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Development and evaluation of a quality assessment tool for equality, diversity, and inclusion (QUALITY-EDI) within healthcare research

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Implementing equality, diversity, and inclusion (EDI) in healthcare research is critical to ensuring findings are translatable and provide the greatest benefit to patients who need it most. A quality assessment scoring tool (QUALITY-EDI) was developed to evaluate the conduct of EDI in healthcare research across all stages of the research cycle. To achieve this, a multidisciplinary working group comprising 22 members was established, including clinicians, researchers, and patient and public advocates. Using the National Institute for Health and Care Research's Research Support Service EDI toolkit as an initial framework, a workshop with 16 public representatives co-designed elements of the proposed QUALITY-EDI tool. The tool was subsequently refined by the working group to have eight domains: research context; study design; data collection; data analysis and interpretation; knowledge mobilisation; research team diversity; patient and public involvement; and budgeting for research inclusion. QUALITY-EDI can be used by researchers, journal editors, reviewers, funders, lay members, and other interest holders to assess and monitor the quality of EDI implementation.

SUMMARY POINTS

- Equality, diversity, and inclusion (EDI) is critical in research to enhance our understanding of disease mechanisms, enabling equitable access to clinical trials and increasing the generalisability of findings
- The QUALITY-EDI assessment tool has been developed to evaluate the conduct of EDI in healthcare research across all stages of the research cycle
- QUALITY-EDI consists of eight domains (each with two subdomains) based on research context, study design, data collection, data analysis and interpretation, knowledge mobilisation, research team diversity, patient and public involvement, and budgeting for research inclusion
- QUALITY-EDI can be used by researchers, journal editors, reviewers, funders, lay members, and other interest holders to assess and monitor the quality of EDI implementation in healthcare research

Healthcare inequalities continue to exist globally, leading to unfair differences in health and wellbeing.[1] People from minoritised backgrounds are often at higher risk of certain medical conditions, and at the same time are less likely to access medical care and to be involved in research,[2-4] which contributes to specific patient groups having poorer health outcomes and experiences.[5-9] Recently, equality, diversity, and inclusion (EDI), also referred to as research inclusion, has gained increasing recognition and importance in healthcare research. Within research, equality means ensuring all individuals have a fair opportunity to participate, while diversity acknowledges the value of including individuals with a variety of identities and lived experiences.[10] Inclusion is ensuring that a wide range of participants from different backgrounds are involved in research.[11] Adherence to these principles ensures that research can deliver the maximum benefit to those groups who need it most.[12-15]

Patient groups whose representation in healthcare and in research falls below their expected population prevalence relative to disease burden are collectively referred to as under-served groups.[16] Barriers to the inclusion of these groups in research include poor outreach to these communities, stigma, cultural beliefs, fear of not being treated with dignity and respect, financial burden, poor communication, and mistrust of the healthcare system.[3 17-19] Patients commonly face multiple barriers to participation in research, which can be particularly challenging when certain diseases disproportionately affect under-served groups.[20]

In healthcare research, the exclusion of participants from diverse backgrounds (whether intentional or not) raises questions about bias and the generalisability of findings.[21 22] Heterogeneous study populations allow for a thorough evaluation of the clinical performance of—for example, a novel test or intervention.[23] The

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greater the variation in study populations, the greater the potential to assess how the diagnostic test or intervention will perform across various subgroups and settings. Integrating EDI into research is therefore essential to ensure that findings are reproducible and relevant, and to consider the needs of different communities. Adequate steps must also be taken to ensure that EDI is appropriately acknowledged in the planning and reporting of research. Currently, there are no established methods for adequately assessing and monitoring the quality of EDI within research.

To help ensure that EDI principles are more effectively integrated into research practices, more explicit guidance and assessment of EDI standards within research is needed. Our aim was therefore to develop a concise tool to assess and monitor the conduct of EDI in healthcare research across all stages of the research cycle, building on a previous toolkit with expert and patient consensus. We also demonstrate the usefulness of the tool by applying it to a contemporary set of articles based on the early detection of gastrointestinal cancers. The proposed quality assessment tool ultimately intends to provide a standardised approach for evaluating EDI implementation, supporting both researchers in strengthening their EDI practices and reviewers in assessing the quality of EDI.

Establishment of working group

MGF and GBH founded the QUALITY-EDI project and established an international, multidisciplinary working group comprising members from diverse settings and expertise. Potential members were identified through a review of relevant literature, professional connections and peer recommendations. The recruitment process was iterative, with new members invited as the group identified needs, to ensure inclusion of the desired backgrounds and experience. The final working group, consisting of 22 members from five different countries, was responsible for the development of QUALITY-EDI (MGF, HK-L, PRB, RB, CN, AP, CMW, WS, KG, SB, PB, DAV, AMM, TR, BDN, LDS, AJC, SH, JFC, VW, PMMB, and GBH). A dedicated executive group (MGF, HK-L, PRB, WS, SB, LDS, JFC, and GBH), which included two public representatives, led the development process.

