Risks in Pharmacy Practice Research

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Degree of Doctorate in Pharmacy

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To the Almighty God, for the wisdom He bestowed and guidance.

Dedication

para sa ligaya ng aking mundo

ABSTRACT

Pharmacy practice research plays a significant role in the advancement and innovation of pharmacy practice and of the pharmacy profession. Through research, novel and extended pharmacy services were developed, evaluated, and implemented. Risks could arise across the research process, and this study aimed to identify the risks and limitations that are encountered when conducting pharmacy practice research and determine strategies to mitigate such risks. The methodology was divided into two phases. Phase 1 involved the identification of limitations and risks from the identified pharmacy practice research studies. This phase included the development and validation of a search strategy, inclusion, and exclusion criteria to identify pharmacy practice research studies considered in the study. Research studies were identified from published studies extracted from PubMed® and from local dissertations extracted from the Open Access Repository of the University of Malta from the year 2015-2022. Risks and limitations were subsequently identified from the retrieved pharmacy practice research studies. Phase 2 included a literature review and a focus group discussion to put forward risk mitigation strategies. A total of 58 local studies, and 399 published studies were included in the review. The majority of the local studies were set in a hospital pharmacy (n=27) where development and implementation of a tool (n=14) was the most common data collection method employed. In contrast almost half (49%) of the reviewed published studies were conducted in a community setting. The most prevalent theme or topic in both local and published studies was extended pharmacy services or intervention which was identified in 20 and 135 studies respectively. For published studies, the most frequently employed study design was Randomised Controlled Trial (n=60) where limited generalisability (n=29) and risk of social desirability bias, unblinding, and small sample size (n=15) were

the top two most reported limitations whereas time constraints (n=20) and small sample size (n=19) were the two most reported limitations for local studies. Time constraints including short follow up period and short duration to measure the effect of the intervention may be mitigated through designing an appropriate time frame for data collection, recruitment, and intervention duration period. Results of the focus group discussion and literature review suggest that closely matching the sample to the target population to ensure representativeness would minimise the risk of generalisability bias. Ensuring respondents' anonymity when assessing self-reported goals, and proper question formatting such as avoiding vague concepts and socially desirable wording, encourages truthful responses from participants and ensures a more accurate response, minimising social desirability bias. A small sample size can be addressed by extending the duration of recruitment period, informing participants of the study's goals and benefit to the society, and ensuring risks are minimised if a test may be required. Awareness of possible limitations and risks that may be encountered in conducting pharmacy practice research studies would allow future researchers to design and plan their research project in a manner that would minimise such risks, ensuring improved quality and robust research.

Keywords: Pharmacy practice research, research bias, risks

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LIST OF ABBREVIATIONS

FGD	Focus Group Discussion
FREC	Faculty of Research Ethics Committee
GDPR	General Data Protection Regulation
IRB	Institutional Review Boars
OAR	Open Access Repository
POCT	Point-of-care testing
POYC	Pharmacy of Your Choice
PPR	Pharmacy Practice Research
RCT	Randomised Controlled Trials
REC	Research Ethics Committee

CHAPTER 1

INTRODUCTION

1.1 Pharmacy Practice

Pharmacy practice has strived for higher professional status through changes in pharmacy education and practice. By the 1950s, the professional pharmacy standing evolved and began to be defined more by the provision of patient care services than by the traditional dispensing of medicines (Toklu, 2013; Urick, 2019). Community pharmacy practice models now include the promotion of various healthy behaviours that aim to improve health and optimise the management of chronic conditions, enhanced interprofessional collaboration between pharmacists and other healthcare professionals, and utilisation of pharmacy information systems allowing pharmacists to deliver better advise to patients and to other healthcare professionals (Abramowitz, 2009; Steed, 2019).

Community pharmacists in the United States provide a variety of services including deprescribing, targeted medication management, adherence programs, medication optimisation, and prevention services delivered through point-of-care testing (POCT) including HBA1c, blood glucose and cholesterol testing (Goode, 2019). Other community pharmacy services include chronic care management services where pharmacists ensure adherence and medication safety of patients with chronic diseases, acute care management services such as management of common acute illnesses and antimicrobial stewardship, telehealth, transitions-of-care services and patient education on medicines, medical conditions, and wellness such as promotion of smoking cessation (Goode, 2019).

In rural community pharmacy practice various expanded pharmacy services have been identified, this includes vaccine administration, screening, and management of infectious diseases such as malaria, early detection and early treatment of long-term conditions

including osteoporosis, diabetes, renal disorders, cardiovascular diseases, and chronic lung conditions including chronic obstructive pulmonary disease (COPD) and asthma (Taylor, 2019).

Expansion of pharmacy practice is also observed in the hospital pharmacy setting. Although hospital pharmacy services vary between countries, ranging from the conventional pharmacy practice of dispensing prescription drugs to a more advanced and clinically focused practices, most hospitals continue to strive towards a more progressive practice through increased direct patient care involvement (Abousheishaa, 2020). Hospital pharmacists provide clinical pharmacy services through designing drug therapy regimens that incorporate core elements of pharmacy care including medication adherence, medication safety, and close monitoring of patients ensuring that optimum therapeutic outcomes are met (Abramowitz, 2009). In United States, hospital pharmacists do not only improve drug therapy monitoring for patients but also responds to issues relating to medicine use's impact on public health. Hospital pharmacists are taking on an active role in participating in opioid stewardship programs, ensuring safe compounding of sterile medications for patients, and reducing the need for hospital readmissions (Pedersen, 2019). Participating in the hospital's multidisciplinary team, hospital pharmacists have established their ability to improve outcomes of care, reduce adverse drug reactions, decrease patients' length of stay, and ultimately reduce total health care costs (Abramowitz, 2009).

High income countries have been in the forefront of innovations in the pharmacy profession, extending pharmacists' role in the healthcare system. For instance, in England, pharmacist independent prescribing services shall be piloted in the beginning of

2023.[1] Funded independent prescribing training are being offered for pharmacists, and since 2021, extensive prescribing training has been incorporated into the curriculum of both foundation and undergraduate programmes such that from September 2026, all newly qualified pharmacists will be independent prescribers on the day of registration.[2] In the US, the practice of pharmacist-administered immunisations, particularly for adult patients, are widely recognised as a crucial responsibility of pharmacists. In 2004, it was estimated that 15,000 pharmacists and pharmacy students had received official training as vaccine specialists through recognised programs (Hogue, 2006).

This shift in pharmacy practice is primarily the outcome of increased demand for existing health-care services as a result of both demographic changes in the population, and the rapid pace of technological change (Bond, 2006). To address this change, evidence-based practice must be established for these novel services to provide the best patient health outcomes (Armour, 2007). Delivering optimum care requires a scientific approach (Garcia-Cardenas, 2020). Hence, research is crucial to the evolution of pharmacy practice and healthcare (Awaisu, 2015). Pharmacy practice research can play a significant role, providing evidence that can both inform new policy and validate the feasibility or benefit of recommendations based on hypothetical solutions (Bond, 2006; Obaid, 2021).

1.2 Pharmacy Practice Research

"Pharmacy practice research" (PPR), also referred to as pharmacy practice-based research is essential in the advancement and innovation of the profession, providing evidence to

[1] The Pharmaceutical Journal [Internet]. Pharmacist independent prescribing pilots will begin across England from 2023; 2022. [cited 2023 May 27]; Available from: https://pharmaceutical-journal.com/article/news/pharmacist-independent-prescribing-pilots-will-begin-across-england-from-2023

[2] National Health Service:England [Internet]. Independent prescribing:Community pharmacy independent prescribing; 2023. [cited 2023 Jul 20]; Available from: https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-integration-fund/independent-prescribing/

support the pharmacy profession's continued expansion to meet healthcare demands (Kritikos, 2013; De Vera 2018). There are two main categories of pharmacy practice research (1) research associated to pharmacy as a data source, for instance, research studies on medication use or prescribing practices; or (2) research involving pharmacy as a research subject such as studies concerning internal pharmacy practices, guideline adherence, or the quality of patient counselling (Koster, 2014). The scope of pharmacy practice research includes studies which focus primarily on the impact of pharmacy practice on health care systems, medicine use and patient care. Pharmacy practice research also explores the clinical, behavioural, humanistic, and economic implications of pharmacy practice, practice changes, and the development of novel services and implementation of innovations.[3]

In addition, the Canadian Pharmacists Association defines pharmacy practice research as a "component of health services research that focuses on the assessment and evaluation of pharmacy practice" (Koshman, 2011). In Middle Eastern Arab countries, prominent themes of pharmacy practice research include clinical research, medicine use, pharmacy practice and services, and pharmacy education and professional development (Obaid et al, 2021). Opinions, perspectives, values, or a range of other subjective domains relating to patients' experiences, perception of pharmacy stakeholders about novel pharmacy services, or pharmacy practice culture are also explored in pharmacy practice research (Haua, 2022).

[3] International Pharmaceutical Federation (FIP) [Internet]. Pharmacy practice research special interest group. International Pharmaceutical Federation;2021. [cited 2023 May 27]. Available from: https://www.fip.org/pharmacy-practice-research

Pharmacy practice research has the potential to have a significant impact not only on pharmacists as a profession but also on patients and hence it is vital that pharmacy practice research identify new areas that may require research and should be carried out in a way that it captures high-quality evidence for medication use, patient-centred care, and delivery of healthcare services (Almarsdottir, 2016; Hasan, 2019). Practitioners and academics from high-income countries have emphasised the significance of having robust evidence-based research to promote effective policy change (Babar, 2018).

Patient teamwork, multidisciplinary collaboration with other healthcare providers, documenting and assessing the outcomes of interventions, as well as patient cultural diversity forms part of the widening scope of pharmacy practice research (Babar, 2015). Various methodologies are applied in pharmacy practice research, from the traditional qualitative and quantitative methods to a more novel and complex approach (Awaisu et al, 2019). The growth of large and complicated data sets, utilising electronic health records, and pharmacy practice researchers' employing a range of mixed approaches could all pose future methodological challenges and ultimately, risks (Babar, 2015; Ma, 2015).

In addition, ethical risks such as physical, psychological, social, legal, and economic harm could also arise in pharmacy practice research as methodologies in some capacity often involve human participants (Loewen, 2014).[4] As every component of health care practice is affected by social relationships and social structures, risks identified in social science research can be relevant to pharmacy practice research (Bissel, 2001). Such risks include

[4] World Health Organization [Internet]. Research ethics committees: Basic concepts for capacity-building. Geneva: Word Health Organization;2009. [cited 2023 May 27]; Available from: https://apps.who.int/iris/bitstream/handle/10665/44108/9789241598002_eng.pdf?sequence=1&isAllowed=y

loss of confidentiality, invasion of privacy, emotional distress, indirect physical injury, discrimination, embarrassment, and stereotyping (Oakes, 2002). Like any other type of research, pharmacy practice research is not without risk. It is crucial that investigators are informed and are aware of the risks pertinent to pharmacy practice research and are knowledgeable on the ways on how to mitigate it.

1.3 Risks in Research

Risk in research has been a topic of discussion for several decades. This is especially true for biomedical research as advancement in medicine depends on research which ultimately involve human participants (Bain, 2017). Several reports, guidelines and declarations have been produced because of unethical practices in medical research which posed risks to human participants. As a response, independent bodies known in most countries as Research Ethics Committee (REC) or in the US, as Institutional Review Board (IRB) were established to evaluate the ethical aspects of research which involve human participants (Rice, 2008; Tusino 2022).

The concept of risk in research became prominent when there were numerous instances of unethical research carried out by various nations during World War II that significantly harmed several people. Such studies were carried out in the name of medical science but with little to no consideration of the harm that participants were subjected to (Gelling, 2016). The Nuremberg Code has been recognised as a landmark document in medical and research ethics and was established as an outcome of the Doctor's trial in Nuremberg in 1947. This legislation which was developed in response to the atrocities of Nazi doctors and researchers' use of human experimentation, placed a crucial emphasis on the rights

and obligations of researchers as well as the research participants' fundamental rights (Ghooi, 2011).

The Nuremberg code stipulates that "the voluntary consent of the human subject is absolutely essential," emphasising that participants in the study must give consent and that the benefits of the study must exceed the risks (Shuster, 1997).

In 1950s, thalidomide was released to treat morning sickness in pregnant women. Multiple reports of severe birth defects surfaced after its released, but it was not until 1961 when two independent clinicians confirmed it was caused by thalidomide (Vargesson, 2015). As a result, UK Medicines Act 1968 was passed (Turner, 2012). The Medicines Act of 1968 requires that all medicines manufactured or marketed in the United Kingdom be licensed by the Medicines Control Agency. The licensing system's goal is to ensure that medicines are assessed for efficacy, safety, and quality (Choonara, 1998). The Tuskegee Syphilis Study, which lasted from 1930s until 1972, was another example of unethical research with little to no regard for safety of human participants; treatment and information were withheld from the subjects, did not give informed consent , and were unaware that they were being denied treatment (Oakes, 2002; Gelling, 2016). Researchers who intend to involve human participants in their research must obtain research ethical approval prior to contacting potential participants and initiating data collection (Gelling, 2016).

The Declaration of Helsinki was released in 1964 by the World Medical Association which was founded in 1947. The document was written in light of a surge in number of

research studies involving unethical medical practices during and post-World War II.[5] The Declaration of Helsinki which has undergone four revisions, serves as the foundation for effective clinical practices used today. The general recommendations of the Declaration of Helsinki are (1) investigations involving humans should be based on the findings of animal and laboratory experiments, (2) research protocols should be examined by an impartial committee before they are carried out, (3) research subjects must give their informed consent, (4) research should only be carried out by people with medical or scientific training, and (5) the benefits must outweigh the risks.[4] A well-defined presentation of possible risks to research participants and a complete risk assessment are significant in medical research (Happo, 2020). Researchers must recognise the risks and implications of their work and safeguard the interest and protect the rights of the participants (Loewen, 2014).

Aside from ethical risks, risk of bias is often encountered in research. Paramount to conducting a sound research study is the understanding of bias (Gerhard, 2008). Bias may emerge at any stage of the research process, from the design of the study, collection and analysis of data, and publication (Pannucci, 2010). Although some biases are only specific to certain research designs and methodological approaches, the general concept of how bias emerges in a study applies similarly across different study designs such as randomised controlled trials (RCTs), prospective observational, retrospective, or quasi-experimental studies. The primary distinction between each research design is the extent of how the researcher can control bias and influence the accuracy of measurements. These

[4]World Health Organization [Internet]. Research ethics committees: Basic concepts for capacity-building. Geneva: Word Health Organization;2009. [cited 2023 May 27]; Available from: https://apps.who.int/iris/bitstream/handle/10665/44108/9789241598002_eng.pdf?sequence=1&isAllowed=y

[5]Declaration of Helsinki [Internet]. [cited 27 May 2023] Available from: https://inside.tamuc.edu/research/compliance/IRB-Protection_of_Human_Subjects/irbDocuments/Declaration.of.Helsinki.pdf

opportunities vary from having complete control in RCTs to having little to none in retrospective studies of electronic databases (Gerhard, 2008).

