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Guidance relevant to the reporting of health equity in observational research: a scoping review protocol

Anita Rizvi ,[1] Daeria O Lawson ,[2] Taryn Young,[3] Omar Dewidar ,[4] Stuart Nicholls,[5] Elie A Akl ,[2,6] Julian Little ,[4] Olivia Magwood ,[7,8] Larissa Shamseer ,[9] Elizabeth Ghogomu,[10] Janet Elizabeth Jull,[11] Tamara Rader,[12] Zulfiqar Bhutta ,[13,14] Catherine Chamberlain,[15,16,17] Holly Ellingwood,[18] Regina Greer-Smith,[19] Billie-Jo Hardy,[20] Matire Harwood,[21] Michelle Kennedy ,[22] Tamara Kredo ,[23] Elizabeth Loder,[24] Michael Johnson J Mahande ,[25] Lawrence Mbuagbaw ,[2] Miriam Nkangu,[4] Patrick M Okwen,[26] Jacqueline Ramke ,[27,28] Janice Tufte,[29] Peter Tugwell,[30] Xiaoqin Wang,[31] Charles Shey Wiysonge ,[23] Vivian A Welch [4]

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For numbered affiliations see end of article.

Correspondence to
Anita Rizvi;
arizv036@uottawa.ca

ABSTRACT

Introduction Health inequities are defined as unfair and avoidable differences in health between groups within a population. Most health research is conducted through observational studies, which are able to offer real-world insights about etiology, healthcare policy/programme effectiveness and the impacts of socioeconomic factors. However, most published reports of observational studies do not address how their findings relate to health equity. Our team seeks to develop equity-relevant reporting guidance as an extension of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. This scoping review will inform the development of candidate items for the STROBE-Equity extension. We will operationalise equity-seeking populations using the PROGRESS-Plus framework of sociodemographic factors. As part of a parallel stream of the STROBE-Equity project, the relevance of candidate guideline items to Indigenous research will be led by Indigenous coinvestigators on the team.

Methods and analysis We will follow the Joanna Briggs Institute method for conducting scoping reviews. We will evaluate the extent to which the identified guidance supports or refutes our preliminary candidate items for reporting equity in observational studies. These candidate items were developed based on items from equity-reporting guidelines for randomised trials and systematic reviews, developed by members of this team. We will consult with our knowledge users, patients/public partners and Indigenous research steering committee to invite suggestions for relevant guidance documents and interpretation of findings. If the identified guidance suggests the need for additional candidate items, they will be developed through inductive thematic analysis.

Ethics and dissemination We will follow a principled approach that promotes ethical codevelopment with our community partners, based on principles of cultural safety, authentic partnerships, addressing colonial structures in knowledge production and the shared ownership, interpretation, and dissemination of research. All products of this research will be published as open access.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To the best of our knowledge, this scoping review will be the first to analyse existing research guidance across the Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status and Social capital (PROGRESS)-Plus framework of sociodemographic factors to inform the development of a guideline for reporting health equity in observational studies.

⇒ The scoping review will follow robust guidelines for conducting a systematic scoping review (Joanna Briggs Institute method), reporting the review (Preferred Reporting Items for Systematic reviews and Meta-Analyses – extension for Scoping Reviews (PRISMA-ScR)) and reporting the literature search (Preferred Reporting Items for Systematic reviews and Meta-Analyses – extension for literature Searches (PRISMA-S)).

⇒ A comprehensive search of multiple bibliographic databases (Embase, CINAHL, MEDLINE and LILACS) and grey literature sources will be conducted by a librarian experienced in scoping reviews.

⇒ We expect to find a diversity of definitions of health equity which may not align with the a priori PROGRESS-Plus framework; this may be a limitation (if the framework cannot be adapted to accommodate every definition) or a strength (if other definitions lead to an enhanced understanding of health equity).

⇒ We expect considerable heterogeneity among the included literature (ie, from various types of organisations and in various formats), which may pose a challenge for consistent and comprehensive data extraction.

