Using PRO EDI in a systematic review

25/4/2024

How to use this example

The PRO EDI participant characteristics table (see https://www.trialforge.org/trial-diversity/pro-edi-improving-how-equity-diversity-and-inclusion-is-handled-in-evidence-synthesis/) provides a structure for describing included study populations that supports equity-related judgements when interpreting review results. The PRO EDI participant characteristics table structure can be used to describe who *should* be represented in the evidence given the disease or illness, and to present who is *actually* represented in the evidence.

The following example shows how the PRO EDI participants table structure and extracted data can be used in a review's Results and Discussion sections. There are other areas where equity-related information could be provided (e.g. who was involved in the choice of treatment outcomes for the review, or what is planned for the analysis) but PRO EDI focuses on describing the participants included in a review, and then using this information to interpret the results. Guidance on providing equity-related information elsewhere in a review can be found in, for example, the Cochrane handbook Equity chapter (https://training.cochrane.org/handbook/current/chapter-16)

The example is based on data provided in this systematic review:

Clemson L, Stark S, Pighills AC, Fairhall NJ, Lamb SE, Ali J, Sherrington C. Environmental interventions for preventing falls in older people living in the community. Cochrane Database of Systematic Reviews 2023, Issue 3. Art. No.: CD013258. DOI: 10.1002/14651858.CD013258.pub2. Accessed 08 February 2024. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013258.pub2/full

V1 25/4/2024 Prepared by Shaun Treweek (University of Aberdeen, UK) on behalf of the PRO EDI team.

Results

Overall characteristics of participants

[**Guidance note**: the table on the next page is created by aggregating PRO EDI information extracted for each included study. Reviewers will find that there is little standardisation in how these characteristics are described in included studies. For some (e.g., ethnicity, socioeconomic status) standardisation is anyway unrealistic as the information is so context specific. The summary table therefore represents the overall assessment by the review team as to what a body of evidence is able to say about each PRO EDI characteristic. Numbers are helpful, but reviewers should not get too bogged down in trying to calculate percentages and averages. In many cases this will not be possible, or meaningful. Rather the intention is to give review users a feel for whether a body of evidence has enough diversity across participant characteristics for the evidence to be equally applicable to all those who may benefit from the treatment, therapy, initiative, or program addressed by the review.

Note too that we have included all characteristics listed in the PRO EDI participant characteristics table, including those our group judged to be non-mandatory and dependent on the review. Reviewers may choose to list just the mandatory items and any others they feel are needed for their review, or just to list all characteristics but make clear that some were not extracted.]

Example Table 1: Summary of the characteristics of participants we would expect to see in the evidence and the actual participant characteristics extracted from the included studies.

PRO EDI participant characteristics		
Characteristic	**The people we would expect to see**	**The people who took part**
Age	A third of people over 65 fall each year, with the risk of fall-related injuries increasing with age. We would expect participants who are older; average age expected to be over 65.	All included studies involved people who were older, with mean ages generally over 70 and often 80.
Sex	All sexes.	Where sex was reported, the majority of participants were female, always over 50% and frequently over 70%.
Gender	Affects all genders. Women have a high risk of indoor falls, men more likely to fall in presence of outdoor environmental hazards.	Where gender was reported, the majority of participants were women, almost always over 50% and frequently over 70%.
Sexual identify	Other characteristics were prioritised for this review.	No extraction.
Ethnicity	Links have been made to ethnicity and falls, largely mediated through socioeconomic status and poorer housing. We would expect participants with a mix of ethnicity reflective of where the study was done.	The included studies say little or nothing about the ethnicity of participants.
Socioeconomic status	Links have been made between lower socioeconomic status and falls linked to poorer housing. People experiencing socioeconomic disadvantage should be included.	A small number of studies did involve people experiencing socioeconomic disadvantage. Most included studies say little or nothing about the socioeconomic status of participants.

Level of education	Other characteristics were prioritised for this review.	No extraction.
Disability	Other characteristics were prioritised for this review.	No extraction.
Location	Falls are a problem seen across the world. We would expect to find studies from around the world in a mix of urban and rural environments.	Almost all studies were done in high income countries, with Australia (7), USA (4), New Zealand (2), France (2) and the UK (2) accounting for 17 of the 22 studies. The included studies therefore say little or nothing about falls interventions in low and middle-income countries. Whether studies involved urban and rural environments was rarely reported. When a study did provide information about local locations, these were generally urban.
Other	No other characteristics were considered.	No extraction.

Synthesis of results

[**Guidance note**: the following two tables are for two interventions assessed in the falls review mentioned on page 1 (https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013258.pub2/full). The example uses a table, but the same information could be done in text. Regardless of tables or text, the approach used could be replicated for all interventions within a review.