Any systematic error in a study's design, conduct, or analysis can be defined as bias. Bias can refer to the researcher's inclination to gather and evaluate data and present it in a manner that favours erroneous conclusions that are consistent with the researchers' preconceptions and political or practical commitments (Hammersley, 1997; Althubaiti, 2016). Bias can also be described as the lack of internal validity or an erroneous evaluation of the link between the exposure and outcome in the target population in which the statistics estimated has an expectation that is not equivalent to the true value (Delgado-Rodríguez, 2004). The most common categories of bias which affects the validity of research include selection bias which is the approach adopted for selecting subjects for a study. This bias could lead to a sample of participants that is not representative of the target population. Measurement bias occur when the approach adopted for collecting or measuring data from a study include issues related to how the outcome was measured. Intervention biases refer to variations in which the intervention or treatment was carried out, or how the participants were exposed to the factor of interest (Krishna, 2010).

The risks encountered in pharmacy practice research are rarely explored in literature, little is known about the experiences and views of pharmacists towards research ethics in this context (Krajnović, 2017). It is extremely important that researchers are informed of the risks as outcomes in these research studies are applied in decision-making involving patient care.

1.4 Risk Management

Risk management is essential to the success of any research project and ensures that it is ethically executed. Risk management is central in ensuring that a research project is of quality, within budget, and completed in time. It is the process of identifying, evaluating, and mitigating risk throughout the research project's life cycle (Daehnhardt, 2021). It is both the researcher and research ethics committees' (RECs) responsibility to evaluate risks to which the study participants are exposed to. REC members carry out risk assessment according to the information the researcher provides on their study protocol. In accordance with the Declaration of Helsinki, prior to obtaining informed consent, all risks should be explained to study participants (Happo, 2020).

Risk management does not eliminate all the potential risks which may arise throughout the course of a research project. It is a process which should be implemented to identify potential risks and benefits of the research project to its stakeholders and ensure that appropriate safeguards are in place to minimise the risk to a level which is deemed acceptable (Daehnhardt, 2021).

1.5 Rationale of the Study

Research involving human subjects require an ethical approval prior to initiation of recruitment and data collection. This process of obtaining an ethical review assures research participants that possible risks in the study have been considered, minimised and are ethically acceptable. Obtaining ethical approval is a responsibility and must be a moral reflex for researchers (Bain, 2017). Aside from ethical risks, other risks which could arise across the entire research process, from research design, recruitment process, analysis of

data, interpretation of results, implementation of results and dissemination are also often overlooked.

In a systematic review conducted by Awaisu et al in 2015, pharmacists acknowledged a lack of competency in several areas of research including research design, implementation, and dissemination despite surveyed pharmacists having previous research-related training. Evidence generated through practice-based research must be accompanied by the appropriate use of reliable methodologies (Awaisu et al, 2019) and is therefore imperative that pharmacists are competent in delivering pharmaceutical care and have the necessary research skills (Awaisu et al, 2015). With the expanding range of methodologies employed in pharmacy practice research, the complexity of the type of data collected, and the participants involved in the study, different risks, and challenges may be encountered and must be addressed to ensure high-quality and ethical research project. This study was developed to explore these risks and shed light on this topic.

1.7 Aims and Objectives

The aims of the study were to identify risks in pharmacy practice research and determine ways how to mitigate such risks.

The objectives were to:

1. Identify risks encountered in pharmacy practice research studies from both local dissertations and published pharmacy practice research studies.
2. Develop a risk minimisation strategy based on the risks identified.

CHAPTER 2

METHODOLOGY

This chapter describes the methods used in identifying risks encountered in pharmacy practice research and in identifying risk minimisation strategies to mitigate those risks.

The University Research and Ethics Committee Application form was completed online and was submitted to the University of Malta Faculty of Medicine and Surgery Research Ethics Committee (FREC) in accordance with the research guidelines. FREC approved the study in September 2022 (Appendix 1).

2.1 Research Design

This study employed a mixed-method approach divided into two phases.

Phase 1 – *Identification of Risks and Limitations in Pharmacy Practice Research Studies*
Local dissertations were identified and extracted from the Open Access Repository (OAR), the institutional repository of the University of Malta (UM). Dissertations by Master of Pharmacy and Doctor of Pharmacy students from 2015-2022 that can be publicly accessed through this platform were included in the study. For published studies, a search strategy, inclusion, and exclusion criteria were developed and validated. Online published studies were extracted from PubMed®, using the search strategy (Table 2.1) and were subsequently screened and assessed for eligibility using the eligibility criteria (Table 2.2).

Table 2.1 Search Strategy for Published Articles

Search string	**(("Pharmacy"[Mesh]) OR ("Pharmacists"[Mesh])) AND (("Pharmaceutical Services"[Mesh]) OR ("intervention") OR ("pharmacy practice") OR ("pharmacy service"))**
Database	PubMed
Publication	2015-2022 (Dec) Free full text Peer-reviewed
Language	English

Table 2.2 Inclusion and Exclusion Criteria

Inclusion criteria	**Exclusion criteria:**
1. **Study design:** primary studies 2. 3. **Setting:** Community Pharmacy, Hospital Pharmacy, and Regulatory 4. • Studies which involve development, evaluation and/or implementation of an intervention, service, or policy. • Studies which involve views or perception of stakeholders (pharmacists, doctors, nurses, patients) regarding a pharmacy-related service or intervention.	**Study design:** secondary studies (systematic review and meta-analyses). 1. Study presented as editorials, protocols, guidelines, and audits.

Validation of Search Strategy, Inclusion, and Exclusion Criteria

A validation form was developed for the proposed search strategy, inclusion, and exclusion criteria. The form was divided into two parts; part 1 referred to the validation of the proposed systematic search strategy for the extraction of published pharmacy practice research studies including the proposed database, search string and filters to be used while part 2 referred to the validation of the inclusion and exclusion criteria. Five academic pharmacists were selected through convenience sampling to validate the search strategy, inclusion, and exclusion criteria. The validation form was created using Google forms and was sent to the panel through electronic mail. A cover letter outlining the aims and objectives of the study was sent together with the validation form. The validation form required the panel to rate their level of agreement on the proposed systematic search strategy, inclusion and exclusion criteria using a 5-point Likert scale, with 1 indicating a strong level of disagreement. The panel was also provided with a field to input any remarks and/or recommended changes. The panels' recommendations were taken into consideration and the search strategy, inclusion and exclusion criteria were modified accordingly.

Local and published pharmacy practice research studies identified which met the inclusion and exclusion criteria were extracted onto an Excel file. The research setting, research topic or theme, research design, data collection method, type of data gathered, and study limitations or risks were the data items that were manually collected and categorised. The study limitations or risks identified by the included pharmacy practice research studies were tallied, categorised, and were presented in a tabular form.

Figure 2.1 illustrates the summary of the procedure employed for the identification of pharmacy practice research studies and its risks and limitations.

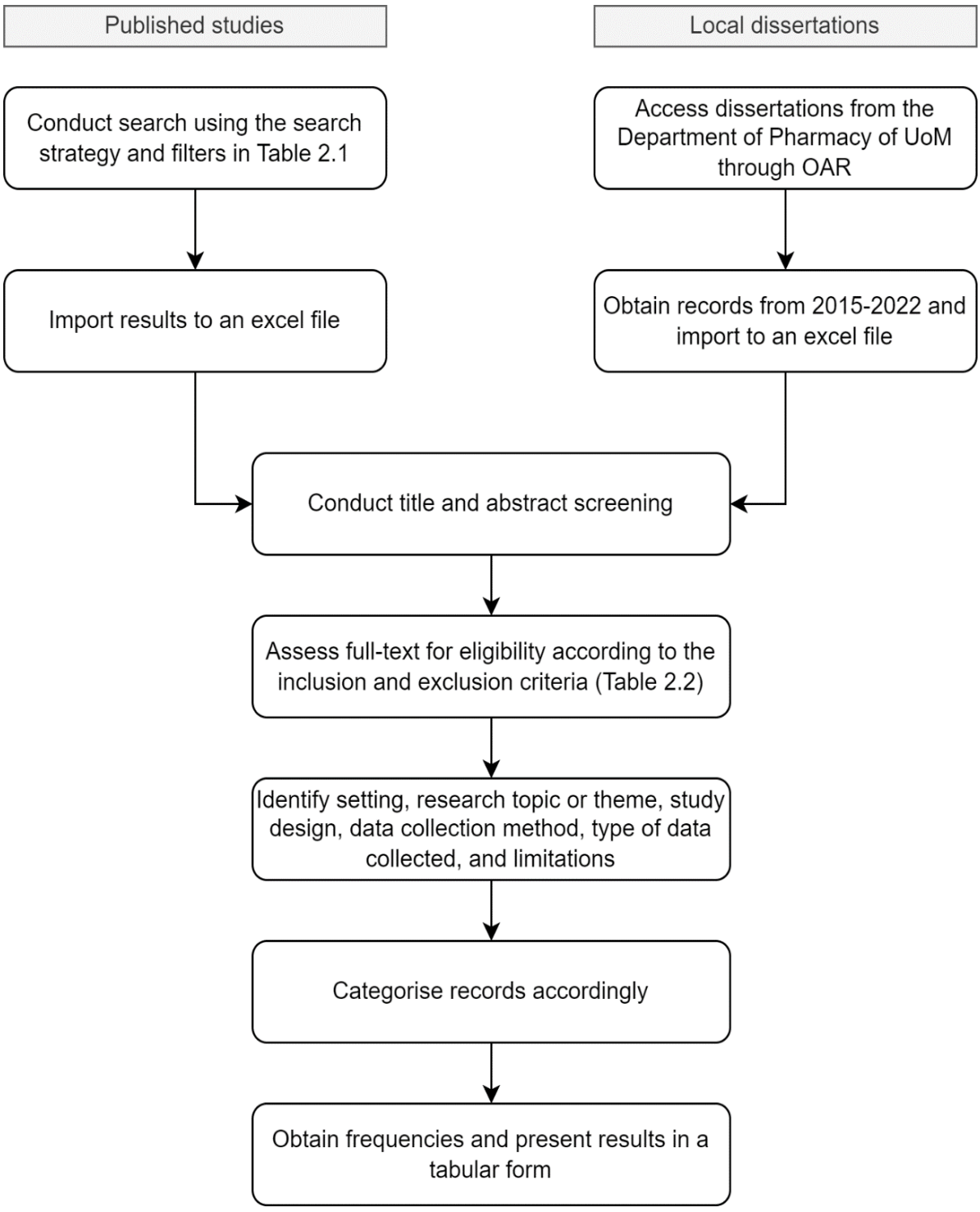


Figure 2.1 Schematic Diagram of Phase 1

Phase 2 – *Identification of Risk Mitigation Strategies*

Identification of risk mitigation strategies were conducted through a literature review and a focus group discussion (FGD). An invitation was sent through an electronic mail to three academic pharmacists and three members of the Faculty of Research Ethics Committee (FREC) Faculty of Medicine and Surgery of the University of Malta (UM) to discuss risk mitigation strategies for the risks identified in Phase 1. The invitation includes a cover letter which states the aim and objectives of the study. The expert panel for the focus group discussion who accepted the invitation consisted of two academic pharmacists and two members of the FREC Faculty of Medicine and Surgery of the UM.

The focus group discussion was led and facilitated by the researcher. The researcher followed the focus group and took note of the discussion. The focus group was divided into three main parts:

Part 1: Introduction and Introductory Questions

The expert panel was welcomed by the researcher and briefly gave an overview of the study and explained that the aims of the focus group discussion was to identify risk mitigation strategies to counter the risks identified in phase 1 of the study. At this part of the discussion, an introductory question was provided to gain insight on the perception of the experts on risks in research and whether they think there is a gap among researchers with their knowledge or awareness of risks encountered in research.

Part 2: Identification of Risk Mitigation Strategies

The researcher and the expert panel went through the identified risks and limitations identified and discussed potential risk minimisation strategies.

Part 3: Webinar

The final part of the FGD sought recommendations from the expert panel regarding potential themes which must be discussed, ideal method of delivery, target participants, and eligible speakers, if a webinar to raise awareness on risks in pharmacy practice research shall be developed and implemented.

2.2 Data Management

Data gathered from the review of pharmacy practice studies were synthesised in a tabular form. Microsoft Excel version 2202 was utilised to manage the quantitative data. Qualitative analysis was employed for the focus group discussion.

Chapter 3

Results

This chapter outlines the results of the retrieval and review of pharmacy practice research studies and focus group discussion and provides data on i.) pharmacy practice research studies, ii.) risks and limitations encountered in pharmacy practice research studies, iii.) risk mitigation strategies.

3.1 Local Pharmacy Practice Research Studies

The initial search of the local pharmacy practice research (PPR) studies from Open Access Repository of the University of Malta generated 545 articles from 2015 - 2022. Duplicate records, articles, abstracts only, poster presentations and editorials were excluded resulting in 234 articles for title and abstract screening. Twenty-four (24) articles which were not publicly accessible, 7 PhD studies and 4 audits were excluded leaving 199 articles for full-text eligibility assessment. Inclusion and exclusion criteria resulted in a final sample of 58 articles for review. Figure 3.1 shows the summary of the result of the retrieval of local pharmacy practice research studies.

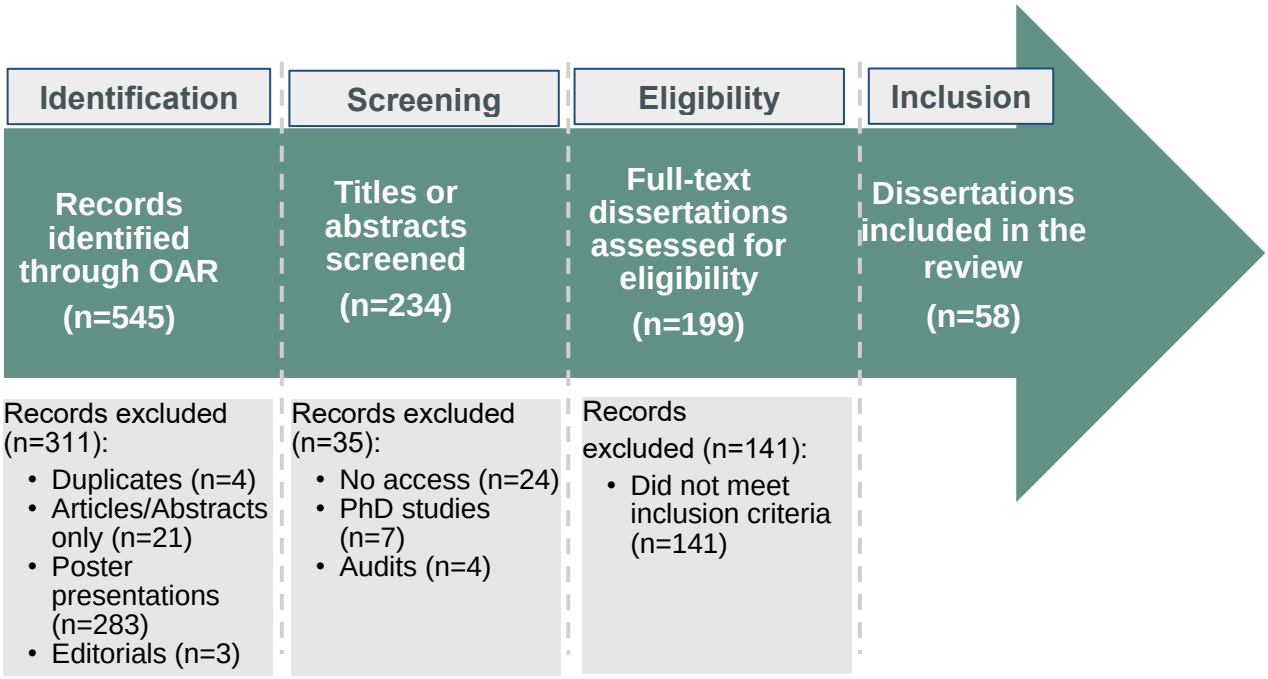


Figure 3.1 Local Studies Included in the Review

Setting

Figure 3.2 shows the distribution of the local PPR studies by setting. There are three pharmacy practice research settings identified from the inclusion criteria, which are community pharmacy, hospital pharmacy and regulatory. A general pharmacy practice setting includes studies which were conducted in both hospital and community pharmacy setting or studies which specified a general pharmacy practice setting. The highest percentage of local PPR studies was hospital pharmacy 47% (n=27), followed by community pharmacy with 36% (n=21), regulatory pharmacy at 14% (n=8), and general pharmacy practice with 3% (n=2).

