

# Strategies for improving diversity, equity, and inclusion in cardiovascular research: a primer

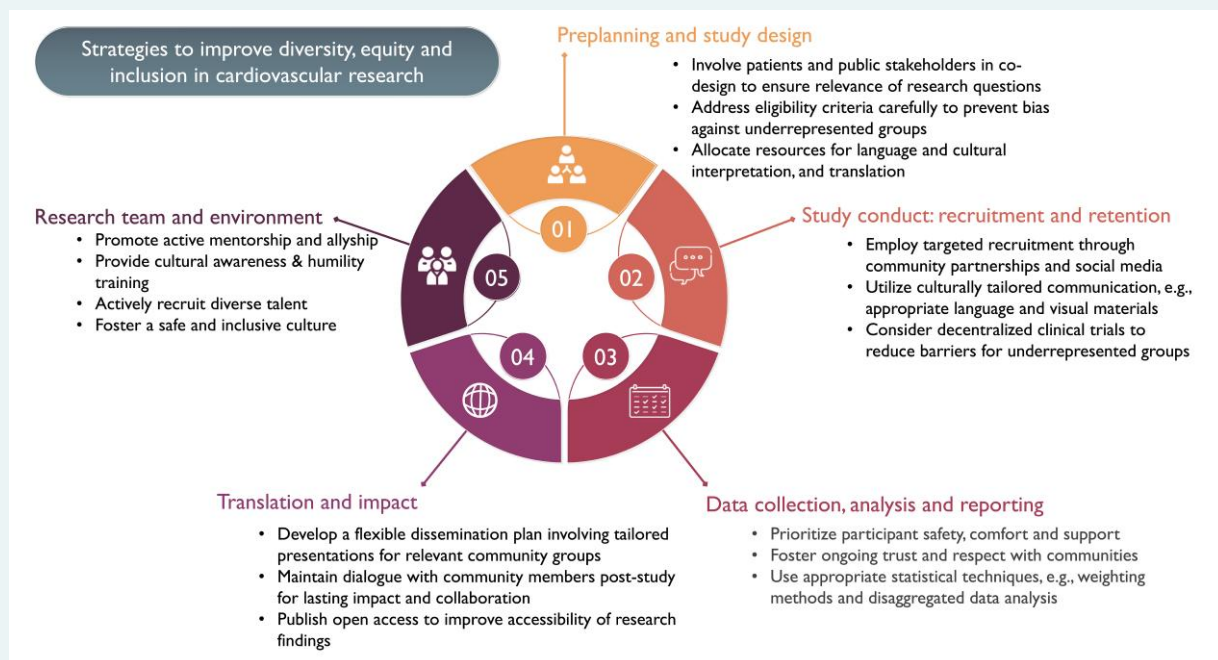
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This paper aims to empower cardiovascular (CV) researchers by promoting diversity, equity, and inclusion (DE&I) principles throughout the research cycle. It defines DE&I and introduces practical strategies for implementation in recruitment, retention, and team dynamics within CV research. Evidence-based approaches supporting underrepresented populations' participation are outlined for each research phase. Emphasizing the significance of inclusive research environments, the paper offers guidance and resources. We invite CV researchers to actively embrace DE&I principles, enhancing research relevance and addressing longstanding CV health disparities.

## Graphical Abstract



## Keywords

Cardiovascular outcome disparity • Cardiovascular trials • Diversity equity and inclusion • Research methods

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### Learning objectives

- Understand diversity, equity, and inclusion (DE&I) in the context of cardiovascular (CV) research and its impact on research findings, translation, and patient outcomes.
- Identify strategies that have demonstrated effectiveness in improving the participation of underrepresented population in CV disease research.
- Develop greater confidence to advocate for the application of strategies and practices presented in the paper to improve DE&I in CV research.

## The problem

Cardiovascular disease (CVD) is a prominent contributor to global mortality and morbidity, impacting people across diverse demographics. Nevertheless, cardiovascular (CV) research, including clinical trials, has traditionally fallen short in demonstrating inclusive practices for diversity, equity, and inclusion (DE&I), notably apparent in the underrepresented enrolment and poorly sustained engagement of underrepresented groups, including women and culturally and linguistically diverse populations.<sup>9–12</sup> Poor DE&I in clinical trials has been well-documented since the early 1990s, and despite many leading research funding bodies developing guidelines and policies mandating the inclusion of women and culturally and linguistically diverse populations in government-funded research,<sup>13</sup> representation of both groups in CV trials remains worse than other specialties.<sup>12,14</sup> A recently published review of 153 landmark CV randomized controlled trials (RCTs) from 1986 to 2019 (including over 1.1 million participants) revealed that only 56% of RCTs reported information about participant race.<sup>3</sup> The review also found that no significant improvement in inclusion of underrepresented racial and ethnic groups has occurred over time.<sup>3</sup> Race can have significant pathophysiological implications in CVD therapy as evidenced in the landmark African–American Heart Failure Trial (A-HeFT), which demonstrated a different response to standard heart failure therapy in African–American populations.<sup>15,16</sup>

