150
	No	50
	NA	0
14. The ID number of the patient or the patient number was written on the paper bag.	**Yes**	145
	No	55
	NA	0
15. Two labels were printed and placed on both the prescription and Schedule V card.	**Yes**	200
	No	0
	NA	0
16. The control card was filled accordingly, *(if applicable)*.	**Yes**	18
	No	0
	NA	182
17. a) Printed labels are not signed.	**Yes**	55
	No	0
	NA	0
17. b) Printed labels are signed by both the dispensing pharmacist and patient, or patient representative.	**Yes**	25
	No	0
	NA	0
17. c) Printed labels are signed by the dispensing pharmacist.	**Yes**	10
	No	0
	NA	0
17. d) Printed labels are signed by the patient, or patient representative.	**Yes**	25
	No	0
	NA	0
17. e) Printed label on Schedule V is signed by pharmacist and patient, or patient representative, and printed label on prescription is signed by patient, or patient representative.	**Yes**	10
	No	0
	NA	0
17. f) Printed label on Schedule V is signed by pharmacist, and printed label on prescription is signed by patient, or patient representative.	**Yes**	20
	No	0
	NA	0
17. g) Printed label on Schedule V is signed by patient, or patient representative, and printed label on prescription is signed by pharmacist.	**Yes**	5
	No	0
	NA	0
17. h) Printed label on Schedule V is signed by pharmacist and patient, or patient representative, and printed label on prescription is not signed.	**Yes**	10
	No	0
	NA	0
17. i) Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist and patient, or patient representative.	**Yes**	5
	No	0
	NA	0

Question		Frequency
17. j) Printed label on Schedule V is not signed and printed label on prescription is signed by patient, or patient representative.	**Yes**	30
	No	0
	NA	0
17. k) Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist.	**Yes**	5
	No	0
	NA	0
18. Pharmacist goes over the medicine(s) to be dispensed with the patient, or patient representative, to ensure that the information conveyed regarding the drug administration is fully understood.	**Yes**	171
	No	29
	NA	0
19. Pharmacist gives information to the patient, or patient representative, in the form of verbal advice.	**Yes**	143
	No	57
	NA	0
20. Pharmacist gives information to the patient, or patient representative, in a written format.	**Yes**	5
	No	195
	NA	0
21. Pharmacist writes the dosage regimen of the medicine(s) on the medicine(s) packaging.	**Yes**	38
	No	162
	NA	0
22. Pharmacist repeats major points of advice given to ensure the information conveyed is fully understood by the patient, or patient representative.	**Yes**	65
	No	135
	NA	0
23. Pharmacist asks the patient, or patient representative, whether they have any problems with the medicine(s) dispensed.	**Yes**	132
	No	68
	NA	0
24. Pharmacist talks privately with the patient, or patient representative.	**Yes**	51
	No	149
	NA	0
25. Pharmacist discusses medication-taking habits with the patient, or patient representative, in concordance with lifestyle and other medicine(s).	**Yes**	50
	No	150
	NA	0
26. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) in a written format).	**Yes**	199
	No	1
	NA	0
27. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) verbally.	**Yes**	119
	No	81
	NA	0

The mean scores were compared to the districts. The mean scores for the following statements were found to vary significantly ($p<0.05$) when compared to the districts: Pharmacist checks that the medicine(s) listed on Schedule V card correspond(s) to prescription and/or label (Q7), collection of medicines (Q10), pharmacist checks expiration date of the product(s) selected (Q12), the name of the patient was written on

the paper bag (Q13), pharmacist goes over the medicine(s) to be dispensed with the patient, or patient representative, to ensure that the information conveyed regarding the drug administration is fully understood (Q18), pharmacist gives information to the patient, or patient representative, in a written format (Q20), pharmacist writes the dosage regimen of the medicine(s) on the medicine(s) packaging (Q21), pharmacist repeats major points of advice given to ensure the information conveyed is fully understood by the patient, or patient representative (Q22), pharmacist asks the patient, or patient representative, whether they have any problems with the medicine(s) dispensed (Q23), Pharmacist talks privately with the patient, or patient representative (Q24), Pharmacist discusses medication-taking habits with the patient, or patient representative, in concordance with lifestyle and other medicine(s) (Q25) and Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) verbally (Q27). The remaining statements vary marginally ($p>0.05$) when compared with the districts.

3.6 Pharmacist Questionnaire

The PQ is another data collection document developed for the study, which is directed towards community pharmacists on duty during the observation study. The PQ was validated before being used in the full-scale observation studies.

3.6.1 Modifications to Pharmacist Questionnaire

The questionnaire was again modified according to the recommendations given by the panel of experts participating in the validation exercise. Changes in the original questionnaire included re-wording to make sentences clearer, re-structuring, such as a recommendation to shorten a question, and addition of new information, such as a

recommendation to add ‘less than 1 year’ to the ranges of pharmacists’ professional experience. Grammatical issues throughout the document were addressed (Appendix 5).

3.6.2 Pharmacist Demographics

The PQ was distributed to 40 community pharmacists and all of them responded to the PQ, giving a 100% response rate. Twenty-two of the pharmacists were male (55%), while the remaining 18 were female (45%). Most pharmacists were aged between 31-40 years (35%, n=14), followed by pharmacists aged between 21-30 years (30%, n=12), 41-50 years (25%, n=10), 51-60 years (7.5%, n=3) and over 60 years (2.5%, n=1). Most pharmacists (25%, n=10) had more than 20 years of professional experience, followed by pharmacists who had between 1-5 years or 6-10 years of professional experience (22.5%, n=9), 11-15 years of professional experience (17.5%, n=7), and 16-20 years of professional experience (12.5%, n=5).

Community pharmacists were asked to describe their status as a pharmacist by picking one or more categorical values. Eight pharmacists described their status as a pharmacist by ticking two categories, while one pharmacist chose three categories, bringing the total of categories chosen to 50. The majority of pharmacists were managing pharmacists (60%, n=30), followed by pharmacists employed on a full-time basis in a community pharmacy or locum pharmacists (12%, n=6), pharmacists who were community pharmacy owners (10%, n=5) and pharmacists employed on a part-time basis in a community pharmacy (6%, n=3). Thirteen of the 30 managing pharmacists involved in this study have 1-10 years of professional experience.

Sixteen pharmacists spent 11-20 hours per week dispensing POYC medicines (40%), twelve spent less than 10 hours per week dispensing POYC medicines (30%), eight spent

21-40 hours per week dispensing POYC medicines (20%), and four spent more than 40 hours per week dispensing POYC medicines (10%).

3.6.3 Time Taken to Prepare POYC Prescription

Pharmacists were asked to state the number of minutes they spend in the processes involved in the supply of POYC medicines for each individual prescription. These processes include the time taken to prepare the medicines, recheck prescription and/or label with the medicines to be dispensed, dispense POYC medicines to patient, give advice for a repeat prescription and give advice for a new prescription. Figure 3.5 indicated the mean durations of time stated and observed by the pharmacists to perform the processes involved in the supply of POYC medicines.

The observed mean duration for the time to give advice to a patient for a new prescription is the largest (9.86), followed by the time to prepare medicines for each individual patient (7.61), the time to dispense POYC medicines to the patient (3.44) and the time to give advice to a patient for a repeat prescription (3.08). The mean duration for the time to recheck the prescription and/or label with the medicines to be dispensed is the lowest (2.19). The mean duration as stated by pharmacists to prepare medicines for each individual patient is the highest (5.37), followed by the time to give advice to a patient for a new prescription (4.78), the time to dispense POYC medicines to the patient (4.00) and the time to give advice to a patient for a repeat prescription (3.11). The mean durations stated by pharmacists in PQ and the observed mean durations obtained during the observation studies carried out were compared, as shown in table 3.7. The stated mean durations of time to dispense POYC medicines to patient and to give advice for a repeat prescription are comparable to the observed mean durations ($p>0.05$). The stated mean durations of time to prepare medicines for each individual patient, to recheck prescription

and/or label with medicines to be dispensed and to give advice for a new prescription vary significantly ($p<0.05$) from the observed mean durations.

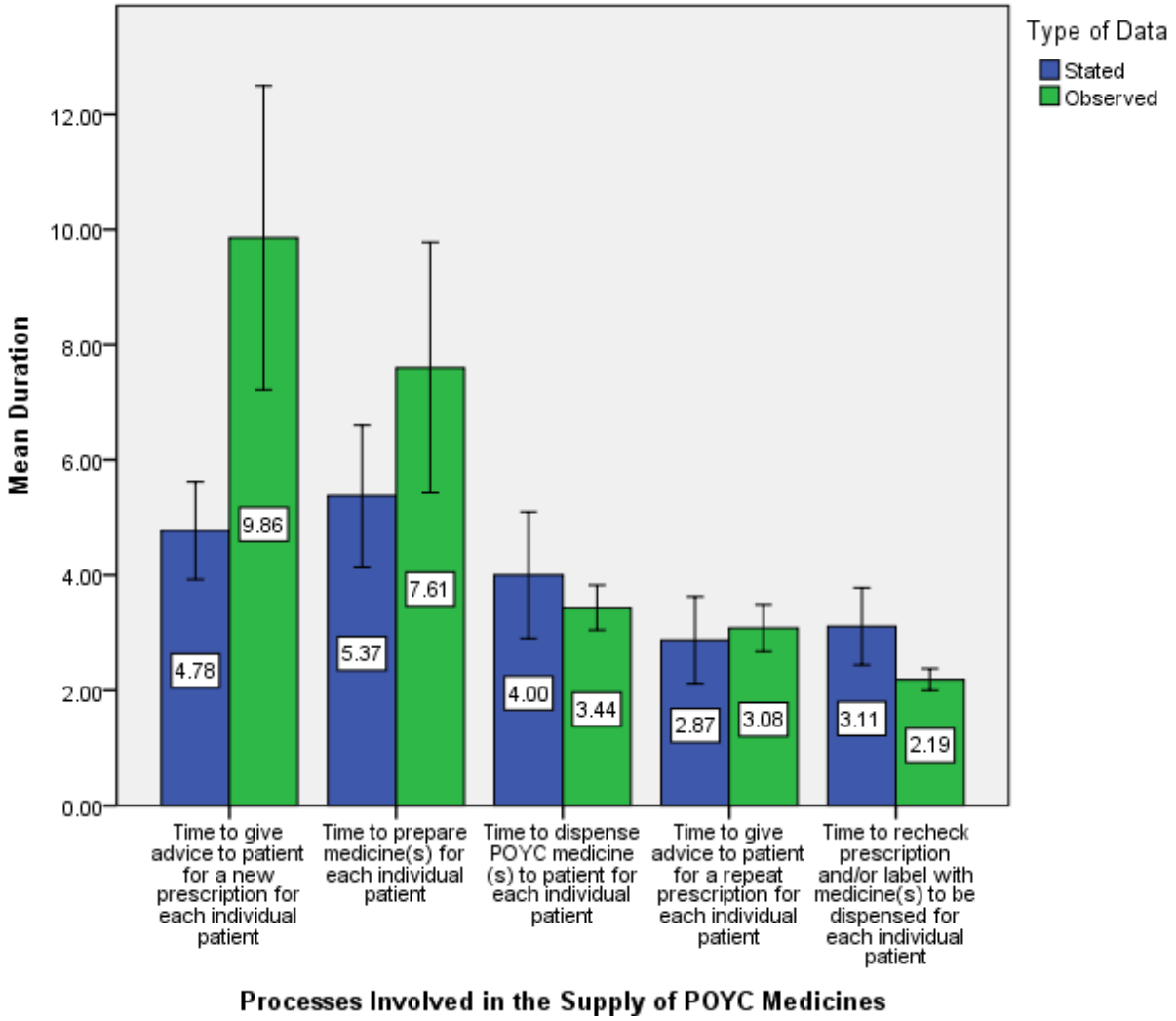

Figure 3.5 – Mean durations of time stated and observed by the pharmacists to perform the processes involved in the supply of POYC medicines

Table 3.3 – Statistical analysis of the observed and stated duration in the processes of the supply of POYC medicines

Process	Type	Sample Size	Mean	Standard Deviation	P-value
Time to prepare medicine(s)	Observed	15	7.61	3.93	0.020
	Stated	40	5.38	3.84	
Time to recheck prescription and/or label with medicine(s) to be dispensed	Observed	200	2.18	1.35	0.011
	Stated	40	3.11	2.10	
Time to dispense POYC medicine(s) to patient	Observed	200	3.44	2.78	0.596
	Stated	40	4.00	3.43	
Time to give advice to patient for a repeat prescription	Observed	193	2.90	0.21	0.810
	Stated	40	2.35	0.37	
Time to give advice to patient for a new prescription	Observed	7	2.85	1.08	0.001
	Stated	40	2.66	0.42	

3.6.4 Risk Analysis

Figures 3.6 and 3.7 show the mean rating scores for the probability of occurrence and severity of consequences, respectively, for the risks listed on the PQ (Appendix 2). Figure 3.8 shows the mean risk priority number (RPN) for each risk, which was calculated by taking an average of the multiplication of the probability of occurrence with the severity of the consequences for every response obtained by the community pharmacists, both of which were measured on a scale from 1 to 5. The RPN ranges from 1 to 25. In all the three related scenarios, the p-value, which is approximately zero, is less than the 0.05 level of significance, indicating that these rating scores vary significantly. This is also displayed by the error bars, where at least two confidence intervals are disjointed, indicating that the mean rating scores differ significantly.

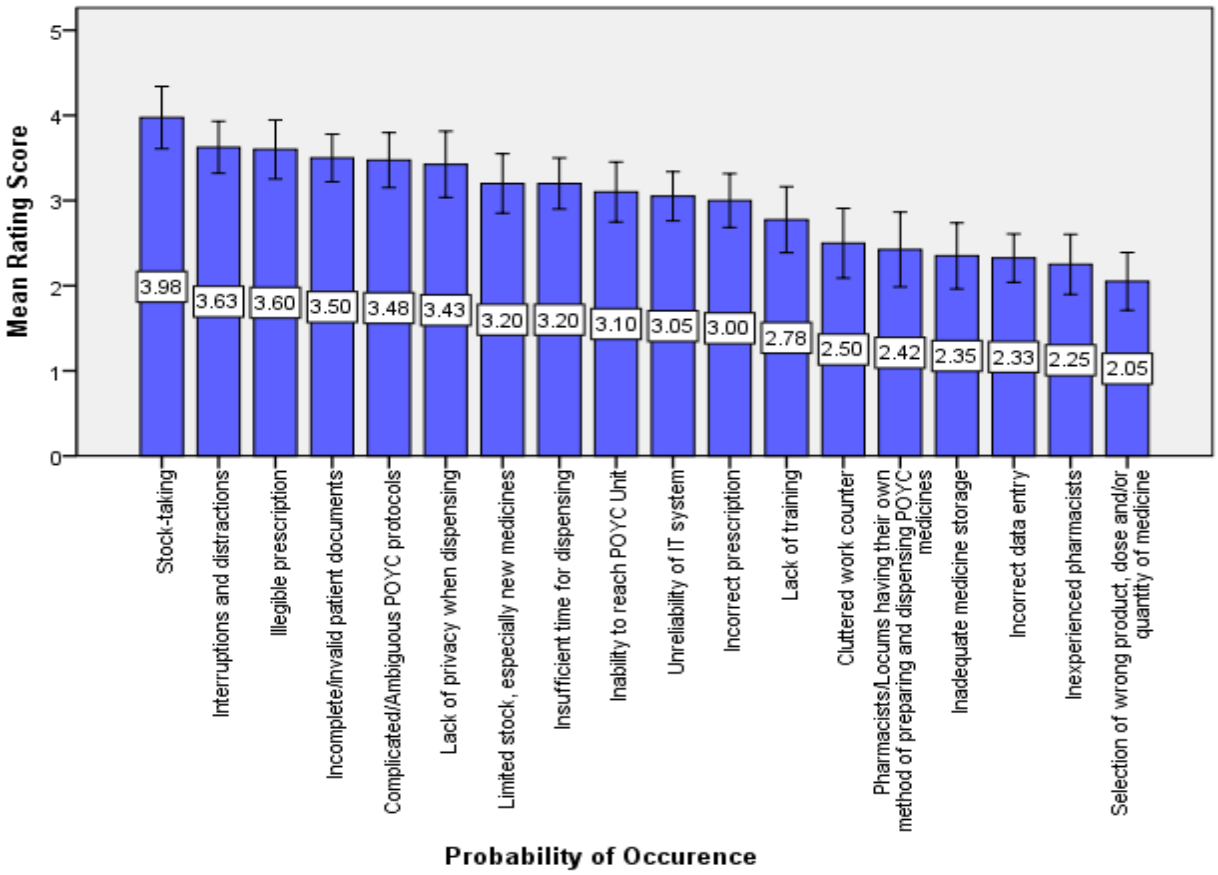

Figure 3.6 – Mean rating scores for the probability of occurrence for each risk

The mean rating score for stock-taking (3.98) is the largest, indicating that it is the most likely to occur. This is followed by interruptions and distractions (3.63), illegible prescriptions (3.60) and incomplete/invalid patient documents (3.50). The mean rating score for selection of wrong product, dose and/or quantity of medicine (2.05) is the smallest, indicating that it is the least likely to occur. This is preceded by inexperienced pharmacists (2.25), incorrect data entry (2.33) and inadequate medicines storage (2.35).

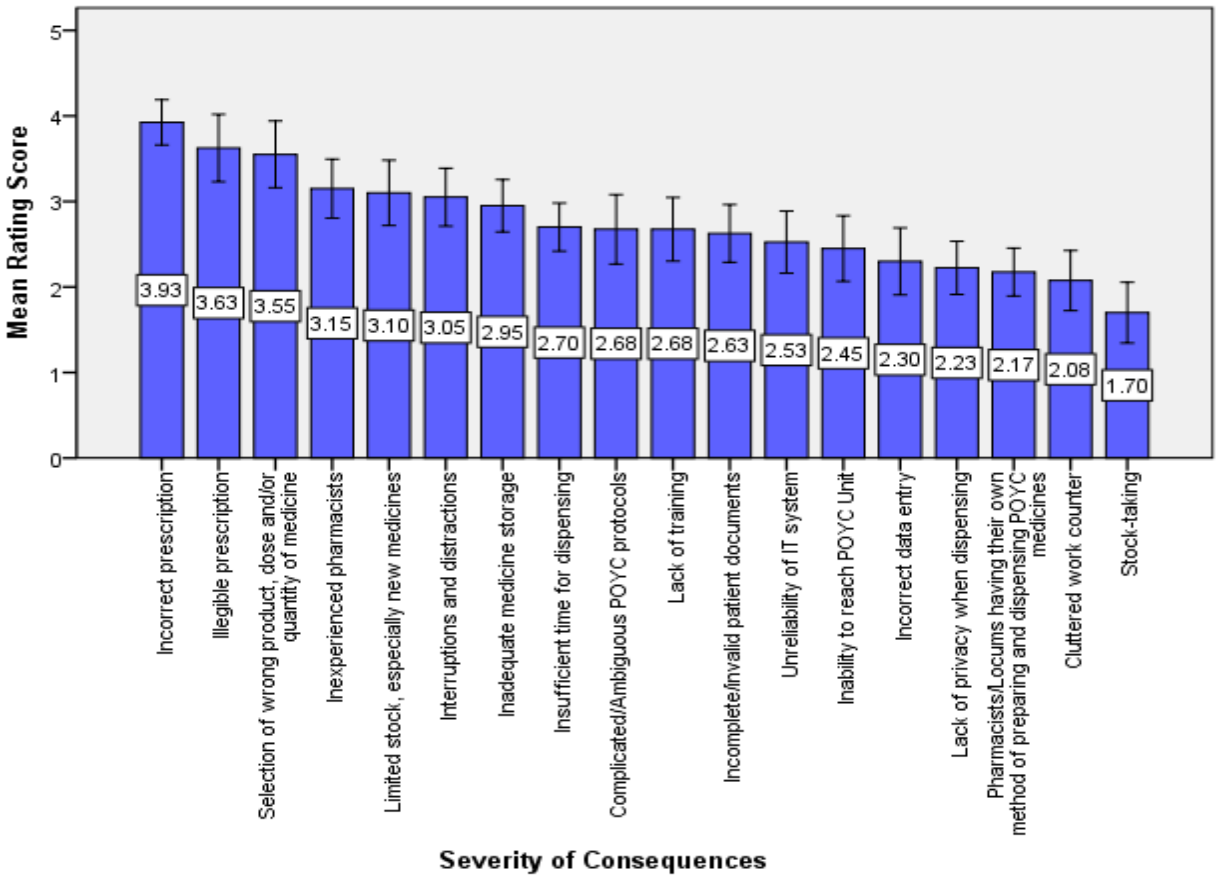

Figure 3.7 – Mean rating scores for the severity of consequences for each risk

The mean rating score for incorrect prescriptions (3.93) is the largest, indicating that it involves the greatest severity of consequences. This is followed by illegible prescriptions (3.63), selection of wrong product, dose and/or quantity of medicine (3.55) and inexperienced pharmacists (3.15). The mean rating score for stock-taking (1.70) is the smallest, indicating that it involves the least severity of consequences. This is preceded by cluttered work counter (2.08), pharmacists/locums having their own method of preparing and dispensing POYC medicines (2.17) and lack of privacy when dispensing (2.23).