During the recruitment process of working group members, we ensured that a wide range of roles were represented with several members bringing experience from more than one area, including primary and secondary care clinicians (MGF, PRB, CMW, DAV, BDN, JFC, and GBH), methodologists (RB, CN, PB, SH, and VW), qualitative researchers (HK-L, RB, and TR), statisticians (CN and LDS), public representatives (WS and SB), clinical research practitioners and research nurses (AP and KG), epidemiologists (AMM, AJC, JFC, VW, and PMMB), and journal editorial staff (PRB, LDS, JFC, PMMB, and GBH; supplementary file 1). The public representatives have a strong interest in EDI, with lived experiences of inequities, and co-designed aspects of the study project and methodology, receiving reimbursement for their time, skills, and expertise in line with the National Institute for Health and Care Research (NIHR) guidance.[24] Some members of the working group (RB, CN, AMM, SH, JFC, VW, and PMMB) have experience in the development of reporting guidelines, such as SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials),[25] CONSORT (Consolidated Standards of Reporting Trials),[26] STARD (Standards for Reporting of Diagnostic Accuracy),[27] and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses),[28] and equity extensions and frameworks.[29-33] The working group conducted the QUALITY-EDI project in two phases: phase 1 for tool development and phase 2 for tool application (fig 1).

Phase 1: Development of QUALITY-EDI assessment tool

Initial framework

The NIHR Research Support Service's (RSS) EDI toolkit was developed in 2022 by coauthors RB and CN, supported by EDI experts, researchers, and public contributors.[32 33] The toolkit comprises eight key topics, accompanied by case studies, to guide researchers on how to embed EDI in applied health and social care research. These topics include historical context and structural inequality; selection of participants, sites, and samples; data collection; data analysis and presentation; dissemination, implementation, and impact; research team; public involvement; and budgeting for inclusion. The toolkit was piloted in four RSS regions in the UK (East Midlands, West Midlands, North West, and East of England), and improvements were made in subsequent focus group meetings. Although the toolkit was not intended to evaluate the implementation of EDI in research, it nevertheless served as a useful starting point and framework for developing the proposed QUALITY-EDI assessment tool. We did not identify other comparable EDI quality assessment tools for healthcare research at the time of development.

EDI workshop with patients and public representatives

We held a half day EDI workshop with patient and public representatives at the Hammersmith Hospital Campus, Imperial College London (London, UK), to review and co-design elements of the tool. To identify participants for the workshop, the project was advertised through several charities and community partnerships (eg, CVS Brent, Reviving Links), online platforms (eg, NIHR People in Research, VOICE), and through existing links to patient and public groups and organisations (eg, Imperial's NIHR Patient and Experience Research Centre). Interested individuals were invited to attend an introductory launch event and asked to complete a brief survey on demographics, meeting preferences, and their interest in improving EDI within research. We received approximately 40 responses to this survey. The working group invited interested individuals based on the need to include members with a range of protected characteristics; and their ability to attend the workshop on the proposed date and time. The workshop included

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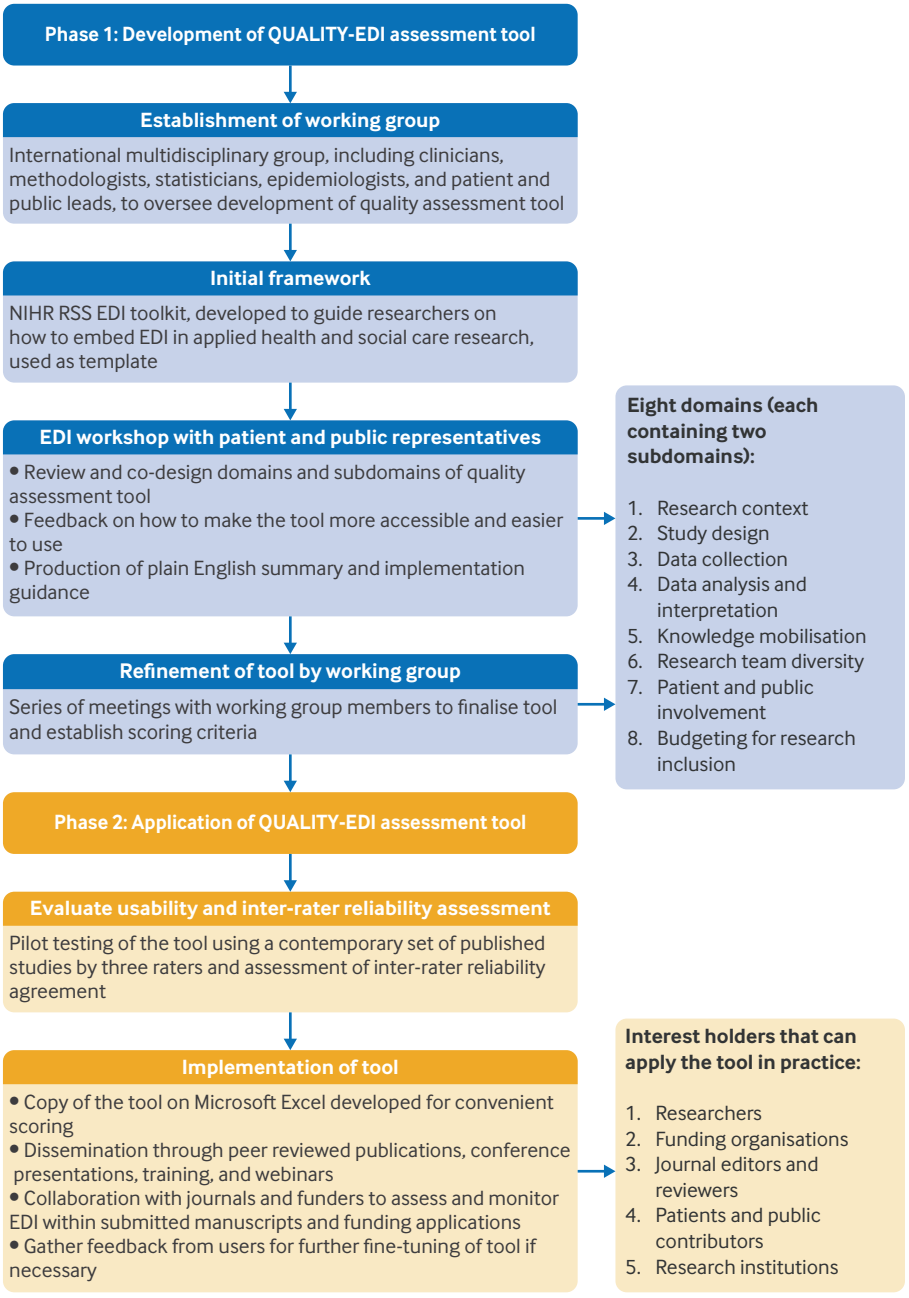


