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Risk Mapping Patterns in Community Pharmacy Error Reporting

Scoping Review

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SPOR Evidence Alliance operates from the St. Michael's Hospital, Unity Health Toronto which is located on the traditional land of the Huron-Wendat, the Seneca, and the Mississaugas of the Credit. Today, this meeting place is still the home to many Indigenous people from across Turtle Island.

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Abbreviations and Definitions

Abbreviations

WHO World Health Organization

Key Definitions

Prevention of Risk: A circumstance, action, or influence that played a part in the origin or development of an incident or increased the risk of an incident[1]

Mitigation of Risk: An action or circumstance that leads to the discovery of an incident and/or that prevents or moderates the progression of such incident towards harming the patient[1]

Adverse Event Negotiation: Actions taken or circumstances altered to make better or compensate any harm after an incident[1]

Key Words: Health, medication, pharmacists, safety

Abstract

Objective: The objective of this scoping review was to understand risk definitions and risk conceptualizations in community pharmacies. One out of four research questions in this review related directly to the Canadian population, whereas the other questions took a global focus. *Introduction*: Two-thirds of the Canadian population were prescribed or took medication in 2021, which indicates the high potential for human error.[2] Unfortunately, incident-capturing systems are under-utilized, and medication errors have been shown to occur four times more often in the community compared to the hospital setting.[3,4] This level of potential and actual error signals the need to improve safety for patients and share prevention and mitigation strategies between pharmacy professionals. *Inclusion Criteria*: The inclusion criteria for this review focused on community pharmacies and their existing risk mapping and/or mitigation strategies. *Methods*: This scoping review was conducted in accordance with the JBI methodology for scoping reviews.[5] A comprehensive search was developed for Ovid MEDLINE and translated to Ovid Embase, Ovid EBM Reviews for Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and CINAHL (EbscoHost). All databases were searched from inception to May 24, 2022, and no language or date restrictions were applied. *Results*: Of the 50 articles included in this review, a total of 17 countries were found as study locations. Two articles focused on a single community pharmacy, whereas 48 articles reviewed practices across multiple pharmacies. One article surveyed patients, where all other articles focused on the staff within pharmacies. As per the WHO definition of prevention, mitigation, and adverse event negotiation, 25 studies focused on preventing, eleven on mitigation, seven on adverse event negotiation, three articles on multiple strategies, and four could not be classified. *Conclusion*: Future research is needed to establish a universal definition of risk in community pharmacy and identify strategies aimed at preventing and mitigating risk.

EXECUTIVE SUMMARY

Objectives: The objective of this study is to determine how risk is defined and utilized within community pharmacy within reporting and policy change practices.

Design: The design of this study is a scoping review.

Method: The scoping review conducted consisted of searching for all available literature related to the research question(s) in various databases and information sources. During the process of abstract and full text review, two independent researchers determined whether a study should be included based on pre-set eligibility criteria. Discrepancies were reviewed by a third researcher for the final decision of inclusion.

Results: From the studies included in this review, 17 countries were found to have one or more articles. The USA had the highest number of studies at 12, followed by the United Kingdom, Canada, Australia, Netherlands, Germany, Finland, with nine, six, four, four, three, and two articles respectively. Finally, the following countries each provided one article: Abu Dhabi region, Denmark, Lebanon, New Zealand, Portugal, Romania, Serbia, South Korea, Spain, and UAE. Articles included were published from 1992 to 2021.

Question 1: How is risk considered, conceptualized, and studied in community pharmacy practice?

No definition of risk was found throughout the articles therefore the WHO (2009) definitions of prevention, mitigation, and adverse event negotiation were used to classify the studies. 20 studies did provide a definition related to errors such as discrepancies, poor outcomes, near-misses, and others.

Two studies out of 50 focused on individual community pharmacies, where the others focused on entire countries, such as Finland, Denmark, and Romania, or areas within these countries, such as states within the United States of America.

Only one article looked at individual patients with all others focusing on pharmacists or pharmacies.

Question 2: How do Canadian pharmaceutical regulators define and generate regulations related to risk?

This review did not result in any Canadian articles discussing pharmaceutical regulators.

Question 3: What are the available resources concerning risk (risk mitigation strategies) in community pharmacy settings?

The WHO defines prevention as a circumstance, action, or influence that played a part in the origin or development of an incident or increased the risk of an incident (2009). Mitigation is defined as an action or circumstance that leads to the discovery of an incident and/or that prevents or moderates the progression of such incident towards harming the patient. Adverse event negotiation is defined as actions taken or circumstances altered to make better or compensate any harm after an incident (WHO, 2009).