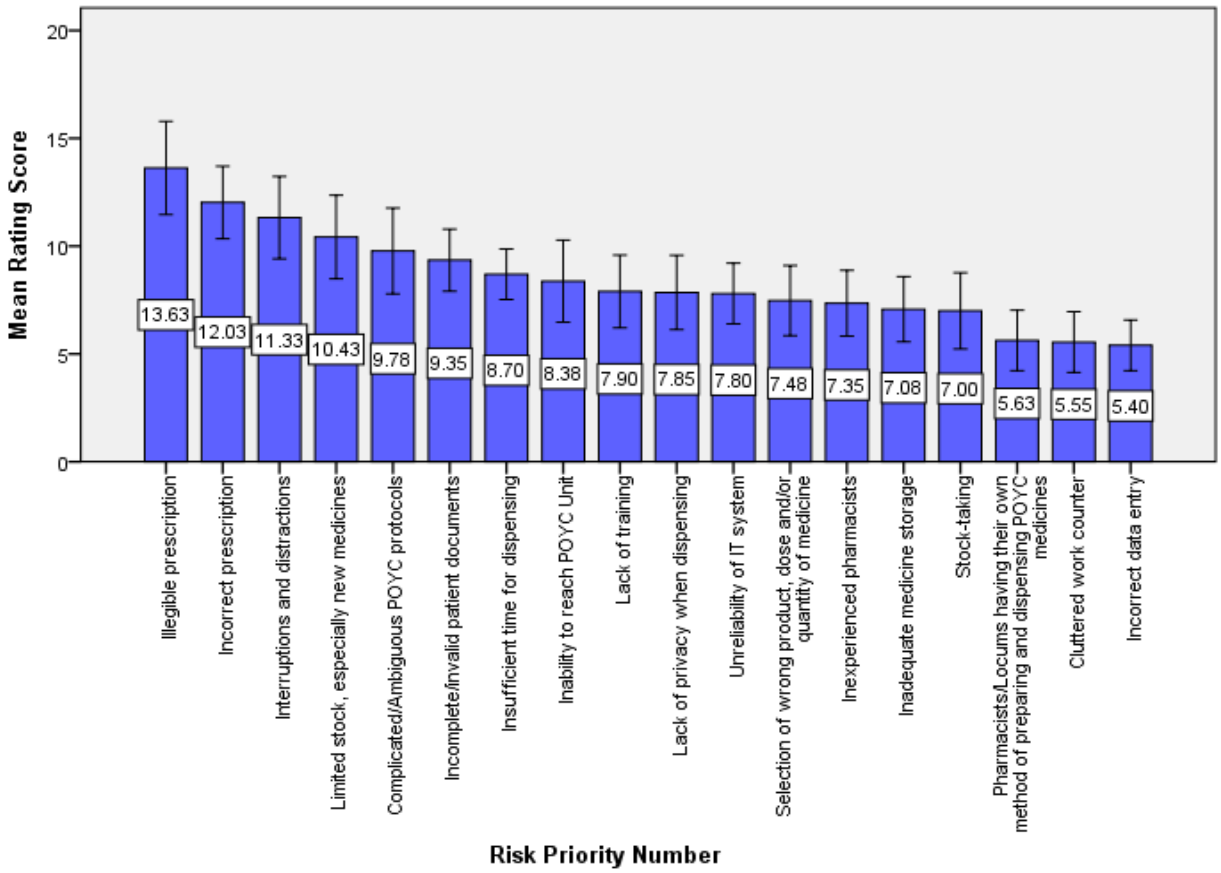

Figure 3.8 – Mean rating scores for the risk priority number for each risk

Risks can then be divided into low, medium, high and extreme risk categories, according to the average RPN. The risks which have an RPN ranging between 1-3 are low-risk, those having an RPN ranging between 4-7 are medium-risk, those having an RPN ranging between 8-14 are high-risk and those having an RPN ranging between 15-25 are extreme-risk.[43] The majority of the risks were categorised as high-risk (n=10, 55.6%), followed by the risks categorised as medium risk (n=8, 44.4%). No risks were categorised in either of the extremes.

The mean rating score for illegible prescriptions (13.63) is the largest, indicating that it is a high-risk. This is followed by incorrect prescriptions (12.03), interruptions and

[43] General Pharmaceutical Council (GPhC). Risk Management Policy Guideline [Internet]. UK: GPhC; 2015 [updated 2017 Jul; cited 2019 Sept 4]. Available from: https://www.pharmacyregulation.org/sites/default/files/gp2015106_ risk_management_policy.pdf

distractions (11.33) and limited stock, especially new medicines (10.43). The mean rating score provided incorrect data entry (5.40) is the smallest, indicating that it is a medium-risk. This is preceded by cluttered work counter (5.55), pharmacists/locums having their own method of preparing and dispensing POYC medicines (5.63) and stock-taking (7.00).

The mean risk priority scores and the groups of pharmacists clustered by their years of profession (1-10 years, 11-20 years and more than 20 years) were compared. The mean risk priority score for the risk of insufficient time for dispensing varies significantly ($p<0.05$) when compared to these groups of pharmacists. All the remaining risks listed in PQ vary marginally ($p>0.05$) when compared with the groups of pharmacists clustered by their years of profession. When the mean risk priority scores were compared with the groups of pharmacists clustered by their mean POYC medicine-dispensing duration per week (less than 10 hours, 11-20 hours and more than 20 hours), the mean risk priority score for the risk of stock-taking was found to vary significantly ($p<0.05$) with these groups of pharmacists. All the remaining risks vary marginally ($p>0.05$) with the groups of pharmacists clustered by their mean POYC medicine-dispensing duration per week.

3.6.5 Other Risks Involved in Dispensing POYC Medicines

Out of 40 pharmacists, nine pharmacists (22.5%) answered in the affirmative when they were asked whether they think there are other risks involved in dispensing POYC medicines which were not previously mentioned, the majority being pharmacists from district 5 (n=5), followed by pharmacists in district 2 (n=2), and pharmacists from district 1 and 4 (n=1 each). No responses were obtained from pharmacists in district 3 regarding other risks involved in dispensing POYC medicines. Table 3.8 summarises the risks mentioned by the pharmacists, as well as their possible causes and consequences/effects.

Each risk was mentioned by one pharmacist, except for the following, which were mentioned by two pharmacists: sending patients from hospital without proper instructions or paperwork, out-of-stock medicines situation, different brands changing constantly, non-compliance of patients and dispensing bag to one patient instead of to another if they have same name and surname.

Table 3.4 – Other risks mentioned by the pharmacists via the pharmacist questionnaire

Risks	Possible causes	Consequences/Effects
Sending patients from hospital without proper instructions or paperwork	Lack of knowledge from hospital on certain protocols, especially from Sir Anthony Mamo Oncology Centre (SAMOC) or other departments like Psychiatry, as well as new or inexperienced staff, and laziness	Unnecessary burdens on patients who need their medicines urgently and who are not entitled until permits are made valid (medication cannot be dispensed until error is corrected, otherwise patients have to buy the medications, but not everybody can afford to do so), resulting in a waste of time
Different General Practitioners (GPs) prescribing the same medicine with varying regimen	Inexperienced GPs and lack of knowledge from the GPs' end	Drug-drug interactions causing improper disease control, aggravation of condition, ultimately resulting in patient condition worsening/hospitalisation
Incontinuity between Mater Dei Hospital (MDH) and regular GP		
Different doses of the same medication on different prescriptions for same time		
Out-of-stock medicines situation	Inability to obtain a suitable tender agreement	Patients left without medication for a stipulated/unknown amount of time with no alternative, causing decreased patient compliance and worsening of condition as patients have higher risks of developing secondary complications, which can easily be avoided. If patients can buy the product, other patients who cannot afford to buy their medicines end up not taking them
Different brands changing constantly	Cheapest brand wins tender, which are often generics	Difficulty for patients to recognise medications, which can lead to allergic reactions, reduced patient compliance and possible worsening of patient condition as patients either do not take the medicines or mistake a medicine with another

Risks	Possible causes Consequences/Effects	
Non-compliance of patients	Patient laziness, forgetfulness, stubbornness, illiteracy, irresponsibility or see that packages are different from usual and think that they were given the wrong medication, as well as frequent changing of brands resulting in different packaging	Worsening of patient condition and development of secondary health problems that can be easily avoided if patient is compliant
Elderly patients with illiterate families/backgrounds	Illiteracy is very common in Malta	The incorrect drug may be given, or drug may be administered incorrectly or in an incorrect dose, worsening patient condition or causing death
Lack of knowledge of the patient's medical history among Health Centre doctors, who still write prescriptions	Constant changing of Health Centre doctors, especially with young and inexperienced ones	The incorrect drug may be prescribed, worsening patient condition
Dispensing bag to one patient instead of another if they have same name and surname	Patient name and ID number not written on bag of medicines/not clearly written, and if written, pharmacists in a hurry do not always check the ID number with the patient	Patient receives the wrong bag of medicines and may not realise they have been given medication that is not theirs (even if the bag is opened and checked in front of them), causing worsening of condition or even patient death
Lack of patient education	Patient, or patient representatives, illiteracy or irresponsibility	Patients may take unnecessary drugs or not take them at all, which may lead to drug overdose, increased drug-drug interactions or under-medication
Not informing patients about increase or decrease in dose of medications	New hospital staff, especially inexperienced ones, and staff laziness	Patients can either under or over medicate, resulting in not treating the condition properly, worsening the condition, or overdosing

Of those nine pharmacists who answered in the affirmative in Q11, seven stated that the risks they mentioned in Q11a were being mitigated, while the remaining two pharmacists stated that the risks were not being mitigated. Table 3.9 summarises the answers given by the pharmacists regarding the strategy used to mitigate the risks.

The two risks that were not being mitigated by the pharmacists were the following: sending patients from hospital without proper instructions or paperwork and out-of-stock medicines situation. Both risks were stated by the pharmacists that they cannot be mitigated by the pharmacists in the community pharmacy. With respect to the insufficient

instructions, patients must present the proper paperwork from hospital for the medicines to be dispensed. With respect to the out-of-stock medicines, pharmacists cannot do anything if there are no alternatives to the out-of-stock medicine or if the medicine is completely out-of-stock.

Table 3.5 – Risk mitigation strategies for the risks that can be mitigated by community pharmacists

Risk	Risk Mitigation Strategy
Different GPs prescribing the same medicine with varying regimen	Discussion of new and past regimen with patient
Different doses of the same medication on different prescriptions for same time	
Incontinuity MDH and regular GP	Discussion of new and past regimen with patient, and calling GP and/or hospital ward if necessary, according to severity
Different brands changing constantly	Every time a brand changes, pharmacists write on bag of medicines and inform patient that packaging of the same medicine has changed, as well as check medicines dispensed with patient, ask them how they are taking it, confirm changes in prescriptions with patients before dispensing, explain to patients what generics are, being extra careful before dispensing and contacting doctors
Lack of patient education	New POYC patients, or when a new set of medications is prescribed, pharmacists tell the patient to bring all the old medications so that pharmacists discard the ones no longer needed and explain clearly about the new (if patient is old or of low IQ, pharmacists ask the patient to be accompanied by a family member, when possible)
Dispensing bag to one patient instead of another if they have same name and surname	Pharmacists/locums are instructed to double-check ID numbers of patients with those written on the bag to make sure patients are getting the correct bag of medication, and make sure dispensing bags are properly labelled
Not informing patients about increase or decrease in dose of medications	Pharmacists confirm changes in prescriptions with patients before dispensing

3.6.6 Risk Mitigation in Pharmacies

Pharmacists were asked whether certain risk mitigation strategies were carried out at the community pharmacy in which they are employed. All of the pharmacists involved in the study stated that they deal with customers one by one (100%, n=40). This was

followed by the practice of stock rotation to decrease the number of expired products on the shelves (97.5%, n=39) and keeping work counters tidy and clear (92.5%, n=37). The least practiced risk mitigation strategy was the use of a dispensing error reporting and analysis system (20%, n=8). This is followed by organisation of training and continuous educational sessions for the pharmacists working in the pharmacy (25%, n=10) and the organisation of additional routine check-ups with patients to discuss their medicines, dosage regimen and administration, etc. (32.5%, n=13). Table 3.10 summarises the number of pharmacies which use the listed risk mitigation strategies.

Table 3.6 – Risk mitigation strategies carried out by the community pharmacies (N=40)

Risk Mitigation Strategy	Frequency	Percentage (%)
Deal with customers one by one	40	100
Practice of stock rotation to decrease the number of expired products on the shelves	39	97.5
Keep work counters tidy and clear	37	92.5
Counsel patients on medicine administration at time of dispensing	35	87.5
Contact physician when encountering problems with prescription	35	87.5
Have reference books e.g. BNF, and online sources e.g. SPCs, at hand when dispensing	35	87.5
Provide information on new drugs and any changes in the POYC system to the pharmacists working in the pharmacy	30	75
Re-check medicine to be dispensed by a different pharmacist to the one who prepared the medicine	29	72.5
Prepare POYC medicines in a quiet room or within an area in the pharmacy where interruptions and distractions by customers, telephone calls and broadcast devices are limited	29	72.5
Storing Sound-Alike/Look-Alike drugs far apart.	28	70
Have a systematic guideline for dispensing POYC medicines for all the pharmacists working at the pharmacy to maintain workflow continuity	27	67.5
Use of dividers to separate Sound-Alike/Look-Alike drugs	23	57.5
Use a dedicated space or room when dispensing POYC medicines to counsel patients in private	16	40
Have more than one pharmacist on duty at a time	14	35
Organise additional routine check-ups with patients to discuss their medicines, dosage regimen and administration, etc.	13	32.5
Organise training and continuous educational sessions for the pharmacists working in the pharmacy	10	25
Use of a dispensing error reporting and analysis system	8	20

3.6.7 Other Risk Mitigation Strategies

Out of 40 pharmacists, four pharmacists (10%) answered in the affirmative when they were asked whether they think there are other risk mitigation strategies which were not previously mentioned in dispensing POYC medicines that can be performed by pharmacists and community pharmacies. The majority of the responses were from pharmacists in district 1 (n=3), followed by pharmacists in district 3 (n=1). No responses were obtained from pharmacists in district 2, 4 and 5. The following are the risk mitigation strategies mentioned by the pharmacists:

i. Work as a team of pharmacists: when the process of preparing and dispensing POYC medicines to patients is done in steps by different staff, the process should be spearheaded by continuous presence of the pharmacist
ii. Place an 'Invalid' label on the patient file in the case that a certain permit is to expire in the near future, so that patients can be informed early about permit renewals and avoid delay in dispensing medicines
iii. Encourage continuous patient counselling by having regular follow-ups with their respective consultants/GPs to ensure optimal revised treatment since prescribing of medicines in advance (six-month treatment) may lead to complacency from both ends

Each risk mitigation strategy was mentioned once by each pharmacist, except for the strategy to encourage continuous patient counselling by the patient's regular GP. This risk mitigation strategy was mentioned by two pharmacists.

Out of 40 pharmacists, sixteen pharmacists answered in the affirmative when they were asked whether they think there are other risk mitigation strategies or improvements that can be implemented by the POYC Unit. The majority of the responses were from

pharmacists in district 1 and 5 (n=5 each), followed by pharmacists in district 3 (n=3), pharmacists from district 2 (n=2) and pharmacists from district 4 (n=1). Table 3.11 shows the risk mitigation strategies or improvements that can be implemented by the POYC Unit mentioned by the pharmacists.

Table 3.7 – Risk mitigation strategies or improvements that can be implemented by the POYC Unit mentioned by the community pharmacies (N=16)

The POYC Unit should ensure that all healthcare professionals involved in the processing of medication are well aware of all the Government protocols with regards to correct prescribing and paper procedures with regards to permits
Stock-taking should be done by a third party, making it a quicker process and the POYC Unit can focus more on the patients
Increase staff of the POYC Unit and increase the number of deliveries to at least twice per week (one main job order and one secondary delivery)
The POYC Unit should take note of the medicine stock expiring in 6 months' time themselves, reducing the community pharmacist's workload and waste of time
The POYC Unit should employ staff who can analyse why an item was not dispensed for a long time, in order to collect stock back
Reduced, improved, simplified and clearer procurement policies, where all protocols of permits should be updated to one simple procedure, removing grey areas where pharmacists may not know whether a certain permit is sufficient or not and reducing pharmacist workload (since pharmacists need to remember too many things instead of focusing on the patients)
Implement more electronic prescriptions
Improved and simplified system of stock ordering
The use of electronic-based documentation in order to avoid paper documents, which should improve safety and efficacy of the system
An online database should be implemented, which shows an immediate 'RED' alert if the maximum dose of a medication is exceeded or if there are any dangerous drug-drug interactions to control the issue of polypharmacy
Abolish prescriptions for 6 months written at Health Centres since patients should be reviewed at a 6-month time interval when prescriptions are written by their regular GPs/consultants and not by a random doctor copying off their previous medication label
POYC need to be more helpful to pharmacists in general
Stock should be controlled solely by each individual pharmacy and not supplied by the government, where each patient will have a smart card with a certain amount of monetary value, depending on the condition, and the patient is able to choose their preferred brand of medication

Issuing of policy where prescriptions can be adjusted by the pharmacist who has continuous treatment knowledge of the patient, unlike the different doctors in Health Centres who shed their different ideas of treatment on the patient prescription without knowing their proper medical history, avoiding treatment mistakes especially in elderly patients
More control on tender issuing which results in regular changes of generic medicine which is a huge set-back to the patients (any change which occurs from POYC side should at least be counteracted so as to minimise any adverse effects)
POYC can explain the documentation protocols to the GPs/consultants, reducing the number of mistakes made which delay the dispensing of POYC medicines
Synchronisation of patient portfolio between all clinics, hospitals, GPs and pharmacies
Medicines can be delivered to pharmacies as named patient packs, so that pharmacists have more time to explain to the patients about their medications and treatments
Computerised system or a database which is integrated with the POYC IT system to automatically detect and flag incompatible medicines and dosages, especially where warfarin is concerned
Listing of expiry dates of medicine stock on the invoice so that short-dated products are dispensed first
Additional separate signatures on printed labels for pharmacists who prepared, checked and dispensed the bag of medicines to the patient, and enforcing pharmacists to make use of the labels
Asking for the pharmacists' feedback and implementing their ideas for improvements

Each risk was mentioned once by each pharmacist, except for the following: reduced and improved procurement policies (mentioned by three pharmacists), and the introduction of a computer system/database integrated with the POYC IT system to detect drug-drug interactions (mentioned by four pharmacists).

3.7 Time-Motion Study Form

The time-motion study form is another data collection document developed for the study. This document, which was used by the principal investigator, was validated before being used in the full-scale observation studies.

3.7.1 Modifications to Time-Motion Study Form

The time-motion study form was again modified according to the recommendations given by the panel of experts participating in the validation exercise. Changes in the original time-motion study form included addition of new questions, namely recommendations to add a description of activities involved in the number of minutes recorded during the preparation and dispensing of POYC medicines, and whether the prescription being recorded is a new or a repeat prescription. Grammatical issues throughout the document were addressed (Appendix 5).

3.7.2 Pharmacy Responses

The time-motion study form was completed in three randomly-selected community pharmacies, which were in district 1, 2 and 5. These pharmacies were labelled as pharmacy A, B and C, respectively, for the sake of anonymity Figures 3.9, 3.10 and 3.11 show the results obtained from the observation studies performed in pharmacies A, B and C, respectively. The figures all show bar graphs representing the time in minutes taken by the pharmacist on duty to prepare the POYC medicines for dispensing according to the number of medicines in the prescription.