An audit of five clinical trials listed on the *American College of Cardiology Top Clinical Trials for 2022*<sup>11</sup> underscores the persistency of the problem in that the majority of participants was Caucasian males, none of the trials clearly reported gender data, and some trials failed to report participant race (see [Supplementary material online, Table S1](#)). Although the proportion of transgendered or gender-diverse individuals (i.e. non-binary or genderqueer), is thought to be small (0.3–0.5% of the world's population), there is a growing need to understand how sex, gender, and gender dysphoria influence CV traits, ischaemic heart disease, and heart failure mechanisms.<sup>17</sup> How we choose to collect this data will influence how well we can identify and elucidate these links. Factors underpinning the continued deficit with regard to female participation include persistent historical and systemic bias in attitudes around the female hormonal profile and reproductive risk and the concurrent contradictory belief that women would have similar responses to drugs as men.<sup>14</sup> In addition, women make up only 10% of CV clinical trials leadership teams or are listed as first or last authors on clinical trial publications.<sup>18</sup>

Diversity, equity, and inclusion deficits in CVD research can also impact guideline development, with guidelines inevitably based on the extrapolation of results obtained in unrepresentative patient populations, potentially exacerbating pre-existing health disparities and hindering the development of effective prevention and treatment strategies for all those affected by CVD.<sup>9,10,19,20</sup> In turn, the makeup of CVD guideline authorship teams reflects disparity in the inclusion of women as chairs or members of guideline development committees. The evidence points to the fact that where women do lead in research teams and in translation, DE&I in participant recruitment and retention, as well as participation in guideline development, improve.<sup>19,21</sup>

The persistent DE&I deficit in CVD research requires a 'root and branch' approach with leadership required at every level of the research ecosystem from trial governance to guideline development. This methods paper is aimed at clinician–researchers who may find themselves

involved at various points in the CVD research cycle and collates evidence and strategies to improve DE&I, applicable at each stage.

## Moving towards a solution: strategies to improve diversity, equity, and inclusion in cardiovascular disease research

As clinician–researchers, we are uniquely placed to advocate for and have an ethical and moral responsibility to design, conduct, and implement research that ensures evidence-based CV care is representative and accessible.<sup>9</sup> Diversity, equity, and inclusion principles need to be incorporated throughout the research cycle, from conceptualization through to translation and knowledge exchange. To do this, it is important to become familiar with existing evidence-based strategies that focus on DE&I across the various phases of the research cycle ([Box 1](#)).

### Pre-planning and study design

Ensuring meaningful and relevant research for underrepresented communities necessitates early involvement of diverse patients, community members, and stakeholders in formulating research questions. One effective approach to achieve this is through research co-design processes.<sup>5</sup> Co-design emphasizes collaboration with the community and makes use of existing strengths and resources, fostering a sense of ownership.<sup>22</sup> Various frameworks and examples have been published that focus on different aspects of the participatory process.<sup>22–28</sup> By adopting a co-design framework, the community is actively engaged in the creation and development of new, innovative, and culturally tailored strategies that address identified problems.<sup>29</sup> Working within an identified co-design conceptual framework that fits the aims of the study is important. For example, Nesbitt and colleagues<sup>26</sup> utilized the user experience design framework (UX design) in the development of a web-based portal for cardiac rehabilitation. In a narrative review of previously published frameworks intended to facilitate lay participation in research, Greenhalgh and colleagues<sup>22</sup> identified a total of 56 resources. Their conclusion is that a universal framework that applies across the board may be less valuable than customizing a variety of resources that can be merged and tailored to the specific research context.<sup>22</sup>

Incorporating patient and community members as part of the research team yields numerous benefits. Firstly, it provides a valuable source of social support, allowing individuals to feel empowered and to actively participate in shaping the research agenda.<sup>30</sup> Additionally, involving community members helps to build trust and establish rapport between researchers and the community, facilitating culturally sensitive engagement throughout the research process.<sup>31</sup> The Australian Consumer Involvement and Engagement Toolkit, a recently published resource,<sup>32</sup> offers practical guidance on authentic partnership with patients and community members in clinical research.

