

VOICE - Variables of Inequities in Clinical Evidence: a practical tool to apply an equity lens in real-world evidence health research

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Background

Health inequalities have long been associated with socioeconomic inequities and the societal phenomena perpetuating these, such as racism, misogyny, intolerance towards different creeds or sexual orientations and generational reproduction of unequal access to educational and labour opportunities^{1, 2, 3, 4, 5, 6, 7}. These social inequities go beyond the private prejudices enforced by individuals on their fellow human beings, rather, they are structurally determined and affect historically marginalized groups systematically across several dimensions of their lives, including health^{6, 8, 9}. As such, within the health sector, policy- and decision-making processes and outcomes tend to reflect these structures of domination when they are unquestioned, perpetuating a societal hierarchy that systematically benefits one group to the detriment of other groups¹⁰. Therefore, it is a fundamental responsibility of researchers from the field of health, striving to influence policy- and decision-making based on scientific evidence, to acknowledge the associations and causal relations of structural socioeconomic determinants of health and human experiences, and reflect this acknowledgment in their study designs. Specifically, this work proposes that, within the OHDSI research network, whose work relies on existing, secondary data to uncover real-world evidence related to the health of the population, a socioeconomic lens should be systematically applied to all research endeavours. In real-world clinical research, seemingly homogeneous data may mask structurally important differences across populations, making the inclusion of health equity variables essential when synthesizing evidence across independent studies, countries, and meta-analytic settings. Descriptive characterizations of ailments through a socioeconomic lens would facilitate more targeted approaches to improving the health of the population. Likewise, applying this perspective to hypothesis-validating analyses, by including confounding or mediating socioeconomic variables, would deliver a more refined understanding of the relations observed between exposures and outcomes of interest. To address health inequities, this work proposes a practical tool for applying an equity lens to any health study, including beyond the scope of the OHDSI network.

