Interventions to Deliver Vaccination to, and Improve Vaccination Rates in, People who are Homeless: A Systematic Review Protocol

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ABSTRACT

Background: In comparison to the general population, people who are homeless have poorer health and health-related outcomes, including for vaccine-preventable diseases. Vaccination is safe, effective and cost-effective, and many vaccination guidelines specifically recommend vaccination in people who are homeless. This systematic review will identify interventions which are effective in delivering vaccination to, and/or at improving vaccination rates in, people who are homeless.

Methods/Design: This systematic review is presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Searches will be undertaken on eight electronic databases, using combinations of search terms and subject headings or index terms. Citation chaining will also be undertaken. Literature will be screened for relevance against inclusion/exclusion criteria firstly by title/abstract and secondly by full text. The selected studies will be assessed for quality using an evidence-based tool appropriate to their methods. Data relevant to the topic will be extracted and examined using meta-analysis and narrative synthesis.

Discussion: This systematic review will address an important gap in the literature about vaccination in people who are homeless. The review's findings are particularly relevant considering the current coronavirus disease (COVID-19) pandemic, which is likely to be managed through vaccination.

Keywords: vaccination, vaccine, immunisation, homeless, COVID-19, coronavirus

1. Background

1.1 Overview of homelessness

There is no universal definition of 'homelessness'; however, it is generally agreed to occur when a person lacks access to suitable housing (Organisation for Economic Cooperation and

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Development, 2019). People who are homeless include those who are unsheltered, as well as those staying in households other than their own, in overcrowded, substandard, untenable or unsafe housing, and in shelters (Organisation for Economic Cooperation and Development, 2019). Among OECD countries for which recent data is available, rates of homelessness as a percentage of total population range from 0.004% (N=4,560) in Japan to 0.940% (N=41,200) in New Zealand (Organisation for Economic Cooperation and Development, 2019). In Australia, where the authors are located, approximately 0.480% (N=116,400) of people are homeless (Australian Bureau of Statistics, 2016). In one-third of OECD countries, including in Australia, homelessness is increasing (Organisation for Economic Cooperation and Development, 2019).

1.2 Health disparities and vaccine-preventable diseases in people who are homeless

In comparison to the general population, people who are homeless experience poorer health and health-related outcomes. People who are homeless are at greater risk of developing a range of mental and physical illnesses, including vaccine-preventable diseases such as hepatitis (Hosseini & Ding, 2018; Noska et al., 2017; Peak et al., 2019), pneumococcal disease (Lemay et al., 2019; McKee et al., 2018; Mosites et al., 2019) and tuberculosis (Bamrah et al., 2013; Khan et al., 2011; Lee et al., 2013; Romaszko et al., 2013). Once ill, people who are homeless have a greater likelihood of hospitalisation, intensive care unit (ICU) admission, and death (Lewer et al., 2020).

There are a number of reasons for these outcomes. In comparison to the general population, people who are homeless are more likely to have multiple chronic comorbidities (Lebrun-Harris et al., 2013), high rates of problematic substance use (Krupski et al., 2015; Lebrun-Harris et al., 2013), and poor nutrition (Fallaize et al., 2017). People who are homeless often live in outdoor, informal and highly-congregate settings, among transient populations, and without access to adequate hygiene facilities (Tsai & Wilson, 2020). Further, people who are homeless often have limited access to healthcare and, subsequently, unmet health needs (Aldridge et al., 2019; Elwell-Sutton et al., 2017). These factors all contribute to illness and facilitate the spread of disease.

1.3 Overview of vaccines and vaccination

A vaccine is a substance which stimulates the immune system to produce antibodies against one or more pathogen(s), thereby reducing the likelihood of future infection with those pathogen(s) (Federman, 2014). To date, vaccines have been developed for >30 different pathogens (Delany et al., 2014). Vaccines may be manufactured to contain whole pathogens (live attenuated or inactivated), parts of pathogens, adjuvants and/or toxoids (Vetter et al., 2017). They may be delivered intramuscularly, intradermally, subcutaneously, intranasally or orally, etc., and in the form of a single dose, a multiple-dose schedule or an annual booster (Vetter et al., 2017).

