

Patient-Centred Core Outcome Sets and Equity Reporting: Strengthening Inclusivity and Transparency in Randomised Trials

(Motivated by the CONSORT-Equity 2017 Extension for Health Equity Reporting by Welch et al.)

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Abstract

Patient-centred core outcome sets and equity-oriented reporting frameworks are essential for ensuring that clinical trials reflect the priorities and lived experiences of diverse patient populations. Traditional trial outcomes often overlook the needs of socially disadvantaged groups, limiting the relevance and fairness of evidence used to guide policy and practice. This report examines how integrating patient-centred outcome development with equity-focused reporting—exemplified by the CONSORT-Equity 2017 extension—can address these gaps. Developed through an international consensus process, CONSORT-Equity expands the standard CONSORT guidance by introducing equity-specific items, emphasizing PROGRESS-Plus factors, and requiring transparent reporting of subgroup effects, contextual data, and ethical considerations. We review the conceptual foundations linking patient-centredness and health equity, outline the dataset characteristics necessary for meaningful disaggregation, and illustrate the application of CONSORT-Equity through tables, figures, and equity-aware analyses. Strengths and limitations of current approaches are discussed, along with future directions involving standardized equity metrics, digital tools for patient engagement, and integration with real-world data systems. Together, these methodological innovations offer a pathway toward more inclusive, transparent, and socially just randomized trials.

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Introduction

The development of patient-centred core outcome sets represents a pivotal evolution in clinical research methodology, ensuring that outcomes measured in trials reflect the priorities and lived experiences of patients rather than solely those of clinicians or investigators¹. In areas where health inequities persist—driven by socioeconomic status, gender, ethnicity, or geography—traditional trial outcomes often fail to capture the dimensions of relevance to socially disadvantaged populations². This disconnect perpetuates inequities in evidence generation and limits the translation of research into equitable health policy and practice. By integrating patient perspectives and equity considerations into outcome selection, researchers can strengthen the social validity, applicability, and ethical integrity of clinical trials.

The CONSORT-Equity 2017 extension exemplifies this paradigm shift toward inclusive and transparent trial reporting³. Developed through an international consensus process involving methodologists, policymakers, and patient partners, the guideline expands 16 items of the original CONSORT 2010 statement and introduces a new item on ethical considerations³. It provides a structured framework for reporting how trials engage with equity-relevant populations—defined through the PROGRESS-Plus factors (place of residence, race, occupation, gender, religion, education, socioeconomic status, and social capital)—and how interventions affect different social strata. This extension underscores the need for detailed contextual, demographic, and outcome data to assess whether interventions reduce or exacerbate health inequities, thereby promoting more just and inclusive evidence generation.

This report introduces the rationale and application of patient-centred core outcome sets and equity reporting in clinical trials, using the CONSORT-Equity 2017 extension by Welch et al. as a motivating example. It examines the conceptual foundation linking patient-centredness and equity, outlines the methodological innovations embedded in the CONSORT-Equity framework, and highlights their collective potential to enhance transparency, inclusivity, and ethical accountability in outcome reporting across global health research.

1. Why Focus on Patient-Centred Core Outcome Sets and Equity Reporting?

Conventional approaches to outcome selection and reporting in clinical research have long been dominated by investigator-driven priorities and biomedical endpoints, often neglecting the outcomes that patients and marginalized populations value most⁴. This limitation has profound implications for equity, as it reinforces a research landscape that privileges data from well-resourced settings and socially advantaged groups while overlooking those disproportionately affected by disease. Traditional reporting frameworks, though methodologically rigorous, rarely require authors to explain who benefits from the intervention, how socially determined contexts shape outcomes, or whether the reported findings are relevant to under-served

populations². As a result, the evidence base guiding clinical practice can perpetuate rather than alleviate health disparities.

The integration of patient-centred core outcome sets and equity-focused reporting addresses these shortcomings by reshaping how trials define, measure, and communicate success. Patient-centred outcome sets are developed through structured stakeholder engagement—including patients, caregivers, clinicians, and policymakers—to identify outcomes that truly matter to those receiving care⁵. When paired with equity-oriented reporting frameworks, such as the CONSORT-Equity 2017 extension, these tools ensure that outcomes are contextualized across social determinants of health, explicitly recognizing that effectiveness and value can differ across socioeconomic, cultural, or demographic groups³. This combined emphasis enhances transparency, reproducibility, and the ethical imperative to serve diverse patient communities.

