may also be identifiable and difficult to keep anonymous. Medical research involving extremely vulnerable populations must clearly communicate such risks thoroughly and clearly to participants while striving to ensure that the likelihood of such negative outcomes is minimized.

Community-based participatory research

One approach to improve the accessibility of clinical research on novel technologies is through community-based healthcare models such as the European Union's Mig-HealthCare. Involving representatives from forcibly displaced populations in the research design will improve recruitment, retention, adherence and success of the intended research by reducing communication and cultural barriers[20]. This approach can promote the participation of these populations in national and state longitudinal cohort survey studies (for example, the National Health and Nutrition Examination Survey and the NYC Social Determinants of Health survey).

Such tools should also collect information regarding immigration status rather than a generic data point of 'foreign born'. This will enable the evaluation of social determinants of health that are specific to this population. Another approach is to highlight the healthcare contributions of forcibly displaced physicians and researchers to promote public engagement with advocacy groups[21]. Table 2 summarizes the challenges and risks, as well as potential solutions to include forcibly displaced persons in novel technology research. ❐

Faten Taki[1]✉, Jacob Lurie[2] and Gunisha Kaur[1]

[1]*Department of Anesthesiology, Weill Cornell Medicine, New York, NY, USA.*
[2]*NewYork-Presbyterian Hospital, New York, NY, USA.*
✉*e-mail: fzt2004@med.cornell.edu*

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Author contributions

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Competing interests

The authors declare no conflicts of interest.

Check for updates

Patient reported outcome assessment must be inclusive and equitable

Patient-reported outcomes are increasingly collected in clinical trials and in routine clinical practice, but strategies must be taken to include underserved groups to avoid increasing health disparities.

Melanie J. Calvert, Samantha Cruz Rivera, Ameeta Retzer, Sarah E. Hughes, Lisa Campbell, Barbara Molony-Oates, Olalekan Lee Aiyegbusi, Angela M. Stover, Roger Wilson, Christel McMullan, Nicola E. Anderson, Grace M. Turner, Elin Haf Davies, Rav Verdi, Galina Velikova, Paul Kamudoni, Syed Muslim, Adrian Gheorghe, Daniel O'Connor, Xiaoxuan Liu, Albert W. Wu and Alastair K. Denniston

Patient-reported outcomes (PROs) collected in clinical trials can provide valuable evidence of the risks and benefits of treatment from a patient perspective, to inform regulatory approvals, clinical guidelines and health policy. PROs are increasingly collected routinely in clinical settings, at an aggregate level for audit and benchmarking, for real-world evidence generation, and as an input or predicted output for clinical decision tools and artificial intelligence (AI) in health[1,2]. At an individual patient level, PROs can be used to facilitate shared decision making, screen or monitor symptoms, and provide timely care tailored to individual needs[3]. PROs are also increasingly used in value-based healthcare initiatives[4].

Efforts to capture and report PRO data should be inclusive and equitable, addressing the diverse needs of all patients with the condition of interest, including groups historically and currently underserved by research[5,6]. Issues of diversity, equity and inclusion (Box 1) have recently been highlighted in PRO ethical guidelines, which have identified a number of concerns to be addressed in PROs research[5].

Lack of representation

Underserved groups are often poorly represented in research and may receive suboptimal clinical care due to a range

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Box 1 | Key terms

Digital inclusion. Many people face barriers to using digital services, including a lack of digital skills or lack of access to infrastructure. Digital inclusion seeks to design services so that they meet all user needs[21].

Diversity, equity 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[12,22].

Health data poverty. Health data are often not representative of the diversity within a population, and so some groups do not benefit from healthcare innovations[7].

Interactive voice response. This allows participants to complete an automated questionnaire via a telephone keypad or by speech recognition.

Patient-reported outcomes. A measurement of a patient's health provided directly by the patient, rather than interpreted by a clinician[23].

Underserved groups. The definition of underserved is context specific and depends on the target population, question being asked, and intervention being tested. Underserved groups may reflect demographic, socioeconomic and health status factors. Examples include, but are not limited to, age, race, ethnicity, sexual orientation, gender identity, socioeconomical or educational disadvantage, individuals with disabilities, rare disease or language or literacy barriers, pregnant women, and those living in remote areas or areas where local service provision is weak or failing[24].

User-centered design. Design processes that are iteratively conducted with end users[12].

Value-based healthcare. "The equitable, sustainable and transparent use of the available resources to achieve better outcomes and experiences for every person"[25].

of cultural, socioeconomic and logistical reasons, in addition to narrowly defined inclusion criteria for research. Lack of representation is compounded by historical mistrust of research and medical institutions that persists in many groups.