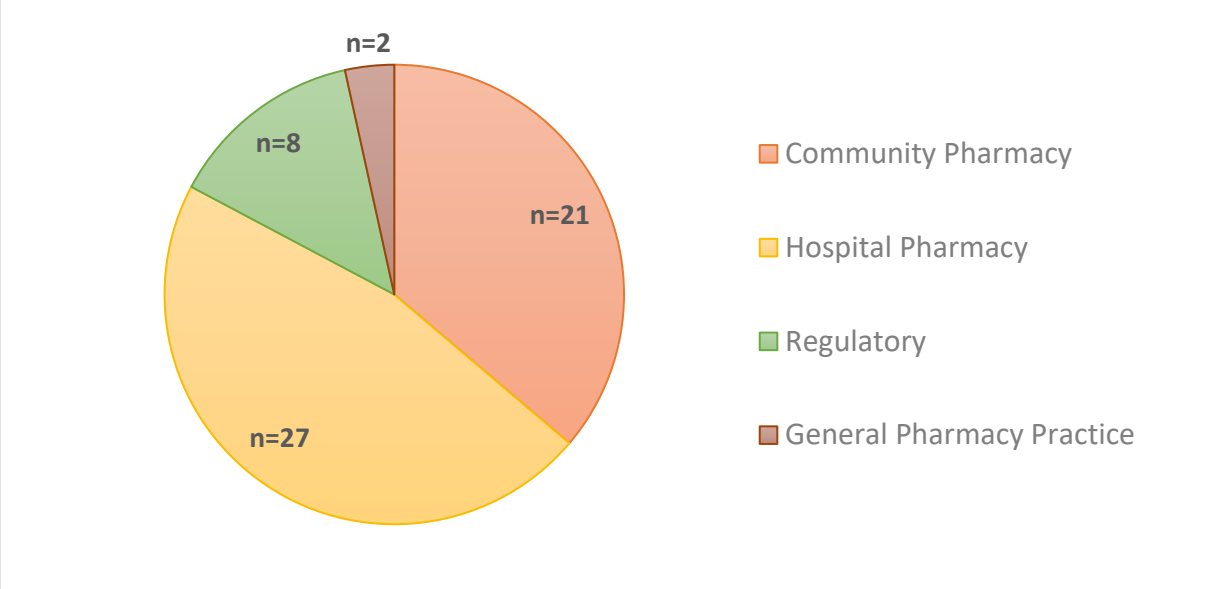


Figure 3.2 Distribution of Pharmacy Research Studies by Setting (N=58)

Type of Data Collected

Studies included in the review were assessed whether the study involved collection of primary data from human participants. Table 3.1 shows the frequency of the type of data collected in the studies by setting. In community pharmacy setting, 20 studies involved collection of primary data from human participants and only one community pharmacy

study involved both primary and secondary data. For hospital pharmacy studies, 11 collected primary data, 10 studies utilised both primary and secondary data, and 6 studies collected secondary data alone. For regulatory pharmacy, 4 studies collected primary data, and 4 studies had utilised both primary and secondary data. All studies (n=2) under general pharmacy practice collected primary data only. Of the 58 local PPR studies, the most frequent type of data collected was primary data, utilised in 37 studies.

Table 3.1 Type of Data Collected by Setting (N=58)

Setting	Type of data collected		
	Primary data	Secondary data	Both
COMMUNITY (N=21)	20	0	1
HOSPITAL (N=27)	11	6	10
REGULATORY (N=8)	4	0	4
GENERAL (N=2)	2	0	0
Total:	37	6	15

Theme or Topic

A total of 9 pharmacy practice research themes or topics were identified namely, *drug information* which focuses on provision of drug information services, through development of drug monograph for certain populations, or through development of practice points for pharmacy stakeholders for a specific medication. This theme or topic also include services which focused mainly on provision of drug information through patient counselling or education. *Medication use* refers to studies which involve medication use review, medication reconciliation, or medication therapy management.

Medicine access is concerned with the issues affecting accessibility and availability of certain medications. *Medicine or patient safety* refers to studies which assess safety of certain medications, this includes interventions on drug-related problems and pharmacovigilance or adverse drug reaction reporting. *Pharmacogenetics* include studies which involves pharmacogenetic testing and studies which assesses stakeholders' view on this topic. *Pharmacy services* include various pharmacy services and interventions including transition of care services, medication assessment tools, pharmaceutical care plan, and other extended pharmacy services. *Point of Care Testing (POCT)* involves studies which explores point of care testing as an extended pharmacy service. POCT is utilised by pharmacists to deliver immediate diagnostic findings as a monitoring tool in patient care and to assist in enhancing medication outcomes (Goble, 2017). *Pharmacy of Your Choice (POYC)* are studies which focuses on pharmacy services through the POYC scheme. The POYC scheme is the national pharmaceutical service of Malta. Patients who are entitled on this scheme benefits from free medicines and pharmaceutical devices from the government of Malta.[6] *Prescribing* refers to studies which explore pharmacy prescribing as an extended pharmacy service.

Table 3.2 shows the distribution of the themes or topics by setting. Both hospital and community pharmacy have pharmacy services or intervention as the most common topic with 13 and 6 studies each respectively. For regulatory, medicine and patient safety was the most common theme with 4 studies, while in general pharmacy practice, one study was focused on pharmacogenetics and one study focused on pharmacy service or intervention. In total, pharmacy service or intervention was the most common theme or

[6]Government of Malta [Internet]. The Pharmacy of Your Choice National Scheme; 2021 [cited 2023 May 27]. Available from: https://deputyprimeminister.gov.mt/en/poyc/Pages/Poyc-scheme.aspx

topic with 20 studies, followed by medication use with 8 studies. Drug information and prescribing were tied for the third spot with 7 studies each.

Table 3.2 Theme or Topic Frequency by Setting (N=58)

Theme or Topic	Setting				
	Community	Hospital	Regulatory	General	Total
Drug information	1	5	1	0	7
Medication use	3	5	0	0	8
Medicine access	0	0	2	0	2
Medicine or patient safety	0	1	4	0	5
Pharmacogenetics	0	0	0	1	1
Pharmacy services (extended services or intervention)	6	13	0	1	20
Point of Care Testing (POCT)	3	1	0	0	4
Pharmacy of Your Choice (POYC)	3	0	1	0	4
Prescribing	5	2	0	0	7
Total:	21	27	8	2	58

Research Design and Data Collection Method

The research design and data collection methods employed in the research studies included in the review were identified and categorised by their setting. No assumptions were made by the researcher during the categorisation of the research design, and data collection method was based solely on the information indicated in the research studies reviewed.

Table 3.3 shows the frequency and distribution of the research design and data collection tool or method utilised in the community pharmacy setting. In the community pharmacy setting, 14 studies did not indicate the research design employed, and 6 other types of

research designs were identified namely, descriptive study, mixed method, pre-post single arm study design, prospective cohort study, prospective observational study, and prospective qualitative and quantitative study design. The most prevalent method of data collection was the use of questionnaires, which was employed in 6 studies.

Table 3.3 Research Design and Data Collection Method of Community Pharmacy Studies (N=21)

Community Pharmacy		
Research design	Data collection method	*Frequency*
Not indicated (n=14)	Questionnaire	4
	Questionnaire and semi-structured interview or FGD	2
	Development of a tool or framework	2
	Development and implementation of a tool/framework	2
	FGD and framework development	1
	Framework development and implementation of service	1
	implementation of service	1
	Implementation of service and questionnaire	1
Descriptive study (n=1)	Questionnaire	1
Mixed methods approach (n=2)	Retrospective analysis and Delphi Technique	1
	Questionnaire and semi-structured interview	1
Pre-post single-arm study design (n=1)	Development of a tool and implementation of intervention	1
Prospective cohort study (n=1)	Telephone survey	1
Prospective observational study (n=1)	Development of a tool and observation sessions	1
Prospective qualitative and quantitative study design (n=1)	Questionnaire and interview	1
	Total:	21

Table 3.4 shows the frequency and distribution of the research design and data collection method used in the hospital pharmacy setting. In this setting, majority of the studies (n=18) did not indicate the research design employed, and 7 other types of research

designs were identified namely, case-control study, cross-sectional prospective study, cross-sectional study, mixed methods approach, observational study, and prospective cohort study. In this setting, development and implementation of a tool was the most common method employed in 14 studies.

Table 3.4 Research Design and Data Collection Method of Hospital Pharmacy Studies (N=27)

Hospital Pharmacy		
Research design	Data collection method	*Frequency*
Not indicated (n=18)	Development and implementation of a tool	7
	Development of framework/service and Questionnaire	2
	Implementation tool	2
	Retrospective analysis and development of a tool	1
	observation visits, development of tool and implementation, questionnaire	1
	Observation, development of tool, pilot study, implementation of intervention	1
	Observation, pre-intervention survey, development, and implementation of service	1
	Pre-intervention interview, implementation of intervention, post-intervention interview	1
	Questionnaire	2
Case-control study design (n=1)	Development and implementation of a tool	1
Cross- sectional prospective study (n=2)	Development and implementation of a tool	1
	Observation, development and implementation of tool, questionnaire	1
Cross-sectional study (n=2)	Development of monograph and Pre &post-questionnaire	1
	Questionnaire	1
Mixed methods approach (n=1)	Observation, implementation of service, development of tool, pilot study and qualitative study	1
Observational study (n=1)	Observation session and FGD	1
Prospective cohort study (n=1)	implementation of POCT	1
Prospective, matched-controlled study (n=1)	Focus group discussion, development, and implementation of tool	1
	Total:	27

Table 3.5 illustrates the frequency and distribution of the research design and data collection method used in the general pharmacy practice and regulatory pharmacy setting. Only two local studies were categorised under the general pharmacy setting, one of the studies did not specify its research design and utilised a questionnaire as a data collection tool, whereas the other study identified as a pilot study involved development and implementation of a tool. In the regulatory pharmacy setting, several data collection methods were used, three studies involved review or retrospective analysis of data or reports. Only one study specified the research design used, which was a quantitative and qualitative approach, while the remaining 7 studies did not specify its research design.

Table 3.5 Research Design and Data Collection Method of General and Regulatory Pharmacy Studies (N=10)

General Pharmacy		
Research design	Data collection method	*Frequency*
Not indicated (n=1)	Questionnaire	1
Pilot study (n=1)	Development and implementation of a tool	1
	Total:	2
Regulatory Pharmacy		
Research design	Methodology/data collection	*Frequency*
Not indicated (n=7)	Analysis of reports and questionnaire	1
	Assessment of regulations and policies, interview, development, and implementation of a tool	1
	Development of educational webinar through FGD	1
	Questionnaire and development of a training program	1
	Questionnaire and Interviews	1
	Retrospective analysis of data, FGD and framework development	1
	Review of reports, FGD, Questionnaire, Development of a webinar	1
Quantitative and Qualitative approach (n=1)	Retrospective analysis of reports and interviews	1
	Total:	8

Identified Study Limitations

To identify the risks encountered in a research study, understanding the limitations and challenges encountered during a research study may help in the mitigation of research related risks. Study limitations highlighted by the authors were tallied and categorised.

Table 3.6 shows the limitations in each of the 5-research process namely recruitment or sample selection, data collection, interpretation and analysis, implementation, and lastly, research design. There are 38 limitations identified with 20 being related to data collection, followed by recruitment or sample selection with 11 different types of limitations identified.

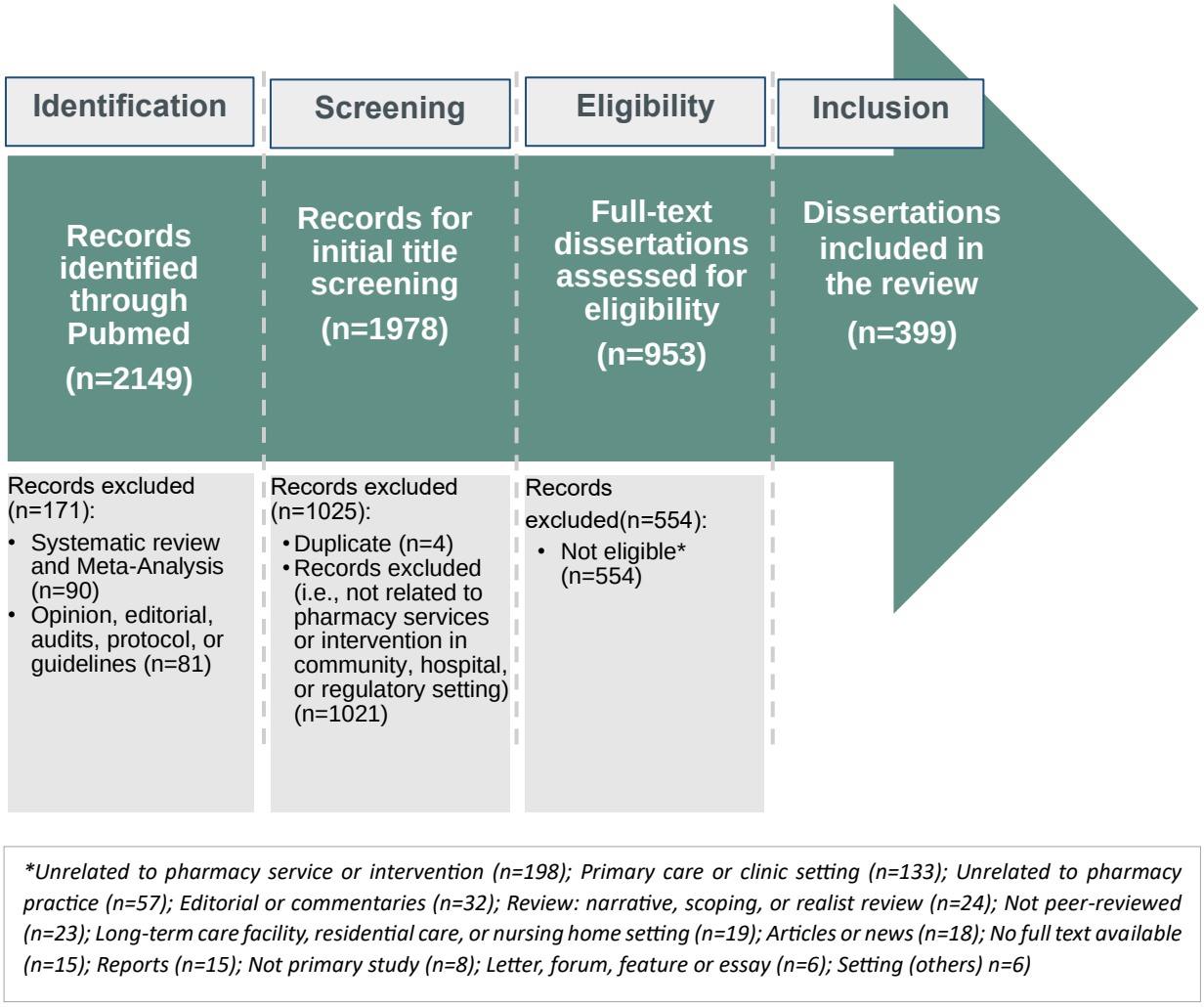
Of the 38 identified limitations, time constraints or logistical limitations was the most (n=20) prevalent which is followed by small sample size (n=19) and by incomplete, unavailable, or missing data and questions using Likert scale (n=8). Other limitations highlighted in five studies each were selection bias, convenience sampling, and the study taking place in a single geographical location.

