An assessment for representation of people from ethnic and racial minorities in PGx clinical trials: a systematic literature review

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Background

- Precision medicine, based on genetic information, is an emerging field of research and practice with potential to improve therapy for patients with a range of diagnosis.
- Ethnic and racial minorities have been underrepresented in the majority of clinical trials in pharmacogenomics (PGx).
- Haga et al. (2014) reported that FDA approved clinical trials for genomic drugs significantly lacked representation from African American and Hispanic populations. This disparity was reinforced in a study conducted by Nagar et al. (2020).
- Kenny et al. (2019) found that Asians and Hispanics were also underrepresented in PGx studies.

Methods

Data sources & searches

PubMed was the primary database that we searched.

- **"Pharmacogen* AND (PRO OR patient reported outcome OR patient-reported outcome OR quality of life OR QoL)" Filters: Clinical Trial, Randomized Controlled Trial.**
- All results were assigned to the USC Mann class 2025 PharmD students during the case conference series
- Data including age, gender, race, patient reported outcome (PRO) category, and disease state were collected
- After the preliminary data was curated, data were validated
- Articles excluded if not a PGx study or PRO not reported.
- The full search strategy is detailed in **Figure 1**

Results

- A total of 80 research articles were initially identified through PubMed database searches
- After reviewing for inclusion and exclusion criteria, 38 articles were identified for analysis
- Gender distribution is relatively balanced
- White individuals composed the largest portion of race included, n=15,234 (86.8%)
- Black individuals composed 6.5% (n=1,138) of the sample
- Asian individuals composed 4.8% (n=842) of the sample
- Hispanic individuals composed 1.9% (n=328) of the sample
- Disease states represented include pain, oncology, psychiatry, infectious diseases, and other chronic diseases
- PROs predominantly focus on Quality of Life (QoL) with general QoL measures (22%), mental health (12%), and pain (9%) most commonly reported
- 46% of PROs were unable to categorize
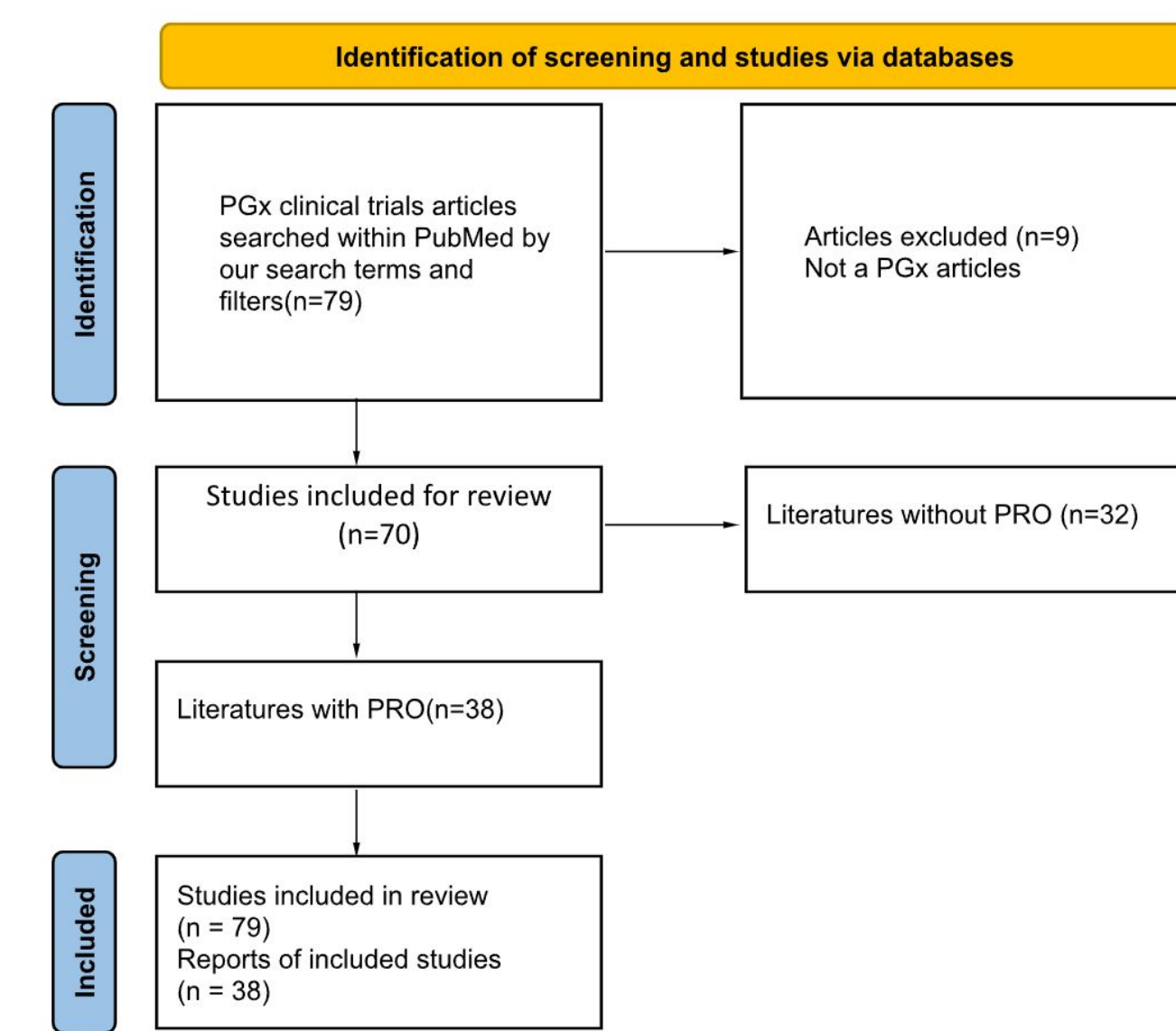- Socioeconomic status was not reported in any studies