PROs can provide valuable evidence of the efficacy and safety of drugs and biologics, which can vary depending on intrinsic and extrinsic factors, including sex, race, ethnicity and age. Clinical trials should provide information that informs the use of therapeutic agents within the target population. However, despite regulatory guidance and public expectations, the composition of study populations in most clinical trials does not always reflect such characteristics, which limits analysis of treatment outcome by subgroup. This failure to achieve meaningful diversity limits information about drug response and measures of safety and efficacy, which may result in health data poverty (Box 1)[7]. In this context, clinical trial results — and PRO data specifically — become biased as they are limited to those populations involved in research, with sectors of the population excluded, or even harmed, as a result. Lack of representative PRO data collection limits understanding of the impact of disease or treatment on patients' symptoms and quality of life, and thus the evidence base on which to provide clinical care, make regulatory decisions and inform health policy. This Comment considers current challenges related to PRO data collection in underserved groups and identifies approaches for greater inclusion.

Barriers to completion

With an increasing focus on PRO data collection to support patient-centered care, it is essential that the needs of underserved groups are addressed (Box 1). A key barrier to PRO data collection in underserved groups is a lack of valid and reliable measures that have been developed in, or are salient to, the target population. Many PRO measures are developed with limited patient input and may not address concepts that matter to underserved groups. Even when individuals from underserved groups are invited to complete PRO measures, they may experience significant barriers to PRO data completion. Individuals with disabilities, such as sight impairment, arthritis or cognitive function, and those in poor health may find completing the measures burdensome or challenging[6]. People with learning disabilities and low literacy have experienced exclusion from the routine monitoring of their health and wellbeing afforded by PROs[8].

Table 1 | Actions to promote representation and participation of under-served groups in PROs

Considerations	Actions
Diversity	
Consider how individuals from all relevant demographics within the target population (including those of differing age, sex, pregnant women, sexual orientation, race, ethnicity, level of education and socioeconomic status) can be included[16].	Involve individuals that are representative of the target population in the identification of key concepts to measure, the development and selection of PROs, the co-design of PRO systems, and data collection. Assess whether PRO measures perform consistently across groups (for example, based on measurement equivalence or differential item functioning).
Clinical characteristics	
Consider the type and severity of disease, the range of symptoms and functional impacts, comorbidities and physical and cognitive disabilities[16].	When heterogeneity in disease symptoms, signs and impacts exists, assess concepts that are most important to a broad range of patients. Minimize functional impacts that may limit a patient's ability to complete PROs (for example, issues of dexterity). Use accessible formats that address the needs of the target population. Allow proxy completion (someone to report the participant's outcomes on their behalf as though they are the patient) for individuals who are unable to complete PROs, for example, due to cognitive impairment. Please note regulatory requirements regarding the use of proxies.
Cultural needs and languages	
Include individuals from relevant cultures and languages within the target population to ensure that results are generalizable. People from distinct cultures may describe their symptoms differently and may have different values or preferences[16].	Be aware of cultural values and preferences, including whether key concepts of interest are appropriately captured via the PRO, and whether data collection is sensitive to the needs of those within the target population. Use validated translations and culturally validated PROs developed in accordance with international guidance[19]. Provide translators or interpreters for interviewer-led completion.
Literacy and health literacy	
Include individuals with all levels of reading, writing and problem-solving abilities, where possible[16].	Format PROs to adhere to accessibility principles including Easy-read versions, large font sizes and ample white space Allow flexibility for patients to choose where to complete PROs and to request assistance from people they know or professionals. Clearly convey the purpose and benefit of PROs to both patients and professionals by reducing intimidation and frustration caused by form filling in general. Ensure that content and training is easy to understand for participants with different literacy levels and educational experience by conducting relevant readability assessments (for example, Flesch–Kincaid grade level or SMOG (simple measure of gobbledygook) index score).
Digital inclusion	
Consider ways to promote digital inclusion.	Provide alternative modes of delivery (for example, bring your own device, provision of device, web completion or voice response systems that do not require internet access, phone calls from staff or in-person PRO completion in clinic). Offer hardcopy for those without smartphones or internet access. Provide training and support to patients and staff.
Regulatory engagement	
Meet with the regulator early during drug development, ask questions and seek advice regarding patient and public engagement, and arrange a regulatory or scientific advice meeting.	Discuss inclusivity in the context of the disease being investigated. Discuss potential barriers to inclusivity and discuss possible regulatory enablers, such as adoption of regulatory guidance that details approaches to increased enrolment of underserved population[20] and legislation requirements to deliver and support this. Use regulatory agency patient engagement tools and resources (for example, Medicines and Healthcare Products Regulatory Agency Innovative Licensing Pathway Patient Tools and US Food and Drug Administration patient-focused drug discovery guidance).