25 studies on prevention strategies within community pharmacies. Four articles focused on improving education for pharmacists and the staff. Five articles focused on improving communication between providers. Four articles determined that the implementation or improvement in e-prescribing technologies should be used. Three articles suggested that implementing medication reviews can help to reduce medication errors when new medications prescribed. Four studies were a mix between multiple medication error prevention strategy, such as education and communication, developing a plan and communication, and decreasing demand on providers and standardizing processes. Five studies could not be classified into a specific group as they all took varied approaches to understanding preventative strategies to reduce risk. For example, three studies used the implement failure mode and effects analysis (FMEA) approach, the software, hardware, environment, and liveware (SHELL) model, or implemented the community health integration through process and ergonomics redesign (CHIPPER) model. Finally, two other studies showed that increased enforcement of dispensing policies was needed to prevent errors or showed that individual doses should be used with children to decrease the chance of errors.

Ten studies included in this review were classified within mitigation with eight studies looking at medication reconciliation, system error, drug-drug interactions, and/or questioning prescriptions, which were found as valuable way to decrease harm to patients. The last two articles focused on (1) areas of the pharmacy process to identify adverse events prior to reaching the patient and (2) the general effectiveness of pharmacist intervention.

Seven articles had the focus of adverse event negotiation, where strategies were found to be using a geometric probability distribution to assess dispensing errors, applying a work domain analysis to an incidence analysis, alter characteristics that lead to a reduction in the amount of quality-related event reports, and improved education on the importance of utilizing reporting systems.
Three articles focused on two or more risk mitigation strategies and therefore were classified in outside of the three WHO definitions.
Four articles could not be classified within the WHO groups. One article was a systematic review, one estimated an information gap, one focused on prescription orders and dispensing errors, and the other studied self-reported dispensing errors.

Conclusion: Though 50 articles were included in the study, there was no article that utilized a clear definition of risk. 20 articles did have a definition related to error yet could not be compared due to mixed conceptualization. This review cannot provide a guide as to how risk is studied in community pharmacies. Based on this lack of standard definition, it points to the need to create one to be disseminated to community pharmacies globally.

Introduction

Pharmacists play a crucial role in the delivery of medication. Given that patient administration errors are difficult to identify, it is typically the pharmacist who is the final point at which medication errors can be identified and mitigated or prevented before they impact a patient.[6] In Canada during 2021, it was shown that two-thirds of the population took or were prescribed a medication in the last 12 months.[2] Given this reach, it is important to ensure that Canadians receive medications that are appropriate and safe for them. Since human errors occur in all healthcare systems, incident reporting systems are a way to track trends and identify safety interventions.[7]

Unfortunately, incident-capturing systems can be under-utilized due to potential disciplinary repercussions, nonexistent reporting systems, or unclear post-incident decision-making frameworks.[3] Furthermore, medication errors have been shown to occur four times more often in community settings compared to the other settings.[4] As such, further exploration of risk within community pharmacies is integral to patient safety.[4] The World Health Organization has defined prevention, mitigation, and adverse event negotiation specific to risk, yet this is not a widely accepted or used definition of risk.[1] This knowledge gap creates disparity in the ability to improve safety for patients and share prevention and mitigation strategies between pharmacy professionals.

The team that conducted this review completed a recent study in which patterns in error reporting were found.[8] This study led to the need to determine how risks are mapped, conceptualized, and mitigated to increase safety enhancements made in community pharmacies.[8] By studying risks, this review aims to inform procedures for evaluating community pharmacy reporting practices.[8]

For this review, the definitions from the World Health Organization (WHO) were used to classify the available resources found related to risk in community pharmacies. The three definitions are as follows:

- Prevention, or detection, is defined as “an action or circumstance that results in the discovery of an incident”[1(p. 13)];
- Mitigation is defined as “actions or circumstances which prevent or moderate the progression of an incident toward harming the patient” [1(p. 13)];
- Adverse event negotiation, or ameliorating actions, is defined as “actions taken or circumstances altered to make better or compensate any harm after an incident” [1(p. 13)].

A preliminary search of PROSPERO, the Cochrane Database of Systematic Reviews and *JBI Evidence Synthesis* was conducted and no current or underway systematic reviews or scoping reviews on the topic were identified. This scoping review was conducted to summarize current literature related to community pharmacy error reporting practices and highlight gaps for future research.