INTRODUCTION

Health inequities are defined as differences in health between groups within a population that are unnecessary, avoidable, unfair and unjust.[1] These disparities persist despite

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over a century of research on health inequities and their causes.[2] Health inequities are experienced across numerous factors such as income, education, geographical setting, age, ethnicity and gender (a term which has been limited to outdated binary concepts, while in fact there exists a wide spectrum of gender identities and expressions).[3] The United Nations has characterised equity-related determinants of health, which impede people from achieving their health potential, into three distinct categories: social, economic and environmental.[4]

Most epidemiological research is conducted as observational studies,[5] which can generate rigorous knowledge and understanding of (1) disease etiology and why disease is distributed inequitably in populations, (2) the differential effects of health policies and programmes on health equity, and (3) interactions between context and intersecting socioeconomic factors. Observational studies also provide an opportunity for knowledge generation in conflict and fragile settings where experimental studies may not be possible. For the purpose of this scoping review, we will consider observational studies to consist of cohort studies, case–control studies and cross-sectional studies.[6]

Observational studies often draw on linked data between different types of administrative databases such as pharmacy, hospital and medical insurance databases. Such data facilitate the collection of sociodemographic characteristics associated with health inequity, such as place of residence, ethnicity, race, income, age and sex. These characteristics are often used to control for potential confounding and can also be used to investigate differences in effects across these characteristics.[7] However, the extent to which observational studies investigate these effects appears to be limited,[8 9] despite the powerful potential for exploring differential outcomes and investigating associations with context. A further constraint is that observational studies using linked data cannot address inequities for populations such as homeless, displaced and migrant communities, which do not always have access to services that provide data to linked databases. The lack of (otherwise) routinely collected information about these populations may result in underestimating the actual extent of health disparities.

Differences in health between social groups are also obscured by the lack of granular health data due to aggregation and averaging of data at the national or state/provincial level.[2] The resulting deficiencies in the analyses and reporting of equity considerations are barriers for synthesising evidence concerning equity. In addition, health systems and policy interventions are often complex, with various interacting components, making it difficult to identify the 'active ingredients' and to implement interventions consistently.[10]

Health equity has been studied since the early 19th century, when severe disparities in health status and mortality between the poor and the rich were first described in academic literature.[11 12] Guidance for the reporting of equity-relevant details, however, has only recently started to emerge, while other guidelines relating to various study designs and specific areas of health research have been published since 1995.[13] Many reporting guidelines are still being developed, as shown by over 100 current registrations for proposed new guidelines on the website of the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network.[14] However, of the 464 published guidelines listed on EQUATOR, only three focus on the reporting of equity-relevant information: one addressing sex and gender,[3] one for systematic reviews[15] and one for randomised trials.[16]

This scoping review is part of a multiphased project to develop an equity extension of the widely used Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.[17 18] We mapped all existing STROBE extensions to assess whether any of the extensions included items relevant to equity (mapping table available at https://osf.io/8abtr/), and we did not find any equity-related items. We also assessed all items from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)-Equity guideline[15] and the Consolidated Standards of Reporting Trials-Equity guideline.[16] Through this process, we developed a draft set of 36 candidate items for a STROBE-Equity extension (online supplemental appendix 1).

This scoping review aims to compile guidance from sources such as ethics boards, funders and journal policies which may be relevant to the reporting of health equity in observational studies, to help inform the development of the new STROBE-Equity extension (Open Science project page: https://osf.io/h57se/). We chose to conduct a scoping review as the evidence synthesis method due to the expected varied types and sources of guidance (eg, institutional web pages, government policies and ethics board documents) which are not typically published in academic journals or indexed in academic databases. A systematic review would not be an appropriate method for this study since we acknowledge that we would not be able to identify every source of relevant guidance from every institution and organisation in every country. Our study objectives also align with three of the reasons proposed by Munn *et al*[19] for conducting a scoping review: (1) 'to identify the types of available evidence in a given field', (2) 'to identify key characteristics or factors related to a concept' and (3) 'to identify and analyse knowledge gaps'. Additionally, a scoping review will allow us to purposively search specific sources of guidance that address health inequities across various sociodemographic factors.

We did not find any existing reviews or protocols for reviews on health equity reporting guidance by searching the following databases: Joanna Briggs Institute (JBI) Evidence Synthesis (searched on 14 June 2021), Cochrane Database of Systematic Reviews (searched on 14 June 2021), Campbell Collaboration online library (searched on 14 June 2021), Evidence for Policy and Practice Information (searched 15 June 2021), Epistemonikos

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(searched 15 June 2021) and PubMed (searched 15 June 2021).

