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A toolkit for capturing a representative and equitable sample in health research - potential in multiple long term conditions research

National Institute of Health and Care Research
Applied Research Collaboration West Midlands and Birmingham Biomedical Research Centre

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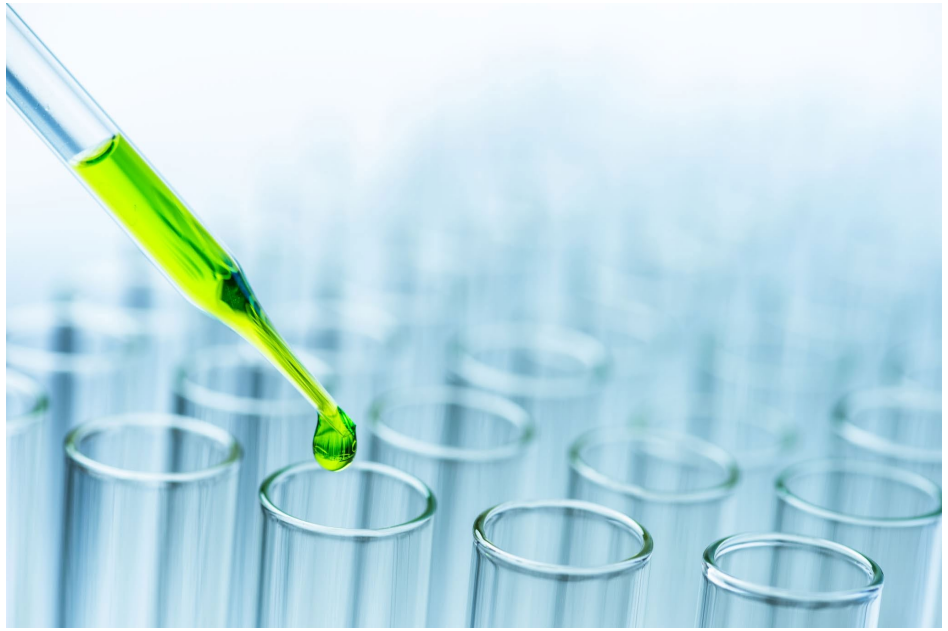
Funding statement

- National Institute of Health and Care Research (NIHR) Applied Research Collaboration West Midlands
- NIHR Birmingham Biomedical Research Centre
- Views expressed do not represent those of the NIHR or Department of Health and Social Care

What is the result of groups being systematically excluded?

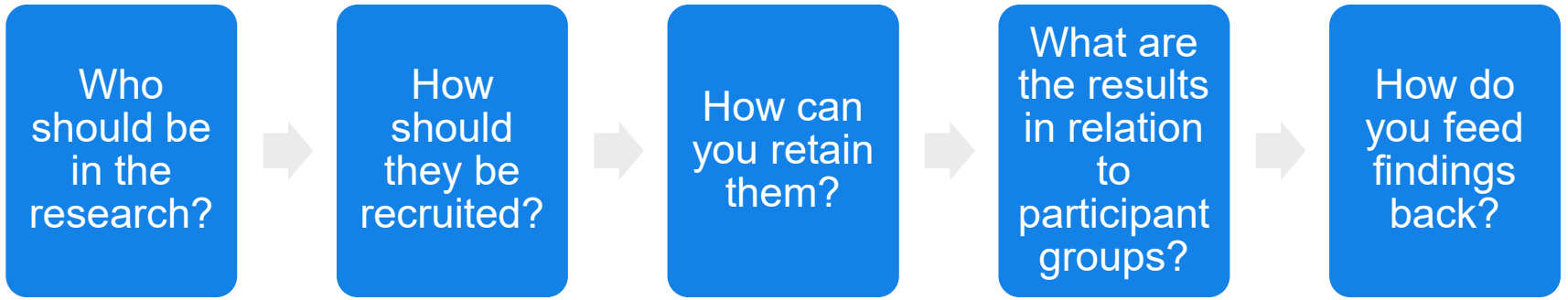


- Participants in research may not be representative of target population
- Conclusions cannot be extended to those not involved
- Benefits and harms remain unknown
- Implication for research quality
- Exacerbation of health inequality and inequity

