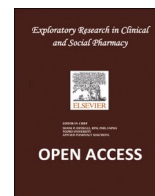


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A scoping review of health system guidelines for pharmacist responsibilities when dispensing opioids

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ABSTRACT

Introduction: Prescription opioid use and evidence of the harm caused by these medicines has increased over the past 20–30 years. Despite a number of system level interventions, the opioid crisis has not yet resolved in Australia or globally. Pharmacists are increasingly required to take a proactive, clinical role to fulfil their responsibility for patient outcomes relating to both medication efficacy and safety.

Aim: To evaluate the current health system guidelines available to pharmacists dispensing opioids and to examine the implications of this guidance on pharmacist responsibility.

Methods: A scoping review was conducted by searching in CINAHL, MEDLINE, Embase, PubMed and Web of Science, in addition to the grey literature and referral from topic experts to collate a list of current health system guidelines relevant to pharmacists dispensing opioids. These guidelines were then examined through thematic analysis and the use of the “Appraisal of Guidelines Research & Evaluation—Health Systems” tool (AGREE-HS).

Results: Ten health system guidelines were identified in the search. Identified guidelines were published in Australia, the United States, and the United Kingdom. Health system guidelines analysed in this study most commonly provide general practice statements that are not specific to opioid medicines. Current guidelines frequently recommend risk assessment, but less commonly provide implementable risk mitigation advice. Additionally, guidelines are of poor overall quality when analysed through metrics relating to their development and implementation.

Conclusion: There are gaps in current health system guidelines which contribute to perceived barriers in pharmacy practice. Current health system guidance does not provide a clear account of the responsibilities of pharmacists when dispensing opioids. This study provides an argument for the development of implementable health system guidelines that support pharmacists in taking direct responsibility for patient outcomes when dispensing opioid medicines.

1. Introduction

Opioids are primarily used in the treatment of acute and chronic pain.¹ Use has increased significantly over the past 20–30 years, especially in relation to the management of chronic non-cancer pain.² In the United States, it is estimated that opioids are used in 17.9% of patients with chronic non-cancer pain.³ In association with the increased use of opioids, there is also significant evidence of opioid-related harms associated with both prescription and illicit opioids.^{4–6} The World Health Organisation estimated that 117,000 people died of an opioid overdose in 2017.^{4,5} In 2021–22, 2.9 million Australians were dispensed opioid

medicines.⁷ These statistics highlight the widespread use of prescription opioids and the harms that opioids are causing around the world. The extent of these harms has been referred to as the “Opioid Crisis”.

Strategies in response to this crisis are being employed at multiple levels; opioid care standards are changing in response to evidence of harm, and policymakers are developing strategies to reduce the prevalence of opioid-related harm.⁸ Prescription Drug Monitoring Programs, which provide health professionals with more information regarding patient’s long and short-term medication histories, have enabled more informed therapeutic decisions in opioid prescribing and dispensing.⁹ In Australia, additional regulatory and policy interventions include the

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reduction in subsidised pack sizes of prescribed opioids, restrictions in treatment duration of post-operative opioid prescriptions as well as restrictions to the list of appropriate indications for opioid treatment.¹⁰ In addition to clinical considerations, there are numerous social and other medical factors related to opioid use and opioid-related harm such as addiction and dependence.¹¹ These considerations necessitate change at multiple levels in the health system, as well as the continued evaluation of these interventions to ensure they have the intended impact.

To reduce opioid-related harm, it is important that changes in professional practice align with policy and regulatory interventions. Recent regulatory changes place pharmacists dispensing opioids in a position where they are required to take a proactive, clinical role, in addition to an emerging role for pharmacists as stewards of opioid safety from a public health perspective. An outcome of the recent regulatory changes is that pharmacists tend to have more information regarding opioid use, and moreover an expectation that they will use this information to minimise harms. Few disagree that pharmacists have an important role to play in reducing opioid-related harm. Clear and specific guidance regarding pharmacist responsibilities when dispensing opioids will support pharmacists to fulfil this role.