Fig 1 | Development process of QUALITY-EDI tool for the assessment and monitoring of EDI implementation and reporting in healthcare research. EDI=equality, diversity, and inclusion; NIHR=National Institute for Health and Care Research; RSS=Research Support Service

16 patient and public representatives from a broad range of ethnicities, socioeconomic backgrounds, ages, disabilities, genders, religions, and sexual orientations (supplementary file 2). Participants were provided with the option of attending the workshop virtually if preferred. The venue chosen allowed for this hybrid approach. It also has good transport links, along with wheelchair accessibility. Participants were reimbursed for their time (including childcare costs) and travel, and refreshments were provided during the workshop.

During this meeting, the aims of the proposed tool were presented along with a clear description of its intended use. We presented eight domains from the NIHR RSS EDI toolkit in the same order. Attendees were asked to provide feedback on the initial tool and each proposed domain. They were encouraged to propose amendments to the tool to improve its accessibility to lay members. Attendees were also asked to anonymously rank each domain (1 to 8) in the tool by perceived importance, with 1 being the most important, using Qualtrics XM software.[34] The purpose

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of this ranking was to determine if it was necessary to apply weighting to the assessment outcomes.

Discussions during the EDI workshop helped to define more explicit criteria and requirements for each subdomain. Although contributors found the tool was user friendly and concise, they requested the inclusion of good practice examples and a glossary of terminology. During the discussions, it emerged that EDI workshop participants were satisfied with the presented domain order, because it mirrored the stages of the research cycle.[35] When participants were asked to rank the domains, no clear hierarchy of domains emerged (supplementary file 3), demonstrating no clear consensus on prioritisation. As a result, any weighting of assessment tool domains was deemed unwarranted. Members of the workshop created a plain English summary describing current EDI issues in research and the potential impact of the tool, along with a suggested implementation strategy for interest holders such as researchers, funding bodies, journal editors and reviewers, public contributors, and research institutions.

Refinement of the QUALITY-EDI tool

Following the EDI workshop, the working group refined the tool to establish the domains and subdomains, as well as the scoring criteria. This process was achieved through a series of meetings with group members and agreed on by consensus using a nominal group technique. Items were not removed; they were refined or expanded after the discussion. The proposed QUALITY-EDI tool comprises eight domains to assess and monitor the quality of EDI implementation in healthcare research: research context; study design; data collection; data analysis and interpretation; knowledge mobilisation; research team diversity; patient and public involvement; and budgeting for research inclusion.

Each domain is divided into two subdomains to provide further descriptors of inclusive strategies. Each subdomain is scored by rating "fully met" (2 points), "partially met" (1 point), and "not reported" (0 points). We opted for a scoring system of three levels, which is similar to established quality appraisal checklists, such as the AMSTAR-2 checklist (yes, partial yes, no),[36] Mixed Methods Appraisal Tool (yes, no, cannot tell),[37] and overall judgments from the revised Cochrane risk-of-bias tool for randomised controlled trials (low risk, some concerns, high risk).[38] The two scores from each subdomain can be added to obtain a total domain score, ranging from 0 to 4. The scores across the eight domains are summed to produce an overall score for the material being assessed, ranging from 0 to 32 points. A higher score reflects a higher quality