The specific research questions for this scoping review are:

1. Does the identified guidance support or refute each candidate item for the STROBE-Equity extension?
2. Does the identified guidance indicate other/additional candidate items for the STROBE-Equity extension?
3. Does the identified guidance indicate a need for specific guideline items in relation to particular populations or contexts?

METHODS AND ANALYSIS

Consultation and integrated knowledge translation

We designed this scoping review in consultation with relevant stakeholders and knowledge users, including policy makers, advisors, programme managers, practitioners and people with lived experience of health inequities.

We will follow a principled approach to ethical collaborative conduct of this research, including development of authentic partnerships, joint ownership of all data collected and collaborative interpretation of results, using principles of cultural safety and of addressing colonial structures in knowledge production.[20 21] We developed a diverse and multidisciplinary team of individuals representing different types of stakeholders, including patients/public, practitioners, policy makers, programme managers, press, payers/purchasers and principal investigators, using a '7Ps' framework adapted from Concannon *et al*.[22]

Our integrated knowledge translation approach will apply a health equity lens by focusing on equitable decision-making within our research team, which involves transparency and which does not perpetuate unequal power relations that filter out the voices or viewpoints of some stakeholders.[23]

Study design

We chose to conduct this scoping review according to the JBI method[24] because this approach is useful for identifying a range of sources of guidance (eg, from published literature, grey literature and expert contacts) and for synthesising broad concepts in the available guidance.[25]

Inclusion criteria

We used the population, concept and context framework of JBI to develop the inclusion criteria for this scoping review.

Population

Guidance related to research with or about people experiencing health inequity will be included. We will consider documents, web content and articles (hereon collectively referred to as 'articles') that pertain to people or groups whose opportunities for health are compromised with respect to any PROGRESS-Plus characteristics (or combination thereof). The PROGRESS acronym stands for Place of residence (eg, country, neighbourhood, urban/rural), Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status and Social capital.[26] The 'Plus' refers to other personal, time-dependent or relationship-dependent factors, such as pregnancy, reproductive capacity, age, disability and sexual orientation.[27]

We recognise that various terms may be used to describe groups experiencing health inequities such as deprived, discriminated against, handicapped, poor, underprivileged, under-resourced, underserved, disadvantaged, marginalised, equity-seeking, racialised or vulnerable; these will all be eligible for searching. In addition, PROGRESS-Plus characteristics intersect with each other and within the context and setting. We acknowledge that the PROGRESS-Plus framework may not cover all equity-related individual or population-level characteristics. Thus, we will judge relevance to health equity by assessing whether the guidance describes a focus on health equity, social justice, disparities or inequalities.

Concept

The concept to be studied in this scoping review is research guidance, in the form of guidelines, policies or recommendations, which would be relevant to the development of reporting guidance that is equity focused. We define reporting guidance as systematically developed, evidence-based and consensus-based statements to assist researchers in composing transparent, concise and comprehensive reports of their studies (adapted from Simera and Altman[28] and the WHO[29]).

We will seek literature on two types of guidance: (1) existing reporting guidance for studies with specific populations or contexts, which can inform the development of a general guideline for reporting health equity, that is, the STROBE-Equity extension, and (2) guidance for any stage or aspect of conducting research with or about populations experiencing health inequity, to inform the development of items in the STROBE-Equity extension for reporting the equity-relevant details of the study in a comprehensive, precise and transparent manner. The analysis of equity-related guidance for the *conduct* of research will be important in developing the candidate items for the STROBE-Equity reporting guideline so that the items in the guideline align with the specific recommendations of diverse stakeholders for conducting various stages of the research.

We will consider guidance for any type of research—experimental, observational or qualitative (including anthropological research, which can provide sociocultural insights regarding health equity and help to mitigate ethnocentric attitudes of health providers and researchers).[30] Although the overall objective of this scoping review is to help inform the development of a STROBE-Equity extension for the reporting of observational health studies, we anticipate that there may be equity-related guidance for many types of research which may be relevant and important.

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Context

For this scoping review, we will use a broad conceptualisation of health which is inclusive of guidance in social sciences that relates to health or well-being. We will consider guidance for any country, population or setting, including displaced populations, refugees, humanitarian settings and conflict zones.