Table 3.6 Study Limitations (N=125)

Research Process	Limitations	*Frequency*
Recruitment/ Sample selection (n=11)	Time constraints (logistical limitations)	20
	Small sample size	19
	Convenience sampling	5
	Selection bias	5
	Study took place in one area/ward/pharmacy	5
	Non-representativeness (purposive sampling)	4
	Cost limitations	2
	Multiple participation (duplicate answers)	1
	Questionnaire distribution (online)	1
	Recruitment challenges	1
	Strict exclusion criteria	1
	Non-response bias	1
	Total:	**65**
Data collection (n=20)	Incomplete/unavailable/missing data	8
	Questions using Likert scale	8
	Close-ended questions	4
	Low response rate	4
	Recall bias	4
	Hawthorne effect	3
	Length of questionnaire	3
	Self-reporting bias	3
	Cognitive bias (intervention administered by different pharmacists)	2
	Ideal answers may have been chosen instead	2
	Response bias (responses depend on patients' truthfulness; responses might not reflect real views of patients)	2
	Construct validity of the tool not assessed	1
	Data quality (possible inconsistencies with the data source)	1
	Language barrier	1
	Non-response bias	1
	Participants could influence each other's response	1
	Patient could be looking up for answers	1
	Reporting bias	1
	Observer bias	1
	Researcher not blinded	1
	Total:	**52**
Interpretation and analysis (n=3)	No control group	2
	Anonymity (difficulty in measuring changes over time)	1
	long term outcome not measured	1
	Total:	**4**
implementation (n=1)	Low applicability	1
	Total:	**1**
Research Design (n=2)	Lack of longitudinal perspective	2
	Not an RCT - no comparison could be made	1
	Total:	**3**
Total= 38	**Total:**	**125**

3.2 Published Pharmacy Practice Research Studies

Published pharmacy practice research studies were extracted from PubMed. The search generated 15,736 results which were narrowed down to 2,149 titles after the application of filters. A total of 171 records comprising of 90 systematic reviews and meta-analyses, and 81 records which were editorials, opinions, guidelines, audits were excluded. A total of 1978 records were left for the title screening which were narrowed down to 953 records after exclusion of duplicates and initial title screening. For full-text assessment for eligibility, 399 studies met the eligibility criteria and were included in the review. Figure 3.3 shows the summary of the result of the retrieval of published pharmacy practice research studies.



**Unrelated to pharmacy service or intervention (n=198); Primary care or clinic setting (n=133); Unrelated to pharmacy practice (n=57); Editorial or commentaries (n=32); Review: narrative, scoping, or realist review (n=24); Not peer-reviewed (n=23); Long-term care facility, residential care, or nursing home setting (n=19); Articles or news (n=18); No full text available (n=15); Reports (n=15); Not primary study (n=8); Letter, forum, feature or essay (n=6); Setting (others) n=6)*

Figure 3.3 Published Studies Included in the Review

Setting

Figure 3.4 shows the distribution of the published PPR studies by setting. A total of 399 published pharmacy practice research studies were included in the review. Community pharmacy occurred the most at 49% (n=196) followed by hospital pharmacy at 42% (n=167). Only 8% (n=32) were general pharmacy practice and regulatory pharmacy occurred least comprising only 1% (n=4) of the reviewed studies.

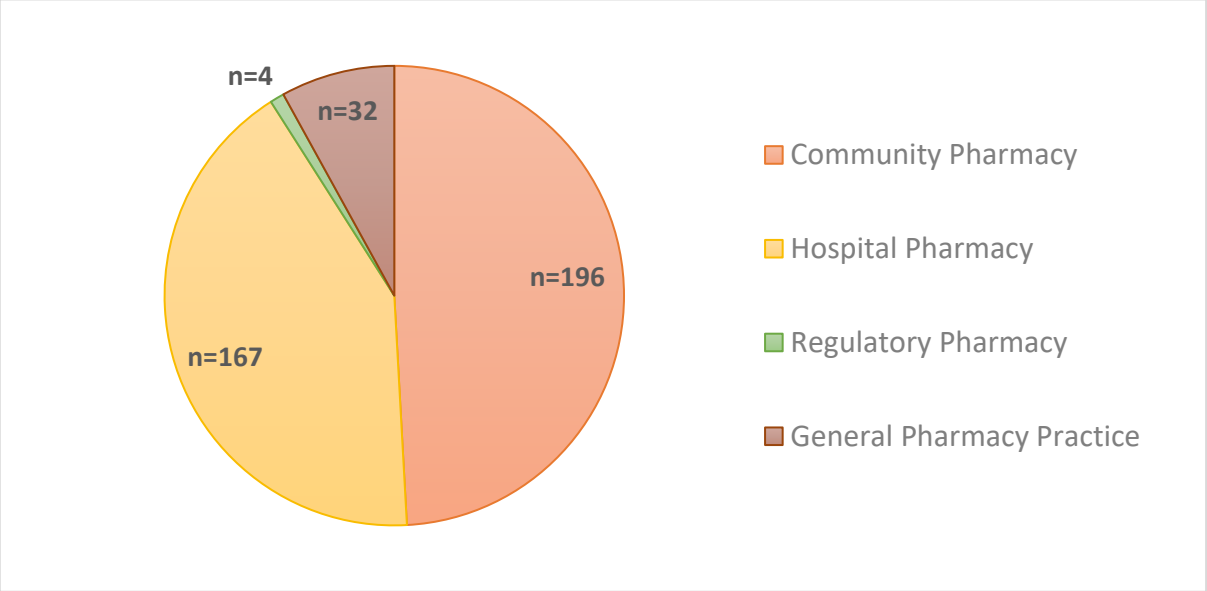


Figure 3.4 Distribution of Pharmacy Research Studies by Setting (N=399)

Type of Data Collected

Table 3.7 shows the frequency of the type of data collected in the studies included in the review by setting. In community pharmacy setting, 177 studies involved collection of primary data from human participants while 6 studies involved collection of solely secondary data, and 13 studies utilised both primary and secondary data. For hospital pharmacy studies. Around 54% (n=91) of the studies made use of primary data, 27% (n= 45) utilised secondary data alone, and 19% (n=31) collected both primary and secondary data. For regulatory pharmacy, none of the studies reviewed made use of secondary data

alone. Three of the regulatory studies reviewed made use of primary data whereas the remaining 1 study has utilised both primary and secondary data. For general pharmacy practice, 29 studies utilised primary data, followed by secondary data occurring in 2 studies, and only one study utilising both primary and secondary data. In summary, 75% (n=300) of the studies utilised primary data, followed by 53 studies which employed secondary data alone and 46 studies used both primary and secondary data.

Table 3.7 Type of Data Collected by Setting (N=399)

Setting	Type of data collected		
	Primary data	Secondary data	Both
COMMUNITY (N=196)	177	6	13
HOSPITAL (N=167)	91	45	31
REGULATORY (N=4)	3	0	1
GENERAL (N=32)	29	2	1
Total:	300	53	46

Theme or Topic

A total of 12 themes or topic were identified from the published pharmacy practice research studies. Of the 9 topics identified from local studies, seven topics namely, drug information, medication use, medicine or patient safety, pharmacogenetics, pharmacy services, POCT, and prescribing were also identified in published studies including 5 additional topics such as antimicrobial or antiviral stewardship, health promotion, disease management, vaccination, and adherence.

Table 3.8 shows the distribution of the themes or topics by setting and the total of the themes accounting for all the setting. For community pharmacy practice, the top three most frequent theme or topic were extended pharmacy services which occurred in 49 studies, followed by drug information or patient counselling (n=34), and disease management (n=26). For hospital setting, extended pharmacy service was the most frequent theme with 71 studies, followed by 32 studies focusing on medication use review or medication therapy management. The third most common hospital pharmacy practice theme or topic is medication or patient safety occurring in 19 studies. For regulatory pharmacy, four different themes or topics have been identified from each of the four studies reviewed, these are health promotion or public health, pharmacists prescribing, vaccination, and extended pharmacy service. In general pharmacy practice, the three most common themes were extended pharmacy services (n=14) prescribing (n=6), and medicine use, and medication and patient safety which both occurred in 4 studies each.

Pharmacy practice settings aside, the three most common themes identified in the reviewed published pharmacy practice studies were extended pharmacy services n=135 followed by medication use and drug information identified in 61 and 49 studies respectively.

Table 3.8 Theme or Topic Frequency by Setting

Theme or Topic	Setting				
	Community	Hospital	Regulatory	General	Total
Adherence	13	6	0	1	20
Antimicrobial or antiretroviral stewardship	5	16	0	0	21
Disease management	26	3	0	1	30
Drug information (patient counselling or education)	34	14	0	1	49
Health promotion/Public Health	5	0	1	0	6
Medication Use (medication review, medication therapy management)	25	32	0	4	61
Medicine or patient safety	13	19	0	4	36
Pharmacogenetics	2	1	0	0	3
Pharmacy services (extended services or intervention)	49	71	1	14	135
Point of Care Testing (POCT)	6	0	0	1	7
Prescribing	4	5	1	6	16
Vaccination	14	0	1	0	15
Total:	196	167	4	32	399

Research Design

Table 3.9 shows the frequency and distribution of the research design used in the community pharmacy setting. In the community pharmacy setting, cross-sectional study was the most frequent research design utilised in 42 studies, followed by randomised controlled trials which occurred in 30 studies, and by qualitative study design (n=28).

Among the 196 studies reviewed under community pharmacy setting, 52 studies did not explicitly indicate the research design in their study, the data collection method were obtained and is presented in the table below. For community pharmacy practice research,

the most frequent data collection method employed was survey or use of questionnaires identified in 25 studies.

Table 3.9 Research Designs of Community Pharmacy Studies (N=196)

STUDY DESIGN			*frequency*
Quantitative Study Design	Observational Study Designs	Cross-Sectional Study Design	42
		Prospective Study Design	3
		Retrospective Study Design	2
	Interventional Study Designs	Randomised Controlled Trial Study Design	30
		Pre-Post Study Designs or Before-After Study Designs	5
		Experimental or Interventional Study Design	2
Qualitative Study Design			28
Mixed-Methods			15
Pilot or Feasibility Study or Implementation Research			11
Other Study Designs	Simulated Patient Technique		3
	Exploratory		1
	Descriptive		2
Not Indicated	Questionnaire/Survey		25
	Intervention		11
	Delphi Method		3
	Interview		3
	Decision-Analytic Modelling		2
	Focus Group Discussion		2
	Cost Analysis		1
	Feasibility and Implementation		1
	Interview And Survey		1
	Questionnaire and Intervention		1
	Service Data Analysis and Questionnaire		1
	Training Followed by Questionnaire		1
Total:			196

Table 3.10 shows the frequency and distribution of the research design used in the hospital pharmacy setting. In this setting, the most frequent research design is randomised controlled trial (n=30), followed by retrospective study design (n=28), and pre-post study design (n=17).

Table 3.10 Research Designs of Hospital Pharmacy Studies (N=167)

STUDY DESIGN			*Frequency*
Quantitative Study Design	Observational Study Designs	Retrospective Study Design	28
		Cross-Sectional Study Design	16
		Prospective Study Design	14
		Case-Control Study Design	1
		Case-Cohort	1
	Interventional Study Designs	Randomised Controlled Trial Study Design	30
		Pre-Post Study Design or Before-After Study Designs	17
		Quasi-Experimental Study Design	6
		Experimental or Interventional Study Design	4
		Non-Randomised Trial Study Design	4
		Crossover Randomised Controlled Trial Study Design	1
Qualitative Study Design			12
Mixed-Methods			7
Pilot or Feasibility Study or Implementation Research			6
Other Study Designs	Discrete Simulation Model		1
	Cognitive Task Analysis		1
	Delphi		1
Not Indicated	Semi-Structured Interview		1
	Interview And Retrospective Analysis		1
	Implementation of Intervention		7
	Analysis of Reports and Review of Pharmacists Intervention		1
	Decision Tree Model		1
	Retrospective		1
	Critical decision method		1
	Questionnaire/ Survey		4
Total:			167

Table 3.11 illustrates the frequency and distribution of the research designs under the general pharmacy practice pharmacy setting. In general pharmacy setting, 9 studies did

not indicate its research design which utilised semi-structured interview (n=7) and survey (n=2) as a data collection method. The most frequent design was cross-sectional study (n=8), followed by qualitative study design and mixed methods study design which both occurred in 4 studies each.

Table 3.11 Research Designs of General Pharmacy Studies (N=32)

STUDY DESIGN			*Frequency*
Quantitative Study Design	Observational Study Designs	Cross-Sectional Study Design	8
		Retrospective Study Design	1
	Interventional Study Designs	Non-Randomised Trial Study Design	2
		Pre-Post Study Designs or Before-After Study Designs	2
		Experimental or Interventional Study Design	1
Qualitative Study Design			4
Mixed-Methods			4
Pilot/Feasibility Study or Implementation Research			1
Not Indicated	Semi-Structured Interview		7
	Survey		2
Total:			32

Table 3.12 shows the frequency and distribution of the research design in regulatory pharmacy setting. In this setting, the research designs identified were varied namely, use of interpretivist approach and policy analysis which are both qualitative research, one cross-sectional study, and one employed a mixed methods study design.

Table 3.12 Research Designs of Regulatory Pharmacy

STUDY DESIGN			*Frequency*
Quantitative Study Design	Observational Study Designs	Cross-Sectional Study Design	1
Qualitative Study Design	Interpretivist Paradigm		1
	Policy Analysis		1
Mixed-Methods			1
Total:			4

Limitations by Research Design

Risks and limitations of the reviewed studies were tallied according to their research study design (Appendix 2).

Limitations for Randomised Controlled Trials

Figure 3.5 shows the three most reported limitations and risks in randomised controlled trials (RCT) of the reviewed published studies. The most common limitation is limited generalisability (n=29), followed by risk of social desirability bias due to self-reported goals, unblinding, and small sample size occurring in 15 studies each. Time limitation (n=13) which results to short follow up period, and short duration to measure effect of outcome or intervention is the third most common limitation.