Change in pharmacist behaviour is challenged by a number of barriers. Research in this area of pharmacy practice has highlighted themes that influence the way pharmacists practice such as: health system hierarchy, role description, practical experience, individual ownership of decisions as well as mentorship when joining the profession.¹² The complexity of these themes mirrors the complex nature of pharmacy practice, and demonstrates the level of change required to address barriers in pharmacy practice. Locally, research evaluating how pharmacists perceive their role in opioid dispensing highlights that pharmacists perceive their responsibility as either independent, shared or limited.¹³

Community pharmacists have a number of professional responsibilities when dispensing prescription medications. Key among these responsibilities is the promotion of safe and effective use of medicines. This general responsibility aligns closely with the foundational principles of Hepler and Strand's 'pharmaceutical care', which emphasises a pharmacist's responsibility to ensure good outcomes for the patients in their care.¹⁴ As the use of opioids increases alongside increasing evidence of opioid harms, pharmacists are increasingly required to ensure the safe and effective use of opioids and to prevent the intentional or unintentional misuse of these medicines.^{4,5,15} Additionally, pharmacists now have access to a variety of programs and tools which can be utilised to monitor the use of opioids such as Prescription Drug Monitoring Programs.^{9,16,17} In light of approaches such as Prescription Drug Monitoring Programs, which enable more informed therapeutic decisions, pharmacists now have an increased capability to identify people at high-risk of opioid-related harm and act in ways to reduce this risk. It is important that pharmacists are well-supported in their role in preventing opioid-related harm. One way that this role can be supported is through the use of professional guidelines that provide explicit advice to pharmacists dispensing opioids. This study defines health system guidelines as documents that address the health system challenge of opioid-related harm by providing recommendations to pharmacists dispensing opioids. This definition has been implemented from advice provided within the Appraisal of Guidelines Research & Evaluation—Health Systems (AGREE-HS) tool.¹⁸ These documents are often classified in a number of categories including policies, codes of conduct, ethical guidelines, practice statements, action plans or strategy documents. It is unclear whether or not there is a consensus in these guidelines on how to approach opioid dispensing, or whether pharmacists have access to practicable advice on the matter.

The aim of this study is to review the current health system guidelines available to pharmacists dispensing opioids. The following research questions were used to guide this investigation: i) what health system guidelines currently exist for pharmacists dispensing opioids? and ii) to what extent to these guidelines clearly articulate pharmacist

responsibility in the context of opioid dispensing?

2. Methods

2.1. Identification of relevant health system guidelines

This scoping review was conducted in adherence to the framework developed by Arksey and O'Malley.¹⁹ A systematic search of the literature was conducted to address the research questions. The development of search strategies aimed to identify local, national and international health systems guidelines that provide recommendations regarding the role of pharmacists when dispensing prescriptions for opioids. The following search terms were used to identify relevant guidelines in all selected databases: 'pharmacist' AND 'opioid' AND 'dispense'. These terms are intentionally broad, bearing in mind the fact that there is no standard terminology for publications relating to professional documents such as health system guidelines. Using these search terms, equivalent database searches were performed in CINAHL, MEDLINE, Embase, Pubmed and Web of Science. By maintaining a broad scope, this search strategy aims to capture as many available documents as possible, with the acknowledgement that a number of other similar guidelines exist, but are not able to be identified by systematic searching methods. A review protocol was not published prior to the study investigation.

In recognition that important health system guidelines may not be found in published literature databases, guidelines for searching the grey literature were followed.^{20,21} A customised Google search was also conducted with the express target of local and international government websites. Finally, a group of experts based in Queensland, Australia were approached to contribute to the list based on health system guidelines they were aware of through their own practice and networks.

The search was initially performed in November 2021. A check for newly published evidence was performed in June 2023; no recently published journal articles met the inclusion criteria for the study. WO performed each of the database searches. The search strategy was developed by WO with the help of a medical librarian and was checked by AL. Evidence screening was performed by WO.

2.2. Selection of relevant health system guidelines

Guidelines that exhibited the following characteristics were included in the study screening. Guidelines that:

- i) address the processes or any other recommendations involved in opioid dispensing,
- ii) have been published or developed by international, national or regional organisations,
- iii) are classified as at least one of the following document types: policy, code of conduct, ethical guideline, practice statement, action plan, strategy document, and
- iv) are written in English.

Documents were excluded if they were classified as a clinical guideline and if the guideline did not relate specifically to opioid dispensing for pain. Clinical guidelines were excluded due to the fact that the characteristics such as intention, development and scope of these documents vary substantially from those of health system guidelines. Furthermore, guidelines were excluded if they exclusively provided advice for opioid replacement therapy, or for alternative therapeutic areas such as voluntary assisted dying. No specific date range was used to exclude guidelines identified in the search strategy. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework²² was applied to report the following three search strategies: 1) grey literature databases, 2) customised Google search and 3) online scientific journal databases. Resources gathered from this search were screened for relevance and to identify duplicate reports.