Table 1 | QUALITY-EDI assessment tool

No	Domain	Description of subdomains	Score (out of 32 points; not reported=0; partially met=1; fully met=2)
1	Research context	a) Description of past exclusions and inequalities within research (eg, previous research excluding certain populations or geographical areas having disproportionately worse outcomes).	
		b) Explanation of possible historical barriers that might affect how under-served groups feel about participation or involvement within the research.	
2	Study design	a) Selection of sites: research conducted in geographical areas where the need is high and disease burden would benefit.	
		b) Selection of participants: description of inclusive recruitment strategy and justifying/avoiding unnecessary exclusion criteria.	
3	Data collection	a) Equitable data collection strategy to address participants' protected characteristics and needs (eg, considering participants' accessibility requirements, regional geographical differences, education, and socioeconomic levels).	
		b) Attempt to overcome barriers related to participant recruitment and retention within research (eg, research carried out at routine hospital appointments, support given to those who live in rural areas or those with accessibility needs, translation of written materials, and use of interpreters).	
4	Data analysis and interpretation	a) Description of EDI protected characteristics, for example, age, sex, ethnicity, socioeconomic level, and disability presented in a table (partially met=minimum of two protected characteristics reported; fully met=at least three protected characteristics reported).	
		b) Quantitative or qualitative analysis of EDI protected characteristics, including discussion of potential bias in study results and sensitivity/subgroup analysis (eg, with gender/ethnicity/socioeconomic groups).	
5	Knowledge mobilisation	a) Dissemination of findings via accessible and inclusive formats, which are tailored to diverse researchers and members of the public (eg, digital accessibility services, different languages, large print/easy ready texts, and audio versions).	
		b) Description of how research is being taken forward to impact and benefit patients/service users across all settings.	
6	Research team diversity	a) Diverse research team including multiple disciplines, institutions, and demographics.	
		b) Description of differences in research design and interpretation by incorporating diverse perspectives and lived experiences.	
7	Patient and public involvement	a) Recruitment and involvement of diverse PPIE contributors (eg, through community events and reaching out to community champions and leaders).	
		b) Public involvement strategy to monitor and address EDI issues within the research.	
8	Budgeting for research inclusion	a) Description of additional costs used for designing inclusive research (eg, PPIE, accessible materials, translation into different languages, travel, and childcare).	
		b) Description of steps that researchers can take to reduce costs and therefore improve accessibility to research.	

EDI=equality, diversity, and inclusion; PPIE=patient and public involvement and engagement.

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of EDI implementation. A free text entry option was also added with each domain for qualitative feedback, along with a glossary of terminology. A version of the QUALITY-EDI assessment tool is presented in table 1.

Phase 2: Application of QUALITY-EDI assessment tool

Systematic review for pilot testing

A systematic review of contemporary studies reporting novel non-invasive methods for the early detection of gastrointestinal cancers was performed to evaluate the usability and performance of the QUALITY-EDI assessment tool. This subject was chosen because of the clinical importance of early cancer detection, exemplified by NHS England's aim to diagnose 75% of cancers in the early stages by 2028,[39] as well as substantial health inequalities within this field.[40-43] These inequalities include an increased risk of gastrointestinal cancers among certain minoritised and deprived groups, reflecting the barriers that these patients may face in accessing testing.

Search strategy

A systematic literature search of Medline, Embase, Emcare, and CINAHL databases was performed (supplementary file 4). Search strategies were formulated using related medical subject headings (MeSH) terms, such as gastrointestinal cancer, oesophageal cancer, gastric cancer, colorectal cancer, early detection of cancer, biomarker, blood, serum, plasma, urine, breath, saliva, faeces, and stool. Articles published in English over five years, between 1 January 2020 and 20 January 2025, were retrieved. This time period was chosen for its association with growing interest and research activities in cancer early detection, as well as concurrent awareness and recognition of EDI considerations within research. This systematic search adhered to PRISMA-ScR guidelines[28] and was developed in line with the Cochrane Handbook for Diagnostic Test Accuracy.[44]

Study selection

All studies reporting non-invasive diagnostic biomarkers for the early detection of oesophageal, gastric, or colorectal cancer in humans were eligible for inclusion. Non-invasive biomarkers were defined as measurable indicators derived from accessible biological samples, including blood, saliva, urine, stool, and breath. Editorial letters, case reports, reviews, and conference abstracts were excluded. Initially, two authors (MGF and HK-L) independently screened titles and abstracts against the inclusion criteria, with any disagreements resolved by a third reviewer (AP). The full manuscripts of potentially eligible studies were independently reviewed to determine ultimate inclusion in the final analysis.

Scoring of literature using QUALITY-EDI

Information extracted from the articles included the author, year, country, study design, single or multicentre study, cancer type, diagnostic biomarkers, and primary outcome measure. The QUALITY-EDI tool was applied to the identified studies by three raters (MGF, HK-L, and AP) independently. The total EDI score (of 32 points) for each manuscript was calculated, and inter-rater reliability was assessed using Fleiss κ coefficient. The Fleiss κ statistic is used to evaluate interobserver agreement in larger groups of categorical variables, where values can be interpreted using a common scale of interpretation: 0.01-0.20 as slight agreement, 0.21-0.40 as fair agreement, 0.41-0.60 as moderate agreement, 0.61-0.80 as substantial agreement, and 0.81-1.00 as almost perfect agreement.[45 46]

Screening process and study characteristics

The initial search yielded 1934 potential articles of interest (supplementary file 5). After exclusion of irrelevant articles, 80 articles[47-126] were included for assessment using the QUALITY-EDI tool (supplementary file 6). The articles comprised 25 (31%) cohort studies, 49 (61%) case-control studies, and six (8%) cross sectional studies, with 34 (43%) studies being multicentre. Studies were conducted in 23 countries, with China (n=33, 41% studies), Japan (n=8, 10%), Egypt (n=7, 9%), and Spain (n=4, 5%) the most frequently represented. Seven (9%) studies presented biomarkers in oesophageal cancer, 23 (29%) presented gastric cancer biomarkers, and 53 (66%) presented colorectal cancer biomarkers. The study characteristics of the 80 articles are summarised in supplementary file 7.