Results

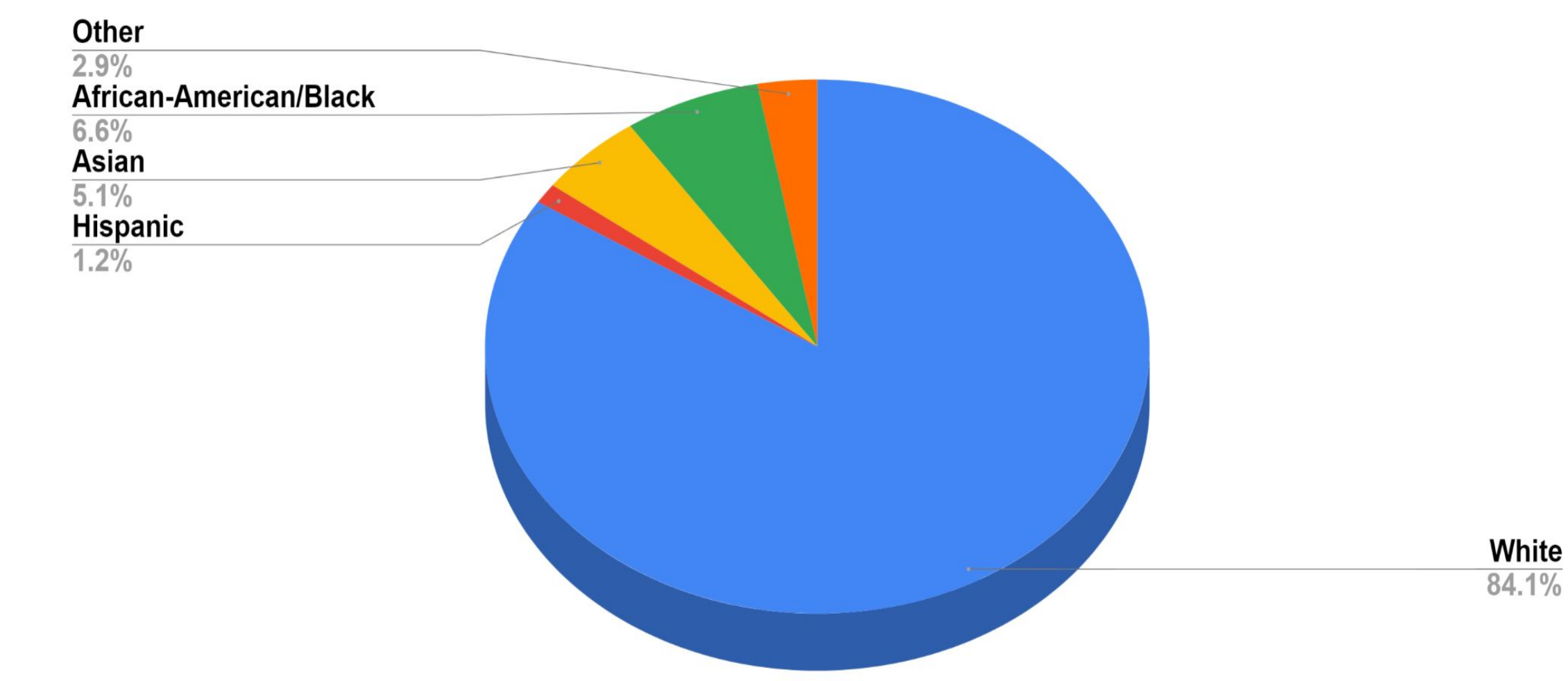Figure1. Flow chart of included and excluded publications