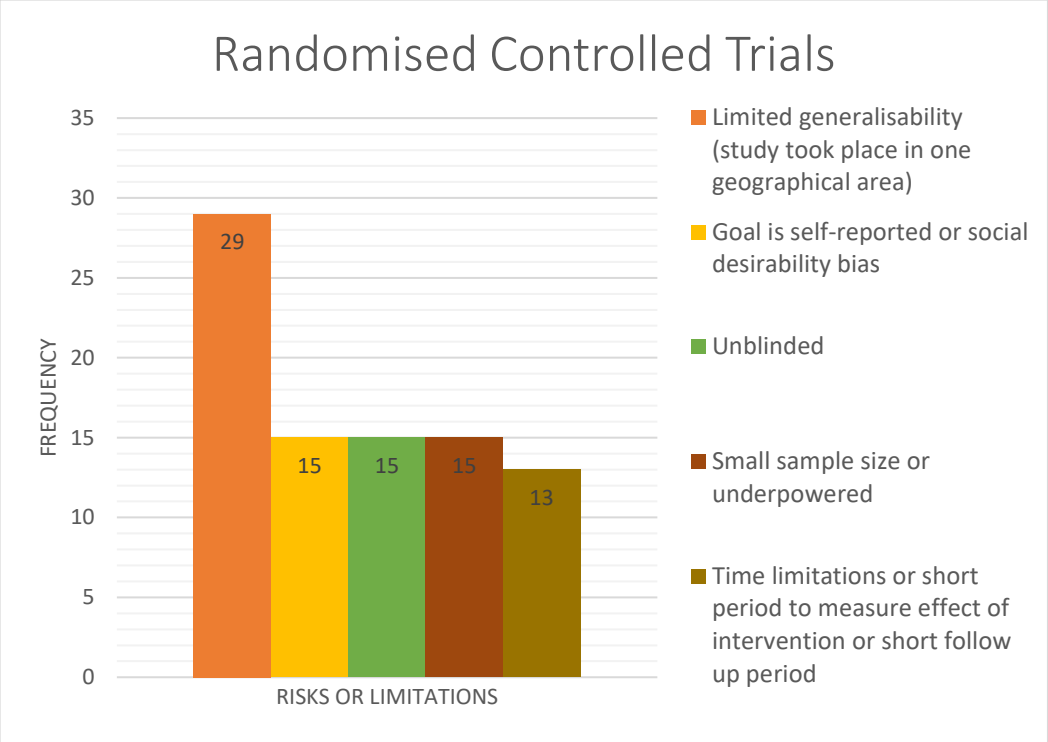


Figure 3.5 Three Most Reported Limitations for Randomised Controlled Trials (N=87)

Limitations for Retrospective Studies

Figure 3.6 illustrates the most reported limitations or risks in retrospective studies of the reviewed published studies. Limited access to data or missing data (n=17) is the most frequent limitation followed by limited generalisability (n=13) and variations with the quality of reporting (n=10) due to interventions being based on pharmacists' judgement or subjectivity.

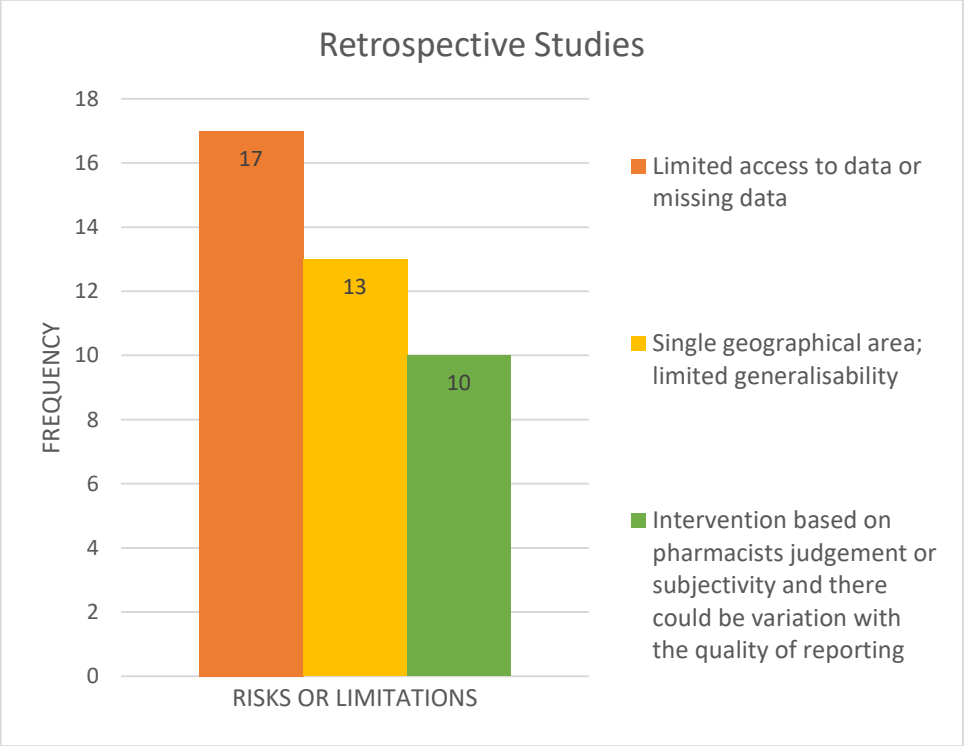


Figure 3.6 Three Most Reported Limitations for Retrospective Studies (N=40)

Limitations for Qualitative Studies

Figure 3.7 shows the most reported limitations or risks in qualitative studies of the reviewed published studies. Sample obtained from limited geographical area, or from single group of experts was the most common limitation occurring in 26 studies, followed by small sample size (n=9), and selection bias (n=7) from the use of non-probability sampling, and strict inclusion or exclusion criteria.

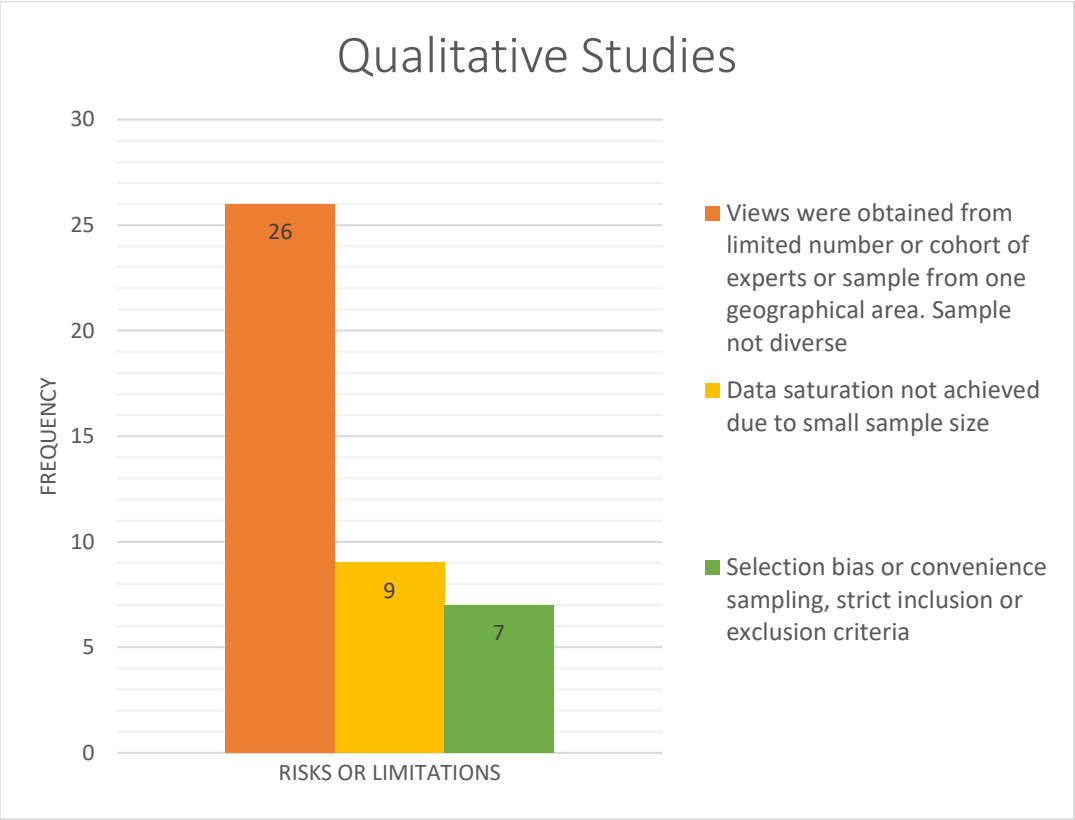


Figure 3.7 Three Most Reported Limitations for Qualitative Studies (N=42)

Limitations for Cross-sectional Studies

Figure 3.8 shows the most common limitations of the reviewed cross-sectional study designs. Social desirability bias or self-reported bias was the most frequently reported limitation occurring in 23 studies, followed by small sample size or low response rate (n=15). Limited generalisability (n=14) was the third most common limitation.

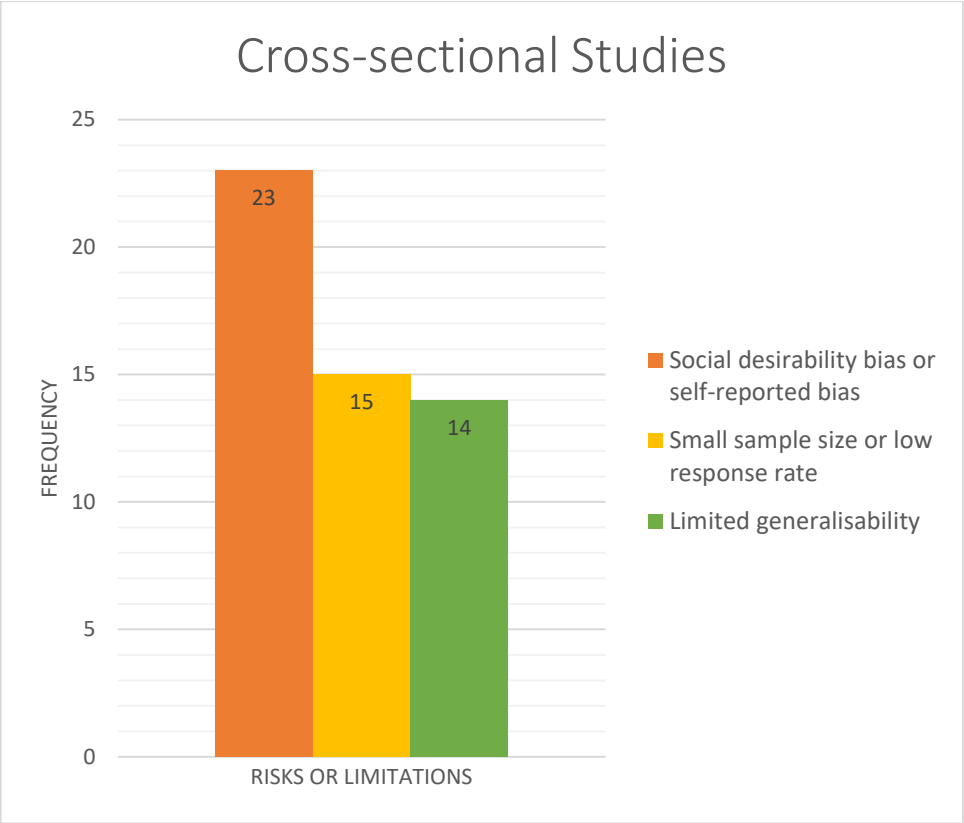


Figure 3.8 Three Most Reported Limitations for Cross-sectional Studies (N=52)

Limitations for Prospective Studies

Figure 3.9 shows the most frequently reported limitations among the reviewed prospective studies. Limited generalisability or being a single centre study was the most reported limitation occurring in 13 studies, followed by lack of access to data or missing data (n=5). Variations between pharmacy operations or inconsistencies in documentation, unmeasured confounder, and lack of a control group were the third most common limitation occurring in 4 studies each.

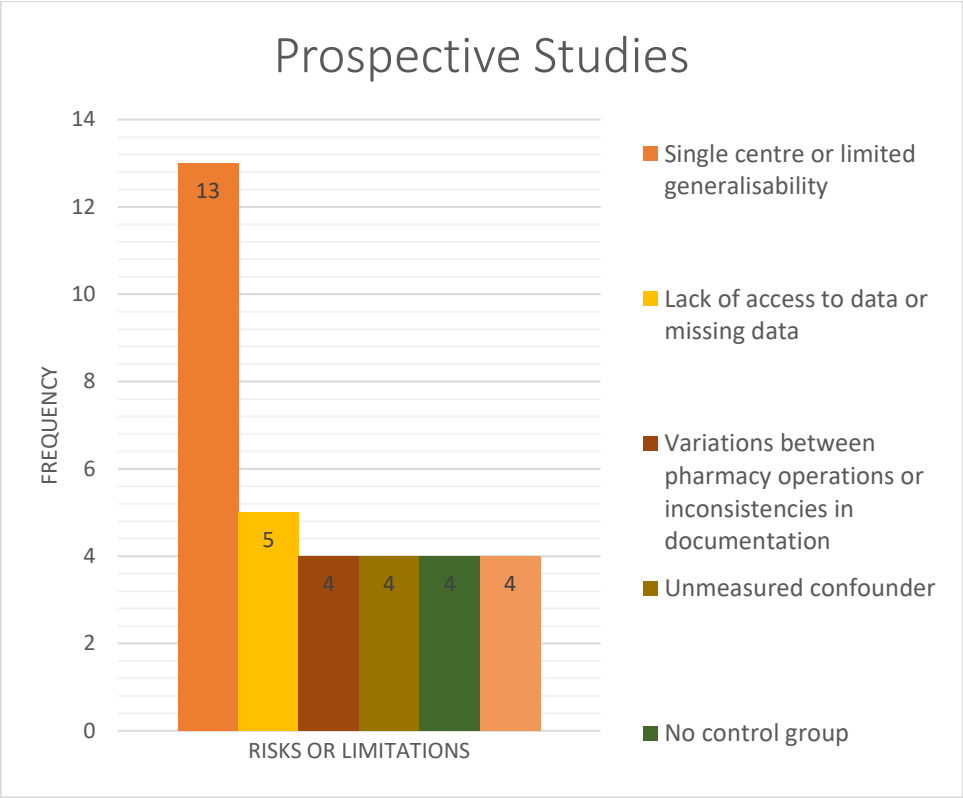


Figure 3.9 Three Most Reported Limitations for Prospective Studies (N=34)

Limitations for Mixed methods Studies

Figure 3.10 illustrates the most frequently reported limitations among the reviewed mixed method studies. Limited generalisability associated with study being conducted on single geographical area or population was the most common limitation (n=13), followed by small sample size resulting to underpowered results and failure to reach data saturation was the most frequently reported limitation (n=10) and recruitment bias such as selection bias or use of purposive sampling (n=6).

