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Identifying harm reduction strategies for alcohol and drug-use in inpatient care settings and emergency departments: a scoping review protocol

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Identifying harm reduction strategies for alcohol and drug-use in inpatient care settings and emergency departments: a scoping review protocol

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ABSTRACT

Introduction

People who use alcohol and/or drugs (PWUAD) are at high risk of medical complications, frequent hospitalization and drug-related death following discharge from inpatient settings and EDs. Harm reduction strategies implemented in these settings may mitigate negative health outcomes for PWUAD. However, the scope of harm reduction strategies used within inpatient settings and EDs is unknown. The objective of this review is to identify and synthesize reported harm reduction strategies that have been implemented across inpatient settings and emergency departments (EDs) for PWUAD

Methods and analysis

This review will include studies from any country and health service reporting on harm reduction strategies implemented in inpatient settings or EDs. The population of interest includes people of any race and age identified as having drug dependence, or individuals who provided care to people with drug dependence and/or use drugs and alcohol. Studies which describe implementation strategies and enablers and barriers to implementation will be included. This review will follow JBI methodology for scoping reviews. Five databases will be searched for relevant terms and a grey literature search will also be conducted. A JBI-certified information specialist will design and run the search. Titles, abstracts and full texts of retrieved studies will be screened in duplicate. Data will be extracted using a standardized form. Extracted data will be synthesized and presented based on implementation strategy employed. The results will be reported using the PRISMA extension for scoping reviews.

Ethics and dissemination

Patient partners with lived experience and relevant knowledge users will be engaged as research team members throughout all phases of the research process. A report detailing context, methodology and findings from this review will be disseminated to knowledge users and relevant community stakeholders. This review will also be submitted for publication to a relevant peer-reviewed journal.

Abstract word count: 293/300

ARTICLE SUMMARY

Strengths and limitations of this study

- This scoping review will be the first of its kind to describe the range of harm reduction strategies for people who use alcohol and/or drugs that have been implemented in inpatient and emergency department settings.
- This scoping review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews
- This scoping review will take an integrated knowledge translation approach by engaging key knowledge users and patient partners throughout the research process.
- Our search will be limited to five databases (MEDLINE All (Ovid), Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and SCOPUS (Elsevier Scopus.com)) and searches for unpublished studies and grey literature will be done using Google's advance search function.
- The findings from this review will be disseminated to relevant knowledge users and community stakeholders, and have the potential to inform relevant decision making regarding the development and implementation of harm reduction strategies.

INTRODUCTION

Alcohol and drug use is associated with significant negative health outcomes. People who use alcohol and/or drugs (PWUAD) have a higher risk of infectious disease, drug related complications and are more likely to be frequently hospitalized when compared to other individuals.[1,2] When seeking care, PWUAD are often discharged against medical advice or expelled as a result of illicit drug use, leading to increased readmission rates and poorer hospital outcomes.[2] Encountering stigma or having negative experiences in hospital settings can prevent PWUAD from seeking medical help.[3] Furthermore, PWUAD have a high risk of drug-related death after being discharged from hospital.[4] Therefore, PWUAD face health-related risks before, during and after receiving medical care, highlighting an urgent need to improve healthcare.

Harm reduction is a pragmatic approach geared toward addressing immediate needs across a wide range of health issues. Harm reduction aims to improve the health, safety and well-being of both the individual and the community.[5,6] Within the context of drug and alcohol use, harm reduction strategies provide alternatives to drug and alcohol abstinence for individuals who cannot or do not want to stop using.[7–9] The Canadian Drugs and Substances Strategy has identified harm reduction as an integral part of their strategy to help address some of the burden associated with substance use.[9] Some of the most common harm reduction strategies used in the context of illegal substances include clean needle distribution, supervised drug intake, and the use of substances like naloxone to temporarily reverse the effects of opioid overdose.[7–9] These strategies aim to improve well-being, lower rates of illness, overdose, and death because of substance use.[6–9] Harm reduction in relation to substance use has been implemented in community-based,[10] home-based[11] and inpatient settings.[12] However, there is a need to further understand the range of these harm reduction strategies.

In inpatient settings and EDs there is some indication that harm reduction strategies could help to improve health outcomes for PWUAD.[13–15] The use of these strategies within inpatient settings and EDs, remains low, despite high numbers of patients hospitalized with substance-induced symptoms[16] and calls for harm reduction implementation in hospital settings.[17] Low uptake of harm reduction strategies has been attributed to inadequate staffing, lack of funding, and stigma surrounding substance use.[18] A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis was conducted and no current or underway systematic or scoping reviews on this topic were identified. Therefore, this study aims to identify and synthesize the literature on harm reduction strategies that have been implemented in inpatient settings and EDs among people who use substances.

REVIEW QUESTIONS

The following questions will guide this review:

1. What harm reduction strategies have been implemented to help alleviate negative health outcomes associated with substance use within inpatient settings and EDs?
2. What are the barriers and enablers to implementing harm reduction strategies in inpatient settings and EDs?
3. What are the common implementation and intervention outcome measures reported?

METHODS AND ANALYSIS

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews.[19] This scoping review will use an integrated knowledge translation approach, working with health system decision makers and patient partners with lived experience through all stages of the review.[20] This scoping review has been registered on The Open Science Framework (OSF) registries (Registration DOI: 10.17605/OSF.IO/P7BHN).

Inclusion criteria

Participants

This review will consider studies that include participants identifying as individuals with drug dependence or PWUAD who have been admitted to inpatient care or have accessed EDs for substance use related issues and/or any other medical issues. This review will also consider individuals who provide care for persons with drug dependence or PWUAD. People of any race, gender and age will be included.