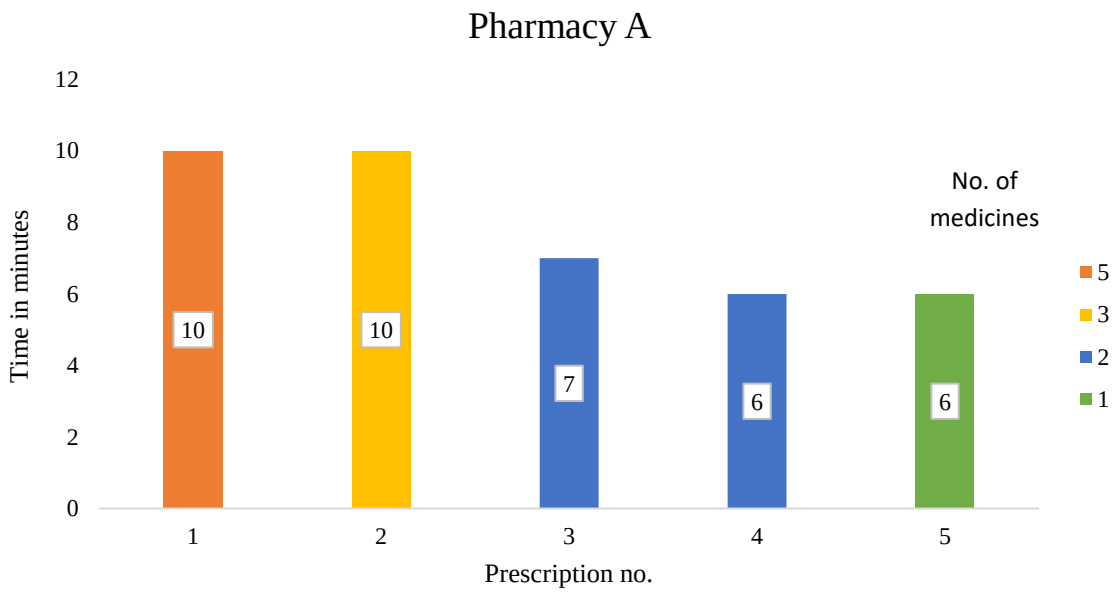

Figure 3.9 – Time taken (in minutes) to prepare the POYC medicines for dispensing in one pharmacy in District 1

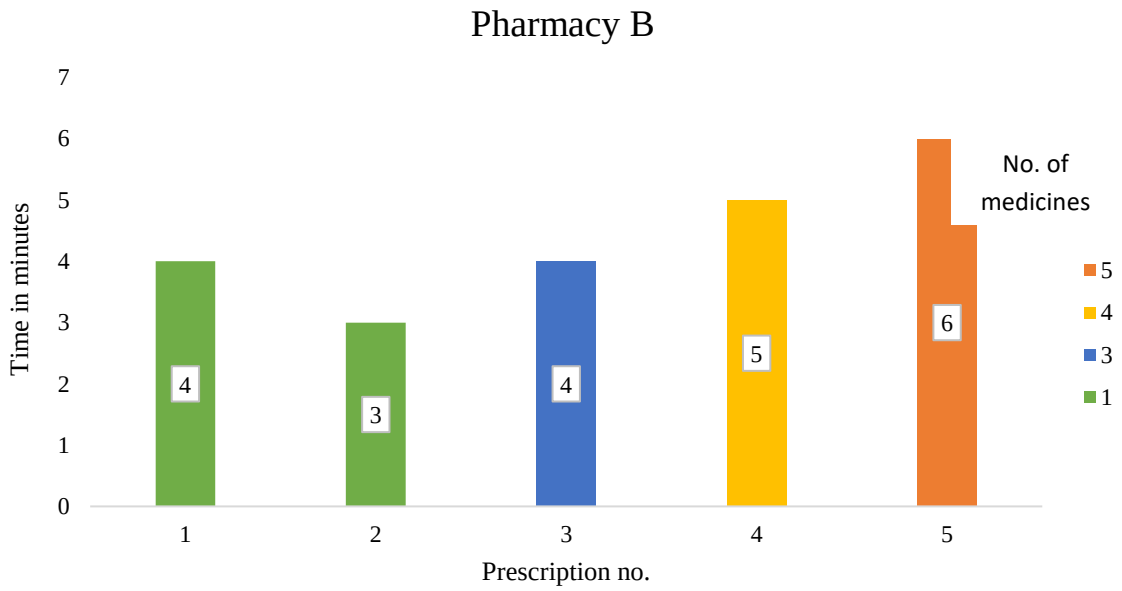

Figure 3.10 – Time taken (in minutes) to prepare the POYC medicines for dispensing in one pharmacy in District 2

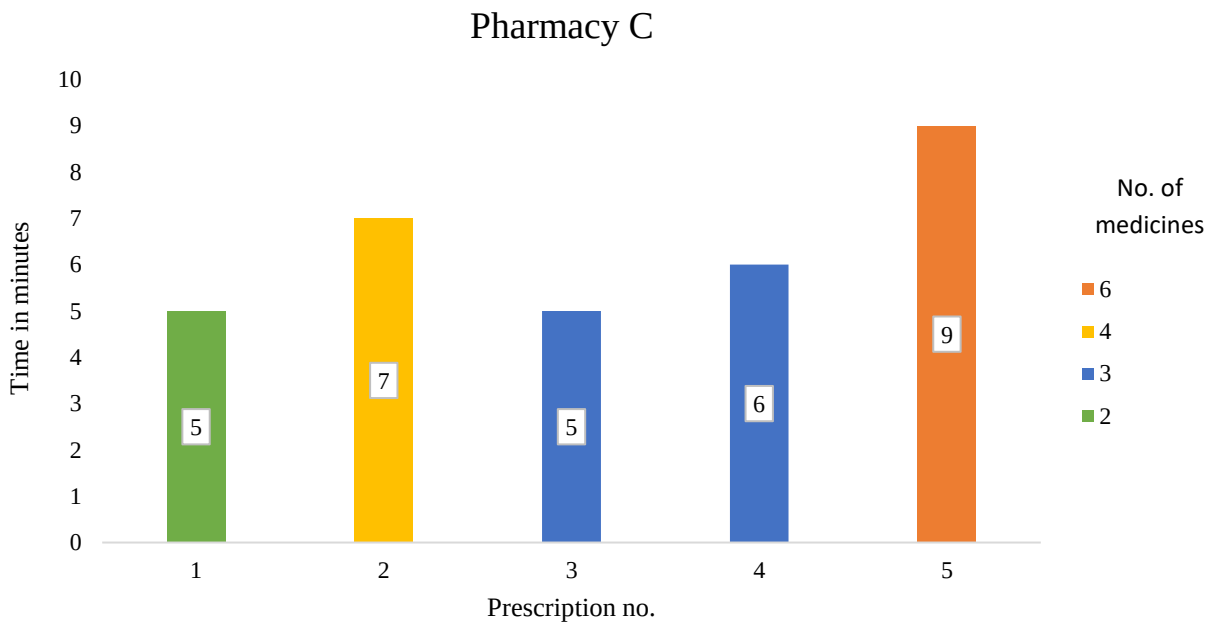

Figure 3.11 – Time taken (in minutes) to prepare the POYC medicines for dispensing in one pharmacy in District 5

Five prescriptions being prepared for dispensing were observed in each of the three pharmacies, bringing the total of prescriptions observed to 15. All of the prescriptions were repeat prescriptions. Regarding the time of day, the observation study in pharmacies A and C was performed in the morning, while in pharmacy B, the observation study was performed in the afternoon.

The average number of medicines in each prescription observed and the average time taken to prepare the prescription, as well as the average time taken in minutes to prepare one medicine for dispensing by pharmacies A, B and C are summarised in table 3.12. The mean duration to prepare the medicines for each individual patient stated by the pharmacist in PQ and the observed mean duration obtained from the time-motion study were compared. The stated and observed mean durations were found to differ significantly from each other.

Table 3.8 – Results obtained from time-motion study in pharmacies A, B and C

	Average no. of medicines	**Average time taken (in minutes) to prepare the prescription**	**Average time taken (in minutes) to prepare one medicine for dispensing**
Pharmacy A	2	7.25	3.57
Pharmacy B	2.8	4.4	2.16
Pharmacy C	3.6	6.4	1.88

3.8 Standard Operating Procedure

The SOP is the document developed containing step-by-step instructions on how to prepare and dispense POYC medicines. This document, which was given to the participating pharmacists, was validated before being used in the full-scale implementation study.

3.8.1 Modifications to Standard Operating Procedure

The SOP was again modified according to the recommendations given by the panel of experts participating in the validation exercise. Changes in the original SOP included addition of new information to give a more detailed purpose for the SOP, re-wording to make sentences clearer, deletion, such as a recommendation to remove any mention of vouchers as they are no longer used, and re-structuring to improve the flow of the procedure. Grammatical issues throughout the document were addressed (Appendix 5).

3.8.2 Changes to the system followed in dispensing POYC medicines due to COVID-19

A small-scale observation study was carried out in two community pharmacies selected by convenience sampling in order to identify changes implemented to the system followed in preparing and dispensing POYC medicines in order to limit the rise in contamination from COVID-19 whilst also serving patients appropriately. Table 3.14 shows a list of the precautions being taken by community pharmacists with respect to the dispensing of POYC medicines to minimise the spread of disease.

Table 3.9 – Precautions taken by community pharmacists with respect to the dispensing of POYC medicines in order to minimise the spread of disease

In case of a repeat prescription, a paperless system is adopted where the patient does not need to present either a white or green prescription. The pharmacist should ask the patient for their ID card number and date of birth (the pharmacist should not handle patients' ID cards), verify with the patient that there has been no change in treatment and dispense narcotic and psychotropic drugs (for one month) or non-controlled drugs (for two months)
In case of a change in treatment, including dose, dosage regimen and treatment, or a new patient, the patient must present an updated Schedule V card, a consultant form (if applicable) and a prescription for narcotic and psychotropic drugs or non-controlled drugs. A photo of the prescription should be sent by the prescribing doctor as an attachment to an email addressed to the pharmacy where the patient is registered. If the patient presents a physical prescription, the pharmacist should not touch it but should take a photo with his/her mobile phone and forward it to the pharmacy address for archive
Pharmacists should provide one of the stickers issued to the patient and ask them to affix it to their Schedule V card. The other sticker issued should be retained by the pharmacist. In case of a narcotic and psychotropic drug, the sticker should be affixed to their POYC Narcotic and Psychotropic Drug Register
The processing of the control card is waived
Document handling should be kept to an absolute minimum and only when necessary. Hands and surfaces coming in contact with patient documents should be cleaned with 70% rubbing alcohol
The patient may send their ID card number and date of birth to the pharmacy by email when due to pick up the medicines so that waiting times at the pharmacy by the patients are minimised

3.8.3 Implementation Responses

The evaluation questionnaire and the SOP were distributed to 10 community pharmacists from 5 different community pharmacies selected by convenience sampling and all of them responded to the questionnaire, giving a 100% response rate. Eight of the pharmacists were female, while the remaining two were male. Four pharmacists were aged between 21-30 years, four pharmacists were aged between 31-40 years and two pharmacists were aged between 41-50 years. Most pharmacists (n=3) had between 1-5 years of professional experience, followed by pharmacists who had between 11-15 years

or more than 20 years of professional experience (n=2), and less than one year, 6-10 years or 16-20 professional experience (n=1).

Community pharmacists were asked to describe their status as a pharmacist by picking one or more categorical values. One pharmacist described their status as a pharmacist by ticking two categories, bringing the total of categories chosen to 11. Four pharmacists were managing pharmacists, three were employed on a full-time basis in a community pharmacy, and three were locum pharmacists. One pharmacist was employed on a part-time basis.

Four pharmacists spent 11-20 hours per week dispensing POYC medicines, three spent less than 10 hours per week dispensing POYC medicines, two spent 21-40 hours per week dispensing POYC medicines, and one spent more than 40 hours per week dispensing POYC medicines.

All the community pharmacists stated that they were able to fully perform the procedure described in the SOP, that they have understood the text of the SOP as a whole and that it represented the content (N=10). All the pharmacists agreed that the information was clear and concise, and that the step-by-step procedure was clearly organised and the sequencing of the sections seemed logical (n=10). Eight pharmacists agreed that the SOP was comprehensive enough to collect all the information needed to address its purpose, while two pharmacists were not sure. Nine pharmacists agreed that the language used in the SOP was appropriate (n=9). Nine pharmacists stated that they believed the SOP to be useful (n=9). All the pharmacists did not find any difficulties in understanding and following the SOP (n=10). Nine pharmacists stated that there were no flaws in the SOP design, while one pharmacist stated that the SOP does not address the problems which may arise during dispensing, such as queries with regards to the patient entitlement and

ordering. Two pharmacists stated that they would include another section in the SOP, one being with regards to returns in the event that a mistake is noted upon checking, such as a change in the entitlement of the patient or the addition of a new medication, and the other being with regards to any problems arising during dispensing including ordering and entitlement of the patient. None of the pharmacists stated that any part of the SOP was unnecessary or repetitive. When the pharmacists were asked if they had any other comments, four pharmacists answered in the affirmative. The suggestions provided included that the language used should be more formal, to take into account any changes in medication, to stress the importance of rechecking prepared POYC medicines with the patient, and to focus on speed and efficiency, especially since pharmacists have a limit of 10 minutes per patient consultation due to recent COVID-19 measures.[44]

3.8.4 Perception on the Changes Made due to COVID-19

Nine pharmacists agreed that the changes implemented during the COVID-19 outbreak were effective in order to limit rise in contamination from COVID-19 whilst also serving patients appropriately, while one pharmacist stated that some patients visit the pharmacy with their paper documentation since they do not know which medicines they are taking, resulting in the pharmacist needing to touch the patient's documents. The pharmacist also stated that the changes implemented to the POYC procedure during COVID-19 did not make it easy to identify the current medication of the patient from previous transactions, reasons being because the patient stopped the treatment, because the patient has a stock at home or because the medication has been OOS for a while.

[44] Times of Malta. Pharmacies told to close by 6pm every day [Internet]. 2020 Mar 21 [cited 2021 Aug 7]; National. Available from: https://timesofmalta.com/articles/view/pharmacies-told-to-close-by-6pm-every-day.779801

Eight pharmacists agreed that these changes have created new risks in the system. One pharmacist stated that the new changes in the system have increased the risk of omitting some medications, while three pharmacists stated that the changes have increased the risk of not providing the patient with the correct amount of medicine in the case of a dosage increase or decrease which the pharmacist is not aware of unless the patient informs the pharmacist, leading to patient dissatisfaction, increased risk of abuse and increased workload. Two pharmacists stated that patients will be reviewed less frequently by their physician or consultant as there is no need to present a prescription at the pharmacy as a result of the new changes. This may also result in over-dosage or under-dosage in case of dangerous drugs of abuse (DDAs). One pharmacist stated that, in cases where the patient does not know what they are taking or when the representative of the patient comes to pick up the medication, the process is time-consuming since the pharmacist must discuss medications with the patient for a lengthy amount of time. One pharmacist stated that the new changes have resulted in dispensing of unwanted items, especially if the history of dispensing is not looked at and the pharmacist dispenses all the medication that the patient is entitled to.

When asked if any of the changes made to the system should be made permanent, seven pharmacists answered in the affirmative, all of which agreed with using a paperless system to reduce the transmission of disease and increase efficiency. The pharmacists who answered in the negative all agreed that the patient should still present a prescription when coming for their POYC medication, which signifies that a physician is aware of the medicines that a patient is taking and that their health condition is being monitored (n=3).

Six pharmacists stated that they prefer the new system instead of the old one. The pharmacists stated that the new system is more effective and efficient because it provides

a faster way to conduct POYC medication dispensing. Pharmacists also stated that it is safer since it reduces the risk of contamination and spread of disease, as well as being more environmentally sustainable since less papers are used. The four pharmacists who answered in the negative stated that they prefer dispensing POYC medication against a prescription since they feel legally protected in this way, especially in cases of prescription-only medicines (POMs) and DDAs. Pharmacists also stated that, without a prescription, patients are given unnecessary medicines, leading to an increased amount of waste.

Chapter 4

Discussion

4.1 Benefits of Risk Identification and Risk Management

Risk management is more complicated than risk identification and requires a more complex process in order to analyse, track and control project risks. Risk identification and risk management will assist organisations in their weakest areas including the control of risks (Raz and Michael, 2001). Risk management strategies are implemented to enhance shareholder value and minimise the probability of risks occurring, including financial distress (Fatemi and Luft, 2002). Project risk analysis and management helps practitioners such as, including healthcare managers, decide what level they are at and make essential modifications. Risk management should not be considered an oncost to their projects, but a fundamental aspect of the project-management (Simister, 1994).

In the case of the healthcare sector, risk management and identification will reduce injury to patients, staff members and visitors within the organisation, both proactively and reactively to prevent incidents and minimise consequences of the incidents, respectively. A risk assessment plan will ensure patient safety, financial stability and potential hazardous issues and medical errors. Each organisation faces unique challenges; thus, an individual risk management plan is required since the latter is not a "one-model-fits-all". The development and implementation of a risk management plan require extensive and ongoing research. Involved strategies require continuous monitoring and possible modifications following risk identification, including probability of occurrence and severity of consequences, in order to mitigate risks and handle them appropriately.[45]

[45] elearning.scranton.edu [Internet]. Pennsylvania: The University of Scranton. The Purpose of Risk Management in Healthcare; 2007 [cited 2021 Aug 7]. Available from: https://elearning.scranton.edu/resource/business-leadership/purpose-of-risk-management-in-healthcare

4.2 Evaluation of Pharmacist Questionnaire

The response rate for the PQ was 100%, which can be considered as extremely good since the best possible response rate was achieved and a response rate of over 60% is normally aimed at (Azzopardi, 2010).

The mean rating score having the highest probability of occurrence was stock-taking, followed by interruptions and distractions. The mean rating score having the highest severity of consequences was incorrect prescriptions, followed by illegible prescriptions. The risk having the highest RPN was illegible prescriptions, followed by incorrect prescriptions. Both risks are classified as high-risk. This is in agreement with previous studies (Peterson et al, 1999; Al-Arifi, 2013). In fact, most prescriptions observed were handwritten. The disadvantage of handwritten prescriptions is illegibility, when compared to computer-generated prescriptions. This can be linked to the pharmacists' perception of illegibility in prescriptions as being the highest rated risk according to its probability of occurrence and severity of consequences. The use of an electronic prescription system is associated with a reduction in dispensing errors concerning illegibility (Volpe et al, 2016). However, when the prescription is printed, the font and type size used, the printer used and the quality of the paper (glossy or matte) used may affect the readability of the labels (Luscombe et al, 1992). A more economical solution is to improve doctors' handwriting (Al-Arifi, 2013). None of the risks involved in preparing and dispensing POYC medicines were classified as extreme-risk, that is, having an RPN of 15 or higher.

Individual attention to customers was identified as being the best mitigation factor to risk occurrence with all pharmacists involved stating that they deal with customers individually. The second most practised risk mitigation strategy was the practice of stock rotation to decrease the number of expired products on the shelves. This demonstrates a

good feature of Maltese pharmacy practice. Such strategies are required to mitigate the risks involved in order to enable a smoother process of dispensing POYC medicines. The least practiced risk mitigation strategy was the use of a dispensing error reporting and analysis system, followed by organisation of training and continuous educational sessions for the pharmacists working in the pharmacy. The need for continuous professional development and update, as well as patient assessment, are important strategies that should be addressed and implemented to facilitate the dispensing process of POYC medicines to patients.

4.3 Evaluation of Observational Studies

The pharmacist dealt with the patient, filled the control card accordingly, where applicable, and checked that patient documents were complete and valid, and that the medicines on the Schedule V card corresponded to the prescription in most prescriptions observed. This demonstrates the skilfulness of Maltese pharmacists to adhere to the code of conduct and accepted standards of good professional practice within the process (Azzopardi, 2000). Pharmacist involvement also demonstrated the professional liability as pharmacists have to ensure that patients receive the right medicine and necessary advice to comply with the dosage regimen.

In most prescriptions, the patient was asked to leave their documents and prescription at the pharmacy and collect the POYC medicines after a few days. This decision was taken by the pharmacist either because of the high number of medicines that need to be prepared and dispensed, or because most pharmacies do not prepare POYC medicines on a Saturday, which may be because the POYC Unit is only open during weekdays, thus they cannot be contacted by pharmacists in case of problems encountered

with regards to patient entitlement.[46] Their limited opening hours may increase the risk of inability to reach the POYC Unit Call Centre or contact via Skype and reduce efficiency.

In most prescriptions, the pharmacist did not ask for any patient identification to compare the name and ID card number with those written on the bag. This may increase the risk of dispensing a medicines bag to the wrong patient, especially in cases where two patients have the same name and surname. Through identification, the pharmacist ensures that patients receive the right medication, who otherwise fails to provide the appropriate counselling and advice (Azzopardi, 2000). However, the pharmacists may have already built such a good rapport with the patient that no identification is needed. This is one major advantage of the POYC Scheme, where patients go to the same pharmacy to pick up their supply of medicines every two months, thus allowing the pharmacist to become more familiar with the patient's conditions and medicines.

In most prescriptions, the pharmacist did not check the expiration date of the product(s) selected. This may be due to the fact that expiration dates of medicines sent from POYC are checked upon their weekly arrival at the pharmacy, thus there is no need to re-check the expiry date of medicines upon dispensing. In addition, most pharmacies perform stock rotation practices in order to reduce the risk of having expired medicines at the pharmacy and ensure that the medicines given to patients are of good quality (97.5%).

There are no rules with regards to who needs to sign the printed label, if even signed at all, since the POYC Unit does not restrict the pharmacists but rather allows them

[46] health.gov.mt [Internet]. Malta: Ministry for Health. POYC Call Centre – Client Support Team; 2020 [cited 2021 Aug 7]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/POYC%20Call%20Centre%20-%20Client%20Support%20Team.aspx

to work in a manner that they deem best. This led to a number of different possibilities for pharmacists on what is done with the labels. The most exercised practice was that the printed labels were not signed at all, followed by the patient or patient representative signing the printed label on the prescription but not the one on the Schedule V card while the pharmacist does not sign either label.

In most prescriptions observed, the pharmacist gave information to the patient in the form of verbal advice, which is especially important for illiterate patients in order to reduce the risk of the patient administering the drug incorrectly or administering the wrong dose, ultimately harming the patient by worsening their condition or even death. Effective counselling and communication skills are required to convey the verbal information to achieve a two-way dialogue with the patient and provide high-quality patient care (Rees, 1996; Chevalier et al, 2017). In addition, in most prescriptions, the pharmacist asked the patient whether they have any problems with the medicine(s) dispensed. Such practices highlight the holistic approach taken by the pharmacist to confirm with the patient their knowledge on how medications should be used effectively, improving patient care.

In most prescriptions observed, the pharmacist did not give information to the patient in a written format, and did not write the dosage regimen of the medicine(s) on their packaging. This may be due to the fact that some patients have already been taking the same medication for the management of their condition for a long period of time, thus the pharmacist may feel that repeating such information is futile. In addition, the physician or consultant may have given the patient certain advice with regards to the dosage regimen that the pharmacist is not aware of, thus providing different advice to that of the doctor resulting in patient confusion and ineffective therapeutic outcome. However, a written explanation of certain information with regards to medicine

administration including dosage regimen may be useful to reduce the risk of patient non-compliance in cases of patient laziness and forgetfulness, or lack of patient education. Both verbal advice and written information provided by the pharmacist to patients upon dispensing a prescribed medication contributes to better management of the patient (McDonough and Bennett, 2006). Compliance with dosage regimen depends on the counselling provided by the pharmacist, among other factors.

In most prescriptions, the pharmacist did not talk privately with the patient or patient representative. This can be attributed mostly to the lack of dedicated space or room in order to offer privacy at the pharmacy. As a result, the patient may not feel safe and does not ask any questions that they might have with regards to the medication(s) being dispensed to them, which may lead to incorrect administration or dosage regimen. In addition, failing to meet confidentiality requirements may cause physical or psychological harm to the patient. A clean and orderly premise is an indicator of a positive appearance and enhances the professional image of the pharmacy (Dhalla, 1992). However, the patient may also not have had any questions that require privacy.