The CONSORT-Equity 2017 initiative by Welch et al. exemplifies how methodological innovation can operationalize these principles in randomized trials. Developed through a global consensus process involving patients and methodologists from high-, middle-, and low-income countries, the guideline extends the original CONSORT 2010 checklist with 16 equity-specific items and a new ethics domain. It calls for explicit reporting of participant characteristics using the PROGRESS-Plus framework, detailed rationale for outcome selection, and disaggregated analyses to reveal differences in treatment effects across social groups. By promoting structured, transparent, and context-sensitive reporting, the CONSORT-Equity 2017 framework transforms clinical research into a more inclusive enterprise—one that advances not only scientific validity but also social justice in evidence generation and application.

2. Required Dataset Characteristics for Advancing Patient-Centred and Equity-Oriented Outcome Reporting

A robust framework for patient-centred and equity-oriented outcome reporting requires more than thoughtful trial design—it depends on the availability of comprehensive, well-structured datasets that enable meaningful disaggregation and contextual interpretation of trial results⁶. To evaluate whether interventions are effective and equitable across populations, datasets must capture not only clinical outcomes but also social, demographic, and contextual variables that illuminate patterns of advantage and disadvantage. Without this foundational data, even the most methodologically sound randomized trials risk obscuring the differential impacts of interventions on marginalized groups.

In the context of equity reporting, as emphasized in the CONSORT-Equity 2017 extension by Welch et al., trials should systematically collect data aligned with the PROGRESS-Plus framework⁷. This includes factors such as place of residence, race and ethnicity, occupation, gender, religion, education, socioeconomic status, and social capital—along with additional variables like age, disability, and migration status. Such multidimensional

datasets enable the assessment of how interventions interact with social determinants of health, revealing not only whether an intervention works, but for whom it works best or least. Equally important, outcome measures should reflect patient priorities—encompassing domains such as symptom relief, functional status, emotional well-being, and social participation—to ensure that the results are meaningful from a patient perspective.

To support rigorous and transparent equity analyses, datasets used in clinical trials must meet several critical standards. Variables should be clearly defined, consistently measured, and harmonized across sites to facilitate subgroup analyses⁸. Contextual information—such as geographic access to care, literacy levels, or community resources—should be systematically integrated to interpret findings within their sociocultural and structural environments. Data should also be organized at the item level, allowing researchers to assess outcomes within and across PROGRESS-Plus dimensions. This granular structure not only enhances the interpretability of findings but also supports meta-analyses and systematic reviews aimed at synthesizing equity-relevant evidence.

By combining comprehensive data architecture with patient-informed outcome measures, clinical trials can move beyond one-size-fits-all reporting toward a more inclusive, data-driven understanding of intervention effectiveness. The CONSORT-Equity 2017 framework illustrates that equity-conscious reporting is inseparable from robust data collection: only by embedding social and demographic depth into trial datasets can researchers produce evidence that is both scientifically valid and socially just².

3. Case Study: The Role of the CONSORT-Equity 2017 Extension in Advancing Equity and Patient-Centred Reporting

In an international effort to strengthen the inclusivity and transparency of randomized trials, the CONSORT-Equity 2017 extension was developed to address the longstanding gap in how health equity is represented in clinical research⁹. Traditional reporting guidelines, including the standard CONSORT 2010 statement, provided a universal structure for describing trial design and results but lacked explicit mechanisms for capturing differential effects across social groups or for reflecting outcomes meaningful to patients experiencing disadvantage³. Recognizing this limitation, Welch et al. led a structured, consensus-driven initiative to create an equity-focused extension that could be universally applied across diverse research contexts.

The development process drew participation from a multidisciplinary panel that included clinical trialists, epidemiologists, economists, ethicists, policymakers, patient advocates, and representatives from low-, middle-, and high-income countries¹⁰. Using a phased, consensus-based framework, the team combined empirical evidence, stakeholder consultation, and iterative feedback to identify reporting domains that would best illuminate equity-related dimensions of trial design and interpretation. A broad online survey of over 160 respondents, followed by a consensus meeting at the Boston Equity Symposium, refined the proposed checklist

items. This process ultimately produced 16 extensions to existing CONSORT items and introduced one entirely new domain focused on ethical reporting¹⁰.