Findings from the QUALITY-EDI tool application and inter-rater reliability assessment

Scoring for each study from the three raters is shown in supplementary files 8-10. The highest score for a single domain was three (of four), achieved for the domains related to research context, study design, data analysis and interpretation. One (1%) study achieved a score of 10 or higher (of 32) from all three raters, with a total of eight (10%) studies scoring zero points. The QUALITY-EDI score of each article, from the three raters, is illustrated in ascending order in supplementary file 11.

Participants' age, sex, and ethnicity were reported in 70 (88%), 64 (80%), and six (8%) studies, respectively. Education and socioeconomic status were each reported in one study (1%). Nine studies (11%) did not report any EDI characteristics. Two (3%) studies reported on patient and public involvement, with no studies reporting on budgeting for research inclusion. Factors such as cognitive dysfunction, complex/chronic illnesses, mental health issues, and learning disabilities were notably unreported. Two (3%) studies conducted a sensitivity or exploratory subgroup analysis stratified by EDI characteristics across the 80 studies.

All three raters found the tool practical and user friendly, and a high level of agreement and inter-rater reliability was observed. An almost perfect agreement (Fleiss' κ 0.81-1.00) was observed in 13 subdomains, with substantial agreement (Fleiss' κ 0.61-0.80) in the remaining three subdomains. The inter-rater reliability

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assessment and median QUALITY-EDI scores for each domain across the 80 studies are provided in table 2.

Following pilot testing of the tool, minor refinements were made to the wording of the subdomains and good practice examples for the domains identified in this review were provided (supplementary file 12). A copy of the tool, in a convenient format suitable for users, is available as a Microsoft Excel spreadsheet in supplementary file 13, and an explanation guide of the tool is provided in supplementary file 14.

Discussion

This study presents a new, concise tool for assessing the implementation of EDI within healthcare research across all stages of the research cycle. The tool comprises eight domains and 16 subdomains, based on research context, study design, data collection, data analysis and interpretation, knowledge mobilisation, research team diversity, patient and public involvement, and budgeting for research inclusion. It was developed by building on an existing EDI framework, with input from multidisciplinary experts, and members of the public and patients. Piloting the tool in a contemporary set of published studies demonstrated a high inter-rater agreement for each subdomain of the tool, along with a lack of EDI conduct and reporting in the identified literature.

QUALITY-EDI tool performance and key findings

There are current national initiatives to increase the number of patients receiving a diagnosis at an early cancer stage, in an effort to improve outcomes. Given this push towards earlier diagnosis, associated research and services must adopt an equitable, diverse and inclusive approach.[127 128] We applied the QUALITY-EDI tool to 80 studies on non-invasive diagnostic biomarkers for the early detection of gastrointestinal cancer as a test model. By evaluating the tool in this field, we have highlighted that reporting and analysis related to EDI, as well as to patient and public involvement and engagement (PPIE) considerations, are limited. Despite cancer related literature indicating that specific populations and geographical areas are often excluded from clinical trials, and that these groups face worse outcomes,[5 129] only a small number of articles mention these occurrences, and none scored in all eight domains of the tool.

Age was a commonly reported demographic characteristic in the included studies. However, participant sex was not reported in one in five studies, and fewer than one in ten studies reported participants' ethnicity. These findings support existing literature, which demonstrates that many clinical trials do not document data on ethnicity, race, or ancestry.[18 130-132] This omission of data results in limited knowledge of inequalities in cancer incidence and outcomes, as well as the effectiveness of specific tests or treatments within different groups.[133 134] The lack of reported ethnicity data hinders our understanding of how social, structural, and environmental factors, including differential access to care, contribute to differences in health outcomes across groups.[135 136] Researchers should also be aware of the terminology used to distinguish populations, for example, race, ethnicity, and ancestry. Ethnicity refers to culture (eg, customs, language, history), while race is a socially constructed classification, often based on physical characteristics, and ancestry refers to the degree to which individuals are related.[137] Where applicable, authors might, in future, conduct an EDI related analysis of the variables (eg, exploratory subgroup analyses with appropriately cautious interpretation), which goes beyond the typical reporting of demographics. The dissemination of findings in accessible and inclusive formats to both participants and the public is also essential. A lack of feedback to participants can erode trust between researchers and participants, as members of communities seek to understand how their

Table 2 | Median QUALITY-EDI score for each domain and inter-rater reliability assessment among three raters