The extracted data in the PRO EDI participant characteristics tables may lead reviewers to consider adjusting the GRADE assessment for particular populations, or to be more specific about the populations to which their single GRADE assessment applies. We have taken the latter approach here, leaving review users to make their own judgements about certainty of the evidence for other populations. The PRO EDI team aims to start work with the GRADE Working Group during 2024 to make more formal recommendations about how to incorporate equity, diversity and inclusion considerations raised by PRO EDI into GRADE assessments.]

Intervention example 1: Home fall-hazard reduction interventions versus control

[from https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013258.pub2/full].

Table 1: Synthesis of results using GRADE assessment for home fall-hazard reduction interventions versus control

Narrative statement	
Home fall-hazard reduction interventions may reduce the rate of falls	
Treatment effect size	**GRADE assessment**
RaR = 0.74 (95% CI = 0.61 to 0.91)	Low (-1 level: study limitations- six of 12 studies high RoB and four uncertain RoB; -1 level: inconsistency)
Populations to whom the GRADE assessment applies	Older people (especially women) in urban and high-income settings. The certainty of the evidence is likely to be lower for other populations.
From 12 studies (Campbell 2005; Chu 2017; Cockayne 2021a; Cumming 1999; Day 2002; Lannin 2007; Lin 2007; Lockwood 2019; Nikolaus 2003; Pighills 2011; Stark 2021; Stevens 2001).	

Intervention example 2: Vision improvement technology interventions versus control

[from https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013258.pub2/full].

Table 1: Synthesis of results using GRADE assessment for vision improvement technology interventions versus control

Narrative statement	
Vision improvement technology interventions may make little or no difference to the rate of falls but the evidence is very uncertain	
Treatment effect size	**GRADE assessment**
RaR = 1.12 (95% CI = 0.84 to 1.50)	Very low (-1 level: study limitations- three of three studies high RoB; -1 level: inconsistency; -1 level: imprecision)
Populations to whom the GRADE assessment applies	Older people (especially women) in urban and high-income settings. The certainty of the evidence is likely to be lower for other populations.
From 3 studies (Cumming 1999; Day 2002; Haran 2010).	

Discussion

Equity-related implications for applicability

[**Guidance note**: this text is most likely to be a narrative assessment by the review team of the applicability implications of the diversity of participants included in a body of evidence. The aim is to give review users a sense of to whom the evidence applies with greatest certainty, and for whom the certainty is much less. Applicability judgements will need to consider at least two things. Firstly, whether individuals with particular characteristics are represented in the evidence; extrapolating to people not included, or not clearly included, introduces uncertainty. Secondly, review teams will need to consider whether there are grounds to believe that people with a particular characteristic and who are largely missing from the evidence could have experienced different outcomes from those included. If the answer to this question is yes, then applicability is more uncertain. In the example given below, we judged that the paucity of evidence from low-income countries did affect applicability, but that lack of information about trans identity did not because we did not think having a trans identify would affect outcomes regarding falls.

These are judgements, and some review users may disagree with them. However, the aim is to highlight who is represented within a body of evidence and help review users to consider this in their own judgements about applicability. The intention is to avoid poor or limited diversity in a body of evidence remaining hidden.]

Discussion text example:

All included studies involved older populations, generally over 70 years old, which is what we would want to see with evaluations of interventions focused on community-based older people. Most participants were women, although this probably simply reflects the gender balance of the older population. Almost the entire evidence base in this review comes from research done in high-income countries and relatively few of those: 17 of the 22 studies were done in just five countries. The applicability of all evidence in this review to low and middle-income settings is therefore very uncertain. Moreover, to a first approximation the included studies provided no information on the ethnicity or socioeconomic status of those taking part. Without special efforts to diversify trial recruitment and retention, trials generally recruit majority ethnicity and higher socioeconomic status people. The applicability of the evidence in this review to ethnic minority people and to people experiencing socioeconomic disadvantage is, at best, uncertain. It is a similar story for rural settings, which do not clearly feature in this evidence base.

Applicability summary table

Populations to whom this body of evidence broadly applies	Older people (especially women) in urban and high-income settings.
Populations to whom the applicability of this evidence should be viewed with caution	People in rural or low-income settings. People who are not from the ethnic majority group in a particular country or region.
Other considerations	Although the evidence does not provide information on genders other than men and women, we judge the evidence to be applicable to people of all genders as described for the populations above.

Equity-related implications for research

Populations for whom further research is a priority	People in low-income countries and settings. Research done in rural settings would be particularly welcome.
Other populations for whom further research would add value	Studies that include more men, perhaps through over-sampling, would be welcome.
Other considerations	Better reporting of ethnicity and socioeconomic status of those involved in studies would reduce uncertainty about applicability of evidence to these populations.

How to cite

PRO EDI interpretation guidance 25/4/2024; https://www.trialforge.org/trial-diversity/pro-edi-improving-how-equity-diversity-and-inclusion-is-handled-in-evidence-synthesis/ [insert access date].

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