Figure 2. Race Distribution among total 70 articles
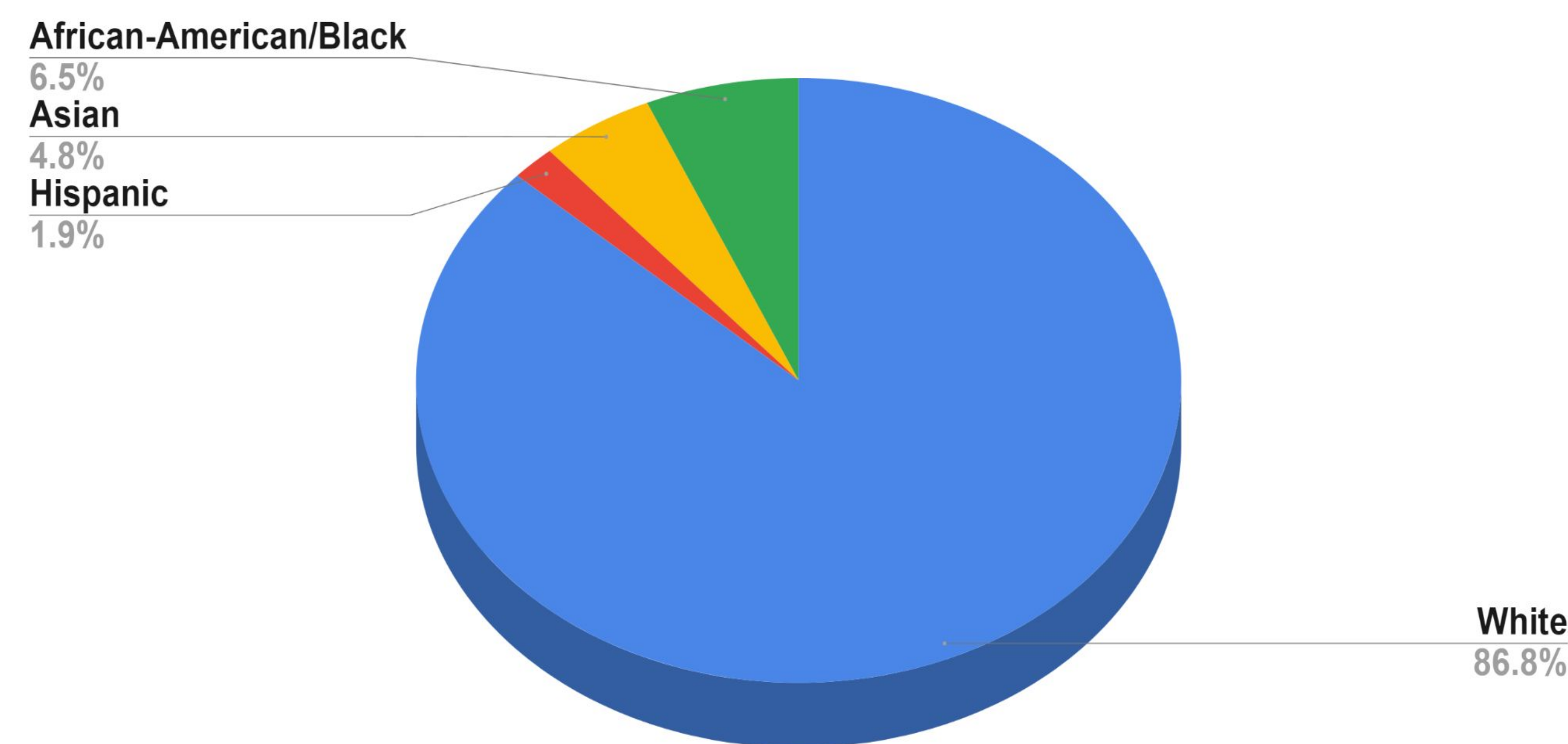
Race Distribution