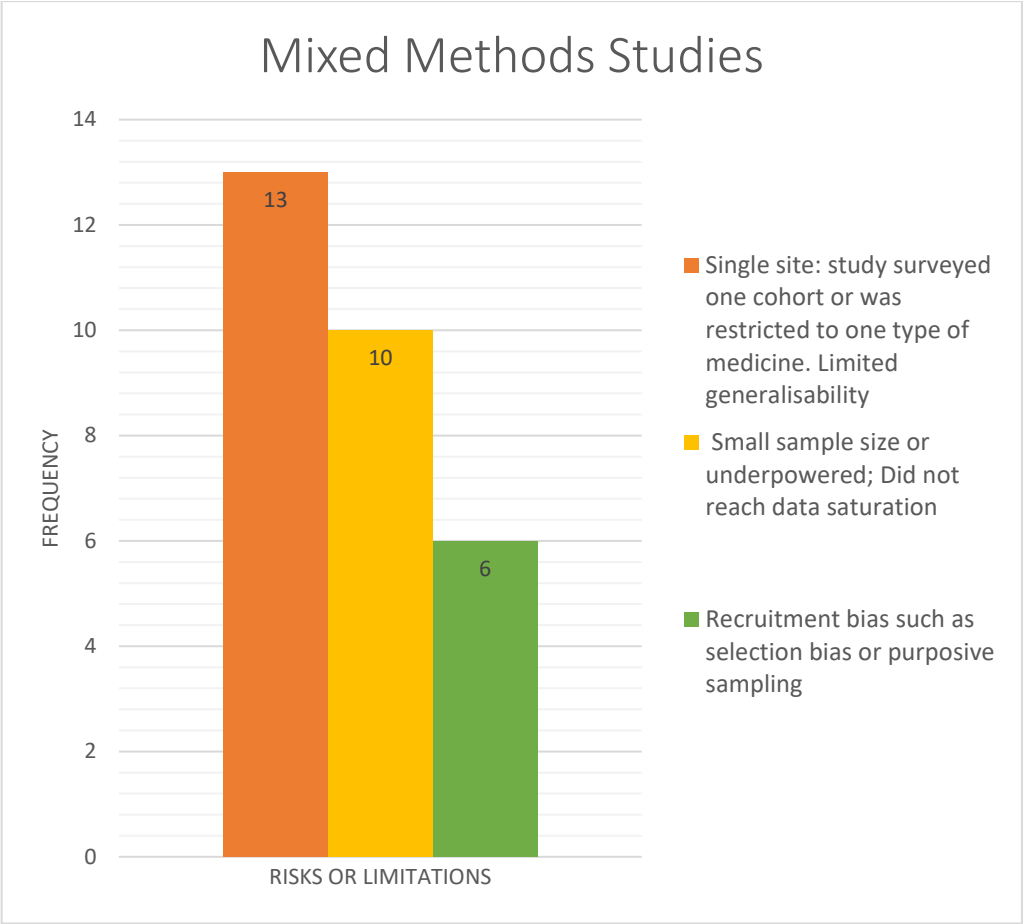


Figure 3.10 Three Most Reported Limitations for Mixed Methods (N=29)

Limitations for Feasibility or Pilot Studies

Figure 3.11 illustrates the most frequently reported limitations in feasibility or pilot studies. Single centre study occurring in 8 studies was the most common limitation followed by limited generalisability (n=6), and small sample size (n=5).

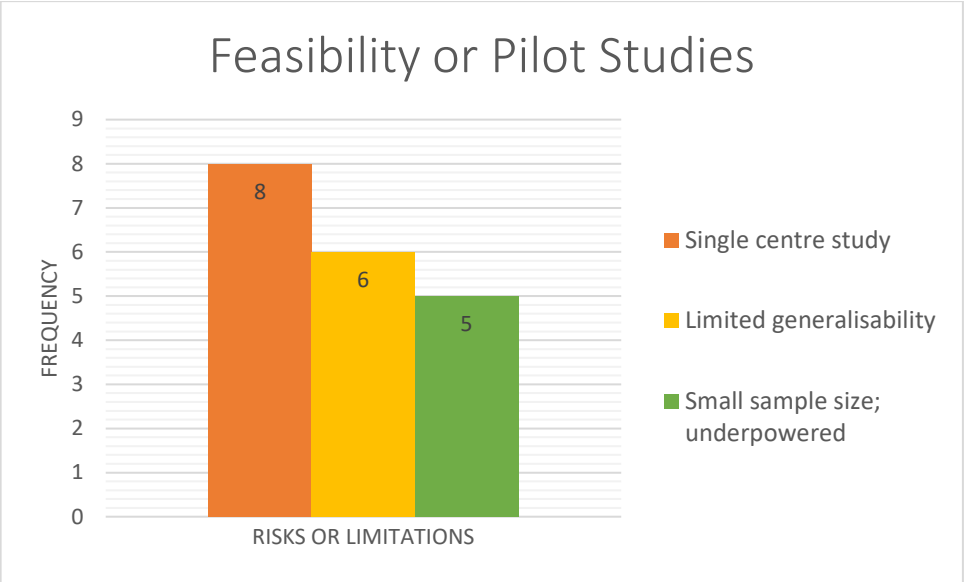


Figure 3.11 Three Most Reported limitations for Feasibility or Pilot Studies (N=19)

Limitations for Pre-post or Before and After Studies

Figure 3.12 shows the most common limitations reported in pre-post or before and after studies. Single centre study occurring in 12 studies was the most common limitation followed by small sample size (n=6), and study design (n=5).

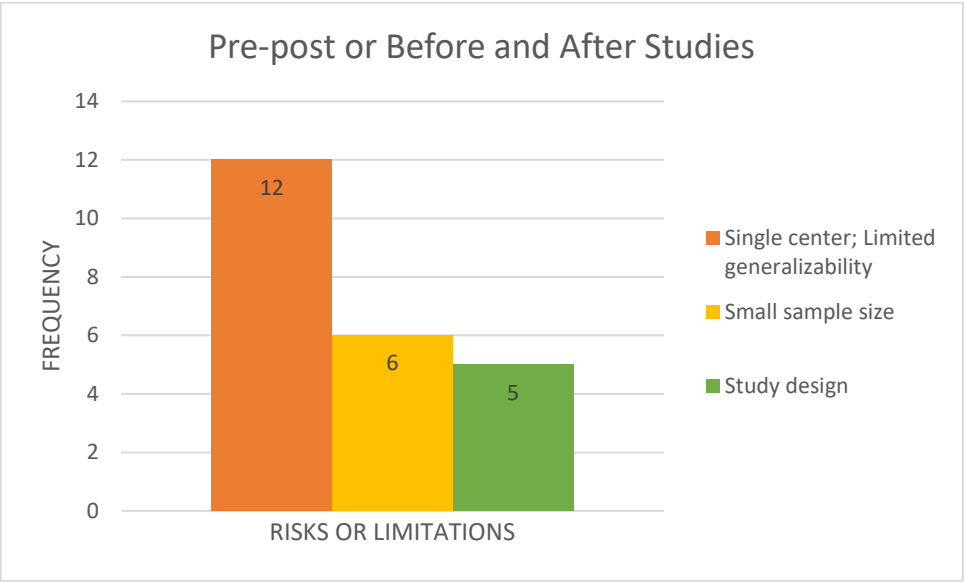


Figure 3.12 Three Most Reported Limitations for Pre-post or Before and After Studies (N=23)

3.3 Focus Group Discussion

Phase two of the study was the identification of risk mitigation strategies through focus group discussion. In this phase of the study, risk mitigation strategies for the risks identified in phase 1 were sought. The FGD also explored views and perception of the panel regarding risks in pharmacy practice research.

The first part of the FGD asked about the risks encountered in research and whether such a topic is significant for researchers; one member of the panel stated that researchers are aware of the risks in research, especially the clinical risks involved. One member highlighted that risk in research can go both ways and may arise for both the researcher and the participant, and hence the researcher needs to be careful not to put him or herself at risk in the process of conducting research.

Three members have pointed out the need of an education or a tool at least to assess the risks encountered in research. It was discussed that there is currently no system in place to gauge the risk, and researchers tend to assume that risks are minimal. Hence, education or use of tool or template which could help assess risks in studies were highlighted to be beneficial.

When asked about gaps in researchers' knowledge or awareness of the risks encountered in research, three essential themes emerged that the panel believes researchers should be more aware of: (1) *informed consent, (2) access to patients' records, and (3) GDPR law.* It was discussed that researchers often fail to make a distinction between consenting for clinical risks for clinical reasons and consenting for research purposes, this includes the distinction for accessing patient records for clinical purpose and for research purpose.

There also seems to be a lack of knowledge about storing, encryption of data, and retention, and lack of awareness of the GDPR.

The second part of the FGD discussed the risk mitigation strategies for ethical risks and risks of bias (Appendix 3). Risk mitigation strategies for risk of physical, psychological, legal, social harm, risk or loss or breach of privacy and confidentiality were discussed among others. Additionally, risk mitigation strategies which can be applied for the most common limitations identified in pharmacy practice research such as small sample size, time limitations, risk of limited generalisability bias, and risk of social desirability bias were also discussed.

The third part of the FGD involved discussion relating to webinar for risks in pharmacy practice research. Expert panel of the focus group discussion were asked about their insight regarding a possibility of a webinar dedicated for discussing risks in pharmacy practice research. If a webinar should be conducted, the panel placed great emphasis on GDPR issues or GDPR law as the preferred topic in addition to the risk mitigation strategies. Target participants of the webinar that were mentioned in addition to pharmacy student and supervisors were possible intermediaries, any research students, medical doctors who are doing research. For speakers to be invited, the panel had mentioned experts in the field of ethics such as members of the ethics committee or a lawyer who could explain and provide insight on GDPR law. The recommended mode of delivery for the course was hybrid and the panel emphasised the incorporation of case studies as an example.

CHAPTER 4

DISCUSSION

This chapter discusses the major findings, puts forward recommendations for further studies, limitations of the research, and conclusion. This study attempted to identify risks and limitations that are encountered in pharmacy practice research including strategies which can be employed to mitigate such risks. Awareness of research risks is essential when considering the appropriate research design and methodology to answer the research question (Smith, 2014). Thorough understanding of the risks and application of risk mitigation measures although may not completely eliminate risks and biases, could improve the quality of research being produce. This study could lead to further discussions and awareness on risks in research, development of courses which could inform and educate research stakeholders, investigate, and fill in knowledge gaps, and ultimately improve research quality.

4.1 Risks and Risk Mitigation Strategies

Recurring risks and limitations observed from both local dissertations and published studies include, time limitations, small sample size, social desirability bias, lack of access to data or missing data, selection bias, and limited generalisability. Time constraints including short follow up period, and short duration to measure the effect of intervention was reported as the most common limitation (n=20) in local pharmacy practice research studies and the third most (n=13) frequently reported limitation in randomised controlled trials of published studies. Time constraints or short duration is consistent with the reported limitations of RCTs in literatures (Kostis, 2016; Saldanha et al, 2022). Implications of RCTs of short duration include potential risk of inaccurate estimates of the lifetime effect of the interventions, may not be able to distinguish between measures of effectiveness, and may be of limited value in determining risks associated with interventions (Kostis, 2016; Saldanha et al, 2022). Expert panel of the FGD recommends

that to minimise these risks, careful consideration should be given to the design of the timeline of the study prior its initiation. This includes allocating adequate period for data collection, recruitment, follow-up, and sufficient period to allow observation of the effects of the intervention.

In local pharmacy practice research studies, small sample size (n=19) emerged as the second most frequent study limitation. In published pharmacy practice research studies, small sample size was among the top three most reported risks and limitations for six study designs namely, RCTs, pre-post study design, feasibility or pilot, mixed methods, cross-sectional, and qualitative studies. From the reviewed pharmacy practice research studies small sample size often resulted from difficulties with recruitment including low response rates from target participants who were unmotivated to participate due to their lack of interest in the research topic, refusals to enrol due to concerns about the risks of the interventions, and short data collection and recruitment period. The FGD's findings recommends that to improve the sample size, recruitment challenges may be addressed by providing research participants the right information about the study's purpose and what is required of them. For instance, in survey-based studies indicating the time required to answer the questionnaire enhances response rate, and ensuring risks are minimised for studies which require tests may improve participation. A study with small sample size would be underpowered to answer the research question and may compromise the study's internal and external validity (Case, 2007; Faber, 2014). In contrast, it is important to note that simply increasing the sample size is not the best approach to minimise the risks associated with a small sample. Although studies which have samples that are larger than necessary will provide more accurate results through better representation of the population, these studies may be expensive and excessively

large samples would be unethical by subjecting more patients to discomfort than necessary to fulfil the study goals. Use of appropriate sampling technique is the most effective approach to ensure that the sample is representative of the population. The sample must be of adequate size, neither too large nor too small (Andrade, 2020).

Missing or lack of access to data is one of the third most common limitation (n=8) reported in local pharmacy practice research studies, the most prevalent limitation reported in retrospective studies (n=17) and the second most common limitation in prospective studies reported in 5 studies. Retrospective studies often rely on analysis of secondary data, and consistent to the result of this study, and of the literatures (Delgado-Rodríguez, 2004; Ramirez, 2018; Talari, 2020) missing data is one of its limitations, and potential source of bias. One risk mitigation strategy which emerged from the FGD was to limit missingness as much as possible during data collection through use of other possible sources. If not addressed, account for the missing data in the study limitation. Missing data in prospective studies is easier to control in comparison to retrospective studies. In prospective studies, measures may be taken during the design by incorporating all variables in the instrument to ensure that no variables are missed (Ramirez, 2018).

Use of Likert-scale in questionnaires is also one of the third most common limitation (n=8) reported in local pharmacy practice research. Psychometric scales or Likert scales have long been struggling with response bias which is particularly concerning in program evaluation due to response shift bias and are also susceptible to social desirability bias and acquiescent responding (Rosenman, 2011; Kreitchmann, 2019). In published pharmacy practice research studies, social desirability bias owing to self-reported goals or data emerged as the predominant limitation in cross-sectional studies (n=23) and

second most prevalent in RCTs (n=15). Self-reported questionnaires are often used to estimate healthcare utilisation and are essential data collection tools used in public health research, clinical practice, and epidemiology. However, the accuracy of such data is of utmost concern (Bhandari, 2006; Marcano Belisario, 2015). External bias caused by social desirability or approval can affect self-reporting data referred to as social desirability bias (Althubaiti, 2016). The main risk mitigation strategies which emerged from the FGD and literature review include ensuring anonymity and confidentiality of the participants. This is especially significant for research studies which explores sensitive topics, it is encouraged that data are to be collected anonymously. This does not only improve respondents' confidence, but anonymity also encourages more truthful answers from respondents reducing social desirability bias. For questions using Likert-scale appropriate question formatting is necessary to limit the risk of social desirability bias. This includes neutral wording of item statements balancing positive and negative items, eliminating ambiguity through keeping questions clear and concise, avoiding vague concepts, and reducing social desirability bias in item wording (Podsakoff, 2011; Paulhus, 2020).

Selection bias is the third most frequently cited limitation in both qualitative studies (n=7) and mixed method study designs (n=6) of the published pharmacy practice research studies. Another significant limitation to note is limited generalisability usually resulted from studies conducted from one single geographical area. This is the most prevalent limitation in 5 study designs of published pharmacy practice research studies namely, RCTs (n=29), qualitative (n=26), prospective (n=13), mixed methods (n=13), and pre-post studies (n=12). This is also the second most common limitation reported in retrospective studies (n=13) and feasibility studies (n=6) and third most in cross-sectional

studies (n=14). The study's generalisability also referred to as external validity is essential in applying research findings. Researchers can strengthen the external validity of their study while resolving issues with internal validity by ensuring sample representativeness and minimising moderating factors that threaten external validity (Ferguson, 2004).

The findings of this study revealed that the main type of data collected and analysed in pharmacy practice research is primary data. Results of the local studies showed that around 89% (n=52) of the studies utilised primary data, where over 63% (n=37) purely primary data and over 25% (n=15) made use of both primary and secondary data. Primary data are collected through different methodologies, for local PPR studies the most common methodology includes the use of a questionnaire, interviews, and focus group discussions. Similar results were also found in published PPR studies where over 75% (n=300) utilised primary data, 46 studies used both primary and secondary data and only 53 made use of secondary data alone. Utilisation and collection of primary data from human participants may pose several risks. The primary role of human participants in research is to serve a data source (Yip, 2016). In collecting primary data, it is essential to consider the type of data to be obtained and the method on how it is collected. It is the researcher's responsibility to "protect the life, health, dignity, integrity, right to autonomy, privacy, and confidentiality of personal information of research participants" (Yip, 2016). It was emphasised in the FGD that researchers must only collect data which is essential to the conclusion of the study, certain variables which is unimportant must be omitted. This type of data collection is known as data minimisation. Important consideration which a researcher must consider when collecting primary data is the need for an informed consent. In this study, informed consent was one of the key ethical

concerns raised during the focus group discussion. Obtaining informed consent is considered as a crucial aspect in research and is a requirement under GDPR (Daehnhardt,2021).