Concept

This review will consider studies that investigate any implementation strategy or intervention designed to reduce harm related to negative health outcomes associated with alcohol and/or drug use. Implementation strategies may include any enablers and/or barriers to facilitating harm reduction strategies. Patient reported outcome measures (e.g., quality of life), and patient reported experience measures (e.g., feeling heard, receiving care asked for) will be included, as well as health outcome measures (e.g., length of stay, healthcare costs, recovery time, discharge against medical advice, readmission rates, overdose rates, mortality) will be considered.

Context

Any healthcare setting that provides inpatient care or has a ED, in any country will be considered. This may include hospital settings, community inpatient day facilities or rehabilitation facilities where individuals receive treatment overnight. Outpatient settings and community-based service settings will be excluded.

Types of sources

This scoping review will include both experimental and quasi-experimental study designs

including randomized controlled trials, non-randomized controlled trials, pre-post studies and interrupted time-series studies. In addition, observational studies including prospective and retrospective cohort studies, case-control studies, cross-sectional studies, case series and individual case reports will be considered for inclusion. Qualitative and mixed methods studies will also be considered for inclusion. Grey literature sources such as policy documents and organizational reports will be included. Evidence syntheses, text and opinion papers will be excluded.

Search strategy

In collaboration with a JBI-trained information specialist, a search strategy will be developed to locate published articles in peer-reviewed journals and grey literature repositories. An initial limited search of MEDLINE All (Ovid) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (Supplementary Table 1) The MEDLINE search strategy will be peer-reviewed by at least one other information specialist before being translated to Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and Scopus (Elsevier Scopus.com). The reference lists of articles selected for full text review will be screened for additional papers. Articles published in English, or those available for English translation will be included. No limits will be placed on date of publication.

Information sources

The databases to be searched include MEDLINE All (Ovid), Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and SCOPUS (Elsevier Scopus.com). Sources of unpublished studies and grey literature will be retrieved via advanced searches in Google. We will not search pre-print servers, as this is not a rapidly emerging topic. However, pre-prints retrieved via the Google search will be screened and considered for inclusion. This topic is not appropriate for clinical trial research; therefore, we will not search trial registries.

Study/Source of evidence selection

Following the search, all identified records will be collated and uploaded into Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) and duplicates removed. Following a pilot test, titles and abstracts will be screened by two independent reviewers for assessment against the inclusion criteria. Potentially relevant papers will be retrieved, and full texts will be assessed against the inclusion criteria by two independent reviewers. Reasons for exclusion of full-text papers will be recorded. Any disagreements that arise between reviewers at each stage of the screening process will be resolved through discussion or with an additional reviewer/s. The results of the search will be

reported and presented following the Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Reviews (PRISMA-ScR).[21]

Data extraction

Data will be extracted from papers that meet inclusion criteria by two independent reviewers using a standardized data extraction tool (Supplementary Table 2). The extracted data will include characteristics of study participants, setting, study design and research objective. Outcome data including the harm reduction strategies or interventions employed by each study, barriers and enablers to implementation, and patient and health outcome data will be extracted.

The data extraction tool will be modified and revised as necessary during the process of extracting data from each included paper. Modifications will be detailed in the final scoping review. Authors of papers will be contacted to request missing or additional data, where required. Although scoping review methodology does not require critical appraisal of studies, upon request from the knowledge user, it was decided that included published peer reviewed papers and guidelines will be appraised using the Mixed Methods Appraisal Tool.[22]

Data analysis and presentation

Extracted data will be synthesized and reported in tables throughout the report. A summary of each paper, including setting, publication date and country will be presented to provide context for the research findings. Outcome data will be reported separately and will be categorized based on barriers and facilitators of implementing harm reduction strategies and/or interventions.

ETHICS AND DISSEMINATION

Given that this scoping review involves collecting and analyzing previously published literature and does not involve research on humans or animals we did not seek ethics approval from a research ethics board. However, during the initial development of the research question and search strategy, all authors completed an equity, diversity and inclusion reflection activity to identify and reflect upon individual bias and position in the literature. It was determined that individuals with lived experience of the topic area would be involved throughout the entire study process, from conceptualization to dissemination.

Results of this scoping review will be disseminated to knowledge users and relevant community stakeholders through an initial report. This document will provide a detailed reporting of context, methodology, findings as well as a lay summary, developed in partnership with our patient partners. Additionally, this review will be submitted as a manuscript for publication to a relevant scientific journal.

ACKNOWLEDGEMENTS

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AUTHOR CONTRIBUTIONS

JC, MS, LB and AC conceptualized the study, designed the search strategy and contributed to writing the manuscript. DC and CJ* contributed to writing the manuscript. SM, LW, DS and AER supported the study conceptualization and informed the search strategy. CJ and MJ provided a patient perspective during conceptualization of the study and edited the manuscript.

COMPETING INTERESTS

The authors declare no competing interests.