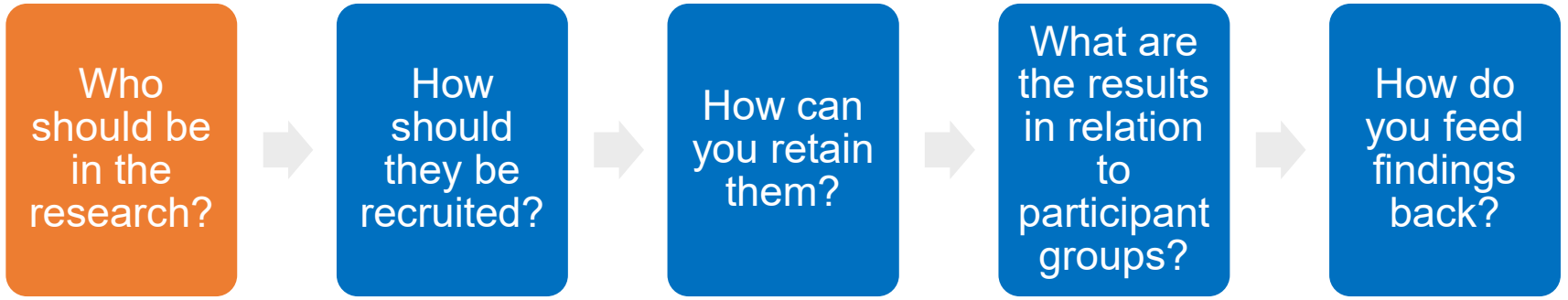
Equality, diversity and inclusion

- Respecting and valuing all forms of difference in individuals
- Acknowledging and allowing for case-specific resource allocation for different individuals to reach the same outcomes
- While positively striving to meet the needs of different people and taking deliberate action to create environments where everyone feels respected and able to reach their potential

Research participants and the **research pathway**



Research participants and the **research pathway**



Project aim

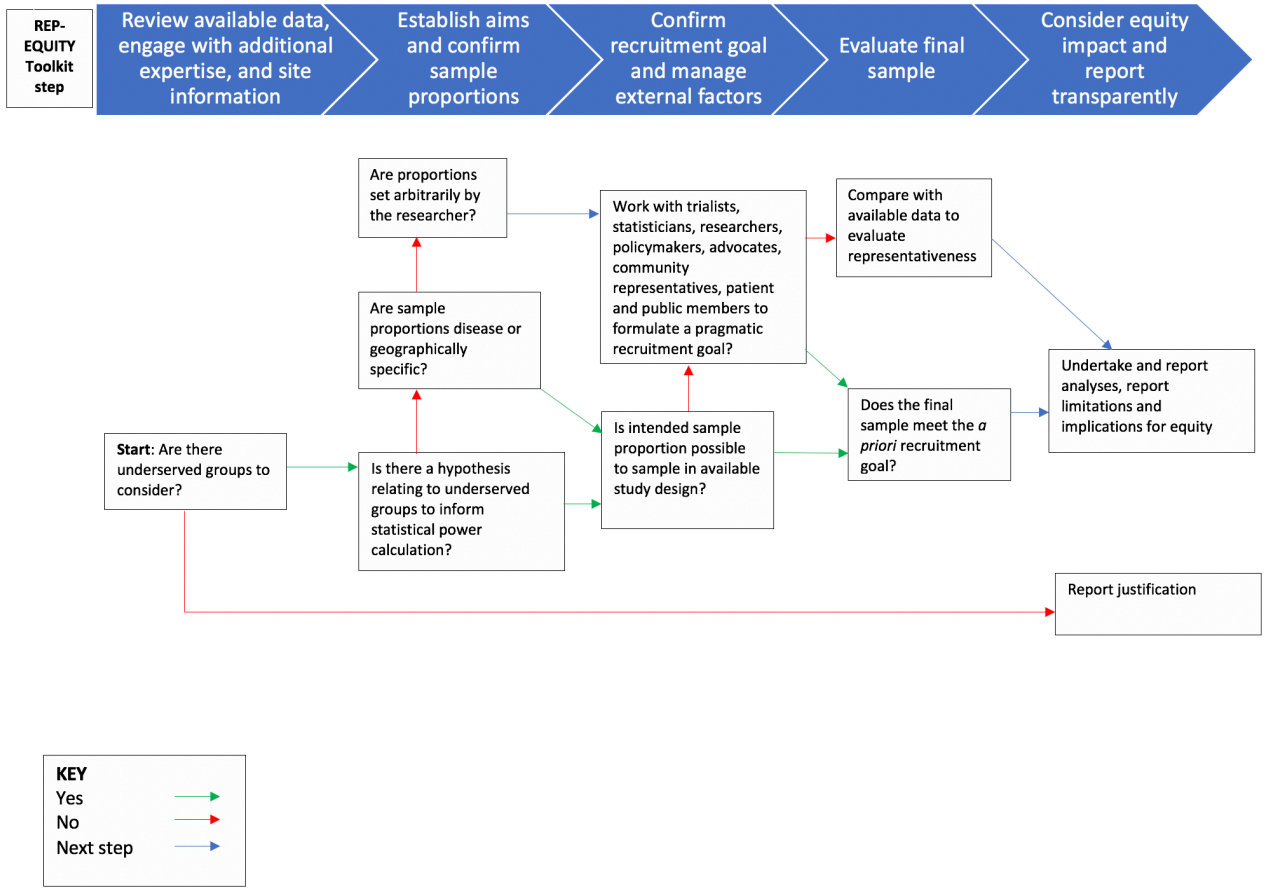
Develop guidance to help researchers get a representative sample of participants in their study that includes underserved groups