In most prescriptions, the pharmacist did not repeat major points of advice given to ensure the information conveyed is fully understood by the patient, and did not discuss medication-taking habits with the patient in concordance with lifestyle and other medicine(s). However, in most prescriptions, the pharmacist asks the patient whether they have any problems with the medicine(s) dispensed, and went over the medicine(s) dispensed with the patient to ensure that the information conveyed regarding the drug administration was fully understood. Such practices assess the commitment by the pharmacist toward confirming with the patient their knowledge on how the medication should be used effectively. The pharmacist is in a position to provide appropriate information to the patient, in a manner which will not overwhelm them (Chevalier et al,

2017). The pharmacist should also be able to make the decision on what information should be withheld in the patient's interest or what information to provide, which goes beyond identifying the information associated with the medicine. This procedure is beneficial because through the feedback obtained from the patient, one could confirm that the prescription was correctly deciphered by the pharmacist. In addition, the adoption of a holistic approach by the pharmacist may improve patient care (Shane and Vogt, 2013).

In most prescriptions observed, the pharmacist compared the medicine(s) selected with the prescription and label to confirm that the correct product(s), dose and quantity were to be dispensed. Rechecking the prescription for unintentional prescribing errors before deciding to dispense medications is an important step in the dispensing process that the pharmacist should perform in order to reduce the risk of dispensing the wrong medication, dose or quantity to the patient.

The stated mean durations of time to prepare medicines for each individual patient, to recheck prescriptions and/or label with medicines to be dispensed and to give advice for a new prescription vary significantly ($p<0.05$) from the observed mean durations. This means that the perceived time taken to perform these activities does not coincide with the actual time taken. Pharmacists were observed to take more time to give advice for a new prescription and to prepare medicines for each individual patient than stated, meaning that pharmacists are giving more importance to these activities than others during the process of supplying POYC medicines. However, pharmacists were observed to take less time to actually recheck prescriptions and/or label with medicines to be dispensed than stated. This may be due to the fact that pharmacists feel stressed due to the high prescription and medicine volume and would rather spend more time on patient advice rather than rechecking the prescription, or due to inexperienced pharmacists and lack of training. However, this may increase the risk of the pharmacist

selecting the wrong product, dose and/or quantity of medicine, leading to inadequate therapeutic outcome, patient harm or medicine wastage.

4.4 Implementation of Standard Operating Procedure

The response rate for the evaluation questionnaire and the SOP was 100%, which can be considered as extremely good since the best possible response rate was achieved and a response rate of over 60% is normally aimed at (Azzopardi, 2010).

The developed SOP was well received by the participating pharmacists since they were all able to fully perform the procedure described, understood the text, and that it represented the content clearly and concisely. In addition, most pharmacists agreed that the SOP was comprehensive enough to collect all the information needed to address its purpose.

The temporary changes in the POYC procedure due to COVID-19 were also well received, with most pharmacists agreeing that these changes were effective to limit contamination while serving patients appropriately. This is because patients do not need to present a prescription to collect their POYC medicines. In addition, patients do not need to leave their documents at the pharmacy for the pharmacist to prepare their medicines. Moreover, patients can visit the pharmacy once to collect their medicines since they can simply call or send an email to the pharmacy with their ID card number and date of birth. The pharmacist can then access the POYC system and prepare their medicines according to previous transactions. This is especially useful in elderly or vulnerable patients since they would only be required to visit the pharmacy once for medicine collection, instead of first leaving their documents with the pharmacist and then returning to collect their medicines.

Although the new changes have decreased the risk of contamination, most pharmacists stated that they have created new risks such as omission of some medicines, less-frequent consultations with doctors and medicine wastage. Nonetheless, most pharmacists agreed to have these changes made permanent since a paperless system will effectively reduce transmission of disease, increase efficiency of the procedure and reduce the use of paper. An SOP such as the one developed for this research is especially useful if these changes in the procedure are to be made permanent.

4.5 Limitations of the Study

One drawback in the study was the small sample size of community pharmacies used for observation studies and implementation of the SOP. This is because such processes are time-consuming and not many community pharmacists were on board with the idea of having an external observer at their pharmacy for at least three hours due to the pandemic. In addition, not all pharmacists were pleased to handle documents provided by the external researcher due to the increased risk of contamination and infection.

Some of the reported findings in this study may have been influenced by selection bias. The responses obtained from pharmacists may not reflect the real scenario since the ideal answer might have been selected instead of what is commonly practised. In addition, the PQ made use of close-ended questions, resulting in bias as the responses available were limited to five options of choice since a five-point Likert scale was used. Another limitation to the questionnaire was that community pharmacists were asked to fill in the PQ during the time that the external researcher was carrying out the observation study. This may have resulted in participating pharmacists to rush in answering the questions and choosing a random answer.

Another limitation of this study was the duration of the implementation phase. The responses obtained from the participating pharmacists may not reflect a comprehensive evaluation of the SOP as two weeks of implementation may not have been long enough. In addition, open-ended questions were used in both the PQ and the evaluation questionnaire. Although such questions provided an in-depth view of the study by allowing the researcher to gather more detailed responses and qualitative data, they may result in a possibility for bias since such questions increase the length of the questionnaires, causing the respondents to rush in answering the questions and choosing an answer which does not require further explanation.

This study made use of random sampling. Simple random sampling is able to obtain an unbiased sample; however, it may not pick up all the elements in the population. Stratified random sampling offers a better representation of population elements that may affect the study hypothesis (Azzopardi, 2010). Since this study was a cross-sectional one, that is, data was collected on only one occasion, a lack of longitudinal perspective presented another limitation to this study.

4.6 Recommendations for Future Studies

This study evaluated pharmacists' perception of the risks involved in preparing and dispensing POYC medicines. A recommendation for further study is to assess the general public's risk perception of POYC dispensing.

Another recommendation for further study is to identify risk mitigation strategies for the risks that were additionally mentioned by community pharmacists in the PQ, that is, sending patients from hospital without proper instructions or paperwork, and out-of-stock medicines. Both risks were stated by the pharmacists that they cannot be mitigated by the pharmacists in the community pharmacy. With respect to the insufficient

instructions, community pharmacists can be electronically sent the proper paperwork and prescriptions needed for patients to obtain their medicines. With respect to the out-of-stock medicines, physicians and consultants may be able to offer an alternative medication with the same therapeutic response.

Another recommendation for future study is the development and implementation of a dispensing error reporting and analysis system. This risk mitigation strategy was the least practiced risk mitigation strategy performed by pharmacists involved in this study. Such a strategy may be able to reduce the risk of dispensing errors. Other case studies that can be considered for future work is the implementation of additional routine check-ups by community pharmacists with patients to discuss their medicines, dosage regimen and administration, etc, as well as the implementation of risk mitigation strategies at the POYC Unit in order to reduce medicine waste, safeguard patient safety and improve efficiency of dispensing.

4.7 Conclusion

Risk was defined in 1981 by Kaplan and Garrick as the combination of "uncertainty and some kind of loss or damage that might be received." Today, in the case of errors in dispensing, the definition of risk can be expanded to include parameters other than uncertainty. For example, statistically determined chances for an occurrence and parameters related to the dispenser or his assistants which could be determined due to the inherent characteristics of the dispenser. Pharmacy risk management is a complex process that surpasses the practice of simply supplying the medication on the patient's prescription, as well as protecting the patient from potential harm, even though it must remain the primary focus of all pharmacists. Risk management is the practice of controlling several risk factors that affect pharmacy practice, and this must also include the protection of pharmacists, pharmacy staff and the pharmacy itself, not just the patient.

By evaluating practices and processes in pharmacy practice through a risk-based approach, although time-consuming, one is able to identify practices that are risky to the patient, and thus, be one step ahead to ascertain patient safety and improve the reliability of the healthcare system by understanding why and how dispensing errors occur. This highlights the importance of using a risk management system in pharmacy practice in order to evaluate whether risks, their probability of occurrence and severity of consequences have changed over time, reducing as much as possible and preventing adverse risks to patients. This research evaluated ways of how risk in preparing and dispensing POYC medicines can be measured and evaluated. Such a study can be used as a reference for similar future studies, as well as a foundation for developing a structure on risk review and management in dispensing medicines.

This study adopted a risk-based and mixed method approach, including qualitative and quantitative research methods, to identify, analyse and evaluate risk factors involved in POYC medication dispensing as part of a risk assessment exercise. Risk mitigation strategies were identified and the best practice that presents the least risk for dispensing POYC medicines was established by developing an SOP for the processes followed in this practice. SOPs can be effective in assuring the reliable and consistent performance of routine tasks involved in medicine dispensing in community pharmacy settings. Maintaining written SOPs is an important step in assuring that a pharmacy has developed a dispensing practice that meets international good pharmacy practice standards, as well as ensuring risk management and harm minimisation to the patient and the pharmaceutical profession by reducing the risk of possible dispensing errors that could occur if a proper medicine dispensing procedure is not adhered to. The PQ developed served as a mean of identifying the risks involved in dispensing POYC medicines and analysing the pharmacists' perception of risk and risk mitigation. The development and implementation

of the SOP served as a basis for reducing the risk of dispensing errors in the process of dispensing POYC medicines. This research evaluated how SOPs can be written, implemented and evaluated, and can be used as a platform for similar research in the future, including dispensing procedures addressing the process of dispensing different types of medicines such as high-risk medicines, and can serve as a framework for the development of SOPs to prepare and dispense medicines in concordance with required standards.

A review of the risks involved in dispensing POYC medicines should be undertaken to evaluate whether risks, their probability of occurrence and severity of consequences have changed over time. Pharmacists should be continuously trained and educated on the professional ethics as healthcare professionals who are duty-bound to safeguard patient safety, especially with the possible introduction of permanent changes to the system followed in dispensing POYC medicines, to ultimately reduce as much as possible and prevent adverse risks to patients.

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Xuereb M. Perception of Pharmacists and Patients of the Pharmacy Of Your Choice Scheme in Community Pharmacies [Dissertation]. Valletta: University Of Malta; 2014.

List of Publications and Abstracts

Two papers are being written to be submitted for consideration for publication in the International Journal of Pharmacy Practice. The papers are titled ‘Risk-Based Analysis of a National Pharmaceutical Service for Free Medicines’ and ‘Standard Operating Procedure for Preparing and Dispensing a National Pharmaceutical Service for Free Medicine: A Pilot Study’.

Appendices

Appendix 1

Data Collection Documents

Community Pharmacy Survey Data Sheet for Dispensing POYC Medicine

Name of Pharmacy and Location:

_____

District number: _____

Date: _____

Time of Day: ○ Morning (8am-12pm) ○ Afternoon (12-4pm) ○ Evening (4-7pm +)

Observed prescription number _____

Number of POYC medicines being dispensed: _____

Type of prescription: ○ Repeat ○ New

Time taken (in minutes) to:

- Recheck prescription and/or label with medicine(s) to be dispensed: _____
- Dispense POYC medicine(s) to patient: _____
- Give advice to patient: _____

Process	Yes	No	N/A	Remarks
1. Patient comes into the pharmacy to collect POYC medicine(s) him/herself.	☐	☐	☐	
2. Patient has more than one comorbidity.	☐	☐	☐	
3. Patient is 60 years old or older (elderly).	☐	☐	☐	
4. Pharmacist deals with the patient, or patient representative.	☐	☐	☐	
5. Pharmacist asks for the patient's ID card for identification by comparing the name and ID card number/patient number with those written on the bag.	☐	☐	☐	
6. Patient documents are checked for completeness and validity.	☐	☐	☐	
7. Pharmacist checks that the medicine(s) listed on Schedule V card correspond(s) to the prescription and/or label.	☐	☐	☐	
8. Pharmacist checks that the medicine(s) listed on Schedule V card correspond(s) to the consultant form, *(if applicable)*.	☐	☐	☐	
9. No problem is identified with the patient documents, or appropriate action is taken to solve the identified problem.	☐	☐	☐	
10. a) Medicine(s) were ready to be collected in a few days after the patient, or patient representative, left the documents at the pharmacy and was asked to come back to collect the medicine(s), **OR**	☐	☐	☐	
b) Medicine(s) were ready to be collected in a few minutes after the patient, or patient representative, handed the documents to the pharmacist and was asked to wait a few minutes while their prescription was being prepared.	☐	☐	☐	
11. Pharmacist compares medicine(s) selected with the prescription and/or label to confirm that the correct product(s), dose and quantity are dispensed.	☐	☐	☐	
12. Pharmacist checks expiration date of the product(s) selected.	☐	☐	☐	

Process	Yes	No	N/A	Remarks
13. The name of the patient was written on the paper bag.	☐	☐	☐	
14. The ID number of the patient or the patient number was written on the paper bag.	☐	☐	☐	
15. Two labels were printed and placed on both the prescription and Schedule V card.	☐	☐	☐	
16. The control card was filled accordingly, *(if applicable)*.	☐	☐	☐	
17. a) Printed labels are not signed, **OR**	☐	☐	☐	
b) Printed labels are signed by both the dispensing pharmacist and patient, or patient representative, **OR**	☐	☐	☐	
c) Printed labels are signed by the dispensing pharmacist, **OR**	☐	☐	☐	
d) Printed labels are signed by the patient, or patient representative, **OR**	☐	☐	☐	
e) Printed label on Schedule V is signed by pharmacist, and printed label on prescription is signed by patient, or patient representative, **OR**	☐	☐	☐	
f) Printed label on Schedule V is signed by patient, or patient representative, and printed label on prescription is signed by pharmacist, **OR**	☐	☐	☐	
g) Printed label on Schedule V is signed by pharmacist and patient, or patient representative, and printed label on prescription is not signed, **OR**	☐	☐	☐	
h) Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist and patient, or patient representative, **OR**	☐	☐	☐	
i) Printed label on Schedule V is not signed and printed label on prescription is signed by patient, or patient representative, **OR**	☐	☐	☐	

Process	Yes	No	N/A	Remarks
j) Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist, **OR**	☐	☐	☐	
18. Pharmacist goes over the medicine(s) to be dispensed with the patient, or patient representative, to ensure that the information conveyed regarding the drug administration is fully understood.	☐	☐	☐	
19. Pharmacist gives information to the patient, or patient representative, in the form of verbal advice.	☐	☐	☐	
20. Pharmacist gives information to the patient, or patient representative, in a written format.	☐	☐	☐	
21. Pharmacist writes the dosage regimen of the medicine(s) on the medicine(s) packaging.	☐	☐	☐	
22. Pharmacist repeats major points of advice given to ensure the information conveyed is fully understood by the patient, or patient representative.	☐	☐	☐	
23. Pharmacist asks the patient, or patient representative, whether they have any problems with the medicine(s) dispensed.	☐	☐	☐	
24. Pharmacist talks privately with the patient, or patient representative.	☐	☐	☐	
25. Pharmacist discusses medication-taking habits with the patient, or patient representative, in concordance with lifestyle and other medicine(s).	☐	☐	☐	
26. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) in a written format).	☐	☐	☐	
27. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) verbally.	☐	☐	☐	

Comments:

_____

_____

_____

Questionnaire to Community Pharmacists on Duty During the Observation Study

- My name is Emily Magro and I am currently reading for an undergraduate degree in Bachelor of Science (Honours) in Pharmaceutical Science at the University of Malta. As part of my research titled 'Risk-Based Processes in Pharmacy Practice', I am conducting a study, in the form of questionnaires and observation studies, to assess the risks associated with dispensing POYC medications. This research will identify pharmacy practice risk factors in order to gain a better understanding on how dispensing errors arise.
- The following questionnaire is to be filled in by the community pharmacist on duty during the observation study. The observation study will be conducted once in each pharmacy to observe the pharmacist dispensing POYC medication for approximately three hours. The questionnaire will take about 10 minutes to answer.
- The information gathered will remain strictly confidential and no information that allows you or the pharmacy to be identified will be shared.

Section I: Demographic Data

1. Age

o 21-30 years
o 31-40 years
o 41-50 years
o 51-60 years
o Over 60 years

2. Gender

o Male
o Female
o Other

3. What best describes your status as a pharmacist? *(you may tick more than one)*:

o Owner
o Managing pharmacist
o Employed full-time
o Employed part-time
o Locum

4. How many years of professional experience do you have?

o Less than 1 year
o 1-5 years
o 6-10 years
o 11-15 years
o 16-20 years
o More than 20 years

5. Is the pharmacy owned by a pharmacist?

o Yes
o No

6. What type of community pharmacy is it?

o Independent pharmacy
o Group of pharmacies *(please state the number of pharmacies)*: _____

7. On average, how many hours per week do you spend dispensing POYC medicines?

o < 10 hours
o 11-20 hours
o 21-40 hours
o > 40 hours

8. State the number of minutes that you spend in performing the following processes related to the supply of POYC medicines for each individual patient (average of 3 medicines):

Process	**Time in minutes**
a. Preparation of the prescription	
b. Rechecking prescription and/or label with medicine(s) to be dispensed	
c. Dispensing medicine(s) to patient	
d. Giving advice to patient for a repeat prescription	
e. Giving advice to patient for a new prescription	

Section II: Risks Involved in Dispensing POYC Medicines

9. Rank the following risks involved in dispensing POYC medicines according to how often you encounter the risk (probability of occurrence) on a scale of 1 (never) and 5 (always) by circling a number from the Likert scale in each risk:

Risk	Probability of Occurrence				
i. Insufficient time for dispensing (process is very time-consuming, sole pharmacist on duty or high prescription number and/or high medicine volume).	1	2	3	4	5
ii. Incomplete/invalid patient documents (patient does not have all the documents required, documents are out-dated or discrepancies between entitlement and prescription).	1	2	3	4	5
iii. Illegible prescription (poor handwriting of physicians).	1	2	3	4	5
iv. Inadequate medicine storage (Sound-Alike/Look-Alike drugs are placed next to each other or overcrowding of shelves).	1	2	3	4	5
v. Selection of wrong product, dose and/or quantity of medicine (pharmacy salespersons handle the dispensing process, medicine to be dispensed is not re-checked against the prescription, medicine to be dispensed is not checked by another pharmacist or packaging of the same product with different doses are very similar).	1	2	3	4	5
vi. Lack of privacy when dispensing (there is no dedicated space or room for dispensing POYC medicines or pharmacist does not talk privately with the patient).	1	2	3	4	5
vii. Interruptions and distractions (pharmacist is interrupted by pharmacy assistants, telephone calls and customers while dispensing POYC medicine or pharmacist is distracted by talkative customers and broadcast devices).	1	2	3	4	5
viii. Unreliability of IT system (discrepancies between patient entitlement on the IT system and the Schedule V card, server problems or lack of updates and improvements of the IT system, e.g. the IT system does not allow checking of drug interactions and/or contra-indications for each medicine).	1	2	3	4	5

Risk	Probability of Occurrence				
ix. Incorrect data entry (data written in the IT system or control card is not re-checked, pharmacy assistants participating in data entry or printed labels do not clearly indicate by who they should be signed, e.g. dispensing pharmacist, pharmacist who checked the prescription before dispensing, etc.).	1	2	3	4	5
x. Cluttered work counter (work counter is not solely used for dispensing medicine to the patient or work counter is not kept tidy, clear and organised).	1	2	3	4	5
xi. Pharmacists/Locums having their own method of preparing and dispensing POYC medicines (lack of continuity as a result of the different methods of dispensing by different pharmacists/locums working at the pharmacy).	1	2	3	4	5
xii. Stock-taking (process is very time-consuming, and process must be performed too frequently, which is every 3 months).	1	2	3	4	5
xiii. Incorrect prescription (lack of knowledge on drug-drug interactions by the physician or wrong dose prescribed).	1	2	3	4	5
xiv. Inexperienced pharmacists (lack of confidence in correcting physician's prescriptions or participation of pharmacy salespersons in dispensing POYC medicines).	1	2	3	4	5
xv. Lack of training (pharmacists are informed late or not at all on new POYC protocols and insufficient educational seminars on dispensing POYC medicines and training for pharmacy technicians in preparing POYC medicines).	1	2	3	4	5
xvi. Limited stock, especially new medicines (POYC medicines stock not renewed frequently enough).	1	2	3	4	5
xvii. Inability to reach the POYC Unit (limited opening hours of the POYC Unit Call Centre, busy operating phone lines make it difficult to get in touch with them or inability to reach POYC Unit via Skype).	1	2	3	4	5
xviii. Complicated/Ambiguous POYC protocols (protocols can be too complex and/or unclear that they may be open to different interpretations e.g. pharmacists may not be sure whether a certain permit is sufficient or not).	1	2	3	4	5

10. Rank the following risks involved in dispensing POYC medicines according to how severely you think the patient is harmed in the occurrence of such risks (severity of patient harm) on a scale of 1 (no harm) and 5 (death) by circling a number from the Likert scale in each risk:

Risk	**Probability of Occurrence**				
i. Insufficient time for dispensing (process is very time-consuming, sole pharmacist on duty or high prescription number and/or high medicine volume).	1	2	3	4	5
ii. Incomplete/invalid patient documents (patient does not have all the documents required, documents are out-dated or discrepancies between entitlement and prescription).	1	2	3	4	5
iii. Illegible prescription (poor handwriting of physicians).	1	2	3	4	5
iv. Inadequate medicine storage (Sound-Alike/Look-Alike drugs are placed next to each other or overcrowding of shelves).	1	2	3	4	5
v. Selection of wrong product, dose and/or quantity of medicine (pharmacy salespersons handle the dispensing process, medicine to be dispensed is not re-checked against the prescription, medicine to be dispensed is not checked by another pharmacist or packaging of the same product with different doses are very similar).	1	2	3	4	5
vi. Lack of privacy when dispensing (there is no dedicated space or room for dispensing POYC medicines or pharmacist does not talk privately with the patient).	1	2	3	4	5
vii. Interruptions and distractions (pharmacist is interrupted by pharmacy assistants, telephone calls and customers while dispensing POYC medicine or pharmacist is distracted by talkative customers and broadcast devices).	1	2	3	4	5
viii. Unreliability of IT system (discrepancies between patient entitlement on the IT system and the Schedule V card, server problems or lack of updates and improvements of the IT system, e.g. the IT system does not allow checking of drug interactions and/or contra-indications for each medicine).	1	2	3	4	5

Risk	Probability of Occurrence				
ix. Incorrect data entry (data written in the IT system or control card is not re-checked, pharmacy assistants participating in data entry or printed labels do not clearly indicate by who they should be signed, e.g. dispensing pharmacist, pharmacist who checked the prescription before dispensing, etc.).	1	2	3	4	5
x. Cluttered work counter (work counter is not solely used for dispensing medicine to the patient or work counter is not kept tidy, clear and organised).	1	2	3	4	5
xi. Pharmacists/Locums having their own method of preparing and dispensing POYC medicines (lack of continuity as a result of the different methods of dispensing by different pharmacists/locums working at the pharmacy).	1	2	3	4	5
xii. Stock-taking (process is very time-consuming, and process must be performed too frequently, which is every 3 months).	1	2	3	4	5
xiii. Incorrect prescription (lack of knowledge on drug-drug interactions by the physician or wrong dose prescribed).	1	2	3	4	5
xiv. Inexperienced pharmacists (lack of confidence in correcting physician's prescriptions or participation of pharmacy salespersons in dispensing POYC medicines).	1	2	3	4	5
xv. Lack of training (pharmacists are informed late or not at all on new POYC protocols and insufficient educational seminars on dispensing POYC medicines and training for pharmacy technicians in preparing POYC medicines).	1	2	3	4	5
xvi. Limited stock, especially new medicines (POYC medicines stock not renewed frequently enough).	1	2	3	4	5
xvii. Inability to reach the POYC Unit (limited opening hours of the POYC Unit Call Centre, busy operating phone lines make it difficult to get in touch with them or inability to reach POYC Unit via Skype).	1	2	3	4	5
xviii. Complicated/Ambiguous POYC protocols (protocols can be too complex and/or unclear that they may be open to different interpretations e.g. pharmacists may not be sure whether a certain permit is sufficient or not).	1	2	3	4	5

11. Do you think there are other risks involved in dispensing POYC medicine which were not mentioned above?
    - Yes
    - No *(skip questions 11a to 11d and go to section III)*

    a. Please state the risks.