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Supplementary Table 1: Search strategy Ovid MEDLINE All

1	Harm Reduction/
2	(harm* adj2 reduc*).ti,ab,kw,kf.
3	(harm* adj2 (minimiz* or minimis*)).ti,ab,kw,kf.
4	or/1-3
5	(stigma* or destigma* or de-stigma*).ti,ab,kw,kf.
6	(addiction* adj2 (consultation* or counsel* or therap* or treatment* or service*)).ti,ab,kw,kf.
7	Opiate Substitution Treatment/
8	(medication assisted therap* or medication assisted treatment*).ti,ab,kw,kf.
9	(opiate substitution* or opiate replacement* or opioid* substitution* or opioid* replacement* or opioid agonist?).ti,ab,kw,kf.
10	(methadone or buprenorphine or naloxone).ti,ab,kw,kf.
11	non-abstinence.ti,ab,kw,kf.
12	or/7-11
13	Needle-Exchange Programs/
14	((needle* or syringe*) adj2 (exchange* or clean* or steril*)).ti,ab,kw,kf.
15	(supervi?ed adj2 (inject* or consum*)).ti,ab,kw,kf.
16	(consumption adj3 site?).ti,ab,kw,kf.
17	overdose prevention site?.ti,ab,kw,kf.
18	or/13-17
19	exp Continuity of Patient Care/
20	((care or healthcare) adj2 (retention or retain* or continuity or continuum)).ti,ab,kw,kf.
21	(aftercare or handoff or hand-off or patient transition* or patient transfer*).ti,ab,kw,kf.
22	(leav* against medical advice or left against medical advice or (leav* adj2 early) or (left adj2 early) or abscond* or (early adj discharge*)).ti,ab,kw,kf.
23	or/19-22
24	((staff or worker* or employee* or system) adj3 (cultur* or attitude* or belief* or misconception* or perception* or perceiv* or resist* or educat* or train* or language)).ti,ab,kw,kf.
25	or/4-6,12,18,23-24
26	exp Hospitalization/
27	Inpatients/
28	(admitted or admission* or hospitalis* or hospitaliz* or inpatient* or in-patient* or overnight*).ti,ab,kw,kf.
29	(emergency department* or emergency room* or emergency unit? or emergency ward* or "accident and emergency").ti,ab,kw,kf.
30	or/26-29
31	Alcoholics/
32	Drug Users/
33	("people who use drugs" or "persons who use drugs" or pwud).ti,ab,kw,kf.
34	("people who inject drugs" or "persons who inject drugs").ti,ab,kw,kf.
35	("people who use alcohol" or "persons who use alcohol" or pwua).ti,ab,kw,kf.
36	((drug or drugs or substance* or opioid* or opiate* or alcohol) adj2 (abuse* or "use" or user or users* or addict* or involve* or depend* or habit*)).ti,ab,kw,kf.
37	(alcoholic* or alcoholism).ti,ab,kw,kf.
38	(addict or addicts or addiction*).ti,ab,kw,kf.
39	overdose*.ti,ab,kw,kf.
40	or/31-39
41	25 and 30 and 40

Supplementary Table 2: Harm Reduction Scoping Review Extraction Form (Draft)

Author, Year	Country	Study Design	Objective	Setting	Participant Characteristics (sample size, age, gender)	Description of Harm Reduction Strategy	Barriers or Enablers to Implementation		Patient-related Outcomes Measured		Health-related outcomes measured			Description of Main Results
							Reported Barriers	Reported Enablers	Satisfaction level	Experience of care	LOS	Mortality Rate	Re-admission rate	

LOS: length of stay

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	5
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	8
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4-5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5-6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Suppl Table 1

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6-7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6-7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	7 – Suppl Table 2
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	7
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Primary Subject Heading:	Addiction
Secondary Subject Heading:	Emergency medicine, Public health, Health policy
Keywords:	PUBLIC HEALTH, Substance misuse < PSYCHIATRY, SOCIAL MEDICINE, PREVENTIVE MEDICINE

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Identifying harm reduction strategies for alcohol and drug-use in inpatient care settings and emergency departments: a scoping review protocol

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ABSTRACT

Introduction

People who use alcohol and/or drugs (PWUAD) are at high risk of medical complications, frequent hospitalization and drug-related death following discharge from inpatient settings and emergency departments (EDs). Harm reduction strategies implemented in these settings may mitigate negative health outcomes for PWUAD. However, the scope of harm reduction strategies used globally within inpatient settings and EDs is unknown. The objective of this review is to identify and synthesize reported harm reduction strategies that have been implemented across inpatient settings and EDs for PWUAD.

Methods and analysis

This review will include studies from any country and health service reporting on harm reduction strategies implemented in inpatient settings or EDs. The population of interest includes people of any race, gender and age identifying as PWUAD, or individuals who provided care to PWUAD. Studies which describe implementation strategies and barriers and enablers to implementation will be included. Studies published in English, or those available for English translation will be included. The following databases will be searched: MEDLINE All (Ovid), Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and SCOPUS (Elsevier Scopus.com). A grey literature search will be conducted. There will be no date restrictions on the search. Titles, abstracts, and full texts will be screened in duplicate. Data will be extracted using a standardized form. The results will be reported using the PRISMA extension for scoping reviews.

Ethics and dissemination

Scoping reviews do not require ethical approval. Patient partners with lived experience and relevant knowledge users will be engaged as research team members throughout all phases of the research process. A report detailing context, methodology and findings from this review will be disseminated to knowledge users and relevant community stakeholders. This review will be submitted for publication to a relevant peer-reviewed journal.

Abstract word count: 292/300

ARTICLE SUMMARY

Strengths and limitations of this study

- To our knowledge this scoping review will be the first of its kind to describe the range of harm reduction strategies for people who use alcohol and/or drugs that have been implemented in inpatient and emergency department settings.
- This scoping review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews and will take an integrated knowledge translation approach by engaging key knowledge users and patient partners throughout the research process.
- Our search will be limited to five databases (MEDLINE All (Ovid), Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and SCOPUS (Elsevier Scopus.com)) and searches for unpublished studies and grey literature will be retrieved and included following the systematic approach to grey literature searching outlined by Godin et al.
- Given that this is a scoping review, it will not contain a meta-analysis of available evidence and will only describe how research in this field is being conducted, the types of evidence that are being produced, and specific knowledge gaps within the literature.
- Our search will be limited to English literature and non-English literature that is available for translation.