Results of the local studies showed that hospital pharmacy practice research setting have utilised the most secondary data (n=6). Similar results were also observed in published studies, wherein around 27% (n=45) of the reviewed hospital pharmacy studies utilised secondary data. For decades, use of 'big data' and electronic health records in research has been the goal of biomedical informatics professionals. Transformation of clinical data into actionable knowledge to help improve patient care has expanded beyond the field of biomedical informatics (Ross, 2014). The type of secondary data used in the hospital setting were patient profiles and medication records. Access to patient records was the second concern that came up during the FGD on gaps among researchers' knowledge gaps regarding risks in research. In the FGD, the panel have pointed out that oftentimes, researchers who have access to patient data due to the nature of their work, perceived that they have the rights to use such patient data for research. According to one FGD panellist, it can be challenging for people to comprehend the crucial distinction between accessing and obtaining patient data records for clinical purpose and for research purposes. Concerns on how the data should be stored, encrypted, and retained also emerged.

4.2 Limitations

The collection of data for the inclusion of pharmacy practice research studies for both local and online published studies were done solely by the researcher. Although careful assessment of each study was made by the researcher, a risk of misclassification bias cannot be ruled out. This can be minimised if an independent person was to validate the results of the systematic search and the classification. Convenience sampling was used in the recruitment of participants for the focus group discussion. Data saturation was not achieved in the focus group discussion owing to the small sample size.

4.3 Recommendations for Future Studies

Further research could explore the implementation of a webinar for pharmacy student researchers regarding risks in pharmacy practice research. Such study may explore the research stakeholders' knowledge, attitudes, and perspective of risks in pharmacy practice research. Themes or topics gathered from the study's findings may be included in the themes or topics to be covered in the informative webinar; it may also contain discussions on risk of biases and ethical risks in pharmacy practice research and the risk mitigation strategies which can be employed.

4.4 Conclusion

This research led to the identification of risks and limitations in pharmacy practice research. Such risks were found to exist in different phases of the research process and could have varying degree of effect on the study. The most common limitations found in the reviewed pharmacy practice research study were related to limited generalisablility owing to limited sample size, sampling bias such as selection bias, and time constraints. Such limitations could threaten the external validity of the study which is essential in

practice research studies. With this knowledge, future pharmacy practice researchers could be aware of limitations and implement mitigation strategies enabling them to plan the choice of research design, data collection method, and the timeline of the conduct of the study. Capacity building, and awareness for researchers in research ethics and the various methodologies, study designs, and analysis employed in pharmacy practice research should be further explored and receive more attention. These findings will inform pharmacy educators or researchers to develop and implement structured programmes aimed at cultivating awareness and understanding of risks in pharmacy practice research. Further research of other research stakeholders such as students' perception and understanding of risks in pharmacy practice research may be explored.

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Appendix 1

Ethics Approval

L-Università ta' Malta

Jaycerie Joy Amar <jaycerie.amar.19@um.edu.mt>

The status of your REDP form (MED-2022-00176) has been updated to Approved

1 message

form.urec@um.edu.mt <form.urec@um.edu.mt> 15 September 2022 at 07:58
To: jaycerie.amar.19@um.edu.mt

Dear Jaycerie Joy Amar,

Please note that the status of your REDP form (MED-2022-00176) has been set to *Approved*.

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

This email has been automatically generated by URECA. Please do not reply. If you wish to communicate with your F/REC please use the respective email address.

Appendix 2

Published Pharmacy Practice Research Studies Limitations by Research Design

Randomised Controlled Trials	
Risks or Limitations	*Frequency*
Limited generalizability/ study took place in one area/hospital	29
Goal is self-reported/ social desirability bias	15
Small sample size/Underpowered	15
Unblinded	15
Time limitations/short period to measure effect of intervention/ short follow up period	13
Limited access to data/missing data	11
Measurement bias	9
Unmeasured confounding variable	9
Loss to follow up/high number of non-completers/participants left within the study period/Attrition bias	7
Outcome assessment did not use a validated tool/ validation tool not fully validated/ Intervention not standardized	7
Selection bias	7
Spillover effect	7
Recruitment challenges	5
Possible confounding	4
Therapist effect	4
Hawthorne/observer effect/performance bias	3
Imbalances between treatment groups at baseline/ unequal distribution	3
Recall bias	3
Change in eligibility/ change in sample size and treatment group	2
Incomplete allocation concealment and analysis or risk of concealment of allocation	2
Not representative	2
Variation in intervention among pharmacists	2
Volunteer bias	2
Choice of intervention is time consuming and susceptible to error	1
Intention to treat analysis not feasible	1
Language barrier	1
Outcome not measured	1
Patient not used to pharmacists taking interest in clinical status	1
Patients may not be adherent to strategies	1
Post-hoc analysis	1
Questionnaire formatting	1
Results of the Usual Care may have been overestimated	1
Sequential activation of the intervention	1
Study Design	1
Timing of the assessment between intervention and control group was different	1
Unexpected confounding	1
Retrospective Studies	
Risks or Limitations	*Frequency*
Limited access to data or missing data	17
Single geographical area; limited generalizability	13
Intervention based on pharmacists judgement or subjectivity and there could be variation with the quality of reporting	10
Study design	9
Unmeasured confounding	9

Selection bias/ sampling bias	7
Small sample size or underpowered	7
Limited generalizability	6
Imbalances between treatment groups at baseline/ unequal distribution	5
Inconsistencies in documented data	5
Unmeasured outcomes	5
Measurement bias	4
Not randomised	4
Time limitations/Short time for data collection	4
No control group	3
Long term effect of intervention not assessed	2
Resource constraints	2
Comparison of medication list corrections and intervention with the control group was not made	1
Confounding	1
Did not account for potential variation which may affect readmission	1
Hawthorne effect	1
Inter-rater reliability not assessed	1
Learning effect	1
Misclassification	1
Non-response bias	1
Possible bias concerning control group due to other factors that were not applied to the covariate	1
Power estimation for the primary outcome was not based on data reported in the literature	1
Prescribers unfamiliarity with the new tech	1
Recruitment challenges	1
Regression to the mean	1
Unable to follow patients longitudinally through the anonymised database	1
Unblinded	1
Whether patients took their medication was impossible to confirm	1
Whether the additional medications are related to the pharmacist-led team approach was not assessed	1
Total:	129
Cross-sectional Studies	
Risks or Limitations	*Frequency*
Social desirability bias or self-reported bias	23
Small sample size or low response rate	15
Limited generalizability	14
Unequal distribution of sample (over or underrepresentation of a certain population)	13
Study design	12
Participants from one geographical area	10
Nonprobability sampling such as quota or convenience sampling	8
Recall bias	8

Selection bias	8
Missing data or lack of access to data	4
Online distribution of questionnaire	4
Variation between pharmacists providing the service	4
Characteristics of respondents vs non-responders not known	3
No open-ended questions or use of close or leading questions	3
Reporting bias	3
Self-administered questionnaire or Dunning Kruger Effect	3
Conducted during peak of Covid-19	2
Details of pharmacists' intervention not collected	2
Findings did not allow comparison	2
Nonresponse bias	2
Unmeasured confounder	2
Use of Likert scale	2
Did not consider all type of transitions of care	1
Disparity in survey description	1
Incentive	1
Instrument not validated	1
Measurement bias	1
No control group	1
Patient could misunderstand questions	1
Pharmacist may have deviated from their regular behaviour	1
Questionnaire formatting such as use of positive statements	1
Questionnaire not detailed	1
Recruitment challenges	1
Resource limitation	1
Response rate not known	1
Risk of sampling frame error	1
Seasonal fluctuation of medicine consumption	1
Survey items were formulated according to the direct TPB methodology	1
Survey was anonymously completed hence response cannot be validated	1
The cut-off score used for positive and negative views were fixed at the middle point which may not actually represent the real views of the respondents.	1
The departments in which the hospital pharmacists practiced were not included in the analysis.	1
Time limitations	1
Use of open-ended questions which carries risk of misinterpretation	1
Volunteer bias	1
Total:	169

Prospective Studies	
Risks or Limitations	*Frequency*
Single centre or limited generalizability	13
Lack of access to data or missing data	5
No control group	4

Selection bias	4
Unmeasured confounder	4
Variations between pharmacy operations or inconsistencies in documentation	4
Hawthorne effect or performance bias	1
Information bias	1
Measurement bias	1
Not blinded	1
Not randomised	1
Not representative	1
Only pharmacists detected and analysed DRP	1
Patients' acceptance of the intervention not assessed	1
Randomisation of pharmacists instead of patients	1
Resource limitation	1
Sample size not calculated	1
Self-reported bias	1
Study design	1
Study was validated at a time when most patients were taking treatments based on protease inhibitors, the use of which has now been reduced.	1
Unbalanced variable between intervention	1
Total:	54
Qualitative Studies	
Risks or Limitations	*Frequency*
Data saturation not achieved due to small sample size	9
Selection bias or convenience sampling, strict inclusion, or exclusion criteria	7
Limited generalizability	6
Self-selection or volunteer bias	6
Social desirability bias or self-reporting bias	5
Study design	5
The principal investigator is the interviewer or interviewer effect bias	5
Covid-19 resulting to small sample size	4
Unequal sample distribution, not representative or overrepresentation	4
Views were obtained from limited number or cohort of experts or sample from one geographical area. Sample not diverse	26
Recruitment challenges resulting to small sample size	2
Response bias	2
FGD conducted online where establishing rapport is difficult	1
High rejection rate	1
Interview question format	1
Interview unearthed no new concepts	1
Language barrier	1
Missing data	1
Recall bias	1

Resource limitation	1
Short duration of the interview	1
Single coder conducted data collection	1
Telephone interview	1
Time constraints	1
Variation among participants proficiency on the topic. Reporting or cognitive bias	1
Total:	94
Mixed Methods	
Risks or Limitations	*Frequency*
Single site: study surveyed one cohort or was restricted to one type of medicine. Limited generalizability	13
Small sample size or underpowered; Did not reach data saturation	10
Recruitment bias such as selection bias or purposive sampling	6
Self-reported bias or social desirability bias	5
Inconsistencies in pharmacists' reporting on consultation notes	4
Voluntary participation or volunteer bias	3
Findings not representative	2
Unable to measure potential modifiers	2
Logistical or resource limitations	2
Loss to follow up	2
Response bias	2
Recall bias	2
Missing data	2
Cost of implementation not estimated	2
No content validation	1
No control group	1
Staff left during the trial	1
Time limitations	1
Data of pharmacists who did not participate were not collected	1
Evaluation of implementation did not include perspectives of physicians and patients.	1
Learning effect	1
Technical problems with database and follow up not as rigorous	1
Records on uptake of the service were incomplete	1
Variations with the extent and range of engagement with participants	1
Only two measures were analysed	1
Construct and analysis were not grounded on a theoretical framework	1
Confounding variable	1
Measurement bias	1
Hawthorne effect	1
Strict exclusion criteria	1
Online FGD	1
Researcher bias	1
Total:	75
Feasibility or Pilot Studies	
Risks or Limitations	*Frequency*

Single study	8
Limited generalizability	6
Small sample size; underpowered	5
Convenience sampling or selection bias	3
Channeling bias	1
Confounding	1
No control group	1
Not randomised	1
Performance bias	1
Seasonal variations	1
Recall bias	1
Recruitment challenges	1
Self-reporting bias or Social Desirability bias	1
Study design	1
Unmeasured confounding	1
Volunteer bias	1
Conflicting results	1
Pharmacists intervention not validated	1
Response bias	1
Observer bias	1
Interruptions during face-to-face consultation	1
Contamination bias	1
Varying recommendations from pharmacists	1
Limited access to data	1
Total:	42
Pre-post or Before and After studies	
Risks or Limitations	*Frequency*
Single center; Limited generalizability	12
No control group	4
Study design	5
Small sample size	6
Possible confounding	2
Instrument not validated formally	2
Intervention was not validated/assessed for appropriateness	1
Lack of randomization	3
Selection bias	2
Time limitations	1
Strict inclusion criteria	1
Measurement bias	2
Missing data	1
Small number of data points	1
No clinical endpoints considered	1
Seasonal variations	2
Considered all-cause readmissions	1

False discovery rate or experiment-wise error in analyses of representativeness of reach was not corrected for	1
Contamination bias or spillover effect	1
Not blinded	2
High dropout rate	1
Unmeasured confounder	2
Social desirability bias	1
Logistical limitations	1
Reporting bias	1
Scarcity of tools to measure knowledge	1
Only one outcome measured or other outcome not measured	2
Variabilities of intervention and outcome	1
Not representative	1
Total:	62

Quasi-Experimental and Intervention or Experimental Study	
Risks or Limitations	*Frequency*
Small sample size	4
Limited generalizability	3
Short duration to assess intervention	3
Unmeasured confounding	3
Not randomised	2
Purposive sampling/selection bias	2
Study design	2
Single centre	2
Interview did not capture reasons for modification	1
Missing data	1
Possible confounding	1
Sample size calculation not adjusted for clustering	1
Strict inclusion criteria	1
Self-reported bias	1
Recall bias	1
Channeling bias	1
Recruitment bias	1
Response bias	1
Selective outcome reporting	1
Analysis bias	1
Missing data	1
Unmeasured outcome	1
Appropriateness of intervention not assessed	1
Intervention did not address other factors	1
Spillover effect	1
No control group	1
Not blinded	1
Baseline attitude or perception not assessed	1
Total:	41

Descriptive	
Risks or Limitations	*Frequency*
Convenience sampling or selection bias	3
No control group	1
Questionnaire not validated	1
Unmeasured confounding	1
No sample size calculation was estimated	1
Small sample size	1
Total:	8
Non-randomised Trial	
Risks or Limitations	*Frequency*
Self-reporting bias or social desirability bias	1
Short interval to measure relapse	1
Study design	1
Seasonal fluctuations	1
Choice of intervention measure	1
Total:	5
Delphi	
Risks or Limitations	*Frequency*
Purposive sampling or selection bias	3
Volunteer bias	3
Conducted online	2
Small sample size	2
Cognitive bias	1
Study design	1
Not validated	1
Sample not representative	1
Loss to follow up	1
Unequal distribution of participants	1
Rapid change in demographic pattern of disease	1
Reduced agreement in the second round	1
Total:	18

Data collection Method	Risks or Limitations	*Frequency*
Simulated Patient Techniques	Limited generalizability; conducted in one geographical area	4
	Hawthorne effect or Performance bias	2
	Recall bias	2
	Volunteer bias	1
	Convenience sampling or selection bias	1
	Pharmacists are not distinguished from assistants	1
	A real patient may communicate more freely vs simulated patients	1
	Variation between simulated patients' performance	1

	Estimates of effectiveness on patient outcomes may be inaccurate	1
	Missing data	1
	Total:	**13**
Feasibility/Implementation of an intervention	Small sample size; limited generalizability	1
	Volunteer bias	1
	Total:	**2**
Cognitive Task Analysis	Self-reported bias	1
	Recall bias	1
	Total:	**2**
Matched Case-Control Study	Short data collection time	1
	Total:	**1**
Questionnaire and Interview	High proportion of certain patient population	1
	Volunteer bias	1
	Service requires trained pharmacists	1
	Total:	**3**
Retrospective Analysis	Small sample size	1
	Short period for follow up	1
	Total:	**2**
Cost-Analysis	Limited generalisability	1
	Total:	**1**
Case-Cohort	Study design	1
	Small sample size	1
	Missing data	1
	Variation between groups	1
	Variation between pharmacist intervention	1
	Limiting generalisability	1
	Total:	**6**
Data Collection Method	**Risks or Limitations**	***Frequency***
Survey	Data collected from limited area; Limited generalizability	9
	Volunteer bias	7
	Small sample size	6
	Social desirability bias or self-reported data	6
	Non-probability sampling (convenience or purposive sampling)	5
	Questionnaire not validated	3
	Response rate unknown	3
	Response bias	3
	Recall bias	3
	Reporting bias	2
	Underpowered	2