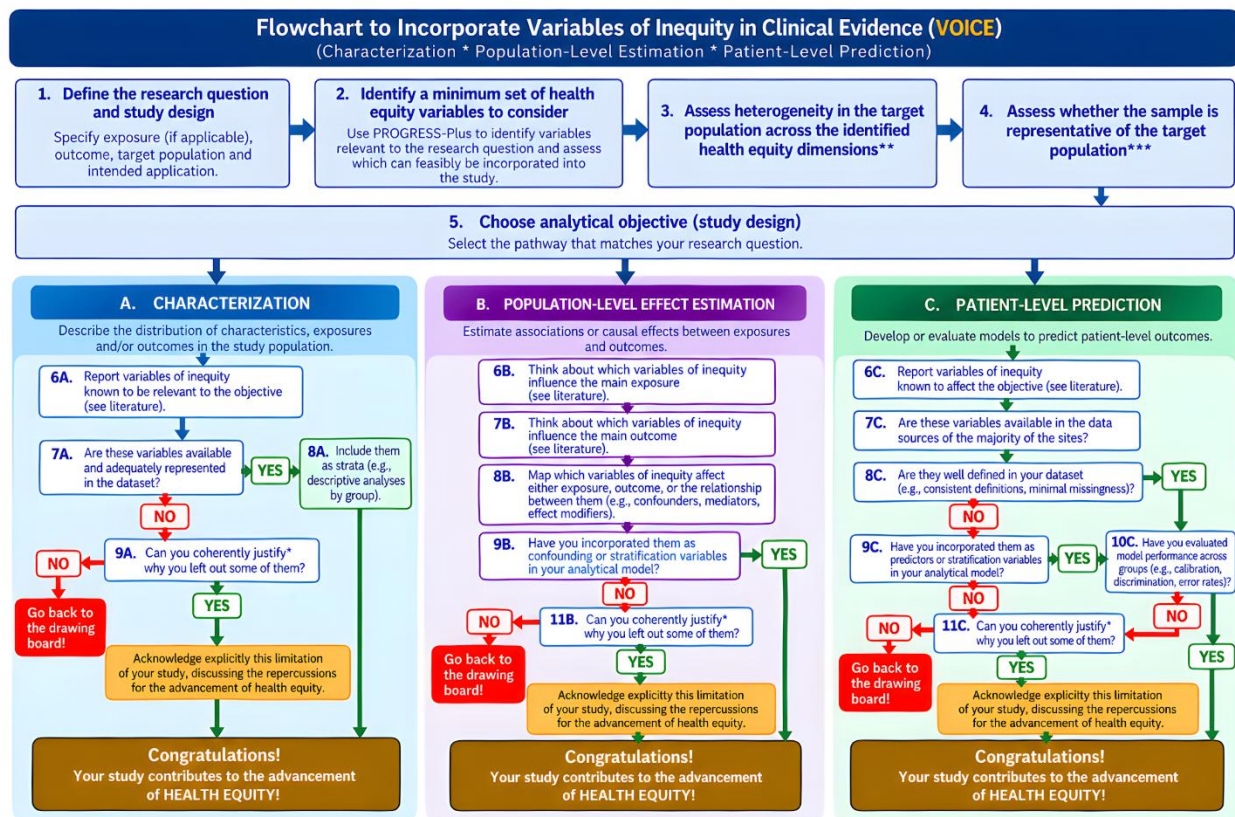
Methods

To address structural socioeconomic determinants in health research, this proposal introduces a practical flow sheet designed to help health researchers acknowledge and account for structural socioeconomic determinants across different types of studies. The flowchart is organized in three parts, corresponding to different types of study designs: Characterization, Population-Level Effect Estimation, Patient-Level Prediction. Each tool part guides researchers through a straightforward assessment of the potential for including an equity lens in their research. The earlier steps of the flowchart are designed as instructions - tasks for the researchers to complete -, whilst later parts ask Yes/No questions related to considerations of socioeconomic inequities and how these manifest in the sample, exposure, outcome and covariables of the study. The chart was designed by four researchers from the field of health, operating in different institutions (three universities, a public health research foundation, and a private consulting company), from two large, continental-scale countries: the United States and Brazil. Discussions for the elaboration of said flowchart were based on scientific literature and the researchers' knowledge of existing data that could inform the content of the tool, and experiences promoting a health equity lens in research studies.

Results

As shown in Figure 1, all three parts of the tool begin with Steps 1-4 that focus on the population of reference of the study, as well as the sample that will be used to run the analyses. This first part encourages the researchers to reflect on the socioeconomic profile of the target population and how this compares to the profile of the sample that is meant to represent that population. This is a routine process in any study that works with a sample population. Nonetheless, this tool underlines that socioeconomic variables are fundamental for this comparison, when health equity is a guiding principle of the research project. The next steps vary according to the study design. For Characterization studies (Column A), the tool requires a literature-based reflection on the characterization objective (disease, treatment patterns, or health outcomes) and how this is affected by socioeconomic factors.

Figure 1. VOICE Flowchart



For Population-Level Effect Estimation studies (Column B), the next few steps guide the researchers through a reasoning on the socioeconomic factors associated with exposure, outcome, or their relationship, and how these should be integrated into the analytical model (as confounders or stratifying variables). This step is crucial in guaranteeing that covariates are employed according to theory-based understandings of their involvement with the exposure and outcome variables. Finally, the Patient-Level Prediction tool (Column C) focuses on the search for all relevant data related to the object of the study, reminding researchers to explore all available data sources.

Depending on the route the answers take the researchers, the outcome would fall into one of the following results:

Figure 2. Basic selection of socioeconomic variables to consider

1. Congratulations! Your study contributes to the advancement of HEALTH EQUITY!
 - a. This answer validates efforts on behalf of the people who conceived the study to incorporate the health equity lens, thus contributing to the uncovering of more informative knowledge on the health of the population and its associated factors;
2. Acknowledge explicitly this limitation of your study, discussing the repercussions for the advancement of health equity.
 - a. This result is a measure proposed to aid those who realistically were not able to apply fully or in part an equity lens, proposing to at least be very transparent with peer readers regarding this defect;
3. Go back to the drawing board!
 - a. Reaching this outcome means that adequate efforts were not made, on behalf of the researchers, to prioritize the incorporation of an equity lens in their study.

Understanding that not all study sites will have the same variety of socioeconomic markers available for mapping, Figure 2 complements the tool by providing a range of possible socioeconomic variables to be considered, inspired by the PROGRESS-Plus dimensions – specifying that this is not exhaustive, and inviting researchers to use their cognitive creativity to identify additional measures of

health inequalities. The list includes: age, common but fundamental variable, especially when it comes to the generation of knowledge to influence policy-making; Race/ethnicity/ancestry as a socio-economic construct; gender, in its ample, most inclusive meaning; income or material deprivation; education level; religious affiliation; geographical location (urban/rural, access to services; socioeconomic segregation, climate factors). Where such data may lack, the expectation is that using the tool will shed a light on these information gaps and promote the future collection of such fundamental information to understand the human condition.