2.3. Extraction of data from included resources

The following information was extracted from the identified guidelines: author, publication date, publication type, country of publication, target audience, geographical audience (national, regional, etc.), document classification.

2.4. Analysis of included health system guidelines

The Appraisal of Guidelines Research & Evaluation—Health Systems (AGREE-HS) tool¹⁸ was used to evaluate health system guideline quality and usability. This tool analyses key aspects of health system guidelines including scope, the composition of the development team, development methods, comprehensiveness of guidance and implementability.¹⁸ Analysed documents can be compared using individual criteria as scored by AGREE-HS, or overall scores as a summation of all criteria. Overall AGREE-HS scores are calculated as a percentage relative to the maximum possible score.¹⁸ In this study, two appraisers assessed each included guideline to complete the AGREE-HS analysis (WO and AL), and overall scores were calculated based upon average item scores.

Additionally, a thematic analysis was conducted in order to discern the characteristics of included health system guidelines.²³ This analysis focussed on identifying two groups of data; explicit guidance regarding pharmacist responsibility as well as key recommendations pertaining to opioid dispensing. Key recommendations were extracted from the guidelines in order to obtain a high-level summary of what the most common or uncommon recommendations are in current opioid dispensing guidance.

3. Results

3.1. Identified health system guidelines

The search strategy (See Fig. 1) yielded ten health system guidelines

Table 1
List of included guidelines.

Title of included guideline	Author	Country of publication	Year of publication
Guidelines on the Dispensing of Opioids ²⁴	Pennsylvania Pharmacists Association	USA	2015
Guidelines for the Safe Prescribing and Dispensing of Opioids ²⁵	Colorado Department of Regulatory Agencies	USA	2019
Prescription Opioid Policy ²⁶	Royal Australasian College of Physicians	Australia	2009
Controlled drugs: safe use and management ²⁷	National Institute for Health and Care Excellence	UK	2016
Standard of practice in pain management for pharmacy services ²⁸	The Society of Hospital Pharmacists Australia	Australia	2019
Pain Management Best Practices Inter-Agency Task Force Report ²⁹	Department of Health & Human Services USA	USA	2019
Controlled Substance Guideline for Missouri Practitioners ³⁰	Missouri Department of Health and Senior Services	USA	2020
Preventing and managing problems with opioid prescribing for chronic non-cancer pain ³¹	NSW Therapeutic Advisory Group	Australia	2015
Monitored Medicines Standard Companion Document ³²	Queensland Government	Australia	2021
Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard ³³	Australian Commission on Safety and Quality in Health Care	Australia	2022

(see Table 1).^{24–33} The majority of included guidelines ($n = 5$) were published in Australia.^{26,28,31–33} Four ($n = 4$) of the guidelines that were included in the analysis were published in the United States.^{24,25,29,30} Additionally, one guideline ($n = 1$) was published in the United Kingdom.²⁷ Most included guidelines are intended for a national audience ($n = 6$), whereas four guidelines ($n = 4$) are published at a state level.

3.2. Responsibility in current health system guidelines

The guidance present in the analysed health system guidelines ranged from explicit advice directly relating to opioid dispensing (see Table 2), to more general advice targeted at higher-level pharmacy practice concepts that are not specific to opioids medicines (see Table 3). Guidelines most commonly included general recommendations, which align with general principles regarding pharmacist responsibilities. Examples of general recommendations include the provision of safe and effective treatment,^{25,26} patient centred care^{25,29,31,32} and both patient and prescriber education.^{26,28,29} Recommendations directly relating to opioid dispensing provided a more detailed account of how pharmacists can identify and mitigate risk when dispensing opioids. Furthermore, this specific advice regarding pharmacist responsibilities when dispensing opioids was infrequent. Specific opioid-related advice included the use of specific risk assessment tools,^{24–29,31–33} risk mitigation strategies^{24,27,29,31,32} and the identification of red-flags such as multiple opioid prescriptions,³¹ multiple prescribers,³¹ invalid prescriptions.²⁵