    _____
    _____
    _____
    _____
    _____
    _____

    b. What may be the possible causes for the risks mentioned?

    _____
    _____
    _____
    _____
    _____
    _____

    c. What are the consequences/effects that may arise from the risks mentioned in question 11a?

    _____
    _____
    _____
    _____
    _____
    _____

    d. Are the risks mentioned being mitigated at the pharmacy?
    - Yes *(answer question i and then go to section III)*
    - No *(answer question ii and then go to section III)*

    i. If yes, how are they being mitigated?

    _____
    _____
    _____
    _____
    _____
    _____
    _____

ii. If no, why are they not being mitigated?

_____
_____
_____
_____
_____
_____
_____

Section III: Risk Perception and Risk Mitigation

12. State whether the following risk mitigation strategies are carried out at the pharmacy by ticking either 'yes' or 'no' for each strategy:

	Risk Mitigation Strategy	Yes	No
i.	Use of dividers to separate Sound-Alike/Look-Alike drugs.	☐	☐
ii.	Storing Sound-Alike/Look-Alike drugs far apart.	☐	☐
iii.	Have more than one pharmacist on duty at a time.	☐	☐
iv.	Use a dedicated space or room when dispensing POYC medicines to counsel patients in private.	☐	☐
v.	Counsel patients on medicine administration at time of dispensing.	☐	☐
vi.	Keep work counters tidy and clear.	☐	☐
vii.	Deal with customers one by one.	☐	☐
viii.	Contact physician when encountering problems with prescription.	☐	☐
ix.	Re-check medicine to be dispensed by a different pharmacist to the one who prepared the medicine.	☐	☐
x.	Have reference books e.g. BNF, and online sources e.g. SPCs, at hand when dispensing.	☐	☐
xi.	Prepare POYC medicines in a quiet room or within an area in the pharmacy where interruptions and distractions by customers, telephone calls and broadcast devices are limited.	☐	☐
xii.	Have a systematic guideline for dispensing POYC medicines for all the pharmacists working at the pharmacy to maintain workflow continuity.	☐	☐
xiii.	Use of a dispensing error reporting and analysis system.	☐	☐
xiv.	Practice of stock rotation to decrease the number of expired products on the shelves.	☐	☐
xv.	Organise training and continuous educational sessions for the pharmacists working in the pharmacy.	☐	☐
xvi.	Provide information on new drugs and any changes in the POYC system to the pharmacists working in the pharmacy.	☐	☐
xvii.	Organise additional routine check-ups with patients to discuss their medicines, dosage regimen and administration, etc.	☐	☐

13. Do you think there are other risk mitigation strategies in dispensing POYC medicine that can be performed by pharmacists/pharmacies which were not mentioned above?
    - o Yes
    - o No *(skip question 13a and go to question 14)*

a. Please state any other risk mitigation strategies.

_____
_____
_____
_____
_____
_____
_____

14. Do you think there can be other risk mitigation strategies or improvements that can be implemented by the POYC Unit?
    - o Yes
    - o No *(end of questionnaire)*

a. Please state any other risk mitigation strategies or improvements that can be implemented by the POYC Unit.

_____
_____
_____
_____
_____
_____
_____
_____

END OF QUESTIONNAIRE

Thank you for your contribution to this study!

Time-Motion Study for the Preparation of POYC Medicine(s) to be Dispensed

The number of medicines on the prescription, whether the prescription is a repeat or a new prescription, and the number of minutes spent by the pharmacist preparing the POYC prescription to be dispensed for each individual patient are recorded.

The number of minutes recorded includes the time taken to:

- Contact the POYC Unit, or whoever must be contacted in case of a POYC or patient-related problem in the patient's documents (respectively)
- Select the medicine(s) and quantity prescribed
- Scan the POYC card
- Record medicine(s) on the IT system
- Write the patient's name and ID number/patient number on the paper bag
- Print and sign the labels
- Fill the control card (if applicable)

This part of the study is performed in three of the pharmacies selected during the observation studies.

Name of Pharmacy and Location: _____

District number: _____

Date: _____

Time of Day: ○ Morning (8am-12pm) ○ Afternoon (12-4pm) ○ Evening (4-7pm +)

Prescription number	Number of medicines	Type of Prescription		Time in minutes
		Repeat	New	
1		☐	☐	
2		☐	☐	
3		☐	☐	
4		☐	☐	
5		☐	☐	

Comments:

_____

_____

_____

Appendix 2

SOP Implementation

Table of Contents

Original	
Authorised Copy	
Reading Copy	

Written by:	Emily Magro	Signature/Date:	**SOP No.: SOP/PMD/001**
Reviewed by:		Signature/Date:	Date issued:
Approved by:	Managing Pharmacist	Signature/Date:	Date reviewed:

<table>
<tr><td rowspan="3">Pharmacy Logo</td><td>Name of Pharmacy, Locality
License No.</td><td rowspan="2">SOP No.:
SOP/PDM/001</td></tr>
<tr><td>Standard Operating Procedure</td></tr>
<tr><td>Preparation and Dispensing of Pharmacy Of Your Choice Medicines</td><td>Version: 01</td></tr>
</table>

1. Objective

The purpose of this standard operating procedure (SOP) is to describe the system to follow in the preparation and dispensing of Pharmacy of Your Choice (POYC) medicines to entitled patients registered for a POYC service.

2. Scope

The purpose of this SOP is to outline the procedure for the accepting of prescription/s, the preparation of the POYC scheme medicines, inputting into the POYC database, and the dispensing of the POYC scheme medicines to the patient or their representative by the managing pharmacist or designate pharmacist/s at X Pharmacy.

3. Responsibilities

The managing pharmacist or designate pharmacist/s at X Pharmacy providing POYC services to entitled patients is responsible for the execution of this SOP throughout the whole process of preparation and supply of the POYC scheme medicines, having read and understood the procedure beforehand.

4. Definitions

4.1 Consultant form

A special document or permit, also known as the “To whom it may concern” note, issued by the consultant doctor specifying the medication and dosage regimen that the patient is entitled to for their condition in the case of a “Treatment as prescribed” clause on the patient’s entitlement card; includes forms DH75 (psychiatric treatment), DH1034 (oncology treatment), DH1020 (dermatology treatment), SLH145 (Schedule II), EMTRF (exceptional patient medication treatment) or CPSU permit (equipment including syringes, catheters, catheter bags, etc.)

4.2 Control card

Also known as the Dangerous Drug Card, or White Card. As per Subsidiary Legislation 31.18, a control card is used by medical practitioners and pharmacists to register the amount of narcotic and psychotropic drugs prescribed and dispensed respectively. The control card is required for medicines listed in the Dangerous Drugs Ordinance (Chapter 101) and Drugs (Control) Regulation (Subsidiary Legislation 31.18)

4.3 Designated pharmacist

The pharmacist responsible for the preparation and/or dispensing of Pharmacy Of Your Choice medicines to entitled patients

4.4 Entitlement card

Schedule V (yellow) or schedule II (pink) cards that contain personal information of the patient (namely ID card number and address) and a list of medications which they are entitled for in the POYC Scheme

4.5 IT system

The POYC online prescriptions system

4.6 OOS

Out-of-stock

4.7 POYC

Pharmacy Of Your Choice

4.8 POYC medicines

Medicines that patients are entitled to take for free as part of the POYC Scheme

4.9 POYC scheme card

Special ID card issued by the POYC Unit containing patient name and ID number, pharmacy name and license number, expiry date, card number and QR code

4.10 Prescription for free drugs

Special doctor's prescription, which is either green for narcotic and psychotropic drugs (valid for one month) or white for non-controlled drugs (valid for two months), used by medical practitioners to prescribe POYC medicine to patient. The use of a prescription form is covered by the Prescription Forms for Free Medicinals Rules (Subsidiary Regulation 458.24)

4.11 SOP

Standard Operating Procedure

5. Procedure

Step	Action
1	**Identify the patient** Ask for a form of identification such as ID card, driver's license or passport
2	**Are the patient's documents valid and complete?** Patient documents include Schedule II and/or Schedule V card, prescription for free drugs, prescription for narcotic and psychotropic drugs (if applicable) and any relevant permit/s, POYC scheme card consultant form/s and/or control card (if available) If NO, go to **step 3**. If YES, go to **step 4**.
3	**Ask the patient to return to the pharmacy with complete documents.** If any of the required documents are expired, the patient needs to meet up with the relative consultant for renewal. If any of the required documents is lost, the patient may be required to call the POYC Unit or Schedule V office to have the documents sent by post, or personally go to the POYC Unit or Schedule V office to sort out documents. X Pharmacy may also call on behalf of the patient.
4	**Check if the patient is due to pick up the POYC medicines** If the medicine needs to be prepared immediately, accept the patient's documents no earlier than 55 days after the last consignment. If the medicines cannot be prepared immediately, accept the patient's documents no earlier than 45 days after the last consignment. If YES, go to **step 5**. If NO, go to **step 6**.
5	**Does the pharmacist need to prepare the medicines immediately or can the patient return to the pharmacy in a few days to collect his/her medicines?** If IMMEDIATELY, go to **step 8**. If COLLECT ANOTHER DAY, go to **step 7**.
6	**Ask the patient to return to pharmacy when they are due to pick up their medicines**
7	**Write the patient's name and ID number on the paper bag**
9	**Find patient on IT system** Scan the code on the POYC scheme card or entitlement card, or enter the patient's ID number and date of birth manually

Step	Action
10	**Check that the items, doses and regimen on the IT system database correspond with the prescription** Make any required modifications to the patient entitlement on the database by clicking on 'New', inputting the doctor's registration number, using the drop-down arrow to find and select the new medication or new dose, entering the quantity for one month, then clicking 'OK'. Previous entitlement can be removed by right clicking on it and selecting 'Delete'. A copy of the patient's entitlement should be sent to: entitlement.poyc@gov.mt. In the case of a new drug, call the Medicines Entitlement Unit on 21232424 or contact them via X Pharmacy's Skype.
11	**Apply patient entitlement on IT system as prescribed** Click on 'Apply Entitlement'
12	**Is a control card available?** If YES, go to **step 13**. If NO, go to **step 14**.
13	**Fill the control card and prescription manually accordingly**
14	**Add doctor's registration number and medicine to be dispensed to patient** Write the doctor's registration number and quantity of medicine to be dispensed
15	**Post medicine to be dispensed to patient** Click on 'Save and Post'
16	**Attach one label on the entitlement card and another on the prescription**
17	**Are the medicines out-of-stock (OOS)?** A list of OOS medicines can be accessed on: deputyprimeminister.gov.mt/en/cpsu/Pages/POYC-OOS.aspx If YES, go to **step 18**. If NO, go to **step 19**.
18	**Provide a form of written agreement of the item and quantity OOS between the pharmacist and the patient** OOS notification should be written at the time of medicine preparation
19	**Recheck the patient's name and ID number, and prescription** Check that the right medicine, the right dose and the right quantity, as prescribed, are dispensed

Step	Action
20	**Confirm the medicine and dosage regimen with the patient** Show the physical aesthetic of the box/es to the patient. In case of a change in brand (hence, a change in the box's colour and shape), inform the patient
21	**Sign both labels and ask the patient, or patient representative, to sign both labels**
22	**Inform patient on next POYC medicine pick-up date** Inform the patient verbally or in a written format of the date 8 weeks following the dispensing of POYC medicines

6. Precautions

6.1 Deal with patients one by one

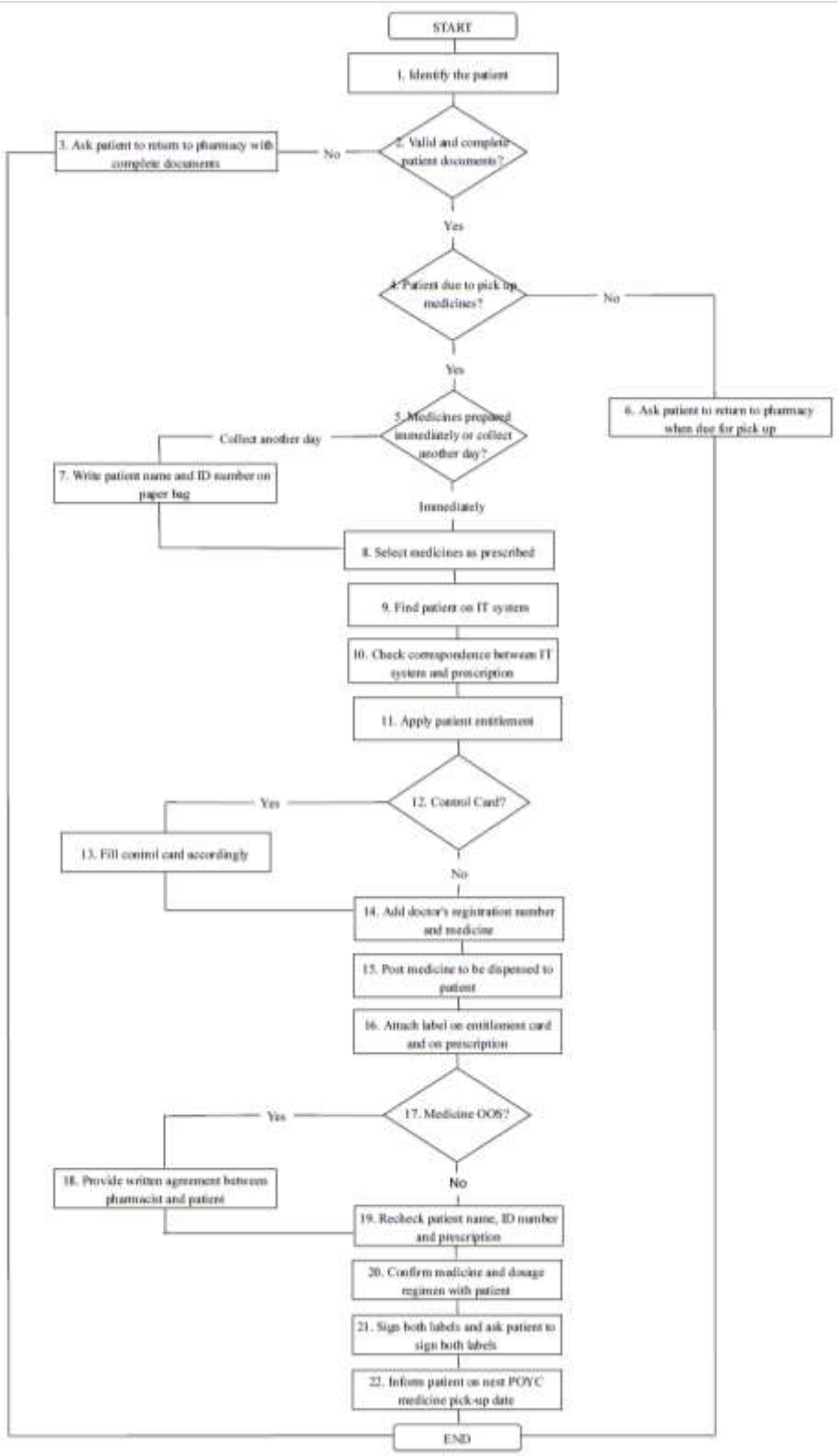
6.2 Keep a tidy and clear work station

6.3 Prepare POYC medicines in a quiet room or within an area in the pharmacy where interruptions and distractions are limited

6.4 Store Sound-Alike/Look-Alike drugs far apart or use dividers to separate them

6.5 Use a dedicated space or room when dispensing POYC medicines to counsel patients in private

7. Process flow chart



8. References

United States Environmental Protection Agency. Guidance for Preparing Standard Operating Procedures (SOPs) [Internet]. Washington: USEPA Office of Environmental Information; 2007 [cited 2020 Apr 14]. Available from: https://www.epa.gov/sites/production/files/2015-06/documents/ g6-final.pdf

9. Appendices

Appendix 1: Read and Understood Form

Appendix 2: Points of Distribution

10. Revision History

Version Number	**Amendments/Reason for change**
01	New

Appendix 1: Read and Understood Form

I have read SOP No. SOP/PDM/001 and understood it.

Full name	Signature	Date

Appendix 2: Points of Distribution

Place of Distribution	**Name**	**Signature**	**Date**

Standard Operating Procedure Evaluation Questionnaire

- My name is Emily Magro and I am currently reading for an undergraduate degree in Bachelor of Science (Honours) in Pharmaceutical Science at the University of Malta. As part of my research titled 'Risk-Based Processes in Pharmacy Practice', I am conducting a study to assess the risks associated with dispensing POYC medicines with the aim of establishing the best practice that presents the least risk for preparing and dispensing POYC medicines.
- The following questionnaire is to be filled in by the community pharmacist participating in the implementation of the standard operating procedure (SOP) for the preparation and dispensing of Pharmacy Of Your Choice (POYC) medicines. The questionnaire will take about 5 minutes to complete. The information gathered will remain strictly confidential and no information that allows you or the pharmacy to be identified will be shared.

Section I: Demographic Data

1. Age

o 21-30 years
o 31-40 years
o 41-50 years
o 51-60 years
o Over 60 years

2. Gender

o Male
o Female
o Other

3. What best describes your status as a pharmacist? *(you may tick more than one)*:

o Owner
o Managing pharmacist
o Employed full-time
o Employed part-time
o Locum

4. How many years of professional experience do you have?

o Less than 1 year
o 1-5 years
o 6-10 years
o 11-15 years
o 16-20 years
o More than 20 years

5. On average, how many hours per week do you spend dispensing POYC medicines?

o < 10 hours
o 11-20 hours
o 21-40 hours
o > 40 hours

Section II: SOP Evaluation

6. Please answer the following questions by ticking either 'yes', 'no' or 'maybe':

Question	Yes	No	Maybe
i. Did you understand that text as a whole?	☐	☐	☐
ii. Was the information clear and concise?	☐	☐	☐
iii. Does the SOP represent the content?	☐	☐	☐
iv. Was the SOP comprehensive enough to collect all the information needed to address its purpose?	☐	☐	☐
v. Was the language appropriate?	☐	☐	☐
vi. Was the step-by-step clearly organised?	☐	☐	☐
vii. Does the sequencing of the sections seem logical?	☐	☐	☐
viii. Could you fully perform the procedure?	☐	☐	☐
ix. Do you believe this SOP is useful?	☐	☐	☐

7. Were there any difficulties in understanding and following the SOP?
   - Yes
   - No *(skip question 7a and go to question 8)*

a. If yes, please state your difficulties:

_____
_____
_____
_____
_____

8. Were there any flaws in the SOP design?
   - Yes
   - No *(skip question 8a and go to question 9)*

a. If yes, please state where the flaws are:

_____
_____
_____
_____
_____

9. Would you include anything else in the SOP?
   - Yes
   - No *(skip question 9a and go to question 10)*

a. If yes, please state any other statements/sections that you think should be included:

_____
_____
_____
_____
_____

10. Are any of the statements unnecessary or repetitive?
    - Yes
    - No *(skip question 10a and go to question 11)*

a. If yes, please state which statements are unnecessary or repetitive:

_____
_____
_____
_____
_____

11. Do you have any other comments or suggestions for improvement for this SOP?
    - Yes
    - No *(skip question 11a and go to section III)*

a. Please state any other comments or suggestions for improvement you may have:

_____
_____
_____
_____
_____

Section III: Impact due to COVID-19

The following questions regard the temporary changes made to the system followed in preparing and dispensing POYC medicines to patients due to COVID-19:

12. Do you think that the changes implemented during COVID-19 outbreak were effective in order to limit rise in contamination from COVID-19 whilst also serving patients appropriately?
    - Yes *(skip question 12a and go to question 13)*
    - No

a. If no, please give a reason for your answer:

_____
_____
_____
_____
_____

13. Do you think that these changes have created new risks in the system?
    - Yes
    - No *(skip question 13a and go to question 14)*

a. If yes, please state the new risks that were created:

_____
_____
_____
_____
_____

14. Do you think any of these changes should be made permanent?
    - Yes *(answer question 14a and then go to question 15)*
    - No *(answer question 14b and then go to question 15)*

a. If yes, please state which changes should be made permanent and why:

_____
_____
_____
_____
_____

b. If no, please give a reason for your answer:

_____
_____
_____
_____
_____

15. Do you prefer the new system instead of the old one?
    - Yes
    - No

a. Please give a reason for your answer:

_____
_____
_____
_____
_____

END OF QUESTIONNAIRE
Thank you for your contribution to this study!