Early planning and budgeting are required to resource the development of inclusive study materials and build partnerships with external community organisations. This aspect of the research planning phase can be daunting for clinician–researchers, and it is useful to access tools and guidance such as the Consumer Involvement Cost Calculator

### Box 1 Definition of key DE&I terms in the context of cardiovascular disease research

**Diversity** is the representation of a wide range of people with different backgrounds, identities, and perspectives in a particular group—in this case, cardiovascular disease (CVD) research participants, research teams, and those involved in research translation. Dimensions may include race, ethnicity, gender, sexual orientation, age, disability, religion, and socioeconomic status.<sup>1</sup>

**Equity** is about, justice, and equal opportunities. It is the recognition that different people may require different resources, support, or accommodations to achieve equitable CVD outcomes, ensuring that their identities do not dictate their access to opportunities in research participation.<sup>2</sup>

**Inclusion** refers to the behaviours and practices that ensure all individuals and groups are valued. It is about making sure participants are representative of the population the treatment or intervention is intended for and that the study results are meaningful and applicable to the target population.<sup>1</sup>

**Underrepresentation** happens when groups or individuals are not adequately or proportionately represented within a particular research setting. It often highlights the need for increased attention to the enhanced opportunities these groups may need to address imbalances and promote equitable participation.<sup>3,4</sup>

**Co-design** is a collaborative approach to cardiovascular research that involves including diverse stakeholders, and people affected by cardiovascular conditions, in designing the proposed research-based solutions. It can be used to address potential barriers that hinder effective research translation across underrepresented groups.<sup>5</sup>

**Culturally tailored communication** involves adapting messages, materials, or strategies to effectively reach and resonate with specific groups. It involves recognizing the cultural norms, values, beliefs, and linguistic preferences of the target audience to ensure that research communication is culturally appropriate, sensitive, and relatable.

**Decentralized clinical trials (DCTs)** leverage remote data collection, allowing participants to complete study requirements from home while still being closely monitored. They can potentially address barriers to diversity, patient participation, and accessibility in the clinical trial recruitment and retention.<sup>6</sup>

**Targeted recruitment** research refers to the deliberate and strategic efforts made to identify and enrol participants from specific demographic or population groups into research studies.<sup>7</sup>

**Community engagement** involves proactive and ongoing collaboration with the communities being served throughout all phases of the research cycle. It requires bidirectional communication, with researchers listening to and learning with the community.<sup>8</sup>

provided by the Australian Clinical Trials Alliance. Clinician–researchers need to be able to advocate for sufficient funding to enable deployment of DE&I strategies and translation of findings back to target groups.

Table 1 provides DE&I strategies and evidenced-based examples for the pre-planning and study design phases.

### Study conduct: recruitment and retention

To ensure that underrepresented populations have an equal opportunity to participate in clinical research, researchers must carefully consider the eligibility criteria.<sup>45</sup> Subjective eligibility criteria that rely on clinician judgement (e.g. a participant's perceived ability to provide informed consent or comply with study procedures) that is likely to disproportionately affect people from underrepresented groups should be avoided. Instead, the use of objective assessments, such as diagnostic tests or biomarker measurements to determine eligibility, may be more appropriate in some circumstances.<sup>45</sup> Cognitive ability can be objectively assessed using an appropriate tool, or a diagnosis of major cognitive impairment may be found in the medical record. But every exclusion criterion need to be scientifically justified and those included as participants should reflect the larger group of all those affected by

the researched disease or condition. For example, cognitive impairment is highly prevalent in heart failure, yet many studies still exclude these patients.<sup>46,47</sup> Including underrepresented groups may require concerted efforts from the research team to successfully recruit and safely retain representative cohorts.

Targeted recruitment strategies, such as partnering with community organisations or using social media platforms to reach underrepresented populations, have been successfully deployed in several studies.<sup>48,49</sup> Ensuring culturally tailored communication strategies includes making sure that the language and visual materials developed in information documents and in interventions are culturally appropriate and relevant.<sup>50,51</sup> Researchers can then use materials that are relevant and resonant with underrepresented populations to communicate the goals, procedures, and potential benefits and risks of the study. Approaching potential participants in places in which they are already active, particularly in settings that are familiar and comfortable to them, and providing incentives relevant to them and their community have also been found to encourage participation.<sup>52</sup> Decentralized clinical trial methods that leverage digital technologies to reduce the need for participants to travel back to the study centre frequently could also be used to address barriers faced by some underrepresented groups.<sup>6</sup>