INTRODUCTION

Alcohol and drug use is associated with significant negative health outcomes. People who use alcohol and/or drugs (PWUAD) have a higher risk of infectious disease, drug related complications and are more likely to be frequently hospitalized when compared to other individuals.[1,2] When seeking care, PWUAD are often discharged against medical advice or expelled as a result of illicit drug use, leading to increased readmission rates and poorer hospital outcomes.[2] Encountering stigma or having negative experiences in hospital settings can prevent PWUAD from seeking medical help.[3] Furthermore, PWUAD have a high risk of drug-related death after being discharged from hospital.[4] Therefore, PWUAD face health-related risks before, during and after receiving medical care, highlighting an urgent need to improve healthcare.

Harm reduction is a pragmatic approach geared toward addressing immediate needs across a wide range of health issues. Harm reduction aims to improve the health, safety and well-being of both the individual and the community.[5,6] Within the context of drug and alcohol use, harm reduction strategies provide alternatives to drug and alcohol abstinence for individuals who cannot or do not want to stop using.[7–9] The Canadian Drugs and Substances Strategy has identified harm reduction as an integral part of their strategy to help address some of the burden associated with substance use.[9] Some of the most common harm reduction strategies used in the context of illegal substances include clean needle distribution, supervised drug intake, substitution therapy, safe supply and the use of substances like naloxone to temporarily reverse the effects of opioid overdose.[7–11] These strategies aim to improve well-being, lower rates of illness, overdose, and death because of substance use.[6–9] Harm reduction in relation to substance use has been implemented in community-based,[12] home-based[13] and inpatient settings.[14] However, there is a need to further understand the range of these harm reduction strategies.

In inpatient settings and emergency departments (EDs) there is some indication that harm reduction strategies could help to improve health outcomes for PWUAD.[15–17] The use of these strategies within inpatient settings and EDs, remains low, despite high numbers of patients hospitalized with substance-induced symptoms[18] and calls for harm reduction implementation in hospital settings.[19] Low uptake of harm reduction strategies has been attributed to inadequate staffing, lack of funding, and stigma surrounding substance use.[20] Yet, to our knowledge the full range of available implementation strategies used in implementing harm reduction strategies and the range of barriers and enablers to implementation has not been adequately described.

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis was conducted and no current or underway systematic or scoping reviews on this topic were identified. Therefore, this study aims to identify and synthesize the literature on harm reduction strategies that have been implemented in inpatient settings and EDs among people who use substances.

REVIEW QUESTIONS

The following questions will guide this review:

1. What harm reduction strategies have been evaluated to help alleviate negative health outcomes associated with substance use within inpatient settings and EDs?
2. How are harm reduction strategies implemented in inpatient settings and EDs?
3. What are the reported barriers and enablers to their implementation?
4. What are the commonly reported outcome measures used to evaluate harm reduction strategies and their implementation in these settings?

METHODS AND ANALYSIS

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews.[21] This scoping review will use an integrated knowledge translation approach, working with health system decision makers and patient partners with lived experience through all stages of the review.[22] This scoping review has been registered on The Open Science Framework (OSF) registries (Registration DOI: 10.17605/OSF.IO/P7BHN).

Inclusion criteria

Participants

This review will consider studies that include participants identifying as individuals with drug dependence or PWUAD who have been admitted to inpatient care or have accessed EDs for substance use related issues and/or any other medical issues. This review will also consider individuals who provide care for persons with drug dependence or PWUAD. People of any race, gender and age will be included.

Concept

This review will consider studies that investigate any intervention or implementation strategy of an intervention designed to reduce harm related to negative health outcomes associated with alcohol and/or drug use. Descriptions of implementation strategies may include any barriers and/or enablers to facilitating harm reduction strategies. This review will consider reported outcome measures, and not outcome data. These will include patient reported outcome measures (e.g., quality of life), and patient reported experience measures (e.g., feeling heard, receiving care asked for), as well as health outcome measures (e.g., length of stay, healthcare costs, recovery time, discharge against medical advice, readmission rates, overdose rates, mortality).

Context

Any healthcare setting that provides inpatient care or has an ED, in any country will be considered. This may include hospital settings, community inpatient day facilities or

rehabilitation facilities where individuals receive treatment overnight. Outpatient settings and community-based service settings will be excluded.

Types of sources

This scoping review will include both experimental and quasi-experimental study designs including randomized controlled trials, non-randomized controlled trials, pre-post studies and interrupted time-series studies. In addition, observational studies including prospective and retrospective cohort studies, case-control studies, cross-sectional studies, case series and individual case reports will be considered for inclusion. Qualitative and mixed methods studies will also be considered for inclusion. Grey literature sources such as policy documents and organizational reports will be included. To our knowledge, evidence syntheses which address our research questions do not exist and so cannot be included in this review. However, the reference lists of any evidence syntheses identified by our search will be reviewed for relevant articles. Text and opinion papers will be excluded.

Search strategy

In collaboration with a JBI-trained information specialist, a search strategy will be developed to locate published articles in peer-reviewed journals and grey literature repositories. An initial limited search of MEDLINE All (Ovid) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (Supplementary Table 1) The MEDLINE search strategy was peer-reviewed by an information specialist before being translated to Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and Scopus (Elsevier Scopus.com) (Supplementary Table 1). The reference lists of articles selected for full text review will be screened for additional papers. Articles published in English, or those available for English translation will be included. No limits will be placed on date of publication.