Domain	Subdomain	Agreement (%)	Fleiss κ coefficient	Median (range) QUALITY-EDI score for each domain (out of 4 points)		
				Rater 1	Rater 2	Rater 3
1) Research context	a)	86.3	0.80	0 (0-3)	0 (0-2)	0 (0-3)
	b)	98.8	0.87			
2) Study design	a)	91.3	0.86	0 (0-3)	0 (0-3)	0 (0-3)
	b)	87.5	0.83			
3) Data collection	a)	92.5	0.87	0 (0-1)	0 (0-1)	0 (0-2)
	b)	95.0	0.87			
4) Data analysis and interpretation	a)	97.5	0.97	1 (0-3)	1 (0-3)	1 (0-3)
	b)	86.3	0.83			
5) Knowledge mobilisation	a)	98.8	0.85	0 (0-2)	0 (0-1)	0 (0-2)
	b)	88.8	0.79			
6) Research team diversity	a)	88.8	0.79	0 (0-1)	0 (0-1)	0 (0-1)
	b)	100	1.00			
7) Patient and public involvement	a)	100	1.00	0 (0-2)	0 (0-2)	0 (0-2)
	b)	100	1.00			
8) Budgeting for inclusion	a)	100	1.00	0 (0-0)	0 (0-0)	0 (0-0)
	b)	100	1.00			

EDI=equality, diversity, and inclusion.

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contribution to research could bring about change in their communities.[131]

Recommendations for research practice

Researchers should proactively seek to include populations and communities typically under-served in research.[131] A proactive approach is needed to build collaborations based on mutual gain and to foster trust between researchers and the community. Researchers can work with community leaders and representatives from these groups from the early stages of study development to tailor the study design, recruitment, and dissemination strategies, making the research sensitive to the perspectives, beliefs, and broader culture of these communities. Recording participant characteristics should be standard practice in clinical research studies where appropriate, such as age, gender, ethnicity, geographical location, social deprivation, sexuality and disability, to enhance understanding of inequalities and the underlying social determinants of health.[134] Researchers ought to be mindful of communities' concerns regarding the use and sharing of data, and must ensure protections for privacy, confidentiality, and the right not to participate.[17 18 131 134]

An effective knowledge mobilisation and dissemination strategy that reaches participants and the wider public is essential.[17 138] Researchers should acknowledge participation and consider the timeliness and inclusivity of results when communicating them. This approach is imperative for trust building, minimising anxiety and stress, and providing reassurance to participants.[139 140] In addition, researchers should work with patient and public representatives to help create lay summaries, media posts, and public reports. These materials should use appropriate wording and formats that cater to people with different backgrounds, abilities, and needs, to ensure a high level of inclusivity and accessibility. PPIE can have several other benefits, such as early identification of issues, refinement of the research question, optimisation of participant recruitment and retention, and dissemination.[141 142] The Department of Health (INVOLVE) unit in the UK has developed tools for researchers to facilitate public participation in research.[143] Researchers should also ensure that adequate funding is available for EDI activities to enable the completion of PPIE activities, the use of interpreters, and the creation of study materials in different languages and multiple accessible formats. Although budgeting information is more commonly provided in research grant applications than in published scientific papers, a record of this information could be included in study protocols, along with further details on the recruitment and sampling strategies.

Implementation of QUALITY-EDI

The QUALITY-EDI tool is designed for use by multiple interest holders throughout the research cycle. It can act as both an implementation guide for researchers and as a measurement tool to assess researchers' conduct of EDI and monitor progress. For example, researchers can use the tool as a checklist at the study design stage, and editors, funders, and reviewers (eg, peer reviewers of journals and funding panels) can assess and score the quality of EDI within submitted manuscripts and funding applications. We are collaborating with funding organisations, such as the NIHR, Cancer Research UK, and the Medical Research Council, for endorsement and future application of the tool. Lay members who sit on these funding panels can also apply the tool to assess EDI within applications. Support from journals, through medical and surgical editor groups such as the International Committee of Medical Journal Editors and the Surgery Journal Editors Group, will be essential to implementing the tool. We will also promote the tool through social media channels (eg, LinkedIn, X), charities and community events.

Through our co-design work with public contributors, we developed a plain English summary for lay members (supplementary file 15), along with proposed practical implementation strategies for interest holders, including researchers, funders, journal editors and reviewers, patients, and research institutions (table 3).

Reporting guidelines and future development

Guidelines are concurrently being developed to inform the reporting of health equity data by ourselves and others. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist has recently been expanded to include 10 equity specific domains for reporting in observational studies.[31] We are also developing EDI reporting guidelines (Standards for Reporting EDI, START-EDI) across multiple study types, such as diagnostic accuracy studies, clinical prediction models, and epidemiological and efficacy/effectiveness studies (including randomised controlled trials). The guidelines are intended to establish minimum standards to help the research community describe EDI methods or techniques in studies with human participants.[144 145]

The reporting guidelines and QUALITY-EDI are complementary: the reporting guidelines help reviewers decide what to report in a manuscript, and QUALITY-EDI retrospectively assesses the quality of conduct, assigning numerical scores ranging from 0 to 32. We hope that reporting guidelines will improve EDI across research and lead to higher scores. The QUALITY-EDI tool can also enable patients, families, and community advocates to assess whether research studies adequately consider their needs. Higher scoring studies are more likely to yield findings that benefit diverse communities, whereas lower scoring studies may miss essential differences in how treatments work across groups. By encouraging researchers to improve EDI practices, we aim to ensure that all patients benefit from medical advances, not just those who have traditionally been included in research.