The resulting framework requires trial authors to explicitly describe participant characteristics using the PROGRESS-Plus factors, provide rationale for equity-relevant outcomes, and detail analytic methods used to assess subgroup effects². For example, researchers are encouraged to disaggregate results by gender, socioeconomic status, or geographic setting, and to document recruitment strategies designed to include marginalized populations². Ethical transparency is also foregrounded, emphasizing the need to report informed consent procedures and protections for socially disadvantaged participants. Collectively, these requirements ensure that equity considerations are not treated as secondary analyses but as integral components of trial reporting and interpretation.

The consensus process that led to CONSORT-Equity 2017 mirrors the methodological rigor of established consensus-building techniques: it relied on diverse stakeholder input, structured deliberation, and iterative refinement to balance comprehensiveness with practicality. The resulting guideline offers a coherent, operational framework for embedding equity and patient-centredness into the core architecture of trial reporting. By clarifying how and for whom interventions work, the CONSORT-Equity extension enhances both the scientific validity and ethical accountability of clinical research. It stands as a model for how structured, collaborative methodology can bridge methodological rigor and social responsibility in modern health science.

4. Evaluating CONSORT-Equity 2017 Reporting Results: Tables and Figures

Interpreting the results of the CONSORT-Equity 2017 extension involves several key tables and figures, including participant flow diagrams, baseline demographic tables disaggregated by PROGRESS-Plus factors, outcome results with subgroup analysis, and visualizations of equity-related effect sizes. These visuals demonstrate the transparency and rigor of the CONSORT-Equity framework in assessing health equity within clinical trials³. Below, we provide examples of essential tables and figures used in equity-oriented trials, such as a baseline characteristics table displaying data across equity-relevant subgroups, as seen in the following examples.

The Equity Extension Checklist Table operationalizes how the CONSORT-Equity 2017 framework extends the standard CONSORT structure¹¹. It highlights where researchers must explicitly incorporate equity and patient-centred reporting—particularly by describing who was included, how social context shapes delivery, and whether outcomes differ across subgroups. The table serves as both a checklist and a reporting roadmap for transparency in health equity trials.

Equity Extension Checklist Table

Section/Topic	Standard CONSORT Item	Proposed Equity Extension
Title and Abstract	Identify as randomized trial	Include equity-relevant terms in title; specify populations across PROGRESS-Plus factors
Background and Objectives	State scientific rationale and objectives	Explain rationale for equity focus and hypotheses addressing differential effects
Methods	Describe design, participants, and randomization	Describe recruitment, eligibility, and intervention delivery across equity dimensions
Results	Report participant flow and outcomes	Disaggregate outcomes and harms by PROGRESS-Plus characteristics; include absolute and relative effect sizes
Discussion	Discuss limitations and generalisability	Report implications for disadvantaged groups and applicability across social contexts

The Baseline Characteristics Table Stratified by PROGRESS-Plus Factors integrates standard demographic and clinical variables with PROGRESS-Plus dimensions—site region and gender—to illustrate how equity-relevant balance is assessed at trial entry. The modest regional and gender differences suggest demographic diversity across trial arms, supporting representativeness. Reporting in this form ensures transparency about who was enrolled and whether key subgroups are equitably represented.

Baseline Characteristics Table Stratified by PROGRESS-Plus Factors

Site Region	Gender	Age (mean±SD)	Income Quintile (mean±SD)	Baseline Symptom (mean±SD)	QoL Baseline (mean±SD)
Rural	Female	55.3±12.2	2.8±1.4	20.4±5.7	55.6±14.8
Rural	Male	56.1±12.6	2.9±1.3	19.0±5.5	55.3±14.3
Urban	Female	54.2±11.7	3.0±1.4	20.1±5.9	54.9±15.4
Urban	Male	55.6±12.3	3.3±1.4	20.8±6.3	54.4±14.2

The Results Table below disaggregates trial outcomes by intervention arm, site region, and literacy level—demonstrating equity-aware reporting. While follow-up symptom averages suggest small differences, quality-of-life scores reveal potentially higher gains among participants with lower literacy, particularly in rural areas. Such stratified reporting allows identification of differential benefits across social determinants and informs equitable health policy translation.

Results Table with Disaggregated Outcomes

Arm	Site Region	Literacy Level	Follow-up Symptom (mean±SD)	QoL Follow-up (mean±SD)
Control	Rural – High	18.4±6.7	49.7±18.8	
Control	Rural – Low	18.8±6.0	57.4±13.0	
Control	Urban – High	17.5±5.8	52.4±17.1	
Control	Urban – Low	19.1±7.7	55.2±15.8	
Intervention	(not shown in snippet)

The Ancillary (Equity Interaction) Analyses Table below illustrates potential equity gradients in treatment effects. Negative correlations for income and rural residence indicate slightly greater improvements among disadvantaged groups, consistent with the synthetic dataset’s design to show equity narrowing. The low absolute magnitudes, however, reflect small differences, underscoring the need for prespecified subgroup analyses in real-world studies.