Information sources

The databases to be searched include MEDLINE All (Ovid), Embase (Elsevier Embase.com), CINAHL with Full Text (EBSCOhost), PsycINFO (EBSCOhost), and SCOPUS (Elsevier Scopus.com). Grey literature sources will be retrieved and included, following the systematic approach to grey literature searching outlined by Godin et al.[23] We will not search pre-print servers, as this is not a rapidly emerging topic. However, pre-prints will be screened and considered for inclusion. This topic is not appropriate for clinical trial research; therefore, we will not search trial registries.

Study/Source of evidence selection

Following the search, all identified records will be collated and uploaded into Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) and duplicates removed. Following a pilot test, titles and abstracts will be screened by two independent reviewers for assessment against the inclusion criteria. Potentially relevant papers will be retrieved, and full texts will be assessed against the inclusion criteria by two independent reviewers. Reasons for exclusion of full-text papers will be recorded. Any disagreements that arise between reviewers at each stage of the screening process will be resolved through discussion or with an additional reviewer/s. The results of the search will be reported and presented following the Preferred Reporting Items for Systematic Reviews and Meta-analyses for Scoping Reviews (PRISMA-ScR).[24]

Data extraction

Data will be extracted from papers that meet inclusion criteria by two independent reviewers using a standardized data extraction tool (Supplementary Table 2). The extracted data will include characteristics of study participants, setting, study design and research objective. Harm reduction strategies employed by each study, barriers and enablers to implementation, and patient and health outcome measures will be extracted.

The data extraction tool will be modified and revised as necessary during the process of extracting data from each included paper. Modifications will be detailed in the final scoping review. Authors of papers will be contacted to request missing or additional data, where required. Although scoping review methodology does not require critical appraisal of studies, upon request from the knowledge user, it was decided that included published peer reviewed papers and guidelines will be appraised using the Mixed Methods Appraisal Tool.[25]

Data analysis and presentation

Extracted data will be synthesized and reported in tables throughout the report. A summary of each paper, including setting, publication date and country will be presented to provide context for the research findings. Outcome measures will be reported separately and will be categorized based on harm reduction strategy and barriers and enablers to implementation.

The planned timeline for this review is to complete the title and abstract screening by end of September 2021, have full-text screening completed by mid-October 2021, have data extraction completed by end of October, have a report finalized for submission to the knowledge user by mid-November 2021, and a manuscript finalized and submitted for publication by end of November 2021.

Patient and Public Involvement

Two patient partners were consulted during the development of the research questions and inclusion/exclusion criteria and provided feedback of the protocol manuscript. Both patient partners will be engaged to co-produce key messages during the results stage and help in the production of a plain language summary, which will be distributed to local community organizations.

ETHICS AND DISSEMINATION

Given that this scoping review involves collecting and analyzing previously published literature and does not involve research on humans or animals we did not seek ethics approval from a research ethics board. However, during the initial development of the research question and search strategy, all authors completed an equity, diversity and inclusion reflection activity to identify and reflect upon individual bias and position in the literature. It was determined that individuals with lived experience of the topic area would be involved throughout the entire study process, from conceptualization to dissemination.

Results of this scoping review will be disseminated to knowledge users and relevant community stakeholders through an initial report. This document will provide a detailed reporting of context, methodology, findings as well as a lay summary, developed in partnership with our patient partners. Additionally, this review will be submitted as a manuscript for publication to a relevant scientific journal.

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AUTHOR CONTRIBUTIONS

JC, MS, LB and AC conceptualized the study, designed the search strategy and contributed to writing the manuscript. DC and CJ* contributed to writing the manuscript. SM, LW, DS and AER supported the study conceptualization and informed the search strategy. CJ and MJ provided a patient perspective during conceptualization of the study and edited the manuscript.

COMPETING INTERESTS

The authors declare no competing interests.

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Supplementary Table 1: Search strategy MEDLINE All (Ovid); Embase (Elsevier Embase.com); CINAHL with Full Text (EBSCOhost); PsycINFO (EBSCOhost); Scopus (Elsevier Scopus.com)