This study represents early stage validation of the tool through reliability assessment. Future work

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Table 3 | Practical implementation guidance and considerations of QUALITY-EDI for interest holders

Interest holders	Practical implementation guidance and considerations	Notes
Practical implementation guidance		
Researchers	Apply the tool at three key stages: study design (use as a checklist to identify EDI considerations before finalising protocols); presubmission (self-assess manuscripts or funding applications before submission to identify gaps); and monitoring (regular evaluation of research practices within teams).	Analysis suggests that researchers can achieve important improvements in QUALITY-EDI score by acknowledging EDI context in their field (subdomains 1a and 1b); describing inclusive recruitment strategies (subdomains 2b and 3b); including basic demographic information beyond age and sex (subdomain 4a); budgeting for accessibility measures such as translation or transport support (subdomains 8a and 8b).
Funding organisations	Apply the tool during the assessment process: require QUALITY-EDI assessment in grant applications (particularly in applications above £50 000 (€58 300; $67 600)); set ideal minimum score thresholds (eg, 15/32 for large grants); provide funding for EDI activities identified through the assessment; use scores to identify applications needing EDI development support and provide feedback for improvement, rather than automatic rejection; and monitor EDI during funding period through progress reports.	Timeline: allow 4-6 additional weeks of development time for applicants to resolve EDI gaps identified during assessment if feasible.
Journal editors and reviewers	Peer review integration: include QUALITY-EDI assessment as part of standard peer review for human studies; train reviewers on EDI principles and scoring consistency; use scores to guide revision requests rather than rejection decisions; and recognise studies scoring ≥20/32 as examples of good practice.	Editorial policy: journals are recommended to establish EDI reporting standards and provide guidance to authors on improving their scores before resubmission.
Patients and public contributors	Research participation decisions: use the tool to assess whether proposed studies adequately consider their community's needs; ask researchers about their EDI approach during recruitment; and advocate for more inclusive study designs in PPIE activities.	Public contributors can use scores to highlight gaps in research funding and institutional practices.
Research institutions	Governance integration: include EDI assessment in research ethics committee reviews; provide training for researchers on using the tool; monitor institutional EDI performance through aggregate scoring; and recognise and reward high scoring research teams.	—
Quality assurance and monitoring		
Training and quality assurance	Consistent application of QUALITY-EDI requires appropriate training for different user groups. Development of the following is recommended: interest holder specific guidance (tailored materials for researchers, funders, editors, and public contributors); worked examples (detailed scoring rationales for studies across different quality levels); calibration exercises (regular opportunities for users to compare scoring and discuss differences); and quality assurance processes (mechanisms to monitor scoring consistency over time).	—
Scoring process	Independent scoring by two assessors with EDI training is recommended, taking about 20-30 minutes per study/funding application. Disagreements should be resolved through discussion using standardised guidance materials.	Addressing low scores: rather than penalising low scores, interest holders should treat them as development opportunities by providing resources and support to improve EDI practices. The ultimate goal is not perfect scores but meaningful progress towards more inclusive research that benefits all communities.
Monitoring progress	Regular reassessments using QUALITY-EDI can track improvements in research inclusivity over time, at both individual study and institutional levels.	—

EDI=equality, diversity, and inclusion; PPIE=patient and public involvement and engagement.

should also assess construct and convergent validity to help strengthen the tool. Construct validity can be evaluated by testing whether higher tool scores are associated with studies that demonstrate strong inclusive research practices. Convergent validity can be assessed by comparing the tool with emerging, equity focused, reporting guidelines (eg, STROBE-Equity or START-EDI), to assess alignment and determine whether the tool is measuring similar underlying concepts of EDI. We have developed a systematic approach, through three key stages, to ultimately ensure that the QUALITY-EDI tool becomes embedded in research practice (fig 2).

Limitations

The study had several limitations. The tool assesses the conduct of EDI, and does not directly assess actual equity outcomes or generalisability of studies. Although the tool includes objective components, it relies on subjective evaluation and was pilot tested by three researchers. A complete evaluation of the tool was not conducted in the broader literature or in selected studies with known varying standards of EDI reporting. Particular domains, such as patient and public involvement and budgeting for research inclusion, scored very poorly and, as a result, showed a high inter-rater reliability and percentage agreement among raters. Furthermore, the choice of descriptors applied for the inter-rater reliability assessment is arbitrary and the magnitude of κ is often influenced by the number of categories in the measurement scale.