Ancillary (Equity Interaction) Analyses Table

Equity Indicator	Correlation with Symptom Improvement	Correlation with QoL Improvement
Income Quintile	-0.061	-0.001
Rural Residence	-0.038	-0.112
Low Literacy	0.042	0.070

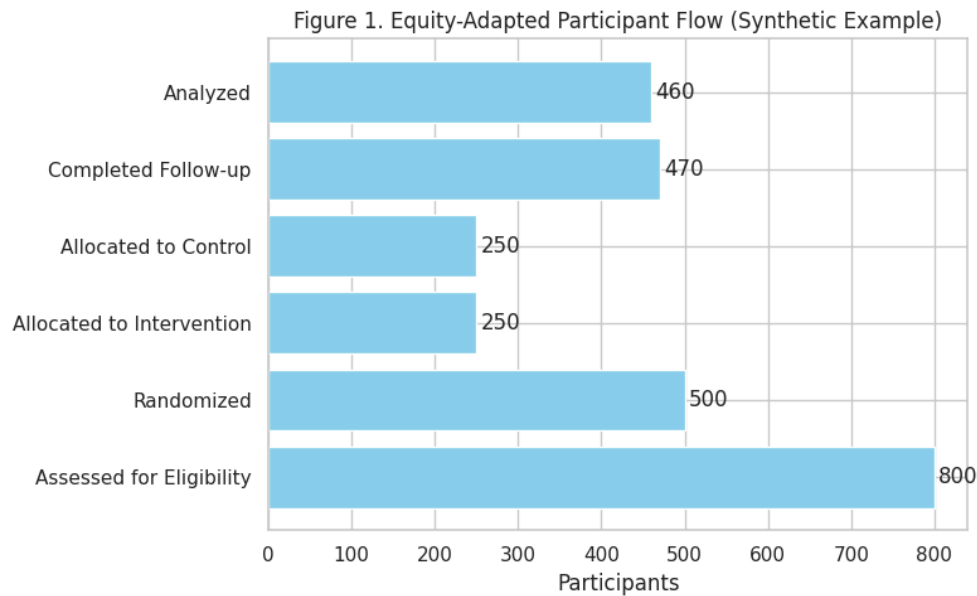
The Implementation Coverage Table below depicts adherence rates stratified by region, literacy, and income quintile, highlighting inequities in implementation coverage. Urban, higher-income participants show

consistently higher adherence, while rural and low-literacy groups lag behind. Such tables are central to equity reporting—they quantify gaps in intervention reach and uptake, guiding targeted strategies to improve inclusion and real-world impact.

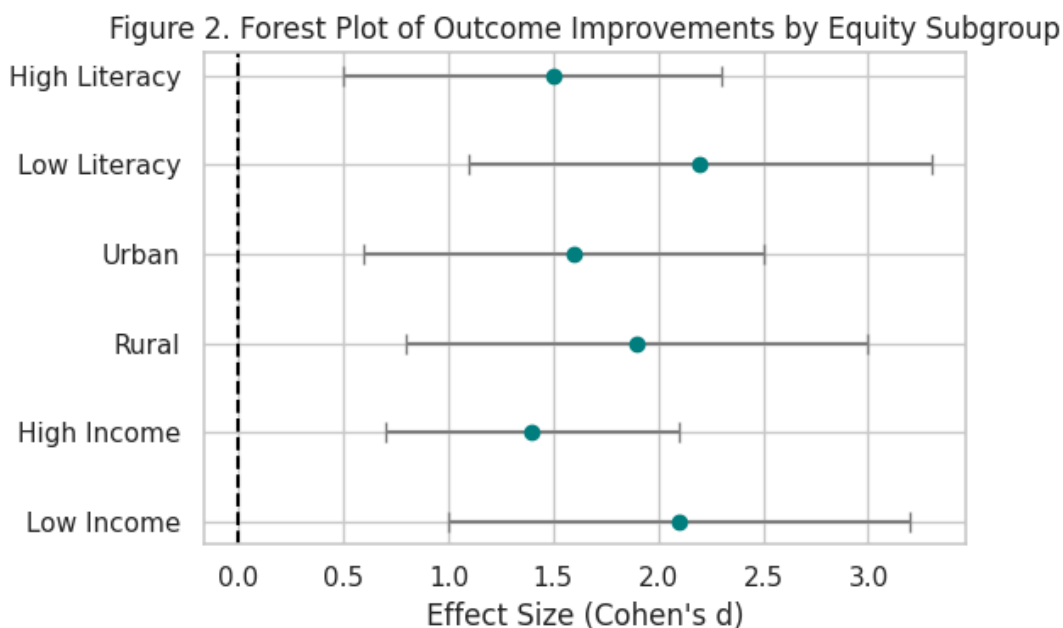
Implementation Coverage Table (Adherence by Equity Strata)