	MEDLINE All (Ovid)		Embase (Elsevier Embase.com)		CINAHL with Full Text (EBSCOhost) - *search mode: Boolean/Phrase*		PsycINFO (EBSCOhost)		Scopus (Elsevier Scopus.com)
1	Harm Reduction/	1	'harm reduction'/exp	1	(MH "Harm Reduction")	1	DE "Harm Reduction"		
2	(harm* adj2 reduc*).ti,ab,kw,kf.	2	(harm* NEAR/2 reduc*):ti,ab,kw	2	(harm* N2 reduc*)	2	(harm* N2 reduc*)	1	TITLE-ABS-KEY((harm* W/2 (reduc* OR minimiz* OR minimis*)) OR stigma* OR destigma* OR "de-stigma" OR (addiction* W/2 (consultation* OR counsel* OR therap* OR treatment* OR service*)) OR "medication assisted therap*" OR "medication assisted treatment*" OR "opiate substitution*" OR "opiate replacement*" OR "opioid* substitution*" OR "opioid* replacement*" OR "opioid agonist*" OR "substitution therap*" OR methadone OR buprenorphine OR naloxone OR "non-abstinence" OR ((needle* OR syringe*) W/2 (exchange* OR clean* OR steril*)) OR ((supervized OR supervised) W/2 (inject* OR consum*)) OR (consumption W/3 site) OR "overdose prevention site*" OR "safe supply" OR ((care OR healthcare) W/2 (retention OR retain* OR continuity OR continuum)) OR aftercare OR handoff OR "hand-off" OR "patient transition*" OR "patient transfer*" OR "leav* against medical advice" OR "left against medical advice" OR (leav* W/2 early) OR (left W/2 early) OR abscond* OR (early W/1 discharge*) OR ((staff OR worker* OR employee* OR system) W/3 (cultur* OR attitude* OR belief* OR misconception* OR perception* OR perceiv* OR resist* OR educat* OR train* OR language)))
3	(harm* adj2 (minimiz* or minimis*)).ti,ab,kw, kf.	3	(harm* NEAR/2 (minimiz* OR minimis*)):ti,ab,kw	3	(harm* N2 (minimiz* OR minimis*))	3	(harm* N2 (minimiz* OR minimis*))		
4	or/1-3	4	#1 OR #2 OR #3	4	S1 OR S2 OR S3	4	S1 OR S2 OR S3		
5	(stigma* or destigma* or de-stigma*).ti,ab,kw,kf.	5	(stigma* OR destigma* OR 'de-stigma*'):ti,ab,kw	5	(stigma* OR destigma* OR "de-stigma*")	5	(stigma* OR destigma* OR "de-stigma*")		
6	(addiction* adj2 (consultation* or counsel* or therap* or treatment* or service*)).ti,ab,kw, kf.	6	(addiction* NEAR/2 (consultation* OR counsel* OR therap* OR treatment* OR service*)):ti,ab,kw	6	(addiction* N2 (consultation* OR counsel* OR therap* OR treatment* OR service*))	6	(addiction* N2 (consultation* OR counsel* OR therap* OR treatment* OR service*))		
7	Opiate Substitution Treatment/	7	'opiate substitution treatment'/exp	7	(MH "Addictions Nursing")	7	DE "Medication-Assisted Treatment"		
		8	'methadone treatment'/exp			8	DE "Methadone Maintenance"		
8	(medication assisted therap* or medication assisted treatment*).ti,ab,kw,kf.	9	('medication assisted therap*' OR 'medication assisted treatment*'):ti,ab,kw	8	("medication assisted therap*" OR "medication assisted treatment*")	9	("medication assisted therap*" OR "medication assisted treatment*")		
9	(opiate substitution* or opiate replacement* or opioid* substitution* or opioid* replacement* or opioid agonist?).ti,ab,kw,kf.	10	('opiate substitution*' OR 'opiate replacement*' OR 'opioid* substitution*' OR 'opioid* replacement*' OR 'opioid agonist$'):ti,ab,kw	9	("opiate substitution*" OR "opiate replacement*" OR "opioid* substitution*" OR "opioid* replacement*" OR "opioid agonist#")	10	("opiate substitution*" OR "opiate replacement*" OR "opioid* substitution*" OR "opioid* replacement*" OR "opioid agonist#")		
10	substitution therap*.ti,ab,kw,kf.	11	'substitution therap*':ti,ab,kw	10	"substitution therap*"	11	"substitution therap*"		

11	(methadone or buprenorphine or naloxone).ti,ab,kw,kf.	12	(methadone OR buprenorphine OR naloxone):ti,ab,kw	11	(methadone OR buprenorphine OR naloxone)	12	(methadone OR buprenorphine OR naloxone)
12	non-abstinence.ti,ab,kw,kf.	13	('non-abstinence'):ti,ab,kw	12	("non-abstinence")	13	("non-abstinence")
13	or/7-12	14	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	13	S7 OR S8 OR S9 OR S10 OR S11 OR S12	14	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13
14	Needle-Exchange Programs/			14	(MH "Needle Exchange Programs")	15	DE "Needle Exchange Programs"
15	((needle* or syringe*) adj2 (exchange* or clean* or steril*)).ti,ab,kw,kf.	15	((needle* OR syringe*) NEAR/2 (exchange* OR clean* OR steril*)):ti,ab,kw	15	((needle* OR syringe*) N2 (exchange* OR clean* OR steril*))	16	((needle* OR syringe*) N2 (exchange* OR clean* OR steril*))
16	(supervi?ed adj2 (inject* or consum*)).ti,ab,kw,kf.	16	(supervi?ed NEAR/2 (inject* OR consum*)):ti,ab,kw	16	(supervi?ed N2 (inject* OR consum*))	17	(supervi?ed N2 (inject* OR consum*))
17	(consumption adj3 site?).ti,ab,kw,kf.	17	(consumption NEAR/3 site$):ti,ab,kw	17	(consumption N3 site#)	18	(consumption N3 site#)
18	overdose prevention site?.ti,ab,kw,kf.	18	'overdose prevention site$':ti,ab,kw	18	("overdose prevention site#")	19	("overdose prevention site#")
19	safe supply.ti,ab,kw,kf.	19	'safe supply':ti,ab,kw	19	("safe supply")	20	("safe supply")
20	or/14-19	20	#15 OR #16 OR #17 OR #18 OR #19	20	S14 OR S15 OR S16 OR S17 OR S18 OR S19	21	S15 OR S16 OR S17 OR S18 OR S19 OR S20
21	exp Continuity of Patient Care/	21	'retention in care'/exp	21	(MH "Continuity of Patient Care+")	22	DE "Continuum of Care"
						23	DE "Discharge Planning"
						24	DE "Aftercare"
22	((care or healthcare) adj2 (retention or retain* or continuity or continuum)).ti,ab,kw,kf.	22	((care OR healthcare) NEAR/2 (retention OR retain* OR continuity OR continuum)):ti,ab,kw	22	((care OR healthcare) N2 (retention OR retain* OR continuity OR continuum))	25	((care OR healthcare) N2 (retention OR retain* OR continuity OR continuum))
23	(aftercare or handoff or hand-off or patient transition* or patient	23	(aftercare OR handoff OR 'hand-off' OR 'patient transition*' OR 'patient transfer*'):ti,ab,kw	23	(aftercare OR handoff OR "hand-off" OR "patient transition*" OR "patient transfer*")	26	(aftercare OR handoff OR "hand-off" OR "patient transition*" OR "patient transfer*")