Types of evidence sources

We will consider articles from peer-reviewed journals and grey literature (including web page content) (see table 1 for examples). We will peruse websites of relevant organisations to seek out grey literature that is not published in academic journals. The provenance of the guidance included in the scoping review may be from any source such as journals, ethics boards, professional associations, academic research teams, and governmental or non-governmental organisations. Guidance described as opinion/viewpoint pieces or found in letters, editorials and case studies will be excluded.

Search strategy

We will search for both published and unpublished guidance relevant to the reporting of health equity in observational studies. Searches will be designed and conducted by a librarian experienced in scoping reviews (TR) using a method designed to optimise term selection.[31] Indexing terms, text words contained in the titles and abstracts of known relevant guidance (table 1), and citations from these examples were used to develop a full search strategy in MEDLINE using the OVID interface (online supplemental appendix 2). Starting with the set of possible guidelines from table 1, keywords and Medical Subject Headings for those articles will be used to develop a search strategy with the following concepts: (1) health equity (using PROGRESS-Plus characteristics); (2) reporting, analysis and design of research; and (3) guidelines or guidance articles. We will then check the yield of the search to assess the relevance of articles retrieved and refine the search accordingly.

The search strategy, including all identified keywords and index terms, will be adapted for other electronic databases and information sources. The reference list of all included sources of evidence will be screened for additional studies. The search will not have a language restriction. Dates will be restricted to 2005 and later since we are interested in recent guidance and conceptualisations of health equity in research. This time frame also aligns with the establishment of the Commission on Social Determinants of Health by the WHO in 2005.[32] The search will be reported according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses Literature Search Extension guideline (for literature searches).[33]

Electronic bibliographic databases

The following electronic bibliographic databases will be searched:

- Embase via OVID.
- MEDLINE via OVID.
- CINAHL via EbscoHost.
- Cochrane Methodology Register via The Cochrane Library (Wiley) Issue 8, 2021.
- LILACS via BIREME–PAHO–WHO Latin American and Caribbean Centre on Health Sciences Information (http://lilacs.bvsalud.org/en/).

Grey literature search

We expect much of the sought-after guidance to be in grey literature, such as institutional reports, research ethics guidance and journal editorial policies.

A grey literature search using Google and a review of key websites suggested by our steering committee members, such as ethics review boards, and funding organisations (see online supplemental appendix 3) will be conducted. In addition to known websites, the first 20 Google results yielded by each relevant phrase or search string will be reviewed.

We will ensure that this search includes organisations based in low-income, lower-middle, upper-middle and high-income countries (HICs) (low-income and middle-income countries (LMICs) and HICs), using the current classifications from the World Bank.[34] We will search sources (eg, patient advocacy organisations and medical associations) which are related to specific groups of people who face systemic and structural barriers to health across PROGRESS-Plus factors.

Guidance will be eligible for inclusion, which is related to participant inclusion, recruitment, retention and engagement, as well as the design, reporting and analysis of research relevant to populations subject to systemic and structural barriers.

Consultation

We will also ask for suggestions of potential source organisations and guidance from the members of our steering committees: technical oversight, patients/public, knowledge users and Indigenous research, and add these to our list of key grey literature sources (online supplemental appendix 3).

Reference list screening

We will screen references from all included guidance. We will use citationchaser[35] (https://www.eshackathon.org/software/citationchaser.html) to import all references into our Covidence database (https://www.covidence.org) for deduplication against other sources and for screening according to the same inclusion criteria as described previously for this scoping review.

Stopping rule

We will use the principle of theoretical saturation[36] to determine when to stop searching for grey literature. First, we will include all relevant guidance identified in academic literature. Then, for grey literature, we will continue the process by searching sources across domains of PROGRESS-Plus and across different stakeholders as defined by our 7Ps framework.