Nine guidelines ($n = 9$) included a recommendation for the administration of risk-assessment tools.^{24–29,31–33} The VIGIL framework³⁴ and the Opioid Risk Tool³⁵ are specific risk-assessment tools recommended by included guidelines. Six guidelines ($n = 6$) recommended specific risk mitigation strategies such as naloxone supply, medication review, specialist referral or patient education.^{24,25,28,29,31,32} Three of these guidelines ($n = 3$) including risk mitigation advice were published in the United States,^{24,25,29} and three guidelines ($n = 3$) were published in Australia.^{28,31,32}

Five guidelines ($n = 5$) made specific reference to pharmacist responsibility.^{25–28,32} Much of this guidance refers to a shared responsibility between health practitioners.²⁵ However, this guidance does not detail the exact nature of this shared responsibility. Queensland Health's 'Monitored Medicines Standard Companion Document' describes the concept of shared responsibility to a further extent, stating that "collaboration does not alter a health practitioner's accountability for the care they provide to patients".³² This level of substantive explanation of the nature of shared responsibility was not found in any of the other documents analysed.

3.3. Quality of included guidelines

The overall AGREE-HS scores of analysed documents ranged between 16.7% and 85% (see Table 4). Guidelines tended to be able to convey the description, causes and priority of the health system challenge most effectively. In contrast, communication regarding the breadth of the development team and the reporting of developmental methods were areas where guidelines generally scored poorly when assessed with the AGREE-HS tool.

Some guidelines scored poorly overall, but demonstrated some merit in one particular area. One example of this can be seen in the Monitored Medicines Standard companion document, produced by Queensland Health; where the guideline scored poorly in criteria measuring developmental transparency and evidence, but scored highly when the orientation and comprehensiveness of the guideline was assessed.³²