	Sample not representative	2
	Few questions in questionnaire; Questionnaire formatting	2
	Selection bias	1
	Study Design	1
	Survey distributed online	1
	Missing data	1
	Characteristics of non-respondents unknown	1
	Measurement error	1
	Non-response bias	1
	Cognitive bias	1
	Total:	61
Interview	Selection bias; Limited generalizability	6
	Recall bias	3
	Social desirability bias	3
	Participants knowledge on the topic may limit their ability to answer specific questions sufficiently	2
	Small sample size	3
	Confirmation bias	1
	Design of the study	1
	Lack validity measures for the questionnaire	1
	Self-selection bias or volunteer bias	1
	Response bias	1
	Question formatting	1
	Analysis was based on interview at one single point	1
	Non-response bias	1
	Data generation and analysis were solely performed by researchers with a pharmacy background.	1
	Single location	1
	Total:	27
Data collection Method	Risks/ Limitations	*Frequency*
Intervention/Pre-post	Strict inclusion criteria; small sample size	9
	Single pharmacy	7
	Intervention made was not validated/assessed	4
	Measurement bias	4
	Lack of access to data; missing data	3
	Limited duration or shorter follow up period	3
	Selection bias	3
	Variation in pharmacy intervention/ some intervention may not be documented	2
	No randomisation	2
	Loss to follow up; Tracing and follow up challenges	2
	Self-reported data	2
	Limited generalisability	2

	Unmeasured confounding	1
	No control group	1
	Unmeasured confounding	1
	Limited data collected	1
	Patients may have responded multiple times	1
	Response rate not known	1
	Assessment conducted by researcher	1
	High dropout rate	1
	Unequal sample distribution	1
	Reporting bias	1
	Used a generic instrument which may not be sensitive to the population	1
	Use of historical control	1
	Validity and reliability of instrument not assessed	1
	Not anonymous	1
	Recruitment challenges	1
	Recall bias	1
	Limited engagement with patient's carer	1
	Unmeasured confounding	1
	Total:	**61**
Decision Analytic Modelling/ Decision Tree Model	Single study; limited generalizability	3
	Unmeasured confounding	1
	Outcome not validated	1
	Number of smokers seen by physician or pharmacists were assumptions	1
	Selection bias	1
	Data source may not be accurate representation or population	1
	Total:	**8**
Analysis of reports and review of intervention	Underreporting or selective or incomplete reporting	2
	Categorisation can be subjective which may result to risk of misclassification	1
	Conducted in one hospital: limited generalizability	1
	Total:	**4**
Critical Decision Method	Single Centre	1
	Total:	**1**

Appendix 3

Risk Mitigation Strategies

ETHICAL RISKS	RISK MITIGATION STRATEGIES
Risk of Physical Harm	For procedures: 1. Individual – The person conducting the procedure (i.e., blood collection, finger-prick, others) are competent and experienced. If possible, a professional who are experienced in doing such procedure (for example – a nurse/doctor). If not, a declaration must be made to ensure that whoever is conducting the procedure has several months/years of experience. → Competence and experience in conducting the procedure must be established. 2. Tools – have the right tools. There must be right tools for the collection of samples and proper disposal of the tools used. 3. Environment – procedures must be conducted in a space where there is peace and quiet 4. Contact – A contact number of a doctor/ a pharmacist where participants can go in case of any complications/ for any queries. Detailed description of the procedure → Detailed description of the approach/procedure should be included in the research protocol to demonstrate that the researcher can provide the best assurances possible that any risk may be minimised. Consent letter → Should include in the consent form the possible risks that may occur (i.e., risk of bleeding or bruising)
Risk of Psychological Harm	1. Consent – especially for children/minors and assent (for minors of reasonable age) 2. Intermediary - Recruit participants through an intermediary. Describe in the consent form through the intermediary what the participants are expected to be doing in a clear and fair manner. 3. Environment - Recruitment and administration of the survey questions/interview must be conducted in a private environment For the interviews or use of questionnaires ▪ May list of questions and have it vetted by a psychologist/ someone experienced to ensure that the questions are formed/worded that is not so abrasive. ▪ Consider the length of the questionnaire – too many questions may put the participants in an uncomfortable position. ▪ For interview – interviewer must be trained to ask questions that does not pose psychological harm.

	▪ when it comes to children, individual mental health conditions or elderly, there should at least be **a person accompanying** the subject who can sort of filter your questions or answer your questions, or at least anyway, give some degree of protection to the patient.
Risk of Legal Harm	Anonymity
Risk of Social Harm	1. Anonymity/pseudo anonymity 2. Data minimisation – only collect necessary data.
Risk of non-harmful intervention	Procedure/ intervention needs to be very well explained in the consent form
Risk of insensitivities to vulnerabilities, exposing individuals to various types of harm/risks	1. Consent and/or assent – children/minors 2. Elderly – consent. If incapable - next of kin – to consent
Risk of Loss/breach of privacy and confidentiality	1. **Anonymity** 2. **Intermediary** 3. **Data minimisation**– collect as little personal data as possible – if it is not integral to the conclusions expected from the study 4. **Metadata** are kept separate from the sample, preferably in a coded manner. But encrypted, in a defined place, for a defined period. The samples, coded, again in a secure place, but only a defined person can access. It cannot be used for any other study, and it must be destroyed. **Collection of unpublished secondary data.** ▪ Through an intermediary and the intermediary will give then provide a pseudonymised data removing the identifiers. ▪ Consent from every patient – to access his/her data get the consent, then from the patient, the intermediary can get the consent for you.
Risk of Incidental Findings	**Referral** - inform the consultant in charge of this patient about the incidental finding. The consultant will then inform the patient of the finding.
Risk of harm to the researcher	If there is a procedure to be performed and a risk of physical harm can occur (i.e., risk of needle stick injuries) • The researcher must be competent enough to perform the procedure. • Should have the right tools and access to appropriate disposal. • It must be stated in the protocol what must be done if such an injury would occur.

Limitations	Risk Mitigation Strategies (RMS)
Time constraints • Short data collection period • Short recruitment period • Short duration or interval to measure effects of intervention • Short follow up period	1. Design study with longer data collection period or field work.
Sampling bias • Selection bias • Volunteer bias	2. With the research question in mind, ensure that a sample is matched closely to the population as much as possible. To ensure that the sample is representative of a population, avoid non-probabilistic sampling (i.e., purposive sampling, convenience sampling). Randomisation is a well-documented tool to reduce bias.[1] Sampling should be random such that every subject has equal probability to be included in the study.[2]
Limited generalizability • Small sample size ○ Recruitment challenges such as patients refusing to participate because of the testing involved • Single centre or study took place on one geographical area • Sample not representative • Questionnaire distribution	3. For recruitment challenges such as respondents' lack of interest/apprehension: Explain the research, what the participants will undergo and the benefit of the research to the community. 4. Employ Benchmarking Method for assessing validity and generalizability and for planning clinical trials[3] 5. For risk of limited generalisablility, refer to RMS 2.
Missing data • Limited access to data	6. Limit missingness where possible during data collection. 7. Data can be missing for multiple reasons:[4]

[1] Krishna Mohan S, Mrsc M, Assistant F. Research Bias: A Review for Medical Students. Journal of Clinical and Diagnostic Research. 2010;4:2320-23242320.doi: https://doi.org/10.7860/JCDR/2010/.677

[2] Simundić AM. Bias in research. Biochem Med (Zagreb). 2013;23(1):12-5. doi: 10.11613/bm.2013.003. PMID: 23457761; PMCID: PMC3900086.

[3] Malmivaara A. Generalizability of findings from randomized controlled trials is limited in the leading general medical journals. Journal of Clinical Epidemiology. 2019;107:36-41.doi:10.1016/j.jclinepi.2018.11.014

[4] Ferreira JC, Patino CM. Loss to follow-up and missing data: important issues that can affect your study results. Jornal brasileiro de pneumologia; J Bras Pneumol 2019;45(2):e20190091.

• Loss to follow up (participants left within the study period) • Unmeasured confounding	a. Missing completely at random (MCAR) • Develop standardized data collection form; monitor quality of data; ensure participant information is up to date b. Missing at random (MAR) • Consider offering benefits and incentives to retain participants; contact participants regularly; consider conducting a pilot study to identify risks factors c. Missing not at random (MNAR) • Offer sufficient support for study respondents; develop strategies to retain participants with high risk of loss to follow-up; develop alternative methods to measure the outcome for participants lost to follow up. 8. If needed, account for it as a limitation of the study.
Social desirability bias • Goal is self-reported (ideal answers may have been chosen) • Questions using Likert-scale	9. For questions using Likert-scale:[5] a. Procedural Remedies • Improve scale items to eliminate ambiguity • Reducing social desirability bias in item wording • Balancing positive and negative items b. Statistical Remedies 10. For questions using Likert-scale a. Consider supplementing with open-ended questions. 11. Reduce social desirability bias in qualitative research through:[6,7] a. Careful planning of research project giving special attention to definition of objectives, choice or research methods, selection of respondents and the explanation of instruments. If possible, investigator should choose more than one source of information

[5] Podsakoff PM, MacKenzie SB, Podsakoff NP. Sources of method bias in social science research and recommendations on how to control it. Annu Rev Psychol. 2012;63:539-69. doi: 10.1146/annurev-psych-120710-100452.
[6] Bispo Júnior JP. Social Desirability Bias in Qualitative Health Research. Revista de saúde pública; Rev Saude Publica 2022;56:101.doi: 10.11606/s1518-8787.2022056004164
[7] Bergen N, Labonté R. "Everything Is Perfect, and We Have No Problems": Detecting and Limiting Social Desirability Bias in Qualitative Research. Qualitative Health Research. 2020 Apr;30(5):783-792. doi: 10.1177/1049732319889354.

	to triangulate the data and conduct interview or focus group after having access to information from other sources. b. For interview scripts or focus group, questions should be formulated in a way as to clarify that there is no problem in sharing positions or revealing socially disapproved actions. Words and expressions which are emotionally charges or may imply value judgement about a certain behaviour should be avoided. c. Ensure privacy and conducive atmosphere, establish rapport d. Confidentiality of data and information should be safeguarded, and anonymity should be assured e. Avoid unexpected participation in interviews and focus groups f. Proper cognitive and relational training of researcher responsible for fieldwork is required. Pre-fieldwork training with data collectors, regular debriefing session, and research team meetings to discuss social desirability tendencies and refine approaches. g. Have sensitivity to identify situations of desirability bias and reflect critically 12. Social Desirability Bias can be addressed through:[8] a. Direct reduction of bias • Maintain respondent's anonymity and ensure confidentiality. b. Indirect reduction of bias • Respondents' anonymity and modify questions to neutralize answers which may appear socially acceptable. c. Testing for bias d. Controlling for the bias • Include a measure for social desirability bias in the analysis
Performance bias	13. Blinding

[8] Larson RB. Controlling social desirability bias. International Journal of Market Research 2019;61(5):534-547.doi: 10.1177/1470785318805305

• Hawthorne effect • Observer or Interviewer bias	
Measurement error bias • Recall bias • Sample integrity may be compromised or possible error in sampling technique resulting to inaccurate results • Results obtained not compared to a laboratory result	14. Checking other sources. You can limit the bias by increasing the number of sources you are checking. 15. Validate tool and ensure that machines used are calibrated well
Cognitive bias • Intervention highly dependent on pharmacists' knowledge and experience	16. Ideally choose pharmacists which reflect the true pharmacist population

Appendix 4

Dissemination

Poster Presented at the 2023 European Association of Faculties of Pharmacy Conference in Valencia, Spain

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

RISKS IN PHARMACY PRACTICE RESEARCH

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INTRODUCTION

The conduct of pharmacy practice research has contributed to the advancement and innovation of professional pharmacy practice. The emergence of large and complex data sets, dealing with electronic health records and pharmacy practice researchers' use of a variety of mixed methodologies could all pose methodological challenges and risks.[1,2] Risks could arise across the research process, from research design, recruitment process, analysis and interpretation of data to implementation of results.

AIMS

To identify risks in pharmacy practice research and determine ways how to mitigate or avoid such risks.

The objectives were to:

1. Identify risks encountered in pharmacy practice research through review of pharmacy practice research studies,
2. Develop a risk minimisation strategy based on the identified risks

METHOD

Phase 1 – Identification of pharmacy practice research studies and their risks and limitations

Phase 1 involved the development and validation of a search strategy and the establishment of inclusion and exclusion criteria to identify pharmacy practice research studies. Studies were retrieved and risks and limitations identified. Records were identified through the Open Access Repository of the University of Malta from 2015-2022.

Phase 2 – Identification of risk mitigation strategies

Phase 2 involved the identification of risk mitigation strategies through literature review and a focus group discussion which consisted of two academic pharmacists and two members of the Faculty Research Ethics Committee of the University of Malta.

RESULTS

- A total of 545 titles were retrieved from the Open Access Repository.
- Duplicates, abstracts, poster presentations, and editorials were excluded, leaving 234 studies for title and abstract screening.
- PhD studies and those which the researcher did not have access to were excluded leaving 199 dissertation studies assessed for eligibility (Figure 1).
- A total of 58 studies were included for the review, of which 27 were set in a hospital pharmacy and 20 focused on a pharmacy service or intervention.
- Time constraint was the most common limitation reported (n=21), followed by a small sample size (n=19) and incomplete data (n=8).
- Mitigation strategies to address the identified limitations include designing the study with a longer data collection period, explaining the benefit of the research to the community and limiting and diagnosing missing data where possible.

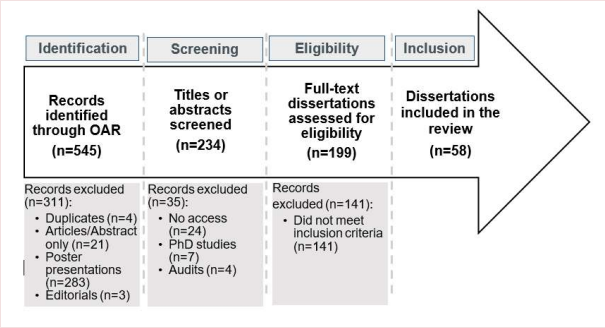

Figure 1. Overview of studies included in the review

CONCLUSION

Through the identification of risks in pharmacy practice research and the development of risk minimisation strategies, this study could contribute to the improvement of the quality and robustness of pharmacy practice-based research studies. Capacity building and awareness of researchers on risks and the various methodologies, study designs, and analysis employed in pharmacy practice research should receive more attention.

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1 Babar Z-, Scahill S, Nagaria RA, Curley LE. The future of pharmacy practice research – Perspectives of academics and practitioners from Australia, NZ, United Kingdom, Canada and USA. Research in Social and Administrative Pharmacy. 2018;14(12):1163-1171. doi: 10.1016/j.sapharm.2018.01.004

2 Ma C, Wong Smith H, Chu C, Taira Juarez D. Big data in pharmacy practice: current use, challenges, and the future [Corrigendum]. Integrated Pharmacy Research and Practice 2021;8:13-14. 10.2147/IPRP.S204832