Systematic reviews show that vaccines – including those for infectious diseases common in people who are homeless, such as hepatitis (Ott et al., 2012; Stuurman et al., 2017; van den Ende et al., 2017; Whitford et al., 2018), pneumococcal disease (Falkenhorst et al., 2017; McLaughlin et al., 2019), and tuberculosis (Roy et al., 2014) – are safe, effective and cost-effective. Vaccines protect not only the person vaccinated, but also the broader population by facilitating population immunity (Orenstein & Ahmed, 2017). Subsequently, most OECD nations have guidelines about vaccination, and many – including Australia's (Australian Government - Department of Health, 2020) – make specific recommendations about vaccination in people who are homeless.

1.4 Vaccination in people who are homeless

There are multiple complexities associated with delivering vaccination to people who are homeless. As noted earlier, people who are homeless frequently have limited access to healthcare. Further complicating this is the fact that public health infrastructure to support vaccination in adults, particularly those from hard-to-reach groups, is often inadequate (Poulos et al., 2010). Vaccinations in adults are often minimally reimbursed, and costs may be prohibitive for people in low-income groups (Doroshenko et al., 2012; Poulos et al., 2010). Research shows that people who are homeless are often ambivalent about vaccination, and that it may be a low priority in their lives (Doroshenko et al., 2012; Poulos et al., 2010). Although there are no systematic reviews on the topic, it is accepted that – in comparison to the general population – vaccination coverage for a range of diseases is lower in people who are homeless (Wood, 2012).

To date, there are no existing systematic reviews about effective interventions to deliver vaccination to, and improve vaccination rates in, people who are homeless. Subsequently, there is a lack of evidence to inform practice in this area. It is reasonable to assume this may reinforce the poorer health and health-related outcomes experienced by people who are homeless.

1.4 Aim of the review

The aim of the proposed systematic review is to address the gaps in the existing literature about vaccination in people who are homeless. The review will achieve this by: (1) identifying, (2) analysing the characteristics of, and (3) evaluating the outcomes of, interventions to deliver vaccination to, and/or improve vaccination rates in, people who are homeless.

1.5 Review question

This review will answer the questions: (1) What interventions have been implemented to deliver vaccination to and/or improve vaccination rates in people who are homeless?, (2) What are the characteristics of these interventions?, and (3) What are the outcomes of these interventions?

2. Methods/Design

2.1 Study design

A systematic review of the existing research literature will be undertaken. Preliminary scoping searches have been completed to inform this protocol (e.g. to determine type and extent of literature available, effective search terms, suitable databases/limiters/data extraction items, etc.). This protocol has been reported using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines (Shamseer et al., 2015) (Additional File #1).

2.2 Participants, intervention design and focus, and outcomes of interest

Eligibility criteria for this review were developed using the PICO (population, intervention, comparator, outcome) framework. Application of the framework to the topic is as follows:
- Population: people who are homeless:
    - The review will use the definition of 'homeless' cited in Section 1.1.
    - The review will consider interventions for homeless adults, youth and/or children.

- Intervention: any intervention implemented to: (1) deliver vaccination to, and/or (2) improve vaccination rates in, people who are homeless:
  - o The review will use the definition of 'vaccination' cited in Section 1.3; the review will consider any type of vaccination, for any type of vaccine-preventable disease.
  - o To 'deliver vaccination' means to vaccinate people who are homeless.
  - o An 'improvement in vaccination rates' may be measured in a variety of ways (e.g. as an increase in the number (N) or percentage (%) of people being vaccinated, N/% completing a vaccination schedule, N/% accepting (versus declining) vaccination, etc.). However, a study considered for inclusion may describe a vaccination intervention *without* measuring an improvement in vaccination rates.
- Comparator: standard approaches to vaccination delivery, or no vaccination delivery.
- Outcome: (1) the intervention's characteristics, and (2) the interventions' outcomes; a comprehensive list of outcomes is provided in Section 2.6.