Importantly, the move to electronic PRO collection, while helpful for some, has created new barriers for others. Barriers to digital inclusion are widespread in underserved populations, with poor accessibility arising from a range of issues (Box 1). Estimates suggest that 37% of the world's 7.8 billion population are digitally excluded, with older people, people on low incomes and other marginalized groups most likely to be affected[9].

A recent study investigating the incorporation of PROs in clinical trials demonstrated that certain patient groups are not represented[10]. Investigators examined PRO capture across ten National Clinical Trials Network oncology trials and found that 24.7% of study participants declined to complete the PROs, and that 62.2% of the participants who agreed to the PRO component declined electronic PRO capture. Racial or ethnic minorities, those with less education and older patients were less likely to consent to electronic PRO collection.

AI health technologies trained and tested on PRO datasets that do not include members of these underserved populations are increasingly being utilized in healthcare. There is a risk that individuals from these groups may systemically receive suboptimal care as a result[11].

Racial and ethnic disparities

Specific challenges have been identified in the inclusion of minority ethnic groups in research and with the use of translated and culturally validated PROs[12,13]. A review of ethnicity reporting and PRO use of cancer trials registered in the National Institute for Health Research portfolio found that only 14 out of 84 (17%) trials collecting PROs reported ethnicity data. Eight (57%) studies were multicentered, multinational trials and the remaining were UK based (43%), suggesting a diverse target population; however, none reported using translated PRO measures even when available[13].

Online collection of PROs may lead to profound racial disparities, as highlighted by Mass General Brigham's PRO data collection, which spans 10 hospitals, 200 clinics and more than 75 specialties in the United States[14]. Before the COVID-19 pandemic, only 17% of PROs were collected using an online patient portal, with the remainder collected via tablet in clinic[14]. PRO completion rates were equitable, irrespective of self-identified race or ethnicity as recorded within the electronic health record. In March 2020, all tablets used for PRO collection were removed from clinics to limit the spread of COVID-19. This rapid transition prompted a shift in the capture of PROs, from primarily in-clinic to use of the online portal; this shift introduced profound disparity in data collection. Patients who self-identified as Black provided PROs at half the rate of white patients, and patients who identified as Hispanic almost stopped completing PROs altogether[14].

Low- and middle-income countries

Further consideration should be given to PRO data collection in low- and middle-income countries (LMICs). Participants from LMICs tend to be underrepresented in the development of PRO measures and there are also indications of a correlation between economic development and research participation, whereby PRO research is more likely to be conducted in upper-middle-income economies, such as Brazil, Russia, India, China and South Africa, than in low-income economies[15]. The challenges of conducting PRO research in LMIC settings include lower literacy levels, which require the use of interview administered questionnaires that can in turn introduce bias; variable adherence to standardized protocols for conducting randomized clinical trials; and cultural diversity. Such challenges require particular attention from research funders and investigators when designing, budgeting and conducting research. Outcomes should be culturally relevant and practical aspects of data collection must be carefully considered for each context.

A growing number of LMICs are proactively looking at collecting and using local evidence to strengthen their healthcare decision-making processes, as a core strategy for progressing towards universal health coverage. A stronger focus on collecting PRO data in LMICs presents a valuable opportunity to entrench patients' perspectives in the health policy discourse.

Widening participation

Barriers to participation in PRO completion, such as access to technology, disability, language and cultural requirements, should be addressed both in the interests of fairness and to ensure results are as accurate and generalizable as possible. Resources required to widen participation should be considered, for example, costs of alternative modes of PRO administration, addressing accessibility requirements, and development of culturally relevant translations.

Existing good practice guidance, such as minimizing participant burden, streamlining PRO administration and using PRO alerts, can be effectively used to promote inclusion and accessibility[5]. Communication of the rationale for PRO assessment (who will access the data and how it will be used) to potential participants may address the concerns of those wary of participating in research or providing information in a routine care setting. The representation and participation of underserved groups in PROs can be increased through the actions in Table 1.

Involvement promotes recruitment

Patient and public input are central to ensuring that PRO research is inclusive, equitable and meets the needs of diverse groups. Input can be facilitated by engaging diverse patient partners in co-design, and the involvement of study cohorts that are representative of the full breadth of the target population. Patients that are representative of the target population should be involved in the identification of concepts that matter to them and should contribute to the selection and/or development of PRO measures[16].

Representativeness in involvement activities can be achieved by addressing barriers that reduce the diversity of contributors, including engagement through community groups, charities and support groups; ensuring that opportunities to get involved are appropriately timed and located; and reimbursement for reasonable expenses. In drug development, a commitment to incorporate diversity and inclusiveness as part of patient-focused drug development efforts is necessary. Early engagement with regulatory agencies is recommended as they can offer advice and support to promote inclusivity.

The aims and benefits of completing PRO measures should be conveyed to participants, with flexibility in the modes of delivery, to increase engagement and participation of individuals from diverse groups[8]. An equity checklist, such as Benkhalti and colleagues' checklist to guide equity considerations in health technology assessment, can be an effective tool[17].