Review Questions

The four questions that guided this review were:

1. How is risk considered, conceptualized, and studied in community pharmacy practice?

2. How do Canadian pharmaceutical regulators define and generate regulations related to risk?
3. What are the available resources concerning risk (risk mitigation strategies) in community pharmacy settings?

Inclusion Criteria

Participants: This review focused on community pharmacies which are defined as pharmacies in out-patient settings and/or outside of the hospital setting. Articles discussing hospital pharmacies as a comparator to community pharmacies were included.

Concept: Existing risk mapping and/or mitigation strategies in community pharmacy settings.

Context: Studies from all countries were included in the search strategy to ensure a broad focus. For this specific review, one research question related directly to the Canadian population, therefore this population will be highlighted in the analysis.

Types of Sources: This scoping review considered both experimental and quasi-experimental study designs including randomized controlled trials, non-randomized controlled trials, before and after studies and interrupted time-series studies. In addition, analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies were considered for inclusion. This review also considered descriptive observational study designs including case series, individual case reports and descriptive cross-sectional studies for inclusion. In addition, systematic reviews that meet the inclusion criteria will also be considered, depending on the research question. Text and opinion papers were also considered for inclusion in this scoping review.

Methods

The scoping review was conducted in accordance with the JBI methodology for scoping reviews.[5] A rapid search approach was employed to locate published studies. A preliminary search was conducted in Ovid MEDLINE and reviewed by the whole team. From this initial search, a more comprehensive search was developed for Ovid MEDLINE and translated to Ovid Embase, Ovid EBM Reviews for Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and CINAHL (EbscoHost). All databases were searched from inception to May 24, 2022, and no language or date restrictions were applied.

The number of search results from all databases and information sources searched was 736. The number of records after removing duplicates in Covidence systematic review software was 623. The total number of records identified for each database and information source is provided in Appendix 1. Search strategies for each database and information source searched are presented in Appendix 2. During data extraction, 3 duplicate articles were removed, and one was removed due to a hospital pharmacy focus. The final set of included studies comprised 50 studies.

The PRIMSA chart can be found in Appendix 3. Data was extracted from papers included in the scoping review by two or more independent reviewers using a data extraction tool developed by the reviewers (Appendix 4).

Results

Article summary

Most studies in this review were observational (n=29), including cross-sectional (n=10), retrospective (n=7), prospective (n=10), and descriptive (n=1). The other 21 studies include qualitative (n=11), literature review (4), quasi-experimental (n=3), randomized control trial (n=1), and systematic review (n=1).

A total of 17 countries were found as study locations. From highest to lowest, the number of countries are as follows: USA (n=12), United Kingdom (n=9), Canada (n=6), Australia (n=4), Netherlands (n=4), Germany (n=3), Finland (n=2), Abu Dhabi region (n=1), Denmark (n=1), Lebanon (n=1), New Zealand (n=1), Portugal (n=1), Romania (n=1), Serbia (n=1), South Korea (n=1), Spain (n=1), UAE (n=1). The studies included in this review span from 1992 to 2021 with 62% of studies published within the last 10 years (n=31).

Question 1: How is risk considered, conceptualized, and studied in community pharmacy practice?

Of the 50 studies included within this review, 20 provided a definition related to the classification of errors. Definitions found were related to interventions, discrepancy, poor outcomes, near-miss, dispensing errors, adverse event, drug-related problems, patient harm, and quality-related events.[9-29] The sole definition found within a Canadian study can be seen in Boyle[30] where quality-related events were defined as “known, alleged or suspected medication errors that reach the patient … as well as medication errors that are intercepted prior to dispensing”. [(p. 77)]

Though a clear gap is present in the use of a risk definition, one article from Australia provided a definition of medication safety; suggesting that medication safety can be defined “not just ‘freedom from accidental injury during the course of medication use’ but by definition also includes ‘activities to avoid, prevent, or correct adverse drug events which may result from the use of medicines’”.[31(p.1382)]

As no clear definition was extracted from the included studies in this review, the WHO definitions for prevention of risk, mitigation, and adverse event negotiation were used (as mentioned above in the introduction).