Systematic reviews, randomised control trials and direct comparative studies will be the focus of this review. In the absence of these, all other study types will be considered, including qualitative, quantitative and mixed-methods studies. Literature will be considered if it reports on a study undertaken in Australia, where the authors are located, or in a similar international context (i.e. New Zealand, Western Europe [including the UK], North America [including the US and Canada], etc.). Only literature published in English, in full-text and in a peer-reviewed journal will be considered. Literature will not be limited by date.

2.3 Search strategy

The searches will use two groups of keywords: (1) those related to 'homelessness', and (2) those related to 'vaccination' (including 'immunisation'). Index terms and subject headings will be used, where these are available on the databases. Boolean operators, parentheses and truncation will be applied where required. Sample search strategies are provided in Additional File #2.

2.4 Information sources

The searches will be undertaken on the following electronic databases: CINAHL Complete (via Ebscohost), ClinicalTrials.gov, Cochrane Library, Embase, MEDLINE (via Ebscohost), PsycInfo (via Ovid), Scopus and Web of Science (via Clarivate Analytics). The reference lists of each piece of literature selected for inclusion in the review will also be manually searched.

2.5 Data collection

The search results will be exported into EndNote X9. Using EndNote's 'find duplicate' function, duplicate items will be removed. The items will then be screened against the eligibility criteria outlined in Section 2.2 in two steps: (1) for all items: by reading the title/abstract, then (2) for the remaining items: by reading the full text. Each step will be completed by one researcher and checked by a second researcher; where needed, agreement will be achieved through discussion or by involving a third researcher. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) chart (Moher et al., 2009) will be used to record the selection process.

2.6 Data extraction

Data will be extracted into an electronic table. Data extraction will be completed by one researcher and checked by a second researcher; where needed, agreement will be achieved through discussion or by involving a third researcher. The data extracted will include:

- Data about the study – the author/s; publication date; country/ies; purpose/aim; design/methods; recruitment/sampling procedures; randomisation procedures (if relevant); data collection procedures; data analysis procedures; study funding; etc.
- Data about the study participants – the sample size; inclusion/exclusion criteria; baseline characteristics including type of homelessness experienced (e.g. sheltered/unsheltered, short-/medium-/long-term, etc.); risk factors for vaccine-preventable diseases; etc.
- Data about the intervention and its characteristics – the provider/s; purpose/aim (e.g. routine prevention, response to outbreak, etc.); site/setting (e.g. clinic, outreach, etc.); size; disease/s targeted; type/s of vaccines delivered; staffing; co-interventions (e.g. reminders, health education, etc.); duration including length of participant follow-up; resource requirements; vaccine funding (e.g. self-funded, government-funded), etc.
- Data about the outcomes of the intervention – including improvement in vaccination rates, as defined in Section 2.2. Secondary outcomes will include: (1) determinants of vaccination uptake, and (2) challenges/barriers to intervention delivery. The review will not consider outcomes associated with serological testing for immunity, or rates of post-vaccination illness, as these measure vaccine (rather than intervention) effectiveness.

2.7 Quality assessment

Literature selected for inclusion will be evaluated using an appropriate evidence-based tool:

- For systematic reviews: the revised Assessing the Methodological Quality of Systematic Reviews (AMSTAR 2) tool (Shea et al., 2017)
- For randomised and quasi-randomised-controlled trials: the revised Cochrane Risk-of-Bias Tool for Randomised Controlled Trials (RoB 2) (Sterne et al., 2019)
- For cohort studies: the Risk of Bias in Non-Randomised Studies of Interventions (ROBINS-1) tool (Cochrane Methods, ND)
- For cross-sectional studies: the Appraisal Tool or Cross-Sectional Studies (AXIS) (Downes et al., 2016)
- For qualitative studies: the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Qualitative Research (Joanna Briggs Institute (JBI), 2019)

2.8 Data synthesis

If possible, a meta-analysis will be undertaken to evaluate the outcomes of the interventions. If a meta-analysis is not possible, and for all other data, a narrative synthesis will be completed.