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Table 1 Examples of relevant guidance from published guidelines, peer-reviewed journals and grey literature

Guidance	Organisation	Type of organisation	PROGRESS dimensions	Dimensions of reporting
Sex and gender equity in research[3]	European Association of Science Editors	Journal editors	Sex and gender	Rationale, methods, results and discussion
NIH policy on sex as a biological variable[41]	NIH	Funder	Sex	Methods and results
Reporting of race and ethnicity in medical and science journals[42]	*Journal of the American Medical Association*	Journal	Ethnicity and race	Abstract, results and methods
Ethical guidance for research with people with disabilities[43]	National Disability Authority	Government	Disability	Methods (recruitment and engagement) and discussion
CONSolIDated critERtia for strengthening reporting of health research involving Indigenous peoples: the CONSIDER statement[44]	Research team	Multidisciplinary	Indigenous people	All
Consolidated Standards of Reporting Trials-Equity[16]	Research team	Multidisciplinary	All PROGRESS-Plus	All
Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Equity[15]	Research team	Multidisciplinary	All PROGRESS-Plus	All
Guide to reporting studies in RRH[45]	RRH	Journal	Place of residence	All
How to integrate sex and gender into research[46]	Canadian institutes of health research (CIHR)	Funder	Sex and gender	Rationale, methods, results and discussion
Tricouncil policy statement: ethical conduct for research involving humans–TCPS 2 (2018)[47]	Canadian institutes of health research (CIHR)	Funder	Indigenous peoples in Canada, Age, Disability	Informed consent
AIATSIS code of ethics for Aboriginal and Torres Strait Islander research[48]	AIATSIS	Government statutory authority	Indigenous peoples in Australia	Methods, informed consent and reporting
Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research[49]	National health and medical research council (NHMRC)	Funder	Indigenous people	Rationale, methods, results, discussion
AH&MRC Ethical guidelines: key principles (2020) V.2.0[50]	Aboriginal health and medical research council of NSW (AH&MRC)	Advocacy association	Indigenous people	Methods, informed consent, reporting
Te Ara tika: guidelines for māori research ethics: a framework for researchers and ethics committee members[51]	Health research council of New Zealand	Funder	Indigenous peoples of Aotearoa, New Zealand	Rationale, methods, discussion

AIATSIS, Australian Institute for Aboriginal and Torres Strait Islander Studies; NIH, National Institutes of Health; RRH, rural and remote health.

After including all relevant guidance identified in academic literature, we will conduct the grey literature search concurrently with the data extraction, checking if the inclusion of additional articles contributes any new evidence, which will indicate whether to continue or stop the search.[37] We will conduct this process with an initial set of 20 articles and subsequent sets of 10 articles to cover a wide array of guidance sources (eg, ethics boards,

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journals and governments) and contexts (eg, LMICs and HICs). Once a set of 10 additional articles no longer contributes new evidence, the search for grey literature will be stopped.

Source of evidence selection

Initial screening

Titles and abstracts of articles retrieved from the electronic bibliographic database search will be screened for potential eligibility using Covidence, each reference by two reviewers independently. In cases of disagreement between two reviewers, a third reviewer will make the decision regarding eligibility. The screening criteria will be tested on a training set of 50 references until the team reaches greater than 75% agreement on inclusion or exclusion.

Full-text screening

We will conduct full-text screening for eligibility using Covidence and the same eligibility criteria, with two reviewers independently screening each reference and providing reasons for excluding references. Conflicts regarding inclusion and exclusion and reasons for the latter will be resolved by discussion between the two reviewers, and a third reviewer will be asked for a final decision in cases where agreement is not reached between the two reviewers.

Data extraction and quality assessment

Data will be extracted by pairs of independent reviewers using a pretested data charting form. The form will be pilot tested on 10 articles, selected to represent various guidance sources (eg, ethics boards and journals) and contexts (eg, LMICs and HICs), to identify if the questions in the charting form needed to be modified or if other questions or categories need to be added to capture all relevant information from the articles.

The charting form will be designed to collect information on the source, type of organisation and methods of development. We will collect details on whether or not the guidance supports the draft STROBE-Equity extension items. If the reviewed guidance suggests additional items, this will be captured as free text with verbatim quotes from the source document.

We will collect details about specific populations which experience health inequity using free-text boxes. This may contribute to expanding on PROGRESS-Plus as a framework.

Since this will be a scoping review of articles on research guidance, we will not conduct methodological quality (ie, risk of bias) assessments as per the JBI manual. To assess the credibility of the guidance, we will collect details on the provenance of the guidance and its development process (eg, expert opinion and consensus).