4. Discussion

This scoping review found that health system guidelines for

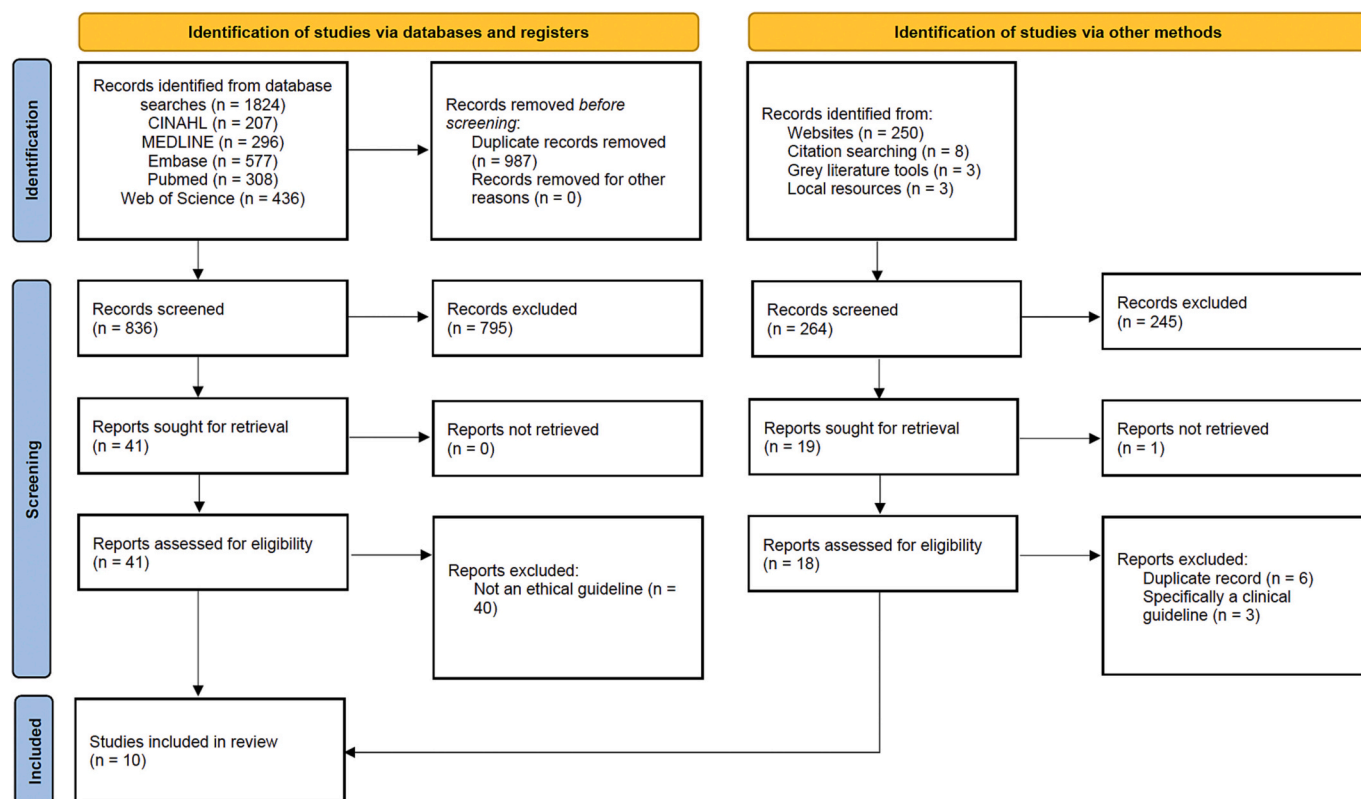


Fig. 1. PRISMA Flowchart for the scoping review search.²²

Table 2
Key Recommendations: Opioid-specific advice.

Opioid-specific Advice (n = number of guidelines)	Examples
Identify risk of opioid related harm (n = 9)	Prescription Drug Monitoring Program use, risk assessment tool use
Mitigate risk of opioid related harm (n = 6)	Naloxone supply
Recommend alternatives to opioid therapy (n = 5)	Non-pharmacological analgesia, non-opioid analgesia
Other clinical recommendations to reduce the risk of opioid related harm (n = 4)	Opioid tapering, opioid trial

Table 3
Key recommendations: General advice.

General advice (n = number of guidelines)	Examples
Quality use of medicines (n = 7)	Promotion of the effective and safe use of opioids.
Multidisciplinary care (n = 6)	Involvement of a pain specialist, communication between pharmacist and prescriber
Education (n = 4)	Explaining the risks and the benefits of opioid medications

pharmacists dispensing opioids provide a number of strong, but general recommendations for pharmacists. Analysed guidelines, at times, failed to provide advice to the level of discrete steps expected of pharmacists in order to fulfil specific tasks when dispensing opioids. Moreover, the guidelines analysed in this scoping review did not frequently describe the specific responsibilities of pharmacists dispensing opioids.

The results of the thematic analysis showed that recommendations in health system guidelines for pharmacists dispensing opioids are often general and do not provide direct advice specific to opioid dispensing. For example, some guidelines make the recommendation that

pharmacists should educate patients when supplying opioid medicines.^{25,28,29,32} This recommendation is parallel to that which is already expected of pharmacists dispensing, and is in contrast to recommendations such as the supply of naloxone nasal spray in patients who are at risk of opioid-related harm. Of course, these general recommendations do already play a role in supporting pharmacists in their overall practice. However, in the context of the public health response to the opioid crisis, where prescription opioids are the cause of considerable levels of harm compared to other medicines, more specific advice that goes beyond general healthcare principles is warranted.

Additionally, much of the available guidance included in opioid dispensing guidelines tended to fall short of detailing the specific responsibilities that pharmacists have when dispensing opioids. Even when health system guidelines did provide advice that directly addressed the role of pharmacists dispensing opioids, this advice most commonly fell short of outlining discrete steps for pharmacists to follow. For example, the majority of included guidelines (n = 9) recommend the use of risk-assessment tools, but fewer guidelines contained any advice pertaining to the mitigation of this risk (n = 6). Moreover, when specific risk mitigation strategies are recommended, there are instances where implementation advice is inadequate. This can be observed in one particular example, where a guideline recommended that naloxone (and naloxone education) be provided "...for certain patients and family members/caregivers when the patient is on chronic opioid therapy."²⁹ It is true that not all patients on chronic opioid therapy are suitable candidates for take-home naloxone supply, and thus, this advice falls short of providing pharmacists with a set of identifying patient characteristics to be implemented in order to target naloxone supply to patients in need. In instances such as this, the Triangle Model of Responsibility can be utilised to understand and communicate elements that affect responsibility; outlining that appropriate "prescriptions" play a role in establishing responsibility.³⁶ In the case of opioid dispensing, "prescriptions" refer to opioid dispensing guidelines, which support pharmacists' understanding of their role and what they are responsible for

Table 4
AGREE-HS Scores.