Standard Operating Procedure Implementation Study - Informed Consent Form for Participating Community Pharmacists

Introduction: My name is Emily Magro and I am currently reading for an undergraduate degree in Bachelor of Science (Honours) in Pharmaceutical Science at the University of Malta. As part of my research titled 'Risk-Based Processes in Pharmacy Practice', I am conducting a study to assess the risks associated with dispensing POYC medicines with the aim of establishing the best practice that presents the least risk for preparing and dispensing POYC medicines.

Aims of Research: The aims of this research are to identify the processes involved in dispensing POYC medicines, determine the risks associated with these processes, identify interventions for risk mitigation, and establish the best practice that presents the least risk for dispensing POYC medicines.

Participation: Your participation is completely voluntary. The choice you make on whether to participate or not will have no bearing on your job or any work-related evaluations. Should you wish to stop participating in the study, you can do so by advising the researcher.

Procedure: The principal investigator will give you a standard operating procedure, which was written by the investigator herself, for the preparation and dispensing of POYC medicines. The investigator will ask you to implement this written document during your time in the pharmacy and refer to it whenever you are to perform the task. After two weeks, the investigator will then ask you to complete an evaluation questionnaire to assess your perception of the SOP.

Confidentiality: The information gathered will remain strictly confidential and no information that allows you or the pharmacy to be identified will be shared. Your responses will remain anonymous and private.

Contact Information: If you have any questions, you can ask them now or later by contacting me, Emily Magro, via email (emily.magro.16@um.edu.mt) or phone (99914798), or my project supervisor, Prof. Anthony Serracino Inglott, via email (anthony.serracino-inglott@um.edu.mt).

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

Consent: I confirm that I have read the information presented above. I have had the opportunity to ask questions related to the study and any questions that have been asked were answered to my satisfaction. With full knowledge of the above and under no obligation to participate, I consent to voluntary participation in this study.

Participant's Name
_____

Name of Pharmacy
_____

Participant's Signature Date _____

_____

Principal Investigator's Signature Date _____

_____

Appendix 3

Project Overview and Validation Panel Demographics

Project Overview

Risk-Based Processes in Pharmacy Practice

Emily Magro

Bachelor of Science (Honours) in Pharmaceutical Science Student

Background

Risk can be defined as the uncertainty of an undesired event taking place. The dispensing process is at risk of error if proper dispensing guidelines are not adhered to since dispensing is a complex process than merely supplying the medication on the patient's prescription. Errors in dispensing by pharmacists, being one main cause of preventable adverse effects, may ultimately lead to patient harm.

Aims

The aims of this research are to:

i. Identify the processes involved in dispensing POYC medicine
ii. Determine the risks associated with these processes
iii. Identify interventions for risk mitigation
iv. Establish the best practice that presents the least risk for dispensing POYC medicines

Objectives

A mixed method approach, including qualitative and quantitative research methods, is adopted for this study. The objectives are:

i. Conduction of a small-scale observation study in 4 community pharmacies, selected by convenience sampling, to identify the processes involved in dispensing POYC medication and any associated risks through observation. This also serves as a pilot study to evaluate the feasibility of a community pharmacy survey data sheet for dispensing POYC medicine and improve the study design prior to conducting the research on a full-scale.
ii. Organisation of an expert focus group to validate the risks identified in the system followed when dispensing POYC medicine. The experts are asked whether they agree with the risks identified and whether there are any other risks involved which were not

mentioned in order to identify experts' opinions on the risks in POYC medicine dispensing processes identified through observation studies. The expert panel, consisting of 3 community pharmacists and 1 physician, will scrutinise the list of risks identified, and their possible causes and consequences.

iii. Development of a survey data sheet for dispensing POYC medicine, which will be used by the researcher during the full-scale observation studies in community pharmacies to identify the actual practices for dispensing POYC medicine. A questionnaire is also developed, which is directed towards the community pharmacists on duty at the time of the observation study. Questions on demographic data, risk involved in the system followed when dispensing POYC medicine and their perception on risk and risk mitigation strategies are asked.

iv. Organisation of a second expert focus group to validate the survey data sheet for dispensing POYC medicine and the questionnaire directed towards the community pharmacist on duty at the time of the observation study, which are assessed for face and content validity by an expert panel, consisting of 2 community pharmacists, 2 physicians and 1 layperson, each of which will be asked the same set of questions and scrutinise the 2 documents.

v. Conduction of full-scale observation studies in community pharmacies. Eight community pharmacies are selected from each of the 5 statistical districts in Malta via random sampling. The pharmacist on duty is approached by the researcher and information on the nature of the study is presented orally and in a written form via the informed consent form, which they are required to sign if they agree to participate. The first 5 POYC prescriptions dispensed by the pharmacist on duty at the start of the study are observed to evaluate the dispensing process and complete the survey data sheet. The observation study in each pharmacy takes about 3 hours and is conducted once in each pharmacy. The questionnaire is handed to the community pharmacist on duty, which they are asked to fill during the observation study.

Validation Panel Demographics

1. Age

o 21-30 years old
o 31-40 years old
o 41-50 years old
o 51-60 years old
o Over 60 years old

2. Gender

o Male
o Female
o Other

3. Years of professional experience

o 1-5 years
o 6-10 years
o 11-15 years
o 16-20 years
o More than 20 years

4. Occupation

o Community pharmacist *(go to question 5)*
o Physician *(go to question 6)*
o Academic *(please state your department)*: _____
o Layperson *(please state your occupation)*: _____

5. Please specify your status *(you may tick more than one)*:

o Owner
o Managing pharmacist
o Employed full-time
o Employed part-time
o Locum

6. Please state your:
   a. Speciality: -
   _____
   b. Place of practice *(you may tick more than one)*:

o Public hospital *(please specify)*: _____
o Private hospital
o Private practice in clinic/pharmacy *(please state in how many)*: _____

Appendix 4

Ethics Approval

No Objection Certificate

This certificate is presented to claim no objection on Emily Magro, a student at the University of Malta reading for an undergraduate degree in Bachelor of Science (Honours) in Pharmaceutical Science, to carry out a research titled 'Risk-Based Processes in Pharmacy Practice' as part of the course requirements.

I am aware that this research involves the conduction of a study in the form of observation studies in community pharmacies in Malta and questionnaires directed towards community pharmacists to assess the risks associated with dispensing POYC medications.

Name: _____

Position: _____

Signature: _____

Date: _____

Community Pharmacy Observation Study - Informed Consent Form for Managing Pharmacists

Introduction: My name is Emily Magro and I am currently reading for an undergraduate degree in Bachelor of Science (Honours) in Pharmaceutical Science at the University of Malta. As part of my research titled 'Risk-Based Processes in Pharmacy Practice', I am conducting a study, in the form of questionnaires and observation studies, to assess risks associated with dispensing POYC medicines.

Aims of Research: The aims of this research are to identify the processes involved in dispensing POYC medicines, determine the risks associated with these processes, identify interventions for risk mitigation, and establish the best practice that presents the least risk for dispensing POYC medicines.

Participation: Your participation is completely voluntary. The choice you make on whether to participate or not will have no bearing on your job or on any work-related evaluations. Should you wish to stop participating in the study, you can do so by advising the researcher.

Procedure: The principal investigator will visit the community pharmacy once and will conduct an observation study, where the researcher will observe the pharmacist on duty dispensing POYC medicines for approximately three hours. The pharmacist will be handed a questionnaire to fill in during the observation. The researcher will not interfere with the dispensing process at any stage. Data will be collected using a survey data sheet developed by the principal investigator.

Confidentiality: The information gathered will remain strictly confidential and no information that allows you, the pharmacy or the patient to be identified will be shared. Your responses will remain anonymous and private. The patient is reassured that they have a right to refuse the researcher to observe their medicine being dispensing and that their privacy is protected.

Contact Information: If you have any questions, you can ask them now or later by contacting me, Emily Magro, via email (emily.magro.16@um.edu.mt) or phone (99914798), or my project supervisor, Prof. Anthony Serracino Inglott, via email (anthony.serracino-inglott@um.edu.mt).

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

Consent: I confirm that I have read the information presented above. I have had the opportunity to ask questions related to the study and any questions that have been asked were answered to my satisfaction. With full knowledge of the above and under no obligation to participate, I consent to voluntary participation in this study.

Participant's Name
_____

Name of Pharmacy
_____

Participant's Signature Date _____

_____

Principal Investigator's Signature Date _____

_____

Request for Ethics Approval (Online Form Application)

UNIQUE FORM ID: 1576_29042019_Emily Magro
No self-assessment issues ticked. Submitting to FREC for records.

L-Università ta' Malta

ETHICS & DATA PROTECTION

PART 1: APPLICANT AND PROJECT DETAILS

1. Name and surname: Emily Magro
2. Applicant status: UM student
3. Faculty: Medicine and Surgery
4. Department: Department of Pharmacy

If applicable

5. Principal supervisor's name: Prof. Anthony Serracino Inglott
6. Co-supervisor's name: Dr Maresca Attard Pizzuto
7. Study-unit code: PHR 3116
8. Student number: 0255298M

9. Title of research project: Risk-Based Processes in Pharmacy Practice
10. Research question/statement & method: Risk can be defined as the uncertainty of an undesired event taking place. The dispensing process is at risk of error if proper dispensing guidelines are not adhered to since dispensing is a complex process than merely supplying the medication on the patient's prescription. Errors in dispensing by pharmacists, being one main cause of preventable adverse effects, may ultimately lead to patient harm. The aims of this research are to identify the processes involved in dispensing POYC medicine, determine the risks associated with the processes identified, identify interventions for risk mitigation and establish the best practice that presents the least risk for dispensing POYC medicines. This will be achieved via observation studies performed in community pharmacies to develop a flow chart of the system followed in dispensing POYC medicine and identify the risks associated with the systematic process. A questionnaire and a survey data sheet are then developed. The survey data sheet is used by the researcher during observation studies carried out in community pharmacies in Malta to evaluate the dispensing process of POYC medicines. The questionnaire is directed towards the community pharmacists on duty during the observation studies. The time taken for pharmacists to perform different processes

involved in dispensing POYC medicines will be recorded in each randomly selected community pharmacy, while the time taken to prepare a POYC medicine prescription is recorded in three of the randomly selected community pharmacies selected.

11. Collection of primary data from human participants?

Yes/Unsure (PLEASE ANSWER NEXT QUESTION)

12. If applicable, explain: a. A maximum of forty community pharmacists will be involved.

b. Eight community pharmacies from each of the five statistical districts in Malta are selected by random sampling (forty community pharmacies in total) and the pharmacist on duty at the time of the observation study is personally approached by the researcher.

ci. The researcher will observe the pharmacist during the process of dispensing POYC medicines.

ii. The researcher will distribute a questionnaire to the pharmacist on duty to fill during the observation, which will take about ten minutes to answer.

d. Approximately three hours per community pharmacy.

e. The community pharmacist will be offered no inducements, no rewards and no compensation for their contribution to this study (participation is completely voluntary).

f. There will be no direct benefit to the pharmacists, but their participation will help in understanding more about risk factors contributing to the occurrence of errors in the POYC medicine dispensing process and identifying interventions for risk mitigation to establish best practices.

PART 2: SELF-ASSESSMENT

Human Participants

1. Risk of harm to participants:
2. Physical intervention:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (SCPD):
6. Human tissue/samples:
7. Withheld info assent/consent:
8. Opt-out at consent/assent:
9. Deception in data generation:
10. Incidental findings:

Unpublished secondary data

11. Was the data collected from human participants?
12. Was the data collected from animals?
13. Is written permission from the data controller still to be obtained?

Animals

14. Live animals out of habitat:
15. Live animals, risk of harm:
16. Dead animals, illegal:

General considerations

17. Cooperating institution:
18. Risk to researcher/s:
19. Risk to environment:
20. Commercial sensitivity
21. Other potential risks:

Self-assessment outcome: No self-assessment issues ticked. Submitting to FREC for records.

PART 3: DETAILED ASSESSMENT

1. Risk of harm to participants:
2. Physical intervention on participants:
3. Vulnerable participants:
4. Identifiable participants:
5. Special Categories of Personal Data (sensitive personal data):
6. Collection of human tissue/samples:
7. Withholding information at consent/assent:
8. Opt-out at consent/assent:
9. Deception in data generation:
10. Incidental findings:
11. Unpublished secondary data - human participants:
12. Unpublished secondary data - animals:
13. Unpublished secondary data - no written permission from data controller:
14. Lasting harm to animals out of natural habitat:
15. Risk of harm to live animals:
16. Use of non legal animals/tissue:
17. Permission from cooperating institution:
18. Risk to researcher/team:

19. Risk of harm to environment:
20. Commercial sensitivity:
21. Other issues
    21a. Dual use and/or misuse:
    21b. Conflict of Interest:
    21c. Dual role:
    21d. Use research tools:
    21e. Collaboration/data/material collection in low/lower-middle income country:
    21f. Import/export of records/data/materials/specimens:
    21g. Harvest of data from social media:
    21h. Other considerations:

PART 4: SUBMISSION

1. Which FREC are you submitting to?: Medicine and Surgery
2. Attachments: Information and recruitment letter*, Consent forms (adult participants) *
3. Cover note for FREC: The following four documents are also included: project proposal, survey data sheet for dispensing POYC medicine, questionnaire directed towards community pharmacists on duty and time-motion study form for three community pharmacies (please note that the information and recruitment letter, and consent form are combined into a one-page document named 'Informed Consent form').
4. Declarations: I hereby confirm having read the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures., I hereby confirm that the answers to the questions above reflect the contents of the research proposal and that the information provided above is truthful., I hereby give consent to the University Research Ethics Committee to process my personal data for the purpose of evaluating my request, audit and other matters related to this application. I understand that I have a right of access to my personal data and to obtain the rectification, erasure or restriction of processing in accordance with data protection law and in particular the General Data Protection Regulation (EU 2016/679, repealing Directive 95/46/EC) and national legislation that implements and further specifies the relevant provisions of said Regulation.
5. Applicant Signature: Emily Magro
6. Date of submission: 29042019
7. If applicable data collection start date: 26062019
8. E-mail address (Applicant): emily.magro.16@um.edu.mt
9. E-mail address (Principal supervisor): anthony.serracino-inglott@um.edu.mt
10. Conclude: Proceed to Submission

Ethics Approval Letter

L-Università ta' Malta

Faculty of
Medicine & Surgery
University of Malta
Msida MSD 2080, Malta

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

www.um.edu.mt/ms

Ref No: **FRECMDS_1819_064**

Tuesday 18th June 2019

Ms Emily Magro
14, "Applegarth",
Triq il-Ħuttaf,
Mosta,
MST 4600.

Dear Ms Emily Magro,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Risk-Based Processes in Pharmacy Practice

The Faculty Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Professor Pierre Mallia
Chairman
Research Ethics Committee

FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt>
Wed 23/12/2020 08:21

To: Emily Magro

Dear Ms Magro,

Since your UREC application is for records FREC does not issue a letter of approval.

Ruth Stivala | Secretary
B.A.(Hons)(Melit.),M.A.(Melit.)

Faculty Research Ethics Committee
Faculty of Medicine and Surgery
Medical School, Mater Dei Hospital
+356 2340 1214

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

On Tue, 22 Dec 2020 at 15:58, Emily Magro <emily.magro.16@um.edu.mt> wrote:

> Dear Ms Stivala,
>
> Thank you for your reply.
>
> Will a new Ethics approval letter be issued with the updated title? Or can I use the one issued previously with the old title in my dissertation?
>
> Thank you and kind regards,
>
> Emily Magro
>
> ---
>
> **From:** FACULTY RESEARCH ETHICS COMMITTEE <research-ethics.ms@um.edu.mt>
> **Sent:** Tuesday, December 22, 2020 3:35:49 PM
> **To:** Emily Magro <emily.magro.16@um.edu.mt>
> **Subject:** FRECMDS_2021_037 - FOR RECORDS
>
> Dear Ms Magro,
>
> 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 and that of your supervisor.
>
> 
>
> **Ruth Stivala** | Secretary
> B.A.(Hons)(Melit.),M.A.(Melit.)
>
> **Faculty Research Ethics Committee**
> Faculty of Medicine and Surgery
> Medical School, Mater Dei Hospital
> +356 2340 1214
>
> https://www.um.edu.mt/ms/students/researchethics

Project Proposal

The study identifies the processes involved in dispensing POYC medicine, determines the risks associated with these processes and identifies interventions for risk mitigation via observation studies in community pharmacies in Malta and questionnaires addressed to community pharmacists on duty during observation. The time taken to prepare POYC prescriptions is also recorded. Focus groups are organised to validate the survey data sheet, questionnaire and time-motion study form.

Project Protocol

Background

Risk can be defined as the uncertainty of an undesired event taking place (Jaafari, 2007). The dispensing process is at risk of error if proper dispensing guidelines are not adhered to since dispensing is a complex process than merely supplying the medication on the patient's prescription (Kelly, 2012). Errors in dispensing by pharmacists, being one main cause of preventable adverse effects, may ultimately lead to patient harm (Perwitasari et al, 2010).

Aims

The aims of this research are to:

i. Identify the processes involved in dispensing POYC medicine
ii. Determine the risks associated with these processes
iii. Identify interventions for risk mitigation
iv. Establish the best practice that presents the least risk for dispensing POYC medicines

Materials and Methods

A small-scale observation study is conducted in four community pharmacies (three independent and one group pharmacies), which are selected by convenience sampling, to identify the processes involved in dispensing POYC medication and any associated risks through observation. A flow chart of the system followed in dispensing POYC medicines is developed. This also serves as a pilot study to evaluate the feasibility of a community pharmacy survey data sheet for dispensing POYC medications and improve the study design prior to conducting the research on a full-scale. The flow chart is validated by the POYC Chief Executive Officer.

An expert focus group is organised to validate the risks identified in the system followed when dispensing POYC medicines. The experts are asked whether they agree with the risks, causes and effects identified, and whether there are any other risks involved which were not mentioned or any they would omit, in order to identify experts' opinions on the risks in POYC medication dispensing processes through observation studies. The expert panel, consisting of three community pharmacists, one physician and the POYC

Chief Executive Officer, are asked to scrutinise the list of risks identified, and their possible causes and consequences.

The following documents are developed:

- A survey data sheet for dispensing POYC medications, which is used by the researcher during the full-scale observation studies in community pharmacies to identify the actual practices for dispensing POYC medicines.
- A questionnaire, which is directed towards the community pharmacists on duty at the time of the observation study. Questions on demographic data, risk involved in the system followed when dispensing POYC medicines and their perception on risk and risk mitigation strategies are asked.
- A time-motion study form, which is used by the researcher to record the time taken for POYC prescriptions to be prepared, which is used in three of the randomly selected community pharmacies.
- An informed consent form, which community pharmacists on duty at the time of the observation study are required to sign if they agree to participate.

A second expert focus group is organised to validate the survey data sheet for dispensing POYC medications, the questionnaire directed towards the community pharmacist on duty at the time of the observation study and the time-motion study form, which are assessed for face and content validity by an expert panel, consisting of two pharmacists, two physicians and one layperson, each of which will be asked the same set of questions and scrutinise the three documents. The layperson is also asked to validate the informed consent form.

Full-scale observation studies in community pharmacies are conducted. Eight community pharmacies are selected from each of the five statistical districts in Malta via random sampling. The pharmacist on duty is approached by the researcher and information on the nature of the study is presented orally and in a written form via the informed consent form, which they are required to sign if they agree to participate. The first five POYC prescriptions dispensed by the pharmacist on duty at the start of the study are observed to evaluate the dispensing process and complete the survey data sheet. The observation study in each pharmacy takes about three hours and is conducted once in each pharmacy. The questionnaire is handed to the community pharmacist on duty, which they are asked to fill during the observation study.

Statistical Methods

The scores of all dispensing process procedures collected via the community pharmacy survey data sheet for dispensing prescriptions of each pharmacy are inputted in Microsoft® Excel® 2016 (Microsoft Corporation, Redmond, Washington) and the mean score of each procedure is calculated.

Statistical analysis of the data is performed using IBM Statistical Package for the Social Sciences® (SPSS) version 23.0 (IBM Corporation, Armonk, New York) using the following tools:

- **Descriptive Statistics**: Mean, Median, Mode, Standard deviation, Skewness, Kurtosis, Range, Minimum and Maximum.