Figure 3. Race Distribution among 38 articles with PROs

Types of Patient-Reported Outcomes and Disease category Distribution
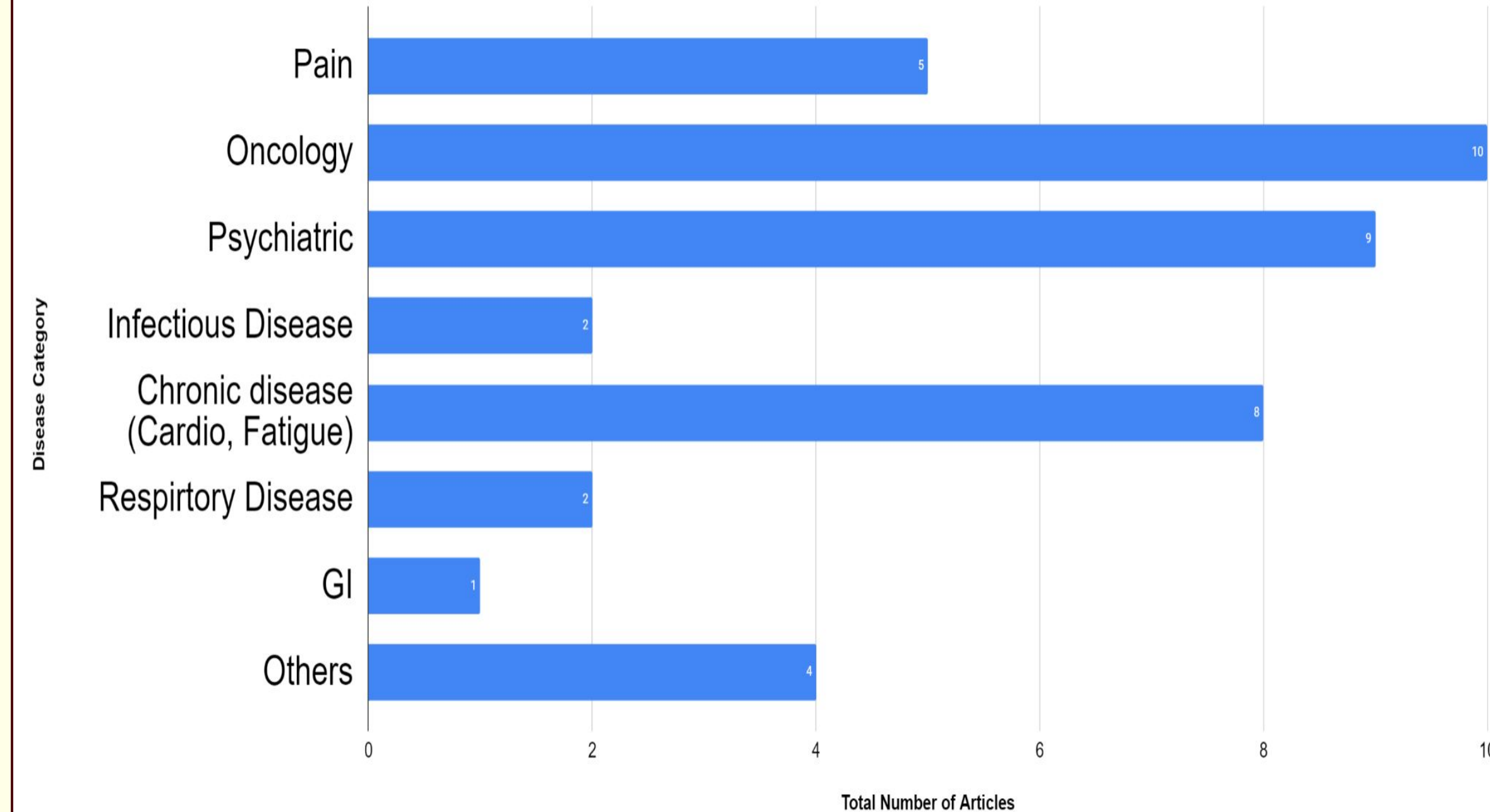