User-centered design

Empowering participants from underserved groups to inform the design and delivery of PROs allows for the identification and mitigation of barriers to successful PRO implementation[17]. PRO measures must be accessible if individuals are to accurately communicate information about their health[18]. User-centred design (Box 1), including usability testing, can help identify the needs of the target group(s) and create functional tools for patients and providers[6].

User-centered design principles can also accommodate people with visual impairment, limited mobility, learning disabilities, low health literacy or numeracy, including the ability to interpret graphical representations of data[6]. Digital inclusion should always be considered, including alternative modes of delivery such as bring your own device, assistive technologies or alternative modes of administration — for example, mail or telephone, including interviewer or interactive voice response (Box 1). Participants may need physical help to turn pages or hold a pen, or assistance with a telephone or computer keyboard. PRO collection that involves participants with different languages requires the availability of validated language and culturally adapted PRO questionnaires.

Practitioners must be sensitive to recognizing when proxy-reported measures may be needed, for example with advancing cognitive decline, to ensure accurate representation of a person's health and functioning[18]. However, it is important to note that in a regulatory setting, use of such measures is discouraged and so early engagement and advice from regulatory agencies is recommended.

Improve clinical care for all

PRO measures and data collection must be reflective of diverse and multicultural societies, to improve research and promote equitable clinical care for the benefit of all patients and the public as a whole. Representative diversity in clinical trials

is vital to ensure that all new medicines and technologies that reach the market are applicable to all the population subgroups that they are intended to serve. Targeted initiatives are needed to ensure that no groups are excluded from participation in PRO data collection, both in research settings and routine clinical care.

Inclusion of underserved populations in PRO data collection will help promote equitable healthcare and reduce health data poverty. Co-design of systems with representative patient input will be central to their successful realization. Resource implications must be considered, and novel approaches evaluated, to promote shared learning and best practice. ❐

Melanie J. Calvert[1,2,3,4,5,6,7,8] ✉, Samantha Cruz Rivera[1,2,3], Ameeta Retzer[1,4], Sarah E. Hughes[1,2,4], Lisa Campbell[9], Barbara Molony-Oates[10], Olalekan Lee Aiyegbusi[1,2,4,5], Angela M. Stover[11], Roger Wilson[12,13,14], Christel McMullan[1,2,6,15], Nicola E. Anderson[1,16], Grace M. Turner[1,6], Elin Haf Davies[17], Rav Verdi[14], Galina Velikova[18], Paul Kamudoni[19], Syed Muslim[1,2,8], Adrian Gheorghe[20], Daniel O'Connor[9], Xiaoxuan Liu[1,2,16,21], Albert W. Wu[22] and Alastair K. Denniston[1,2,3,7,16,21,23]

[1]Centre for Patient Reported Outcomes Research, Institute of Applied Health Research, University of Birmingham, Birmingham, UK. [2]Birmingham Health Partners Centre for Regulatory Science and Innovation, University of Birmingham, Birmingham, UK. [3]DEMAND Hub, University of Birmingham, Birmingham, UK. [4]National Institute for Health Research (NIHR), Applied Research Collaboration (ARC) West Midlands, Birmingham, UK. [5]NIHR Birmingham Biomedical Research Centre, University Hospital Birmingham, University of Birmingham, Birmingham, UK. [6]NIHR Surgical Reconstruction and Microbiology Research Centre, University Hospital Birmingham, University of Birmingham, Birmingham, UK. [7]Health Data Research UK, London, UK. [8]UK SPINE, University of Birmingham, Birmingham, UK. [9]Medicines and Healthcare products Regulatory Agency (MHRA), London, UK. [10]Health Research Authority, London, UK. [11]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA. [12]NCRI Consumer Forum National Cancer Research Institute, London, UK. [13]Health Research Authority Patient Involvement Network, London, UK. [14]Patient partner, University of Birmingham, Birmingham, UK. [15]Trauma Science Research, University of Birmingham, Birmingham, UK. [16]Academic Unit of Ophthalmology, Institute of Inflammation and Ageing, University of Birmingham, Birmingham, UK. [17]Aparito Limited, Wrexham, Wales, UK. [18]Leeds Institute of Medical Research at St James's, University of Leeds, Leeds, UK. [19]EMD Serono Inc, Healthcare Business of Merck KGaA, Darmstadt, Germany. [20]Imperial College London, London, UK. [21]University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK. [22]Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA. [23]National Institute of Health Research Biomedical Research Centre for Ophthalmology, Moorfields Eye Hospital NHS Foundation Trust and University College London, Institute of Ophthalmology, London, UK.
✉*e-mail: m.calvert@bham.ac.uk*

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