- **Inferential Statistics**:

1. *Shapiro-Wilk Test*: To test the null hypothesis that the pharmacies follow a normal distribution when dispensing POYC prescriptions.
2. *Friedman Test*: To test the null hypothesis that the mean rating scores vary marginally between a number of related statements.
3. *Chi Square Test*: To test the null hypothesis that there is no significant difference between the two categorical variables (e.g. between the stated time taken by pharmacists and the time taken recorded during the observation studies to prepare, recheck and dispense POYC prescriptions, as well as to give advice to patients).

For all the tests, the null hypothesis is accepted if $p > 0.05$ level of significance and rejected if $p < 0.05$.

Discussion

Quality risk management begins with the identification of potential risk factors and collection of information on their possible negative impacts (Sax and Andersen, 2018). Validation of the dispensing process in community pharmacies can allow for a better understanding on why and how dispensing errors occur in order to safeguard patient safety and reliability of the health care system (Azzopardi, 2000). Through case studies, one can determine the risk involved in the dispensing process and identify best practices by community pharmacists to minimise the occurrence of future errors.

Costings

There are no costs associated with this research.

Time Plan

- **April 2019**: Pilot study in four community pharmacies to identify the processes involved in dispensing POYC medication and any associated risks through observation, as well as to evaluate the feasibility of a survey data sheet for dispensing prescriptions. Development of a questionnaire directed towards community pharmacists, a community pharmacy survey data sheet, a time-motion study form and an informed consent form. Organisation of an expert focus groups for the validation of the risks identified in the system followed when dispensing POYC medicines. Organisation of a second expert focus group for the validation of the documents developed.
- **May 2019**: Submission of Research Ethics form (for FREC records purposes only).
- **June – July 2019**: Conduction of full-scale observation studies research in community pharmacies in Malta.
- **August – September 2019**: Conduction of full-scale observation studies research in community pharmacies in Malta. Development and update of the project's literature review and methodology.
- **October – December 2019**: Analysis of results and further literature search.

Appendix 5

Validation changes made to the Data Collection Documents and the Standard Operating Procedure

Community Survey Data Sheet

Before Validation	Amendment	Reason for Amendment	After Validation
/	Insertion	The type of prescription may alter the system followed by the pharmacist in dispensing POYC medicines	Type of prescription: Repeat or New
Time taken to dispense POYC medicine to patient in minutes.	Insertion	The process of dispensing POYC medicines involves other activities than handing the medicines to the patient	Time taken (in minutes) to: · Recheck prescription and/or label with medicine(s) to be dispensed · Dispense POYC medicine(s) to patient · Give advice to patient
5. Pharmacist asks for the patient's ID card for identification by comparing the name and ID card number with those written on the bag.	Insertion	Some community pharmacies may work with a system where the patient is assigned a unique identification number which is used for the sole purpose of dispensing POYC medicines.	5. Pharmacist asks for the patient's ID card for identification by comparing the name and ID card number/patient number with those written on the bag.
7. Pharmacist checks that the medicines listed on Schedule V card correspond to the prescription.	Insertion	Pharmacists may confirm that the medicine(s) being dispensed correspond to those listed on the Schedule V card either by checking the prescription or the printed label.	7. Pharmacist checks that the medicine(s) listed on Schedule V card correspond to the prescription and/or label.
10a. Patient, or their representative, are asked to come back in a few days to collect the medicines.	Re-wording	Improvement of the flow of the sentence.	10a. Medicine(s) were ready to be collected in a few days after the patient, or patient representative, left the documents at the pharmacy and was asked to come back to collect the medicine(s)
10b. Patient, or their representative, are asked to wait a few minutes while their prescription is being prepared.	Re-wording	Improvement of the flow of the sentence.	10b. Medicine(s) were ready to be collected in a few minutes after the patient, or patient representative, handed the documents to the pharmacist and was asked to wait a few minutes while their prescription is being prepared.
11. Pharmacist compares medication selected with prescription to confirm that the correct product, dose and quantity are dispensed.	Insertion	Pharmacists may confirm that the medicine(s) dispensed match those on the Schedule V card by checking the prescription or the printed label.	11. Pharmacist compares medicine(s) selected with the prescription and/or label to confirm that the correct product(s), dose and quantity are dispensed.

Before Validation	Amendment	Reason for Amendment	After Validation
17a. Printed labels are signed by both the dispensing pharmacist and patient, or their representative, before the medicines are dispensed. b. Printed labels are signed by the dispensing pharmacist before the medicines are dispensed.	Insertion	Different pharmacies have their own way in which they utilise the printed labels.	17a. Printed labels are not signed. b. Printed labels are signed by both the dispensing pharmacist and patient, or patient representative. c. Printed labels are signed by the dispensing pharmacist. d. Printed labels are signed by the patient, or patient representative. e. Printed label on Schedule V is signed by pharmacist, and printed label on prescription is signed by patient, or patient representative. f. Printed label on Schedule V is signed by patient, or patient representative, and printed label on prescription is signed by pharmacist. g. Printed label on Schedule V is signed by pharmacist and patient, or patient representative, and printed label on prescription is not signed. h. Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist and patient, or patient representative. i. Printed label on Schedule V is not signed and printed label on prescription is signed by patient, or patient representative. j. Printed label on Schedule V is not signed and printed label on prescription is signed by pharmacist.
25. Pharmacist speaks calmly with the patient, or their representative.	Deletion	Repetition	/
27. Pharmacist reminds the patient, or their representative, of the date of the next pick up of medicines.	Insertion and re-structuring	The manner in which the pharmacist reminds the patient, or their representative, about the next pick-up date is important to identify.	26. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) in a written format). 27. Pharmacist reminds the patient, or patient representative, of the date for the following POYC medicine(s) pick-up (8 weeks) verbally.

Pharmacist Questionnaire

Section I

Before Validation	Amendment	Reason for Amendment	After Validation
The following questionnaire is to be filled in by the community pharmacist on duty during the observation study, the latter of which will be conducted once in each pharmacy to observe the pharmacist dispensing POYC medication for approximately three hours.	Re-structuring	Too long	The following questionnaire is to be filled in by the community pharmacist on duty during the observation study. The observation study will be conducted once in each pharmacy to observe the pharmacist dispensing POYC medication for approximately three hours.
4. How many years of professional experience do you have? ・ 1-5 years ・ 6-10 years ・ 11-15 years ・ 16-20 years ・ More than 20 years	Insertion	Pharmacists who have worked in a community pharmacy for less than one year are also included in the study.	4. How many years of professional experience do you have? ・ Less than 1 year ・ 1-5 years ・ 6-10 years ・ 11-15 years ・ 16-20 years ・ More than 20 years
8d. Giving advice to patient	Insertion and re-structuring	The time taken by the pharmacist to give advice to the patient varies substantially, depending on the type of prescription.	8d. Giving advice to patient for a repeat prescription 8e. Giving advice to patient for a new prescription

Section II

Before Validation	Amendment	Reason for Amendment	After Validation
9/10i. Insufficient time for dispensing (process is very time-consuming, sole pharmacist on duty or high prescription volume).	Insertion	Pharmacies can have few patients but still have a large number of medicines to dispense, or numerous patients but a small number of medicines to dispense.	9/10i. Insufficient time for dispensing (process is very time-consuming, sole pharmacist on duty or high prescription number and/or high medicine volume).
9/10ii. Incomplete/invalid patient documents (patient does not have all the documents required, documents are out-dated or discrepancies between Schedule V card and prescription).	Re-wording	Medicines listed on the prescription must correspond to the IT system as well, and not just the Schedule V card.	9/10ii. Incomplete/invalid patient documents (patient does not have all the documents required, documents are out-dated or discrepancies between entitlement and prescription).

Before Validation	Amendment	Reason for Amendment	After Validation
9/10viii. Unreliability of IT system (discrepancies between patient entitlement on the IT system and the Schedule V card, server problems or lack of updates and improvements, e.g. drug interactions and contra-indications checker for each medicine, of the IT system).	Re-wording	Sentence was unclear.	9/10viii. Unreliability of IT system (discrepancies between patient entitlement on the IT system and the Schedule V card, server problems or lack of updates and improvements of the IT system, e.g. the IT system does not allow checking of drug interactions and/or contra-indications for each medicine).
9/10xi. Locums having their own method of preparing and dispensing POYC medicines (lack of continuity as a result of the different methods of dispensing by different locums working at the pharmacy).	Insertion	All pharmacists, including those employed on a part-time and full-time basis, must be taken into consideration.	9/10xi. Pharmacists/Locums having their own method of preparing and dispensing POYC medicines (lack of continuity as a result of the different methods of dispensing by different pharmacists/locums working at the pharmacy).
9/10xv. Lack of training (pharmacists are informed late or not at all about new POYC procedures, lack of educational seminars about dispensing POYC medicines or lack of training for pharmacy technicians in dispensing POYC medicines).	Re-wording	Improvement of the flow of the sentence.	9/10xv. Lack of training (pharmacists are informed late or not at all on new POYC protocols and insufficient educational seminars on dispensing POYC medicines and training for pharmacy technicians in preparing POYC medicines).
/	Insertion	The protocols issued by the POYC Unit may also be a source of risk.	9/10xviii. Complicated/Ambiguous POYC protocols (protocols can be too complex and/or unclear that they may be open to different interpretations e.g. pharmacists may not be sure whether a certain permit is sufficient or not).
11d. How are the risks mentioned being mitigated at the pharmacy?	Insertion and re-structuring	Even though there might be the presence of risk, the latter can either be addressed or left untreated.	11d. Are the risks mentioned being mitigated at the pharmacy? · Yes *(answer question I and then go to section III)* · No *(answer question ii and then go to section III)* i. If yes, how are they being mitigated? ii. If not, why are they not being mitigated?

Section III

Before Validation	Amendment	Reason for Amendment	After Validation
12xi. Prepare POYC medicines in a quiet room or area in the pharmacy to avoid interruptions and distractions by customers, telephone calls and broadcast devices.	Re-wording	Improvement of the flow of the sentence.	12xi. Prepare POYC medicines in a quiet room or within an area in the pharmacy where interruptions and distractions by customers, telephone calls and broadcast devices are limited.
/	Insertion	Another risk mitigation strategy was suggested.	12xvii. Organise additional routine check-ups with patients to discuss their medicines, dosage regimen and administration, etc.
/	Insertion	Another question was suggested.	14. Do you think there can be other risk mitigation strategies or improvements that can be implemented by the POYC Unit? · Yes · No *(end of questionnaire)* a. Please state any other risk mitigation strategies or improvements that can be implemented by the POYC Unit.

Time-Motion Study Form

Before Validation	Amendment	Reason for Amendment	After Validation
/	Insertion	This will aid the investigator during the actual observation study to make sure that only those processes are included in the number of minutes recorded.	The number of minutes recorded includes the time taken to: ・ Contact the POYC Unit, or whoever must be contacted in case of a POYC or patient-related problem in the patient's documents (respectively) ・ Select the medicine(s) and quantity prescribed ・ Scan the POYC card ・ Record medicine(s) on the IT system ・ Write the patient's name and ID number/patient number on the paper bag ・ Print and sign the labels ・ Fill the control card (if applicable)
/	Insertion	The time taken to prepare the POYC prescription may vary depending on whether the prescription being prepared is repeat or new.	Type of Prescription: Repeat or New

Standard Operating Procedure

Before Validation	Amendment	Reason for Amendment	After Validation
2. This SOP applies to the managing pharmacist or his/her designate/s at X Pharmacy, providing POYC services to entitled patients registered with the said pharmacy.	Insertion and re-structuring	A more detailed purpose for the SOP is given.	2. The purpose of this SOP is to outline the procedure for the accepting of prescription/s, the preparation of the POYC scheme medicines, inputting into the POYC database, and the dispensing of the POYC scheme medicines to the patient or their representative by the managing pharmacist or designate pharmacist/s at X Pharmacy.
3. The managing pharmacist or his/her designate/s at X Pharmacy providing POYC services to entitled patients is responsible for the execution of this SOP, having read and understood the procedure beforehand.	Insertion and re-structuring	A clearer indication of the responsibilities of the pharmacist should be provided.	3. The managing pharmacist or designate pharmacist/s at X Pharmacy providing POYC services to entitled patients is responsible for the execution of this SOP throughout the whole process of preparation and supply of the POYC scheme medicines, having read and understood the procedure beforehand.
4.1 Document issued by the consultant doctor specifying the treatment that the patient is entitled to for their condition	Insertion and re-structuring	A more detailed definition is required, also including the different forms that pharmacists could be presented with.	4.1 A special document or permit, also known as the "To whom it may concern" note, issued by the consultant doctor specifying the medication and dosage regimen that the patient is entitled to for their condition in the case of a "Treatment as prescribed" clause on the patient's entitlement card; includes forms DH75 (psychiatric treatment), DH1034 (oncology treatment), DH1020 (dermatology treatment), SLH145 (Schedule II), EMTRF (exceptional patient medication treatment) or CPSU permit (equipment including syringes, catheters, catheter bags, etc.)
4.2 Also known as the Dangerous Drug Card, or White Card, used by medical practitioners and pharmacists to register the amount of dangerous drugs of abuse prescribed and dispensed	Insertion and re-structuring	The inclusion of the subsidiary legislation with regards to the regulation of controlled drugs makes the definition more legitimate and complete.	4.2 Also known as the Dangerous Drug Card, or White Card. As per Subsidiary Legislation 31.18, a control card is used by medical practitioners and pharmacists to register the amount of narcotic and psychotropic drugs prescribed and dispensed respectively. The control card is required for medicines listed in the Dangerous Drugs Ordinance (Chapter 101) and Drugs (Control) Regulation (Subsidiary Legislation 31.18)

Before Validation	Amendment	Reason for Amendment	After Validation
4.4 Schedule V (yellow) or Schedule II (pink) cards that contain information on the patient and their entitlement to free medication	Inclusion	Including the type of information available on the entitlement card makes it easier to identify.	4.4 Schedule V (yellow) or Schedule II (pink) cards that contain personal information of the patient (namely ID card number and address) and a list of medications which they are entitled for in the POYC Scheme
4.8 The Pharmacy Of Your Choice medicines as dispensed by X Pharmacy	Re-wording	Definition was unclear.	4.8 Medicines that patients are entitled to take for free as part of the POYC Scheme
4.10 Special doctor's prescription, which is either green for controlled drugs (valid for one month) or white for non-controlled drugs (valid for two months), used by medical practitioners to prescribe POYC medicine to patient	Insertion and re-structuring	Definition lacked detail.	4.10 Special doctor's prescription, which is either green for narcotic and psychotropic drugs (valid for one month) or white for non-controlled drugs (valid for two months), used by medical practitioners to prescribe POYC medicine to patient. The use of a prescription form is covered by the Prescription Forms for Free Medicinals Rules (Subsidiary Regulation 458.24)
4.12 Document containing QR code for single use of POYC medicine dispensing and pick-up	Deletion	Vouchers have long been obsolete and are all expired.	/
5. (step 2) **Are the patient's documents valid and complete?** Patient documents include Schedule II and/or Schedule V card, prescription for free drugs, POYC scheme card or vouchers, and any relevant permits, consultant form and/or control card	Insertion	All possible patient documents should be included.	5. (step 2) **Are the patient's documents valid and complete?** Patient documents include Schedule II and/or Schedule V card, prescription for free drugs, prescription for narcotic and psychotropic drugs (if applicable) and any relevant permit/s, POYC scheme card consultant form/s and/or control card (if available)
5. (step 3) **Ask the patient to return to the pharmacy with complete documents** Patient may be required to go to POYC Unit to sort out documents	Insertion	A more detailed explanation should be given.	5. (step 3) **Ask the patient to return to the pharmacy with complete documents** If any of the required documents are expired, the patient needs to meet up with the relative consultant for renewal. If any of the required documents is lost, the patient may be required to call the POYC Unit or Schedule V office to have the documents sent by post, or personally go to the POYC Unit or Schedule V office to sort out documents. X Pharmacy may also call on behalf of the patient.

Before Validation	Amendment	Reason for Amendment	After Validation
/	Insertion	An additional step should be performed before preparing the medicines.	5. (step 4) **Check if the patient is due to pick up the POYC medicines** If the medicine needs to be prepared immediately, accept the patient's documents no earlier than 55 days after the last consignment. If the medicines cannot be prepared immediately, accept the patient's documents no earlier than 45 days after the last consignment.
/	Insertion	Addendum to the newly added step 4.	5. (step 6) **Ask the patient to return to pharmacy when they are due to pick up their medicines**
5. (step 7) **Are the medicines out-of-stock (OOS)?** A list of OOS medicine can be accessed on: deputyprimeminister.gov.mt/en/cpsu/Pages/POYC-OOS.aspx	Re-structuring	This step should be performed at the time of dispensing.	5. (step 17) **Are the medicines out-of-stock (OOS)?** A list of OOS medicines can be accessed on: deputyprimeminister.gov.mt/en/cpsu/Pages/POYC-OOS.aspx
5. (step 8) **Record OOS medicine on an out-of-stock sheet and give it to the patient**	Re-wording	There is no official OOS sheet provided by the POYC Unit.	5. (step 18) **Provide a form of written agreement of the item and quantity OOS between the pharmacist and the patient** OOS notification should be written at the time of medicine preparation
/	Insertion	Any changes must be made before clicking 'Apply Entitlement', otherwise the process must be restarted.	5. (step 10) **Check that the items, doses and regimen on the IT system database correspond with the prescription** Make any required modifications to the patient entitlement on the database by clicking on 'New', inputting the doctor's registration number, using the drop-down arrow to find and select the new medication or new dose, entering the quantity for one month, then clicking 'OK'. Previous entitlement can be removed by right clicking on it and selecting 'Delete'. A copy of the patient's entitlement should be sent to: entitlement.poyc@gov.mt. In the case of a new drug, call the Medicines Entitlement Unit on 21232424 or contact them via X Pharmacy's Skype.

Before Validation	Amendment	Reason for Amendment	After Validation
5. (step 14) **Is a control card available?**	Re-structuring	This step should be performed before clicking 'Save and Post'	5. (step 12) **Is a control card available?**
5. (step 17) **Confirm the medicine and dosage regimen with the patient**	Insertion	The patient is agreeing to what you are saying is written on the prescription and identify any disagreements.	5. (step 17) **Confirm the medicine and dosage regimen with the patient** Show the physical aesthetic of the box/es to the patient. In case of a change in brand (hence, a change in the box's colour and shape), inform the patient

Appendix 6

Results obtained from Observation Studies for Each Pharmacy

Results Obtained from Observation Studies Performed in District 1 Pharmacies

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Avg. no. of meds.		3.6	2.6	3.2	2.8	3	3	2.8	2.6
Type of Rx	**Repeat**	5	5	5	5	4	5	4	5
	New	0	0	0	0	1	0	1	0
Avg. time to recheck Rx (mins.)		1.6	2.2	1.5	2.2	2	1.4	2.2	0.9
Avg. time to dispense (mins.)		4	3.4	0.8	3.2	4.2	1.2	3.6	0.9
Avg. time to give advice (mins.)		3.4	3.8	1.4	2.2	5.2	0.4	3.8	1
Q1	**Yes**	5	5	4	3	3	5	5	5
	No	0	0	1	2	2	0	0	0
	NA	0	0	0	0	0	0	0	0
Q2	**Yes**	3	1	3	1	2	3	2	3
	No	2	4	2	4	3	2	3	2
	NA	0	0	0	0	0	0	0	0
Q3	**Yes**	3	3	2	1	1	3	2	3
	No	2	2	3	4	4	2	3	2
	NA	0	0	0	0	0	0	0	0
Q4	**Yes**	5	4	5	5	5	5	5	5
	No	0	1	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q5	**Yes**	0	0	0	0	1	1	0	0
	No	5	5	5	5	4	4	5	5
	NA	0	0	0	0	0	0	0	0
Q6	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q7	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q8	**Yes**	0	1	0	0	0	1	0	0
	No	0	0	0	0	0	0	0	0
	NA	5	4	5	5	5	4	5	5
Q9	**Yes**	5	5	5	5	5	2	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q10a	Yes	0	0	5	5	2	2	3	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q10b	Yes	5	5	0	0	3	0	2	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q11	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q12	Yes	0	0	0	0	4	0	0	0
	No	5	5	5	5	1	5	5	5
	NA	0	0	0	0	0	0	0	0
Q13	Yes	0	0	5	5	2	5	5	5
	No	5	5	0	0	3	0	0	0
	NA	0	0	0	0	0	0	0	0
Q14	Yes	0	0	5	5	2	5	5	5
	No	5	5	0	0	3	0	0	0
	NA	0	0	0	0	0	0	0	0
Q15	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q16	Yes	1	1	2	0	1	1	0	1
	No	0	0	0	0	0	0	0	0
	NA	4	4	3	5	4	4	5	4
Q17a	Yes	5	0	0	0	0	5	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17b	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17c	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17d	Yes	0	0	0	5	5	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17e	Yes	0	0	5	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17f	Yes	0	5	0	0	0	0	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17g	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q17h	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17i	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17j	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17k	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q18	Yes	5	5	4	4	5	2	5	1
	No	0	0	1	1	0	3	0	4
	NA	0	0	0	0	0	0	0	0
Q19	Yes	5	5	1	3	5	0	5	3
	No	0	0	4	2	0	5	0	2
	NA	0	0	0	0	0	0	0	0
Q20	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q21	Yes	2	0	0	0	2	1	1	0
	No	3	5	5	5	3	4	4	5
	NA	0	0	0	0	0	0	0	0
Q22	Yes	0	1	0	1	4	0	3	0
	No	5	4	5	4	1	5	2	5
	NA	0	0	0	0	0	0	0	0
Q23	Yes	4	3	3	3	3	0	5	4
	No	1	2	2	2	2	5	0	1
	NA	0	0	0	0	0	0	0	0
Q24	Yes	0	5	0	0	0	0	0	1
	No	5	0	5	5	5	5	5	4
	NA	0	0	0	0	0	0	0	0
Q25	Yes	1	1	1	0	2	0	1	0
	No	4	4	4	5	3	5	4	5
	NA	0	0	0	0	0	0	0	0
Q26	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q27	Yes	4	1	0	5	5	0	4	1
	No	1	4	5	0	0	5	1	4
	NA	0	0	0	0	0	0	0	0