Overview

- Guide researchers in attaining a representative sample that is equitable and inclusive of underserved groups
- Seven-step evidence-based approach
- Integrates contribution from those with lived experience
- Facilitates reflection on sample limitations and transparent reporting of process
- Promote generalisability, research quality, health equity
- Build trust between research institutions and those underserved by research

The REP-EQUITY Toolkit

- Methodological systematic review and synthesis, finalised in a consensus workshop
- Define: relevant groups, aim, sample requirements, recruitment goals, management of external factors, evaluation, and legacy
- Step-by-step flow diagram
- Checklist



Retrospective case study (Newsome, P. N. et al. Granulocyte colony-stimulating factor and autologous CD133-positive stem-cell therapy in liver cirrhosis (REALISTIC): an open-label, randomised, controlled phase 2 trial. Lancet Gastroenterol. Hepatol. 3, 25–36 (2018))

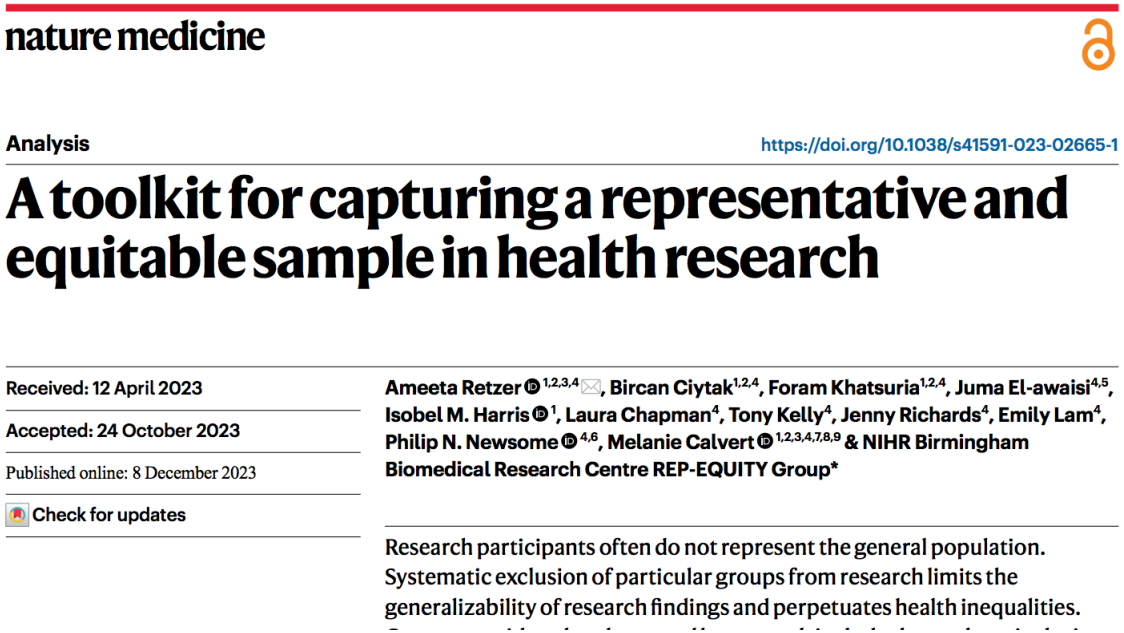
REP-EQUITY Step	**Retrospective case study response** (Newsome, P. N. et al. Granulocyte colony-stimulating factor and autologous CD133-positive stem-cell therapy in liver cirrhosis (REALISTIC): an open-label, randomised, controlled phase 2 trial. Lancet Gastroenterol. Hepatol. 3, 25–36 (2018))
1. What are the relevant underserved groups?	- Literature review identified potentially underserved groups - individuals with **cirrhosis and associated conditions**, specific **racial and/or ethnic groups** (Hispanic/Latinx, white, Japanese, Bangladeshi), **groups by gender** (men, varying risk in women) and **sexual minority groups** (men who have sex with men and transgender women (relating to hepatitis risk)). - A team in Birmingham led the trial; trial participants were recruited from the **UK population**. - Trial initiation pre-dated datasets such as CPRD and novel data extraction software, but information from the literature review is available and could now be used in combination with these resources.
2. What is the aim in relation to representativeness and equity?	- **No specific hypotheses** relating to underserved groups were made - The aim could have been to attain **a just and equitable distribution of the risks and benefits of research** or to undertake **exploratory analyses**.
3. How will the sample proportion of individuals with underserved characteristics be defined?	- Trial funded by NIHR and a UK charity; thus, proportions may reasonably be derived from **UK populations**, adjusted for disease prevalence - The most common causes of liver cirrhosis are alcohol consumption, diet and hepatitis; thus, **proportions could be established based on the resulting health burden**.