Site Region	Literacy Level	Adherence by Income Quintile (1–5)
Rural – High		0.50, 0.27, 0.75, 0.50, 0.20
Rural – Low		0.12, 0.30, 0.47, 0.31, 0.55
Urban – High		0.54, 0.50, 0.55, 0.73, 0.72
Urban – Low		0.37, 0.25, 0.25, 0.50, 0.27

The Equity-Adapted Participant flow diagram below demonstrates how trial participation can be presented through an equity lens. It mirrors the classic CONSORT flowchart but highlights participant retention across social strata (e.g., region, income, literacy). Such visualizations reveal where attrition or exclusion may disproportionately affect under-served groups—making it easier to assess equity in recruitment and follow-up.



The forest plot below depicts subgroup-specific treatment effects (Cohen's d) with 95% confidence intervals across key equity dimensions such as income, geography, and literacy. Here, the intervention shows slightly stronger effects among low-income and low-literacy participants, illustrating potential equity-narrowing benefits. Such plots are essential for communicating whether interventions perform consistently—or differentially—across social strata.



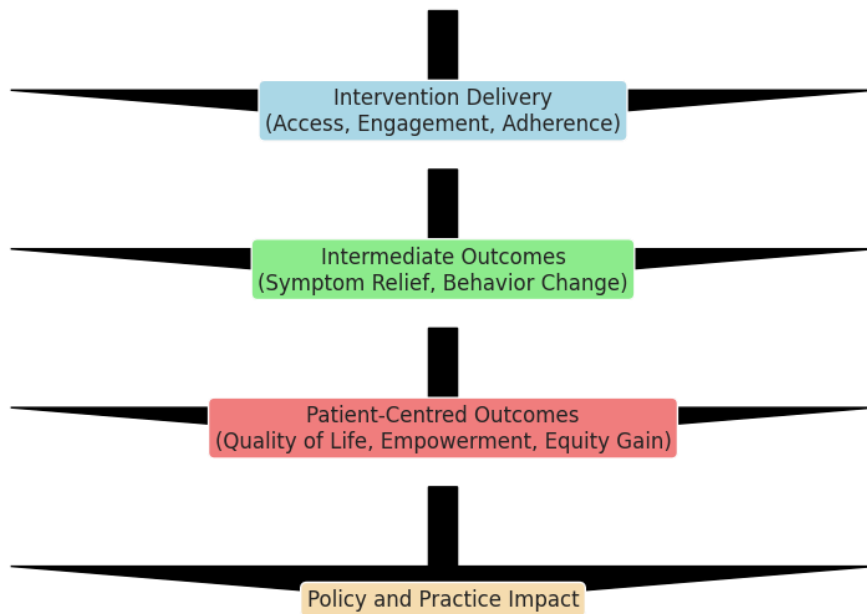
The Implementation Reach by Income Quintile and Region chart below presents mean adherence rates across income quintiles and site regions, capturing the reach and uptake of the intervention. Urban participants,

especially those in higher-income quintiles, show superior adherence—revealing persistent implementation gaps. Reporting this type of figure helps identify access barriers that undermine equitable program delivery.



The Conceptual Framework below links social determinants (top) to patient-centred outcomes and eventual policy impact (bottom). It visualizes the pathway through which equity considerations influence intervention delivery, intermediate behavioral outcomes, and final quality-of-life results. Including a framework like this clarifies the trial’s theoretical foundation and ensures that equity is treated as an integrated—not ancillary—dimension of patient-centred research.