		transfer*).ti,ab,kw, kf.									
24	(leav* against medical advice or left against medical advice or (leav* adj2 early) or (left adj2 early) or abscond* or (early adj discharge*)).ti,ab,kw,kf.	24	('leav* against medical advice' OR 'left against medical advice' OR (leav* NEAR/2 early) OR (left NEAR/2 early) OR abscond* OR (early NEAR/1 discharge*)):ti,ab,kw	24	("leav* against medical advice" OR "left against medical advice" OR (leav* N2 early) OR (left N2 early) OR abscond* OR (early N1 discharge*))	27	("leav* against medical advice" OR "left against medical advice" OR (leav* N2 early) OR (left N2 early) OR abscond* OR (early N1 discharge*))				
25	or/21-24	25	#21 OR #22 OR #23 OR #24	25	S21 OR S22 OR S23 OR S24	28	S22 OR S23 OR S24 OR S25 OR S26 OR S27				
26	((staff or worker* or employee* or system) adj3 (cultur* or attitude* or belief* or misconception* or perception* or perceiv* or resist* or educat* or train* or language)).ti,ab,kw,kf.	26	((staff OR worker* OR employee* OR system) NEAR/3 (cultur* OR attitude* OR belief* OR misconception* OR perception* OR perceiv* OR resist* OR educat* OR train* OR language)):ti,ab,kw	26	((staff OR worker* OR employee* OR system) N3 (cultur* OR attitude* OR belief* OR misconception* OR perception* OR perceiv* OR resist* OR educat* OR train* OR language))	29	((staff OR worker* OR employee* OR system) N3 (cultur* OR attitude* OR belief* OR misconception* OR perception* OR perceiv* OR resist* OR educat* OR train* OR language))				
27	or/4-6,13,20,25-26	27	#4 OR #5 OR #6 OR #14 OR #20 OR #25 OR #26	27	S4 OR S5 OR S6 OR S13 OR S20 OR S25 OR S26	30	S4 OR S5 OR S6 OR S14 OR S21 OR S28 OR S29				
28	Hospitalization/	28	'hospitalization'/exp	28	(MH "Hospitalization")	31	DE "Hospitalization"				
29	Inpatients/	29	'hospital patient'/de	29	(MH "Inpatients")	32	DE "Hospital Admission"				
						33	DE "Psychiatric Hospitalization"	2	TITLE-ABS-KEY(admitted OR admission* OR hospitalis* OR hospitaliz* OR inpatient* OR overnight* OR "emergency department*" OR "emergency room*" OR "emergency unit*" OR "emergency ward*" OR "accident and emergency")		
						34	DE "Hospitalized Patients"				
30	(admitted or admission* or hospitalis* or hospitaliz* or inpatient* or in-patient* or overnight*).ti,ab,kw,kf.	30	(admitted OR admission* OR hospitalis* OR hospitaliz* OR inpatient* OR 'in-patient*' OR overnight*):ti,ab,kw	30	(admitted OR admission* OR hospitalis* OR hospitaliz* OR inpatient* OR overnight*)	35	(admitted OR admission* OR hospitalis* OR hospitaliz* OR inpatient* OR overnight*)				

31	(emergency department* or emergency room* or emergency unit? or emergency ward* or "accident and emergency").ti,ab,kw,kf.	31	('emergency department*' OR 'emergency room*' OR 'emergency unit$' OR 'emergency ward*' OR 'accident and emergency'):ti,ab,kw	31	("emergency department*" OR "emergency room*" OR "emergency unit#" OR "emergency ward*" OR "accident and emergency")	36	("emergency department*" OR "emergency room*" OR "emergency unit#" OR "emergency ward*" OR "accident and emergency")				
32	or/28-31	32	#28 OR #29 OR #30 OR #31	32	S28 OR S29 OR S30 OR S31	37	S31 OR S32 OR S33 OR S34 OR S35 OR S36				
33	Alcoholics/	33	'drug dependence'/exp	33	(MH "Substance Abusers+")	38	DE "Drug Abuse"				
34	Drug Users/	34	'injection drug user'/exp	34	(MH "Substance Dependence")	39	DE "Drug Dependency"				
		35	'recreational drug use'/exp			40	DE "Opioid Use Disorder"				
						41	DE "Alcohol Use Disorder"	3	TITLE-ABS-KEY("people who use drugs" OR "persons who use drugs" OR pwud OR "people who inject drugs" OR "persons who inject drugs" OR "people who use alcohol" OR "persons who use alcohol" OR pwua OR ((drug OR drugs OR substance* OR opioid* OR opiate* OR alcohol) W/2 (abuse* OR "use" OR user OR users* OR addict* OR involve* OR depend* OR habit*)) OR alcoholic* OR alcoholism OR addict OR addicts OR addiction* OR overdose*)		
						42	DE "Substance Use Disorder"				
35	("people who use drugs" or "persons who use drugs" or pwud).ti,ab,kw,kf.	36	('people who use drugs' OR 'persons who use drugs' OR pwud):ti,ab,kw	35	("people who use drugs" OR "persons who use drugs" OR pwud)	43	("people who use drugs" OR "persons who use drugs" OR pwud)				
36	("people who inject drugs" or "persons who inject drugs").ti,ab,kw,kf.	37	('people who inject drugs' OR 'persons who inject drugs'):ti,ab,kw	36	("people who inject drugs" OR "persons who inject drugs")	44	("people who inject drugs" OR "persons who inject drugs")				
37	("people who use alcohol" or "persons who use alcohol" or pwua).ti,ab,kw,kf.	38	('people who use alcohol' OR 'persons who use alcohol' OR pwua):ti,ab,kw	37	("people who use alcohol" OR "persons who use alcohol" OR pwua)	45	("people who use alcohol" OR "persons who use alcohol" OR pwua)				
38	((drug or drugs or substance* or opioid* or opiate* or alcohol) adj2 (abuse* or "use" or user or users* or addict* or involve* or depend* or habit*)).ti,ab,kw,kf.	39	((drug OR drugs OR substance* OR opioid* OR opiate* OR alcohol) NEAR/2 (abuse* OR 'use' OR user OR users* OR addict* OR involve* OR depend* OR habit*)):ti,ab,kw	38	((drug OR drugs OR substance* OR opioid* OR opiate* OR alcohol) N2 (abuse* OR "use" OR user OR users* OR addict* OR involve* OR depend* OR habit*))	46	((drug OR drugs OR substance* OR opioid* OR opiate* OR alcohol) N2 (abuse* OR "use" OR user OR users* OR addict* OR involve* OR depend* OR habit*))				
39	(alcoholic* or alcoholism).ti,ab,kw,kf.	40	(alcoholic* OR alcoholism):ti,ab,kw	39	(alcoholic* OR alcoholism)	47	(alcoholic* OR alcoholism)				
40	(addict or addicts or addiction*).ti,ab,kw,kf.	41	(addict OR addicts OR addiction*):ti,ab,kw	40	(addict OR addicts OR addiction*)	48	(addict OR addicts OR addiction*	4	#1 AND #2 AND #3		