REP-EQUITY Step	**Retrospective case study response** (Newsome, P. N. et al. Granulocyte colony-stimulating factor and autologous CD133-positive stem-cell therapy in liver cirrhosis (REALISTIC): an open-label, randomised, controlled phase 2 trial. Lancet Gastroenterol. Hepatol. 3, 25–36 (2018))
4. What are the recruitment goals?	- Trial sample size derived from **power calculations to detect clinically important effects on liver function** - Trial eligibility criteria were **comprehensive** and stratification was not used. - **No particular recruitment goals** were set except for recruitment to reflect health burden by aetiology, which would influence recruitment goals related to underserved groups.
5. How will external factors be managed?	- Stem cell research is limited by the availability of facilities required for storage; thus, **sites were selected on this basis** and under pre-existing collaborative arrangements. - Depending on the intended aetiological proportions, the selected sites (Birmingham, Nottingham, Edinburgh (UK)) may be **assessed for whether recruitment goals are viable**. - Exclusion criteria relating to hepatitis C infection and antiviral time present barriers to trial entry for certain groups.
6. How will representation be evaluated?	- Final sample included 53 men and 28 women. Age was reported, whereas ethnicity was not reported. - **Final sample could be evaluated against available data for representativeness** in the context of trial aims and **monitored during the trial** to allow adjustments as required.
7. What will be the legacy?	- Rationale and methods to formulate sample proportions were not reported - Sample characteristics reported allow for **appraisal of the applicability of results and meta-analyses**. Retrospective use of tools for **equality impact assessment** will enable consideration of equity implications.

Application in multiple long-term conditions research?

- Those underserved by research are also more likely to get multiple long-term conditions
- What are the gaps? How can these be met using the Toolkit?
- Are there cases when these methods are more or less useful?

Access the paper here ->



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Analysis

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Check for updates

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Research participants often do not represent the general population. Systematic exclusion of particular groups from research limits the generalizability of research findings and perpetuates health inequalities.