Title of included guideline	Mean item 1 score	Mean item 2 score	Mean item 3 score	Mean item 4 score	Mean item 5 score	Overall score (%) [*]
Guidelines on the Dispensing of Opioids ²⁴	1.5	1.0	1.5	3.5	3.5	20.0
Guidelines for the Safe Prescribing and Dispensing of Opioids ²⁵	5.5	1.5	2.0	3.5	2.5	33.3
Prescription Opioid Policy ²⁶	7.0	4.0	5.5	5.5	5	73.3
Controlled drugs: safe use and management ²⁷	6.0	7.0	7.0	5.0	5.5	85.0
Standard of practice in pain management for pharmacy services ²⁸	4.0	4.0	2.5	2.0	3.0	35.0
Pain Management Best Practices Inter-Agency Task Force Report ²⁹	7.0	5.0	3.0	6.0	5.0	70.0
Controlled Substance Guideline for Missouri Practitioners ³⁰	1.0	1.0	1.5	3.0	3.5	16.7
Preventing and managing problems with opioid prescribing for chronic non-cancer pain ³¹	4.5	5.5	3.5	4.0	2.5	50.0
Monitored Medicines Standard Companion Document ³²	3.5	1.0	1.5	5.5	4.0	35.0
Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard ³³	6.0	4.5	4.0	5.0	4.5	63.3

^{*} Overall scores are scaled to the maximum possible score.¹⁸

when dispensing opioids.³⁶ Therefore, by providing more complete and actionable advice, it could be the case that guidelines are more effectively translated into practice.

Half ($n = 5$) of the guidelines provided a global statement detailing the nature of the responsibility pharmacists have when they are dispensing opioid prescriptions (i.e. individual responsibility, shared responsibility). Most guidelines did not address the exact nature of responsibility, particularly when discussing more complex models of responsibility such as shared responsibility. Queensland Health's explanation of shared responsibility makes clear that even within a collaborative model of care, individual practitioners retain individual responsibility for their own actions.³² Similarly, the principles set out by Hepler and Strand make clear that pharmacists have a direct responsibility for the outcomes of their patients.¹⁴ In reviewing health system guidelines under this light, it is evident that most currently available guidelines fail to adequately describe and support pharmacist responsibility on the same level that is expected by Hepler and Strand.¹⁴

There are instances where guidelines recommend the use of existing risk assessment tools. The Pennsylvania Pharmacist Association²⁴ recommends the use of the VIGIL framework³⁴ and the Opioid Risk Tool.³⁵ The VIGIL tool was principally designed to allow physicians to appropriately prescribe opioids and to place the majority of the regulatory

burden on pharmacists in order to identify aberrant drug behaviours such as diversion and misuse, while minimising the impact of tightening regulatory measures on legitimate opioid patients.³⁴ The VIGIL framework is so named as it describes five key steps as part of the risk assessment process: verification, identification, generalisation, interpretation, and legalisation.³⁴ Prescription Drug Monitoring Programs now fulfil this role effectively and efficiently. The Opioid Risk Tool³⁵ is a questionnaire that is designed to be administered by physicians when patients are prescribed opioids for the first time, and is therefore of secondary use to pharmacists dispensing opioids. These examples speak to the history of risk assessment in opioid dispensing, and the role that Prescription Drug Monitoring Programs now have in identifying risk in opioid patients. Moreover, these programs and tools tend not to provide specific advice to pharmacists regarding how and when to provide risk mitigation strategies to patients at high risk of opioid-related harm.

4.1. Strengths and limitations of this study

While this scoping review used systematic methods to search both the published and grey literature, there is a possibility that the search strategy did not collect the full extent of current opioid dispensing guidelines. This is predominantly due to the nature of guideline publication and the inherent difficulty in accessing these resources in a systematic way. For example, some number of guidelines may be published through private, internal networks or are not publicly available for other reasons. While it is difficult to make inferences relating to other guidelines that exist and were not detected in this search, this limitation speaks to the accessibility and therefore the implementability of such guidelines. In this way, if pharmacists are unable to access these guidelines, the recommendations contained within them are inert.

No clinical guidelines were included in the analysis for this study. This is due to the difference in development and intention between clinical recommendations and health system recommendations. The development of clinical guideline recommendations is, typically, based on existing evidence, whereas health system guidelines have more flexibility to address ethical and professional practice expectations.

Guidelines were excluded if they were not originally published in English. This limits the extent to which this report can account for all global health system guidelines relating to opioid dispensing. Furthermore, this study is limited in the extent to which a range of cultural contexts are accounted for in guidelines published in languages other than English.