The conceptualization of risk has been classified into practices that related to individual pharmacies or multiple pharmacies. Forty-eight studies reviewed practices within multiple pharmacies and the remaining two studies each focused on a single community pharmacy. The characteristics of the studies that included multiple pharmacies are summarized in tables 1 and 2. Forty-nine studies focused on the staff within pharmacies and the one remaining study surveyed patients.[22]

The two studies with an individual community pharmacy focus were: Johnson[19] and the review by Sears.[8] Johnson[19] compared patients' electronic medical records and the medication fill history seen at the Family Medical Clinic and Pharmacy on the University of Oklahoma campus in the USA. Forty-one percent of discrepancies found were due to inactive medications listed as active within the electronic medical record.[19] There were six mean medication discrepancies for each patient, with medication discrepancies increasing with non-Family Medical Clinic prescriber use.[19]

The study by Sears[8] focused on an independent pharmacy in Canada, where pharmacists spoke fluent Farsi and English. This study examined individual patients through a survey to determine self-reported medication errors.[8] This study found that most patients did not know the medication(s) they were taking and why they are taking their medications and that taking multiple medications increased the probability of errors.[8]

Table 1: Studies including multiple pharmacies (country, region, state, or city level)

Country	Area
Canada	Nova Scotia (n=4)[11,12,30], Montreal (n=1)[28], Ontario (n=1)[32]
Germany	Saxony-Anhalt state (n=1)[25], North Rhine-Westphalia state (n=1)[27], Berlin (n=1)[22]
New Zealand	Single district health board (n=1)[6]
USA	*Single state:* Maryland (n=1)[18], Oklahoma (n=1)[19], Wisconsin (n=1)[33], Hawaii (n=1)[34], North Carolina (n=1)[35], Nebraska (n=1)[36], Texas (n=1)[37], Arizona (n=1)[38] *Multiple states* (n=4)[14,24,39,40]
Netherlands	Entire country (n=3)[7,13,41], Southwest region (n=1)[29]
Australia	Entire country (n=1)[42], Sydney (n=2)[31,42], Victoria (n=1)[43]
United Arab Emirates (UAE)	All seven UAE regions (n=1)[17], Abu Dhabi (n=1)[45]
United Kingdom	Entire country (n=4)[3,9,15,46], England (n=3)[20,47,10], England and Wales (n=1)[48], Brighton (n=1)[16]

Table 2: Studies including multiple pharmacies (entire country level only)

Prevention Strategy	Studies
Finland	n=2[49,50]
Denmark	n=1[21]
Lebanon	n=1[26]
Portugal	n=1[51]
Romania	n=1[23]
Serbia	n=1[52]
Spain	n=1[53]
South Korea	n=1[54]

The article by Lewinski[22] focused on surveying individual patients across multiple pharmacies in Germany. These authors determined the number of patients that experienced drug-related problems by having participating community pharmacists survey patients. It was found that 21.0% of patients were affected by drug-related problems that were most likely to be caused by self-medication and new medications.[22]

Given that no articles examined in this review clearly defined risk, there is a variation and subjective nature to the way risk was studied. For example, Stojkovic[27] completed a prospective risk analysis by using a failure mode and effects analysis (FMEA), defined as "a proactive tool used to identify potential vulnerabilities in complex, high-risk processes and to generate remedial actions to counteract them before they result in adverse events". [(p. 1159)] This study did not provide a specific definition to risk and no other studies included in this review used a framework, making grouping or comparisons next to impossible.

Even though there are four studies within this review that used medication discrepancies as their risk focus, all studies presented their information in vastly different ways. Hockley[16] and Tamblyn[28] provided no definition of medication discrepancies yet discussed the implications of these errors to patient safety and well-being. Johnson[19] classified medication discrepancies rather than clearly defining them. The six categories were: "therapeutic duplication, medication exclusion from one medication list or the other, medications that should be designated inactive in the active EMR medication list, and differences in medication strength, dosage form, or dosing regimen".[19(p. 525)] The sole clear definition was stated as "any medication for which the original prescription differed from either the instructions on the DCI [discharge instruction sheet] or the label of the dispensed medication" by Johnson[18(p. 2)]

Question 2: How do Canadian pharmaceutical regulators define and generate regulations related to risk?

The search strategy used for this review did not result in any articles with a pharmaceutical regulator lens; therefore, no definition or generation of regulations related to risk could be identified. The librarian on this project completed an additional search of the CADTH website which did not result in additional articles meeting our inclusion criteria.

Question 3: What are the available resources for managing risk (risk mitigation strategies) in community pharmacy settings?