In addition, we recognise that the authors of the studies may have undertaken activities covered by the tool (eg, an inclusive recruitment strategy or PPIE contribution) without specifically reporting them in their manuscript. We focused on peer reviewed literature for pilot testing and did not consider grey literature (eg, lay reporting, research dissemination, conference abstracts) and study protocols. Conducting and reporting on EDI are also likely to be more comprehensive in more applied, equity-focused studies, such as implementation science research. Finally, reviewers should consider the national context when assessing EDI, because regulations,

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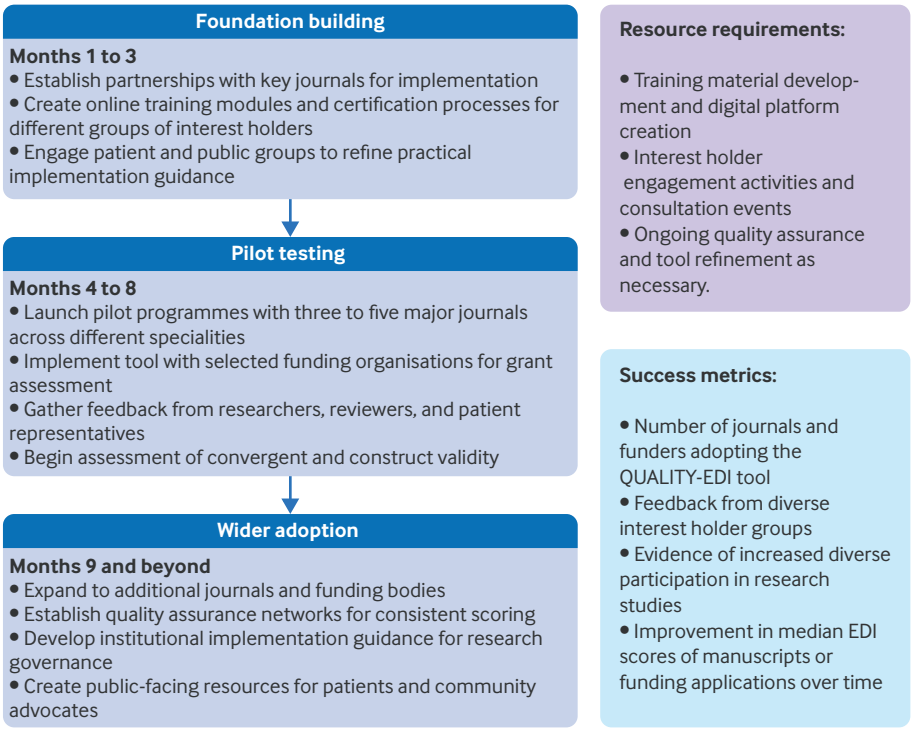


Fig 2 | Implementation strategy to embed QUALITY-EDI tool in research practice. EDI=equality, diversity, and inclusion

requirements, and research practices vary by country, potentially influencing reporting outcomes. For example, access to data on EDI characteristics can be restricted by national privacy laws and regulations, as well as by sensitivities associated with certain identities, particularly ethnicity and sexual orientation. The political landscape is also subject to change in the future, including EDI commitments related to funded health research and government programmes.

The QUALITY-EDI tool was also applied to this present study to help identify strengths and limitations (supplementary file 16), and scored 31 points (out of 32) after assessment. Study design (domain 2) received a score of three points out of four. Although the public representatives were from different areas of the UK, the EDI workshop was held in only one site (London, UK). Several workshops could have been held across different sites to further improve the study design. As an example, knowledge mobilisation (domain 5) obtained full scores as a plain English summary and practical implementation guidance was produced by public representatives, and a broad dissemination strategy to reach members of the public has been described. Regarding patient and public involvement (domain 7), two public representative leads were embedded as full members of both the working group and executive group throughout all phases of development, providing continuous public involvement that shaped methodology, tool design, and dissemination. As a result, this domain also obtained maximum scores.

Conclusion

The QUALITY-EDI assessment tool presented can be used to evaluate the quality of EDI implementation in healthcare research studies. It can be used by researchers and reviewers to formally and quantitatively assess published literature, or by funding panel members to evaluate EDI in submitted applications and identify high quality examples of EDI implementation and reporting. Researchers and funders can monitor the progress and compliance of EDI in research projects using the tool to identify issues and respond accordingly. The tool can also act as an implementation guide to improve EDI and support research teams with less experience in this area.

Our application of the tool to contemporary literature found that EDI implementation is not reported consistently and is sometimes absent, particularly in key areas including research design, data collection, analysis, PPIE, and dissemination. This inconsistency demonstrated the need to standardise EDI implementation and reporting to help researchers improve the quality and impact of their research. Designing and delivering research that includes under-served groups may provide further understanding of their specific health needs and health inequalities, ultimately leading to the development of more effective interventions, tests, and treatments. Enhancing representation in research could inform the development of policies and guidelines to resolve health inequalities and ultimately improve patient care.

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Ethical approval: The study has received ethical approval from the Imperial College London Research Ethics Committee (study ID 7592283).

Data sharing: The data that support the findings of this study are available on request from the corresponding author.

Patient and public involvement: Patients and the public were involved in the design, conduct, reporting, and dissemination plans of this research. See the methods and analysis sections for further details.

Dissemination to participants and related patient and public communities: To disseminate the new quality assessment tool, we are collaborating with funding organisations and journals. The tool will also be promoted through social media channels, charities and community events. See the discussion section for further details.

Transparency: The guarantor of the manuscript affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Supplementary material

Supplementary file 13: Microsoft Excel spreadsheet of the QUALITY-EDI assessment tool

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