5. Conclusion

In light of the evidence of significant harm from dispensed opioid medicines and the increased responsiveness from the health system to this harm, pharmacists play a role in ensuring the safe and effective use of prescription opioids.⁴⁻⁶ Effective clinical and health system guidelines are key tools in supporting the role of pharmacists.³⁶ This study has identified gaps in current health system guidelines for opioid dispensing. In overview, there is a lack of direct and actionable normative advice for pharmacists dispensing opioids for pain. It is evident that change is required on multiple levels in order to lead to beneficial and effective practice change. The development of health system guidelines that support the responsible dispensing of prescription opioids seems to be a necessary step in addressing the change in practice required in this important therapeutic area.

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Author note

The authors made the following contributions. William Manning Olsen: Conceptualization, Writing - original draft, Writing - review and edit. Chris Freeman: Conceptualization, Writing - review and edit. Adeleke Adewumi: Conceptualization, Writing - review and edit. Adam La Caze: Conceptualization, Writing - review and edit.

Declaration of Competing Interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Thank you to Christine Dalais, who advised the development of the search strategy for this scoping review.

Appendix

A.1. Appendix

Web of science search terms

Search term

1. TS = (pharmacy OR pharmacist* OR pharmacies)
2. AND
3. TS = (opioid* OR opiate*)
4. AND
5. TS = (dispens*)

A.2. Appendix B

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist

Section	Item	PRISMA-ScR checklist item	Reported on page #
Title	1	Identify the report as a scoping review.	1
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	6–7
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	7
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	8
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	9
Information sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	9
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	28
Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	9
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	10
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	10
Critical appraisal of individual sources of evidence	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	10
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	13
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	11–12
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	16
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	14, 16
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	13–16
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	13–16
Limitations	20	Discuss the limitations of the scoping review process.	20
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	21
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	22

A.3. Appendix C

VIGIL Process³⁷**VIGIL Process and directions****Verifications:**

1. The prescriber should verify or discuss each of the following:
 - The prescriber should discuss with each patient goals for opioid therapy
 - Verify past opioid history given by the patient with the pharmacist
 - Have a discussion about past use patterns including inappropriate use

2. The pharmacist should verify or discuss with the prescriber:
 - Verify any new high dose prescriptions with the prescriber
 - Document the diagnosis for each new prescription
 - Notify the prescriber of any problem patterns in usage

- Verify any new high dose prescriptions with the prescriber
- Document the diagnosis for each new prescription
- Notify the prescriber of any problem patterns in usage

Identification:

3. Both the Pharmacist and the Physician have a responsibility to ensure the identity of the patient
4. ID must be presented at patient visits or when picking up a prescription
5. If it is not the patient picking up the prescription, then that person needs to provide identification

Generalisation:

6. The pharmacist, physician, and patient all agree to work together and adhere to a working agreement
7. The pharmacist and physician agree to provide medications and prescribe when needed and appropriate
8. The patient agrees to follow another set of rules that may include things like:
 - Not requesting early refills
 - Only using one pharmacy
 - Only using one prescriber for controlled substances
 - Keeping controlled substances in a secure place
 - Not waiting to fill prescriptions until you are out of medications
 - Notifying your pharmacists as soon as possible of new dosages or medications to ensure they have them in stock

Interpretation:

9. The prescriber or pharmacist may use a validated instrument to attempt to predict the patient's likelihood to misuse the substance

Legalisation:

10. Meeting all requirements of state and local agencies for prescriptions is crucial as well to ensure the integrity of the process

A.4. Appendix D

Opioid Risk Tool³⁵

Item	Mark each box that applies	Item score if female	Item score of male
1. Family history of substance abuse			
Alcohol	<input type="checkbox"/>	1	3
Illegal drugs	<input type="checkbox"/>	2	3
Prescription drugs	<input type="checkbox"/>	4	4
2. Personal history of substance abuse			
Alcohol	<input type="checkbox"/>	3	3
Illegal drugs	<input type="checkbox"/>	4	4
Prescription drugs	<input type="checkbox"/>	5	5
3. Age (mark box if 16–45)	<input type="checkbox"/>	1	1
4. History of preadolescent sexual abuse	<input type="checkbox"/>	3	0
5. Psychological disease			
Attention deficit disorder, obsessive-compulsive disorder, bipolar, schizophrenia	<input type="checkbox"/>	2	2
Depression	<input type="checkbox"/>	1	1
Total		–	–
Total score risk category			
Low risk: 0–3			
Moderate risk: 4–7			
High risk: ≥8			

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