Analysis and presentation of the evidence

We will use the principle of framework synthesis to analyse the data. This approach involves the mapping of concepts/data to an a priori framework,[38] which in this scoping review is a preliminary STROBE-Equity checklist of candidate items (online supplemental appendix 1). If we find extracted data that do not match the items (or categories) in the checklist, we will conduct an inductive thematic analysis to develop new items and/or categories as needed based on the data.[39] As such, the a priori framework will serve as a basic model which can be expanded or reduced by adding, modifying and/or removing items.[38]

We will analyse the extracted data by looking for common items across diverse populations and inequities, as well as items that relate to specific contexts or vulnerabilities. As well, we will analyse any differences in guidance across our preliminary set of candidate items (eg, identifying different or additional considerations for 'study design'). We will also analyse guidance specifically for Indigenous research, as well as for research in conflict and fragile settings, which face increased risks of inequity and where research reporting could miss out key populations more easily than in non-conflict settings. Indigenous research will be an important focus of this scoping review, to align with the objectives of the overall STROBE-Equity project, which involves a parallel stream, led by Indigenous coinvestigators, to assess the relevance of the developed guidance for Indigenous research.

After the analysis is completed, we will hold a meeting with the lead author and the four principal investigators to develop new and/or refine existing candidate items based on the data synthesis. Any candidate items relating to research involving Indigenous communities will be developed by Indigenous coinvestigators and the Indigenous research steering committee (composed of five Indigenous researchers from Canada, Australia and Aotearoa, New Zealand).

We recognise that the STROBE framework may not be compatible with reporting guidance for Indigenous research. If the analysis of the data confirms this, which will be determined in consultation with the Indigenous researchers on the team, then the scoping review will be conducted in parallel with Indigenous and 'global' streams, which will be presented as two reports.

The results of the scoping review will be presented as a map of the extracted data in tabular form based on the a priori framework. The table will summarise what, if any, extracted data contributed to modifications of the proposed STROBE-Equity checklist.

If the scoping review is conducted in parallel streams, the results for guidance on research involving Indigenous people will be presented according to categories (or domains) that emerge during the inductive thematic analysis of the data, as described previously.

Potential impact of this scoping review

We will report our scoping review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews guideline.[40]

This scoping review will synthesise and chart available research guidance across dimensions of health equity, and the results will be used to inform the development of

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an equity extension to the STROBE reporting guideline. This scoping review may also be helpful to organisations and individuals who are seeking research guidance that includes health equity considerations.

Potential limitations

We acknowledge that one limitation of our approach is that we will not be able to review all available guidance (eg, every ethics board, governmental or NGO guidance document) that may be relevant to the reporting of health equity in observational studies. To address this, we have developed a structured approach for our grey literature search that will seek a balance between sources originating in HICs as well as LMICs (eg, HIC funding agencies and LMIC funding agencies) as well as across all PROGRESS-Plus characteristics. This strategy will help to avert overemphasising any one element of PROGRESS-Plus or focusing only on guidance from some countries or settings. Another possible limitation is the diversity of definitions we expect to find regarding health equity and equity-seeking populations. To synthesise these diverse definitions, we will categorise definitions according to the PROGRESS-Plus framework and will revise, if needed, to encompass definitions which do not fit the PROGRESS-Plus framework. This may help to strengthen/enhance the current understanding of health equity and equity-seeking populations to move forward with more accurate and comprehensive concepts. A third possible limitation is that we expect to find considerable heterogeneity among the included literature (ie, from various types of organisations and institutions, and presented in various formats and levels of detail) which may pose a challenge for consistent and comprehensive data extraction. A fourth possible limitation is that we will only include articles in English and those that we can obtain English translations of, so we may miss some issues or concepts about health equity from certain settings. Lastly, a fifth possible limitation is that the experience of health inequity may depend on the interaction of social identities with contextual factors and systems which may not fit in the PROGRESS-Plus framework. To mitigate this, we will explore modifying the framework or defining systems issues separately.

ETHICS AND DISSEMINATION

This scoping review does not require ethics approval since there are no human participants. We will follow a principled approach to codeveloping this research with our knowledge users, patients/public and Indigenous steering committees.[20] This approach follows principles of ethical partnerships, co-ownership of data, collaborative interpretation of results, participatory research, cultural safety and inclusion, and protection of cultural knowledge in research. The results will be published in open-access peer-reviewed journals and will also be disseminated through conference presentations. The international members of our team who are fluent in languages other than English will be encouraged to submit abstracts and presentations for conferences held in other languages. We will also publish a summary on our STROBE-Equity Open Science Framework project page and on our Cochrane Equity website (https://methods.cochrane.org/equity/welcome).