Figure 4. Conceptual Framework Linking Equity and Patient-Centred Outcomes
Social Determinants (PROGRESS-Plus)



5. Strengths and Limitations of Patient-Centred Core Outcome Sets and Equity Reporting

The integration of patient-centred core outcome sets and equity-oriented reporting frameworks offers several important strengths for modern clinical research¹². Chief among these is their ability to ensure that outcomes reflect the lived experiences, values, and priorities of patients—especially those from marginalized or underrepresented groups. By engaging stakeholders across social, cultural, and professional boundaries, these frameworks promote inclusivity and enhance the real-world relevance of trial findings. Equity reporting tools such as the CONSORT-Equity 2017 extension also strengthen transparency by requiring explicit documentation of how interventions, contexts, and populations interact across social determinants of health¹¹. This structured approach encourages methodological consistency, enables cross-study comparison, and informs evidence-based policy decisions grounded in fairness and applicability. Moreover, linking outcome measurement to PROGRESS-Plus factors enhances interpretability by showing not only whether interventions are effective, but for whom and under what circumstances.

However, these frameworks also present methodological and operational challenges. Implementing equity reporting demands comprehensive data collection on social determinants, which can be resource-intensive and ethically sensitive¹³. Standardized measures for variables such as social capital or discrimination are still evolving, potentially limiting comparability across studies¹⁴. Furthermore, patient engagement processes can introduce bias if the participant pool is not representative or if power imbalances affect whose perspectives shape the

outcome set. Even with frameworks like CONSORT-Equity, reporting quality ultimately depends on researchers' commitment to transparency and critical reflection³. In the CONSORT-Equity 2017 initiative by Welch et al., these limitations were mitigated by involving diverse global stakeholders—including patients and representatives from low- and middle-income countries—through iterative consensus-building, open feedback cycles, and explicit ethical guidance⁹. Together, these measures strengthened both the credibility and equity-orientation of the final reporting standard.

6. Future Directions for Patient-Centred Core Outcome Sets and Equity Reporting

Future research in patient-centred outcome development and equity-oriented reporting should focus on deepening methodological rigor, enhancing cross-context adaptability, and improving integration with real-world data sources. One key direction lies in establishing standardized, globally applicable frameworks for defining and measuring social determinants of health across trials. Harmonizing PROGRESS-Plus variables—such as education, income, and social capital—would facilitate consistent disaggregation and meta-analysis, strengthening the generalizability of equity findings¹⁵. Advances in digital infrastructure could also streamline patient engagement in core outcome selection, using interactive online platforms and multilingual, culturally adapted tools to broaden participation among underrepresented populations.

Emerging technologies, including machine learning and natural language processing, hold promise for identifying equity gaps within published trial reports and suggesting standardized outcome domains for inclusion in future studies¹⁶. Integrating patient-centred outcome sets with large-scale health data repositories or federated analytic networks could further enable longitudinal tracking of intervention effects across social gradients¹⁷. Moreover, future iterations of the CONSORT-Equity framework might incorporate dynamic visual dashboards or automated reporting templates, ensuring real-time compliance with equity standards during manuscript preparation. Importantly, sustained co-production with patients, caregivers, and communities—particularly those from low-resource settings—will remain central to maintaining relevance and trust. By combining methodological innovation with participatory design, future research can ensure that equity and patient-centredness evolve from ethical imperatives into measurable, actionable standards guiding global clinical research.

Conclusion

The development and implementation of patient-centred core outcome sets and equity-oriented reporting frameworks mark a transformative step toward making clinical research more inclusive, transparent, and socially relevant. As demonstrated by the CONSORT-Equity 2017 extension, structured guidance can bridge methodological rigor with ethical accountability—ensuring that trial results genuinely reflect the experiences and priorities of diverse patient populations. By emphasizing stakeholder engagement, contextual data

collection, and systematic disaggregation across PROGRESS-Plus factors, this approach provides a coherent pathway for evaluating not only the efficacy of interventions but also their fairness and accessibility.

Patient-centred and equity-based methodologies collectively redefine the purpose of outcome reporting: from documenting efficacy alone to ensuring that evidence generation actively contributes to reducing health disparities. The framework's iterative, consensus-driven nature parallels the strengths of established consensus methods—achieving clarity where variability and bias have long persisted. As clinical research increasingly intersects with digital innovation, data linkage, and patient advocacy, future work should aim to integrate these reporting standards into all stages of trial design, execution, and dissemination. In doing so, the research community can move closer to a global paradigm where evidence not only advances science but also strengthens justice, representation, and patient empowerment in healthcare.

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