As per the WHO definition of prevention, mitigation, adverse event negotiation, 25 studies focused on preventing, 11 on mitigation, seven on adverse event negotiation, three studies on multiple strategies, and four could not be classified. Strategies and sources can be found within the tables 3-9.

Table 3: Single prevention strategies

Prevention Strategy	Studies
Enhance education	(n=4)[8,17,18,51]
Improve communication between providers, including information sharing	(n=5)[16,29,42,44,47]
Implement or improve e-prescribing technologies	(n=4)[33,41,49,50]

Implement medication reviews or checklists for new medications	(n=3)[22,25,32]

Table 4: Multiple prevention strategies

Prevention Strategy	Studies
Enhance education and improve communication between providers, and include information sharing	(n=2)[12,23]
Develop a plan and improve communication between providers, and include information sharing	(n=1)[45]
Decrease demand on providers and standardize processes	(n=1)[52]

Table 5: Other prevention strategies

Prevention Strategy	Studies
Implement failure mode and effects analysis (FMEA) approach to determine risks	(n=1)[27]
Implement software, hardware, environment, and liveware (SHELL) model to determine areas for improvement	(n=1)[3]
Implement community health integration through process and ergonomics redesign (CHIPPER) to improve communication	(n=1)[7]
Increase enforcement of dispensing policies	(n=1)[38]
Implement the use of individual doses for children	(n=1)[35]

Table 6: Mitigation strategies

Mitigation Strategy	Studies
Implement medication reconciliation	(n=6)[6,13,14,19,21,31]
Identify and fix system error(s)	(n=1)[48]
Identify and fix drug-drug interaction	(n=1)[54]
Increase questioning prescriptions	(n=1)[15]
Implement pharmacy processes to identify adverse events	(n=1)[53]
Increase pharmacist interventions on prescription errors	(n=1)[24]

Table 7: Adverse event strategies

Adverse Event Strategy	Studies
Alter contributing factors that would then lead to a reduction in the amount of quality-related event reports	(n=3)[10,11,30]
Use of geometric probability distribution to assess dispensing errors	(n=2)[9,40]
Improve education on the importance of utilizing reporting systems	(n=1)[36]
Increase in the application of work domain analysis to an incidence analysis	(n=1)[46]

Table 8: Multiple strategies

Strategies	Studies
Prevention: create structured education programs Mitigation: in pharmacies with higher errors provide additional personnel Adverse event: create a non-punitive reporting system	(n=1)[26]
Prevention: implement a medication incident reporting system Adverse event: track mistakes from reporting system to guide strategies for improvements	(n=1)[43]
Prevention: implement a medication incident reporting system Adverse event: track mistakes from reporting system and measure medication related hospitalizations to guide strategies for improvements	(n=1)[34]

Table 9: Unclassifiable articles

Strategies	Studies
Estimate the information gaps between emergency room doctors and community pharmacists to guide strategies for improvement, such as increasing access to electronic medical records	(n=1)[28]
Examine the association between high workload and stressors in community pharmacies	(n=1)[20]

Discussion

Within the 50 articles included in this study, 20 provided a definition related to the classification of errors, yet no article clearly defined risk. The range of location focus, from individual pharmacies to groups of pharmacies within an entire country, prevents coherent comparisons.[4] What is evident is a striking lack of standardization, a notable absence of risk definition and conceptualization, and a range of strategies that are contextually centric. While context is an essential factor in the development of risk related strategies, a common standard to define and address medication risk related issues may benefit and improve medication safety within community pharmacies. An initial definition of risk can be taken from the WHO which states “risk is the probability that an incident will occur”.[1(p.16)]

Conclusion

This scoping review compiled information related to risk mapping strategies and definitions used within community pharmacy. By reviewing primary studies and grey literature, this review has found a lack of universal definition and utilization of risk prevention, mitigation, and adverse event negotiation strategies. Future research is needed to establish a universal definition of risk in community pharmacy and identify strategies aimed at preventing and mitigating risk.

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Appendix 1

Database Import	# Records Imported
Initial Medline Search (May 19, 2022)	96
CINAHL	100
Update Medline Search (May 24, 2022)	135
Ovid Embase	168
CENTRAL	22
Scopus	320

Appendix 2

Total number of records identified for each database and information source

Database: Ovid MEDLINE(R) ALL <1946 to May 24, 2023>
Search Strategy:
1 Community Pharmacy Services/

2 ((community or retail) adj1 pharmac*).ab,ti,kw.