2.9 Ethics

Approval from a research ethics committee is not required for this systematic review.

3. Discussion

This systematic review addresses an important gap in the existing literature about vaccination in people who are homeless. The review is also particularly relevant in the context of the current coronavirus disease (COVID-19) pandemic. Research among residents of homeless shelters in the United States in March/April/May 2020 identifies COVID-19 infection rates of between 2.1% and 67.0%, far higher than in the general population (Baggett et al., 2020; Ghinai et al., 2020; Imbert et al., 2020; Mosites et al., 2020; Yoon et al., 2020). Modelling studies show that people who are homeless are significantly more likely than those in the general population to be hospitalised, to be admitted to ICUs, and to die from COVID-19 (Culhane, 2020; Lewer et al., 2020). People who are homeless may also be disproportionately impacted by the negative socioeconomic impacts of COVID-19 responses (Perri et al., 2020).

The best option for reducing the enormous health and socioeconomic impacts of COVID-19 – both in people who are homeless, and in the general population – is a vaccine (World Health Organization, 2020b). At mid-October 2020 there are 44 vaccine candidates undergoing clinical evaluation (World Health Organization, 2020a). This review will provide evidence about how a COVID-19 vaccine, if developed, and other vaccines can be delivered to people who are homeless in an effective and cost-effective way. By providing evidence to inform practice, the review may contribute to improving the health and health-related outcomes of people who are homeless.

However, the limitations of this systematic review must also be considered. In the scoping searches undertaken, few high-quality studies (e.g. randomised controlled trials, direct comparative studies, etc.) were identified. The studies which were identified are heterogeneous, and this may prevent meta-analysis and cause difficulties in evaluating and comparing the effects of the interventions. Further, there is no scope in this project to examine literature published in languages other than English. The utility of the review must be interpreted in the context of these limitations.

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Appendix

Additional File #1
PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) Checklist (Shamseer et al., 2015)

Section and topic	Item No	Checklist item	Location in submission
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Title
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	N/A
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Authors and Affiliations
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Authors' Contributions
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	Funding Statement
Sponsor	5b	Provide name for the review funder and/or sponsor	
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	Sections, 1.1, 1.2, 1.3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Sections 1.4, 1.5

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	Section 2.2
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	Section 2.4
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	Section 2.3, Additional File #2
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Section 2.5
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)	Section 2.5
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	Section 2.6
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	Section 2.6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Section 2.6
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	Section 2.7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	
	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)	Section 2.8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	

	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
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)	Section 2.7

Additional File #2

Search #1: homeless*

Search #2: (vaccin* OR immuni*)

CINAHL Complete with subject headings: (MM "homeless persons" OR MM "homelessness" OR Search #1) AND (MH "immunization+" OR Search #2)

Clinical Trials.gov (Search #1) AND (Search #2)

Cochrane Library: (Vaccination [MeSH] AND Search #1) AND (Homeless persons [MeSH] AND Search #2)

Embase with index terms: ('homeless person'/exp OR homeless*) AND ('immunization'/exp OR Search #2)

MEDLINE (via EBSCOhost) with subject headings: (MH "homeless persons+" OR homeless*) AND (MH "vaccination+" OR Search #2)

PsycInfo: [(exp Homeless/) OR Search #1] AND [(exp Immunization/) OR Search #2]

Scopus: (Search #1) AND (Search #2)

Web of Science: (Search #1) AND (Search #2)

Note: The term 'vaccination' refers to receiving a vaccine, whereas the term 'immunisation' refers to the process of receiving a vaccine *and* developing immunity to the pathogen/s the vaccination covers (Australian Government - Department of Health, 2018). Both terms are used interchangeably in the literature. Therefore, both terms are used in the searches.