Figure 4. Disease Category and number distribution

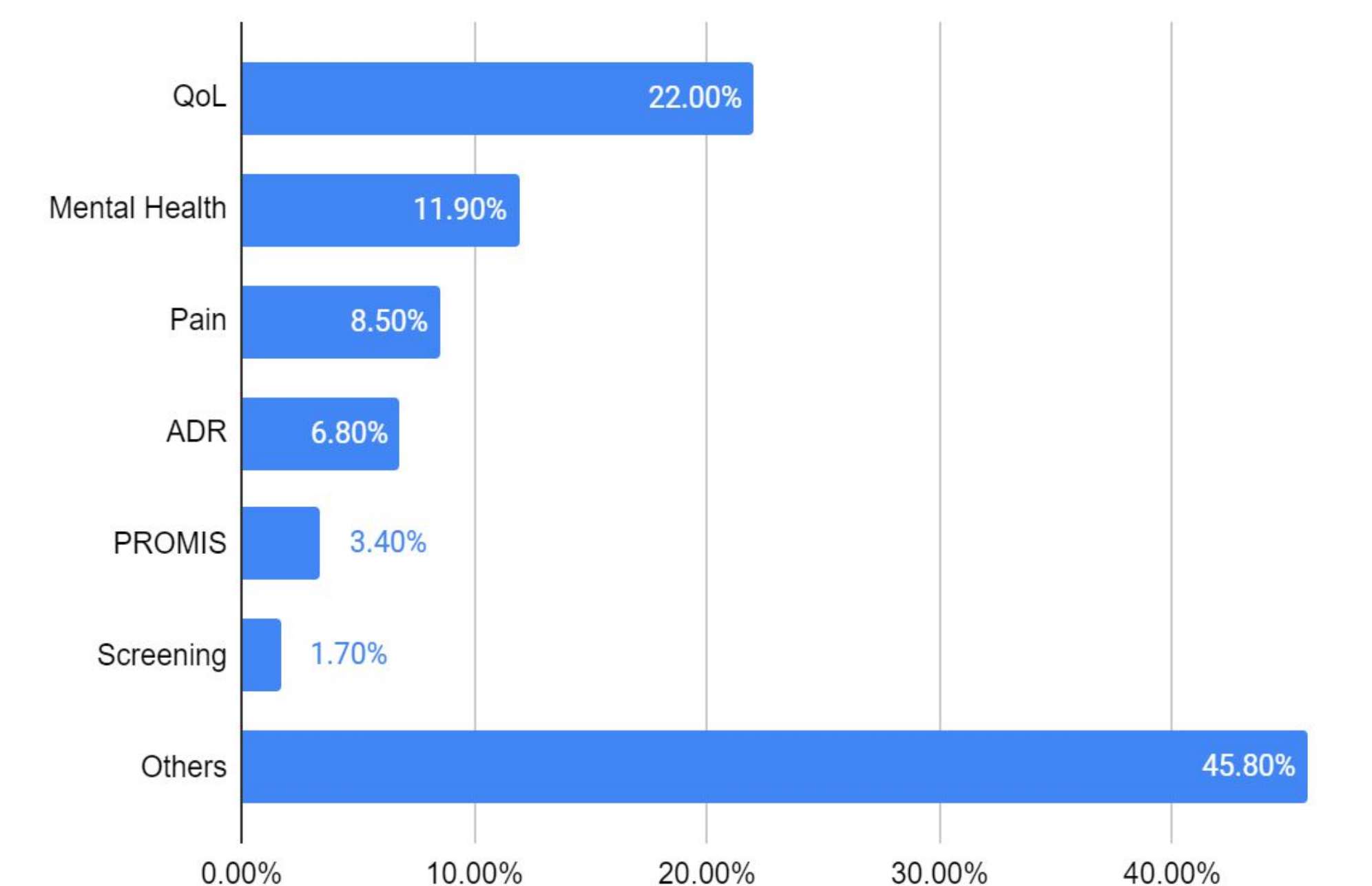*"Others" measures include Various disease and DDIs; Psoriasis; Hydrocodone VS CYP DDIs; PE)

Figure 5. Types of patient-reported outcomes

*Others include unspecified or unclear PRO measures

Discussion

- Races, other than White, are underrepresented in PGx studies which use PROs as a QoL metric
- Socioeconomic status was not reported in studies we identified, so unable to identify if lower socioeconomic status is underrepresented in our sample
- Nearly half of PROs published are not well defined, making interpretation and application difficult
- PROs vary significantly based on disease states

Limitations:

- This review only includes PGx clinical trials available on PubMed before August 2023, and published in English.
- This review only focuses on those studies that included QoL results or PROs as a keyword for indexing.
- One of our assumptions is that patients with higher socioeconomic status are likely overrepresented in studies utilizing PROs, although socioeconomic status was not routinely reported with results

Future Directions

- Future research should include more diverse populations, focusing on people with race and ethnicity currently underrepresented.
- Future studies should clearly collect, curate, and index the frequency and types of PROs included
- Future research should include socioeconomic status as a baseline characteristic to ensure those people from lower socioeconomic status are included and may benefit from advances in precision medicine.

Conclusion

- Our research shows that the current PGx trials mainly included white population (84%), in general, and 86.8% in PRO-containing trials
- All other populations are underrepresented both in general PGx trials and PRO-containing trials.
- Oncology, Neuropsychiatric, Pain, and Chronic Diseases are the most prominent populations in current PGx studies.
- Current PRO's in PGx trials are mainly composed of QoL (22%) and mental health (11.9%) with a significant portion of the outcome measures with unstandardized PRO's.

Reference

-Please see appendix for reference of all the articles reviewed in our study.