Author affiliations
[1]School of Psychology, University of Ottawa Faculty of Social Sciences, Ottawa, Ontario, Canada
[2]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada
[3]Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa
[4]School of Epidemiology and Public Health, University of Ottawa, Ottawa, Ontario, Canada
[5]Clinical Epidemiology, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
[6]Department of Internal Medicine, American University of Beirut, Beirut, Lebanon
[7]CT Lamont Primary Care Research Centre, Bruyère Research Institute, Ottawa, Ontario, Canada
[8]Interdisciplinary School of Health Sciences University of Ottawa, Ottawa, Ontario, Canada
[9]Knowledge Translation Program, Li Ka Shing Knowledge Institute, St Michael's Hospital, Unity Health Toronto, Toronto, Ontario, Canada
[10]Bruyère Research Institute, Ottawa, Ontario, Canada
[11]School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada
[12]Freelance health research librarian, (no affiliation), Ottawa, Ontario, Canada
[13]Centre for Global Child Health, SickKids Center for Global Child Health, Toronto, Ontario, Canada
[14]Institute for Global Health & Development, The Aga Khan University, Karachi, Sindh, Pakistan
[15]Centre for Health Equity, School of Population and Global Health, University of Melbourne, Melbourne, Victoria, Australia
[16]Judith Lumley Centre, School of Nursing and Midwifery, La Trobe University, Melbourne, Victoria, Australia
[17]Ngangk Yira Research Centre for Aboriginal Health and Social Equity, Murdoch University, Perth, Western Australia, Australia
[18]Department of Psychology, Department of Law, Carleton University, Ottawa, Ontario, Canada
[19]Healthcare Research Associates, LLC/Strategically Targeting Appropriate Researchers (S.T.A.R.) Initiative, Apple Valley, California, USA
[20]Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada
[21]Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand
[22]College of Health Medicine and Wellbeing, The University of Newcastle, Newcastle, New South Wales, Australia
[23]Cochrane South Africa, South African Medical Research Council, Cape Town, South Africa
[24]Department of Neurology, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA
[25]Epidemiology and Biostatistics, Kilimanjaro Christian Medical University College, Moshi, United Republic of Tanzania
[26]Effective Basic Services (eBASE) Africa, Bamenda, Cameroon
[27]London School of Hygiene & Tropical Medicine, London, UK
[28]School of Optometry and Vision Science, The University of Auckland, Auckland, Auckland, New Zealand
[29]Hassanah Consulting, Seattle, Washington, USA
[30]University of Ottawa Department of Medicine, Ottawa, Ontario, Canada
[31]Michael G. DeGroote Institute for Pain Research and Care, McMaster University, Hamilton, Ontario, Canada

Twitter Taryn Young @TarynYoung3, Larissa Shamseer @larissashamseer, Tamara Kredo @tamarakredo and Charles Shey Wiysonge @CharlesShey

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ORCID iDs
Anita Rizvi http://orcid.org/0000-0002-3826-1439
Daeria O Lawson http://orcid.org/0000-0002-6487-3367
Omar Dewidar http://orcid.org/0000-0001-6420-887X
Elie A Akl http://orcid.org/0000-0002-3444-8618
Julian Little http://orcid.org/0000-0001-5026-5531
Olivia Magwood http://orcid.org/0000-0003-0262-5621
Larissa Shamseer http://orcid.org/0000-0003-3690-3378
Zulfiqar Bhutta http://orcid.org/0000-0003-0637-599X
Michelle Kennedy http://orcid.org/0000-0001-9691-068X
Tamara Kredo http://orcid.org/0000-0001-7115-9535
Michael Johnson J Mahande http://orcid.org/0000-0002-7750-7657
Lawrence Mbuagbaw http://orcid.org/0000-0001-5855-5461
Jacqueline Ramke http://orcid.org/0000-0002-5764-1306
Charles Shey Wiysonge http://orcid.org/0000-0002-1273-4779
Vivian A Welch http://orcid.org/0000-0002-5238-7097

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