Results Obtained from Observation Studies Performed in District 2 Pharmacies

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Avg. no. of meds.		2.8	2.8	4	3.8	4.4	2.8	2	3.8
Type of Rx	**Repeat**	5	5	5	5	5	5	5	5
	New	0	0	0	0	0	0	0	0
Avg. time to recheck Rx (mins.)		1.7	1.8	1.75	1.2	2	3.2	0.8	1.6
Avg. time to dispense (mins.)		1.6	2.2	1.75	1.6	3.8	4	0.9	1.6
Avg. time to give advice (mins.)		2	1.2	2.25	1	3.2	5.4	0.4	2.6
Q1	**Yes**	4	5	4	4	5	4	3	4
	No	1	0	1	1	0	1	2	1
	NA	0	0	0	0	0	0	0	0
Q2	**Yes**	2	1	4	4	4	1	1	2
	No	3	4	1	1	1	4	4	3
	NA	0	0	0	0	0	0	0	0
Q3	**Yes**	3	2	4	4	4	2	5	3
	No	2	3	1	1	1	3	0	2
	NA	0	0	0	0	0	0	0	0
Q4	**Yes**	5	5	5	5	5	5	3	5
	No	0	0	0	0	0	0	2	0
	NA	0	0	0	0	0	0	0	0
Q5	**Yes**	0	4	1	0	0	0	2	0
	No	5	1	4	5	5	5	3	5
	NA	0	0	0	0	0	0	0	0
Q6	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q7	**Yes**	5	5	5	5	5	5	0	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	5	0
Q8	**Yes**	1	1	0	1	2	0	5	1
	No	0	0	0	0	0	0	0	0
	NA	4	4	5	4	3	5	0	4
Q9	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q10a	Yes	5	5	5	5	4	0	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q10b	Yes	0	0	0	0	1	5	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q11	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q12	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q13	Yes	5	5	5	5	4	0	5	5
	No	0	0	0	0	1	5	0	0
	NA	0	0	0	0	0	0	0	0
Q14	Yes	5	5	5	5	4	0	5	5
	No	0	0	0	0	1	5	0	0
	NA	0	0	0	0	0	0	0	0
Q15	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q16	Yes	1	0	0	0	0	0	0	1
	No	0	0	0	0	0	0	0	0
	NA	4	5	5	5	5	5	5	4
Q17a	Yes	0	5	5	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17b	Yes	0	0	0	0	0	5	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17c	Yes	0	0	0	5	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17d	Yes	0	0	0	0	5	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17e	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17f	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17g	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q17h	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17i	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17j	Yes	5	0	0	0	0	0	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17k	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q18	Yes	5	4	5	5	5	5	5	5
	No	0	1	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q19	Yes	3	1	0	2	4	5	0	5
	No	2	4	5	3	1	0	5	0
	NA	0	0	0	0	0	0	0	0
Q20	Yes	0	0	0	0	0	1	0	0
	No	5	5	5	5	5	4	5	5
	NA	0	0	0	0	0	0	0	0
Q21	Yes	1	0	1	0	3	2	0	0
	No	4	5	4	5	2	3	5	5
	NA	0	0	0	0	0	0	0	0
Q22	Yes	0	0	5	0	3	5	0	1
	No	5	5	0	5	2	0	5	4
	NA	0	0	0	0	0	0	0	0
Q23	Yes	3	5	0	4	5	4	5	3
	No	2	0	5	1	0	1	0	2
	NA	0	0	0	0	0	0	0	0
Q24	Yes	0	0	0	0	0	5	0	0
	No	5	5	5	5	5	0	5	5
	NA	0	0	0	0	0	0	0	0
Q25	Yes	0	1	0	1	1	1	0	2
	No	5	4	5	4	4	4	5	3
	NA	0	0	0	0	0	0	0	0
Q26	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q27	Yes	4	5	1	2	5	5	5	4
	No	1	0	4	3	0	0	0	1
	NA	0	0	0	0	0	0	0	0

Results Obtained from Observation Studies Performed in District 3 Pharmacies

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Avg. no. of meds.		2.6	2.8	3.2	2.8	2.6	2.8	3.6	3.2
Type of Rx	**Repeat**	5	5	4	5	5	4	5	5
	New	0	0	1	0	0	1	0	0
Avg. time to recheck Rx (mins.)		1	2.4	2	1.4	2	1	2.2	1.1
Avg. time to dispense (mins.)		1.8	4.6	3.4	3	4.2	1.2	2.8	1.3
Avg. time to give advice (mins.)		0	4.2	4.2	4.4	6	1.6	3	1.6
Q1	**Yes**	4	5	5	4	5	4	5	4
	No	1	0	0	1	0	1	0	1
	NA	0	0	0	0	0	0	0	0
Q2	**Yes**	2	2	2	3	2	1	3	3
	No	3	3	3	2	3	4	2	2
	NA	0	0	0	0	0	0	0	0
Q3	**Yes**	3	3	2	4	2	1	5	1
	No	2	2	3	1	3	4	0	4
	NA	0	0	0	0	0	0	0	0
Q4	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q5	**Yes**	0	0	0	0	5	0	0	0
	No	5	5	5	5	0	5	5	5
	NA	0	0	0	0	0	0	0	0
Q6	**Yes**	5	5	5	5	5	0	5	5
	No	0	0	0	0	0	5	0	0
	NA	0	0	0	0	0	0	0	0
Q7	**Yes**	5	5	5	5	5	0	5	5
	No	0	0	0	0	0	5	0	0
	NA	0	0	0	0	0	0	0	0
Q8	**Yes**	0	1	0	0	1	0	0	1
	No	0	0	0	0	0	0	0	0
	NA	5	4	5	5	4	5	5	4
Q9	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q10a	Yes	0	2	4	5	0	5	3	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q10b	Yes	5	3	1	0	5	0	2	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q11	Yes	5	5	5	5	5	0	5	5
	No	0	0	0	0	0	5	0	0
	NA	0	0	0	0	0	0	0	0
Q12	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q13	Yes	0	2	4	5	0	5	3	5
	No	5	3	1	0	5	0	2	0
	NA	0	0	0	0	0	0	0	0
Q14	Yes	0	2	1	5	0	5	3	5
	No	5	3	4	0	5	0	2	0
	NA	0	0	0	0	0	0	0	0
Q15	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q16	Yes	0	2	0	0	1	0	0	1
	No	0	0	0	0	0	0	0	0
	NA	5	3	5	5	4	5	5	4
Q17a	Yes	5	0	0	0	0	5	5	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17b	Yes	0	0	0	0	0	0	0	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17c	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17d	Yes	0	0	5	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17e	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17f	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17g	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q17h	**Yes**	0	0	0	5	5	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17i	**Yes**	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17j	**Yes**	0	5	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17k	**Yes**	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q18	**Yes**	0	5	5	5	5	2	5	5
	No	5	0	0	0	0	3	0	0
	NA	0	0	0	0	0	0	0	0
Q19	**Yes**	0	5	5	5	5	2	2	1
	No	5	0	0	0	0	3	3	4
	NA	0	0	0	0	0	0	0	0
Q20	**Yes**	0	3	1	0	0	0	0	0
	No	5	2	4	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q21	**Yes**	0	1	1	0	0	0	1	1
	No	5	4	4	5	5	5	4	4
	NA	0	0	0	0	0	0	0	0
Q22	**Yes**	0	5	2	4	5	0	2	0
	No	5	0	3	1	0	5	3	5
	NA	0	0	0	0	0	0	0	0
Q23	**Yes**	1	5	3	5	5	1	5	2
	No	4	0	2	0	0	4	0	3
	NA	0	0	0	0	0	0	0	0
Q24	**Yes**	0	5	5	0	5	4	5	0
	No	5	0	0	5	0	1	0	5
	NA	0	0	0	0	0	0	0	0
Q25	**Yes**	0	5	1	4	4	0	2	0
	No	5	0	4	1	1	5	3	5
	NA	0	0	0	0	0	0	0	0
Q26	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q27	**Yes**	3	5	3	2	4	1	4	1
	No	2	0	2	3	1	4	1	4
	NA	0	0	0	0	0	0	0	0

Results Obtained from Observation Studies Performed in District 4 Pharmacies

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Avg. no. of meds.		3.6	3.2	3.6	1.8	3.2	2	3.2	2.4
Type of Rx	**Repeat**	5	5	5	5	5	5	5	5
	New	0	0	0	0	0	0	0	0
Avg. time to recheck Rx (mins.)		1.8	1.4	2.6	1.2	2.2	1.8	1.3	1
Avg. time to dispense (mins.)		4.2	2.4	2.8	1.6	3	2.8	1	2
Avg. time to give advice (mins.)		0	3.2	4.6	1.8	2.2	2	2.2	1
Q1	**Yes**	4	4	5	2	5	5	5	4
	No	1	1	0	3	0	0	0	1
	NA	0	0	0	0	0	0	0	0
Q2	**Yes**	5	3	4	4	3	1	3	3
	No	0	2	1	1	2	4	2	2
	NA	0	0	0	0	0	0	0	0
Q3	**Yes**	5	2	2	3	2	2	3	3
	No	0	3	3	2	3	3	2	2
	NA	0	0	0	0	0	0	0	0
Q4	**Yes**	5	5	5	5	5	5	5	4
	No	0	0	0	0	0	0	0	1
	NA	0	0	0	0	0	0	0	0
Q5	**Yes**	0	0	0	5	5	0	0	0
	No	5	5	5	0	0	5	5	5
	NA	0	0	0	0	0	0	0	0
Q6	**Yes**	5	5	5	1	5	5	5	5
	No	0	0	0	4	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q7	**Yes**	1	5	5	1	5	5	5	0
	No	4	0	0	4	0	0	0	5
	NA	0	0	0	0	0	0	0	0
Q8	**Yes**	0	1	2	0	1	0	1	0
	No	0	0	0	2	0	0	0	1
	NA	5	4	3	3	4	5	4	4
Q9	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q10a	Yes	2	5	5	4	5	1	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q10b	Yes	3	0	0	1	0	4	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q11	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q12	Yes	0	0	0	0	5	0	0	0
	No	5	5	5	5	0	5	5	5
	NA	0	0	0	0	0	0	0	0
Q13	Yes	2	5	5	4	5	1	5	5
	No	3	0	0	1	0	4	0	0
	NA	0	0	0	0	0	0	0	0
Q14	Yes	2	5	5	4	5	1	5	5
	No	3	0	0	1	0	4	0	0
	NA	0	0	0	0	0	0	0	0
Q15	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q16	Yes	0	0	0	0	1	0	1	0
	No	0	0	0	0	0	0	0	0
	NA	5	5	5	5	4	5	4	5
Q17a	Yes	5	5	0	0	5	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17b	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17c	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17d	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17e	Yes	0	0	0	0	0	0	5	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17f	Yes	0	0	0	0	0	0	0	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17g	Yes	0	0	5	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q17h	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17i	Yes	0	0	0	5	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17j	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17k	Yes	0	0	0	0	0	5	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q18	Yes	0	5	5	5	3	5	3	3
	No	5	0	0	0	2	0	2	2
	NA	0	0	0	0	0	0	0	0
Q19	Yes	0	5	5	5	3	5	2	3
	No	5	0	0	0	2	0	3	2
	NA	0	0	0	0	0	0	0	0
Q20	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q21	Yes	0	1	1	0	1	3	2	0
	No	5	4	4	5	4	2	3	5
	NA	0	0	0	0	0	0	0	0
Q22	Yes	0	0	5	1	0	0	2	0
	No	5	5	0	4	5	5	3	5
	NA	0	0	0	0	0	0	0	0
Q23	Yes	0	1	5	5	5	2	1	0
	No	5	4	0	0	0	3	4	5
	NA	0	0	0	0	0	0	0	0
Q24	Yes	0	0	0	5	0	0	0	5
	No	5	5	5	0	5	5	5	0
	NA	0	0	0	0	0	0	0	0
Q25	Yes	0	0	2	0	1	2	1	0
	No	5	5	3	5	4	3	4	5
	NA	0	0	0	0	0	0	0	0
Q26	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q27	Yes	0	2	5	1	4	3	2	1
	No	5	3	0	4	1	2	3	4
	NA	0	0	0	0	0	0	0	0

Results Obtained from Observation Studies Performed in District 5 Pharmacies

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Avg. no. of meds.		2.6	3	3.8	4	3.2	3	3	3.2
Type of Rx	**Repeat**	5	5	5	5	5	5	5	5
	New	0	0	0	0	0	0	0	0
Avg. time to recheck Rx (mins.)		1.8	2.6	1.8	3.8	2.8	3.8	2.6	2.8
Avg. time to dispense (mins.)		2.4	4	2.8	8	4	3.4	4.6	4
Avg. time to give advice (mins.)		3.4	4	2.4	5.4	3	3.6	2.6	4.8
Q1	**Yes**	5	3	5	5	5	5	5	5
	No	0	2	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q2	**Yes**	1	5	3	3	2	2	3	3
	No	4	0	2	2	3	3	2	2
	NA	0	0	0	0	0	0	0	0
Q3	**Yes**	1	2	3	3	2	2	3	3
	No	4	3	2	2	3	3	2	2
	NA	0	0	0	0	0	0	0	0
Q4	**Yes**	5	3	5	4	5	5	5	5
	No	0	2	0	1	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q5	**Yes**	0	0	5	0	4	0	0	1
	No	5	5	0	5	1	5	5	4
	NA	0	0	0	0	0	0	0	0
Q6	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q7	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q8	**Yes**	2	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	3	5	5	5	5	5	5	5
Q9	**Yes**	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q10a	Yes	0	4	5	5	5	4	4	4
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q10b	Yes	5	1	0	0	0	1	1	1
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q11	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q12	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q13	Yes	0	5	5	5	5	5	4	4
	No	5	0	0	0	0	0	1	1
	NA	0	0	0	0	0	0	0	0
Q14	Yes	0	0	5	5	5	5	4	4
	No	5	5	0	0	0	0	1	1
	NA	0	0	0	0	0	0	0	0
Q15	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q16	Yes	1	0	0	1	0	0	0	1
	No	0	0	0	0	0	0	0	0
	NA	4	5	5	4	5	5	5	4
Q17a	Yes	0	0	5	0	0	0	5	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17b	Yes	5	5	0	0	5	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17c	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17d	Yes	0	0	0	0	0	5	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17e	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17f	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17g	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0

		Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Q17h	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17i	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17j	Yes	0	0	0	5	0	0	0	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q17k	Yes	0	0	0	0	0	0	0	0
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q18	Yes	5	5	5	5	5	5	5	5
	No	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q19	Yes	5	4	4	5	5	5	5	5
	No	0	1	1	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0
Q20	Yes	0	0	0	0	0	0	0	0
	No	5	5	5	5	5	5	5	5
	NA	0	0	0	0	0	0	0	0
Q21	Yes	5	0	0	5	1	2	1	0
	No	0	5	5	0	4	3	4	5
	NA	0	0	0	0	0	0	0	0
Q22	Yes	4	0	0	5	4	5	1	1
	No	1	5	5	0	1	0	4	4
	NA	0	0	0	0	0	0	0	0
Q23	Yes	5	5	5	4	0	2	1	5
	No	0	0	0	1	5	3	4	0
	NA	0	0	0	0	0	0	0	0
Q24	Yes	0	0	0	0	1	5	0	0
	No	5	5	5	5	4	0	5	5
	NA	0	0	0	0	0	0	0	0
Q25	Yes	2	2	2	2	2	2	1	3
	No	3	3	3	3	3	3	4	2
	NA	0	0	0	0	0	0	0	0
Q26	Yes	5	5	5	5	5	5	4	5
	No	0	0	0	0	0	0	1	0
	NA	0	0	0	0	0	0	0	0
Q27	Yes	1	5	5	0	5	5	1	5
	No	4	0	0	5	0	0	4	0
	NA	0	0	0	0	0	0	0	0

Appendix 7

Risk Priority Numbers for Each Pharmacy

RPNs from PQs from District 1 Pharmacies

	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Qi	6	6	9	10	12	12	6	6
Qii	3	12	4	10	4	9	4	4
Qiii	6	1	8	8	12	16	20	9
Qiv	12	15	3	2	6	9	6	6
Qv	12	16	3	4	6	12	6	6
Qvi	3	6	12	5	8	12	6	8
Qvii	6	9	8	10	8	8	9	6
Qviii	4	12	3	4	2	12	6	6
Qix	4	4	4	1	9	9	9	2
Qx	5	15	1	4	10	4	6	6
Qxi	10	3	2	4	6	2	9	4
Qxii	4	3	4	5	5	6	16	4
Qxiii	20	12	10	6	12	16	6	6
Qxiv	12	4	6	2	9	12	4	4
Qv	15	5	2	2	6	12	9	6
Qvi	15	9	9	2	25	9	9	6
Qvii	4	6	4	2	4	12	16	1
Qxviii	4	9	2	4	16	16	9	4

RPNs from PQs from District 2 Pharmacies

	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Qi	12	9	6	8	4	2	12	9
Qii	3	6	16	6	12	8	15	16
Qiii	15	25	16	8	12	20	15	25
Qiv	3	12	3	9	2	1	3	9
Qv	5	10	3	6	6	2	5	6
Qvi	5	8	9	6	12	6	15	6
Qvii	15	16	12	6	3	6	16	12
Qviii	6	12	12	6	4	12	6	16
Qix	5	6	9	4	3	3	3	6
Qx	1	4	1	6	1	1	15	6
Qxi	1	9	3	2	4	1	16	8
Qxii	1	12	15	8	10	1	4	9
Qxiii	10	16	9	4	8	15	12	8
Qxiv	5	12	6	4	2	2	15	5
Qv	2	6	3	6	4	6	20	10
Qvi	1	4	9	6	8	15	20	12
Qvii	2	12	15	6	12	1	2	16
Qxviii	3	16	15	6	12	6	2	12

RPNs from PQs from District 3 Pharmacies

	Pharmacy 1	**Pharmacy 2**	**Pharmacy 3**	**Pharmacy 4**	**Pharmacy 5**	**Pharmacy 6**	**Pharmacy 7**	**Pharmacy 8**
Qi	10	6	16	15	12	9	6	12
Qii	10	12	9	8	9	9	16	16
Qiii	20	6	12	25	4	6	25	16
Qiv	16	3	4	3	8	6	20	8
Qv	12	4	8	1	3	4	20	4
Qvi	8	2	4	15	6	1	3	6
Qvii	9	4	5	9	6	9	25	9
Qviii	5	4	8	3	8	12	6	16
Qix	6	1	2	15	2	6	12	8
Qx	9	6	2	9	1	2	12	4
Qxi	10	3	1	1	2	2	12	3
Qxii	5	3	5	3	5	4	25	5
Qxiii	16	6	15	25	9	8	5	6
Qxiv	8	4	8	2	6	4	8	3
Qv	15	6	8	10	16	2	16	1
Qvi	15	12	10	3	12	16	20	8
Qvii	1	4	12	9	8	8	10	8
Qxviii	5	6	12	2	10	9	20	9

RPNs from PQs from District 4 Pharmacies

	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Qi	15	16	6	8	9	4	9	8
Qii	12	20	8	8	4	6	6	8
Qiii	20	20	16	16	20	8	2	9
Qiv	12	8	6	8	6	2	2	4
Qv	15	5	12	4	8	3	2	8
Qvi	25	6	8	6	4	2	4	5
Qvii	25	9	16	12	25	6	12	10
Qviii	6	20	9	8	8	6	2	1
Qix	3	8	8	6	4	2	2	2
Qx	5	4	6	8	6	1	3	2
Qxi	1	3	9	9	4	1	6	8
Qxii	25	5	8	3	10	2	5	5
Qxiii	20	6	16	16	15	6	6	12
Qxiv	1	3	16	16	10	2	4	6
Qv	1	1	12	16	6	2	4	9
Qvi	25	8	4	8	9	3	16	8
Qvii	25	8	6	4	9	6	16	3
Qxviii	25	9	16	12	16	2	3	10

RPNs from PQs from District 5 Pharmacies

	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Pharmacy 5	Pharmacy 6	Pharmacy 7	Pharmacy 8
Qi	12	4	12	1	6	6	9	8
Qii	12	9	8	12	8	1	15	16
Qiii	15	6	20	12	12	4	15	20
Qiv	12	4	16	15	6	6	4	3
Qv	15	10	16	20	1	3	5	8
Qvi	15	15	6	25	6	6	3	8
Qvii	20	9	16	25	6	12	15	9
Qviii	12	12	6	12	6	12	3	4
Qix	9	8	1	16	2	2	6	4
Qx	12	3	2	16	2	4	15	2
Qxi	9	9	9	20	1	4	8	6
Qxii	12	4	9	10	3	2	5	10
Qxiii	16	15	20	9	16	16	12	20
Qxiv	12	8	20	9	6	16	6	12
Qv	9	6	8	9	9	20	4	12
Qvi	12	12	4	20	6	2	16	9
Qvii	12	12	12	25	9	2	2	9
Qxviii	12	6	20	25	9	2	6	9

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