3 1 or 2

4 exp Risk Management/
5 risk/ or exp risk assessment/

6 4 or 5

7 3 and 6

EBM Reviews - Cochrane Central Register of Controlled Trials <April 2022>

1 Community Pharmacy Services/

2 ((community or retail) adj1 pharmac*).ab,ti,kw.

3 1 or 2

4 exp Risk Management/

5 risk/ or exp risk assessment/

6 4 or 5

7 3 and 6

Embase Classic+Embase <1947 to 2023 May 17>

1 ((community or retail) adj1 pharmac*).ab,ti,kw.

2 "pharmacy (shop)"/

3 risk management/

4 risk reduction/ or risk perception/

5 1 or 2

6 3 or 4

7 5 and 6

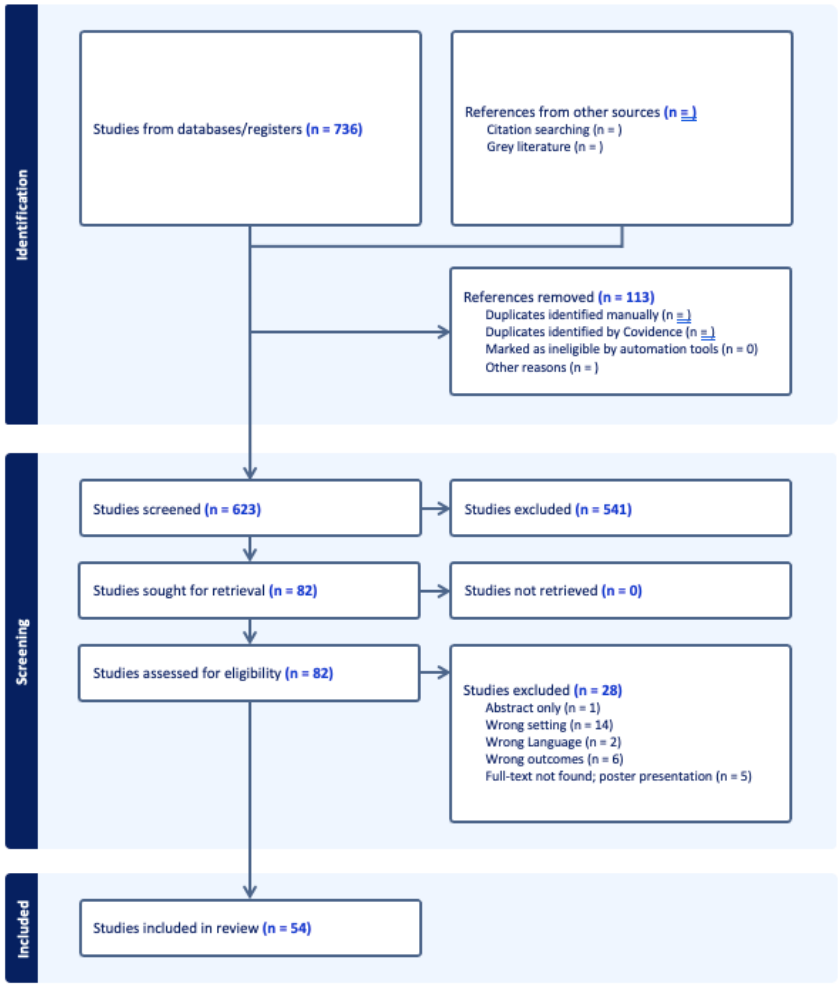
CINAHL – May 24, 2022

#	**Query**
S5	S1 AND S4
S4	S2 OR S3
S3	(MH "Risk Assessment")
S2	(MH "Risk Management+")
S1	(MH "Pharmacy, Retail")

Scopus Search

(TITLE-ABS-KEY (risk* W/1 (manage* OR assess*))) AND (TITLE-ABS-KEY ((retail OR community) W/1 pharmac*))

Appendix 3



Appendix 4

Table 1: Characteristics of included studies

Author(s)	Year	Risk definition	Conceptualization	Investigation
			Such as individual, system, and location	How risk is studied

Table 2: Available resources concerning risk/risk mitigation/adverse event negotiation

Author(s)	Year	Resources	Risk Prevention	Risk mitigation strategies	Adverse event negotiation

Table 3: Comparison community pharmacy and information technology industry

	Author(s)	Year	Community pharmacy	Information technology industry
Risk conceptualization				
Risk definition				
Risk prevention				
Risk mitigation				
Adverse event negotiation				
Regulation resources				
Regulatory practices				