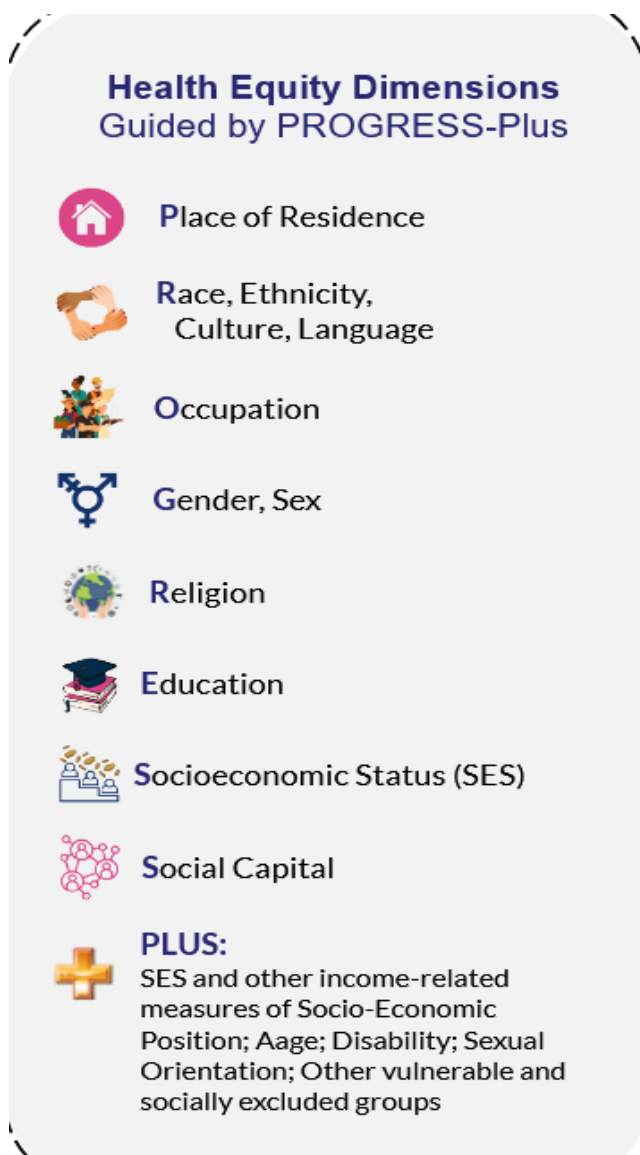


Table 1. VOICE in comparison with other health equity frameworks

Framework	VOICE (2026)	SDOH in OMOP (2021)	PROGRESS Plus (2002)	STROBE RECORD Equity Extensions (2007)
Primary Purpose	Decision support flowchart guiding researchers through whether and how to incorporate equity variables at each stage of study design	Standardizes representation of social determinants of health data (e.g., via SDOH domain tables, standard concepts, Z-codes) within the OMOP Common Data Model	Checklist of justified equity relevant stratifiers (Place of residence, Race/ethnicity, Occupation, Gender, Religion, Education, Socioeconomic status, Social capital, Plus: age, disability, sexual orientation)	Reporting guidelines to ensure equity-relevant variables and health inequality dimensions are transparently described in observational studies
Format	Interactive flowchart with branching Yes/No logic and outcome statements	Data model terminology standard	Static taxonomy checklist	Reporting checklist
Stage of Research Applied	Study design and planning stage (prospective, before/during analysis)	Data curation/ETL stage (before analysis)	Primarily used at analysis and reporting stage to decide which subgroups to examine	Reporting or publication stage (retrospective, post-analysis)
OMOP/OHDSI Specificity	Purpose-built for OHDSI/OMOP-CDM-based studies, but not limited to OMOP	OMOP-native, but focused on data structure, not analytic decision making	Not specific to OMOP; general purpose equity variable list	RECORD is tailored to routinely collected data, but not OMOP-CDM specific

Conclusion

The infrastructure to include contextual socioeconomic variables has already been developed in the Community and is being tested by OHDSI researchers: the OMOP GIS Vocabulary Package. The purposes of this extension are, among other things, to facilitate the linkage of environmental exposures to persons, standardize representation of these exposure types, intensities, and measurement units, as well as support multi-domain exposures. Its foundational structure is represented by the *external_exposure* table, which enables the integration of sociodemographic, and other geo-spatially linked data into observational health research workflows.

The extension table described above represents a technical tool to facilitate the inclusion of health equity as a necessary dimension of any health study, and complements the conceptual tool presented in this abstract with the same purpose. Subsequently, it is a promising moment to prioritize the promotion of health equity across all health research.

Based on the widespread verbal recognition of the importance of addressing health inequities amongst the research fora that this work has been developed for, it is hoped that, after appreciation and suggestions of eventual improvements in the content of the tool, the OHDSI community will adopt it as a systematic step in the development of studies applying the OMOP Common Data Model.

We also expect constructive criticism from the OHDSI Global Community to continue improving this tool as an approach to promote an equity lens in health research.

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