41	overdose*.ti,ab,kw, kf.	42	overdose*:ti,ab,kw	41	overdose*	49	overdose*	5	#4 AND NOT (INDEX(medline) OR INDEX(embase))
42	or/33-41	43	#33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42	42	S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41	50	S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49		
43	27 and 32 and 42	44	#27 AND #32 AND #43	43	S27 OR S32 OR S42	51	S30 OR S37 OR S50		
	6519 results 2021-07-07		**8795 results 2021-07-07**		**2358 results 2021-07-07**		**3568 results 2021-07-07**		**479 results 2021-07-07**
	Amended search 2021-09-15		*Amended search 2021-09-15*		*Amended search 2021-09-15*		*Amended search 2021-09-15*		*Amended search 2021-09-15*
	6698 results 2021-09-15		**9379 results 2021-09-15**		**2581 results 2021-09-15**		**3801 results 2021-09-15**		**506 results 2021-09-15**
									Full string:

((TITLE-ABS-KEY((harm* W/2 (reduc* OR minimiz* OR minimis*)) OR stigma* OR destigma* OR "de-stigma" OR (addiction* W/2 (consultation* OR counsel* OR therap* OR treatment* OR service*)) OR "medication assisted therap*" OR "medication assisted treatment*" OR "opiate substitution*" OR "opiate replacement*" OR "opioid* substitution*" OR "opioid* replacement*" OR "opioid agonist*" OR "substitution therap*" OR methadone OR buprenorphine OR naloxone OR "non-abstinence" OR ((needle* OR syringe*) W/2 (exchange* OR clean* OR steril*)) OR ((supervized OR supervised) W/2 (inject* OR consum*)) OR (consumption W/3 site) OR "overdose prevention site*" OR "safe supply" OR ((care OR healthcare) W/2 (retention OR retain* OR continuity OR continuum)) OR aftercare OR handoff OR "hand-off" OR "patient transition*" OR "patient transfer*" OR "leav* against medical advice" OR "left against medical advice" OR (leav* W/2 early) OR (left W/2 early) OR abscond* OR (early W/1 discharge*) OR ((staff OR worker* OR employee* OR system) W/3 (cultur* OR attitude* OR belief* OR misconception* OR perception* OR perceiv* OR resist* OR educat* OR train* OR language)))) AND (TITLE-ABS-KEY(admitted OR admission* OR hospitalis* OR hospitaliz* OR inpatient* OR overnight* OR "emergency department*" OR "emergency room*" OR "emergency unit*" OR "emergency ward*" OR "accident and emergency")) AND (TITLE-ABS-KEY("people who use drugs" OR "persons who use drugs" OR pwud OR "people who inject drugs" OR "persons who inject drugs" OR "people who use alcohol" OR "persons who use alcohol" OR pwua OR ((drug OR drugs OR substance* OR opioid* OR opiate* OR alcohol) W/2 (abuse* OR "use" OR user OR users* OR addict* OR involve* OR depend* OR habit*)) OR alcoholic* OR alcoholism OR addict OR addicts OR

addiction* OR overdose*))) AND NOT (INDEX(medline) OR INDEX(embase))

Supplementary Table 2: Harm Reduction Scoping Review Extraction Form (Draft)

Author, Year	Country	Study Design	Objective	Setting	Participant Characteristics (sample size, age, gender)	Description of Harm Reduction Strategy	Barriers or Enablers to Implementation		Patient-related Outcomes Measured		Health-related outcomes measured			Description of Main Results
							Reported Barriers	Reported Enablers	Satisfaction level	Experience of care	LOS	Mortality Rate	Re-admission rate	

LOS: length of stay

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	5
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	8
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4-5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5-6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Suppl Table 1

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6-7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6-7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	7 – Suppl Table 2
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	7
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.