Cultural sensitivity during recruitment could include considering the role of family. In Western culture, privacy and patient confidentiality often require that healthcare professionals (HCPs) talk with the patient alone, but in many cultures, the family is part of the decision-making processes. Asking consent for potential participant to take part in a research programme may be a 'family business' rather than a lone decision to be made by the potential participant. You will more often be directed to 'ask my wife or my partner or my son or my daughter' for consent. Some cultures are collectivist in orientation, and potential participants may be more receptive when the benefits of the research are not only for the individual but also for the family and the community at large. For example, some Asian people view self as an extension of significant others and as such they are all included in the discussion about important matters such as participating in a clinical trial.<sup>53</sup>

**Table 1 Pre-planning and study design**

Strategies	Examples in CVD research
Identify community leaders, gatekeepers forming steering committees. Partner with community organizations to build long term community-based relationships and trust. <sup>33</sup>	Partnership Program to Reduce Cardiovascular Health Disparities: health service with predominately underrepresented patient population partners with a research centre with strong a track record. Cultural competence and sensitivity, along with inclusion of physicians, nurses, and staff from diverse backgrounds, helps build trust with patients, enhancing recruitment and retention. <sup>34</sup>
Establish diverse community advisory panels and community partnerships for ongoing input into the research process. <sup>33,35</sup>	Co-design is an emerging field in CVD research—which can inform the complete research cycle.
Engage patients and other stakeholders early in the design process to ensure that interventions are tailored to needs/preferences.	Co-design frameworks reported in CVD research include the following:
Use co-design framework to guide design process and ensure interventions are developed using co-design methodology.	(1) Behaviour Change Wheel <sup>23</sup>
Be flexible and adaptable as the needs and preferences may change over time.	(2) Social cognitive theory <sup>24</sup>
Use a range of co-design activities, such as focus groups, co-design workshops, and advisory group meetings, to engage patients and other stakeholders in the design process. <sup>4</sup>	(3) Medical Research Council (MRC) framework <sup>25</sup>
Simplify study protocols and procedures to reduce burden on participants and test study materials for cultural sensitivity. Provide language interpretation services and translated materials. <sup>33</sup>	(4) Ophelia approach <sup>27</sup>
Identify barriers to recruitment and retention of target subgroups and design study elements specifically to address them. <sup>38</sup>	(5) Integrated knowledge translation theoretical approach <sup>28</sup>
Setting appropriate recruitment targets—adequately powering the trial. <sup>9</sup>	(6) User experience <sup>26</sup>
A well-designed trial ensures representative enrolment [where the ratio of trial participants to the prevalence of the disease among different demographic groups (prevalence ratio, PPR) is between 0.8 and 1.2] which helps to provide accurate estimates of treatment effectiveness and subgroup differences. <sup>38</sup>	Use social media to improve patient and public involvement (PPIE). Closed Facebook groups can be used to establish and facilitate feedback on aspects of your project. This approach enabled researchers investigating CVD risk communication in the UK to increase the size, diversity, and impact of a pool of potential PPIE participants. <sup>36</sup>
Seek race/ethnicity/sex/age-specific data from existing databases that aggregate information from multiple trials or registries. <sup>9</sup>	Translation of cardiac rehabilitation (CR) materials into Mandarin. Establish a four-phase process to develop and translate evidence-based CR materials, culturally validated for natives and immigrants:
	(1) Preparation
	(2) Translation and adaptation
	(3) Review by healthcare providers based on Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P)
	(4) Think-aloud review by patient partners
	(5) Finalization <sup>37</sup>
	Increasing participation of women in CVD research
	(1) Address deficient care and referral patterns by increasing awareness among healthcare providers about the importance of women's participation in clinical trials.
	(2) Use novel recruitment approaches like social media, internet forums, email, apps, and text messaging.
	(3) Address financial and caregiver barriers, distance to study site, etc.
	(4) Improve cultural sensitivity and communication style of the research team.
	(5) Address concerns about risk, mistrust, and lack of awareness among potential participants. <sup>38</sup>
	Consider decentralized approaches that leverage remote digital monitoring to reduce burden of trial participation. <sup>6</sup>
	Identifying differences in effect of sacubitril–valsartan vs valsartan in women compared with men.
	Subgroup of interest (in this case women) is pre-specified and of sufficient size. Statistical test for interaction is carried out, to establish if an interaction between sex and the effect of treatment persisted in multivariable analysis which included all pre-specified subgroups.
	This approach allowed study to identify a greater treatment effect on heart failure hospitalization in women than men. <sup>39</sup>
	No drug-eluting stent (DES) trials prior to 2013 were powered to assess the safety and efficacy of DES in women because only a small proportion of recruited participants were women. This paper therefore used pooled analysis of 43 904 patients to investigate their safety and efficacy in women. <sup>40</sup>
	The PLATINUM Diversity Study prospectively enrolled patients receiving everolimus-eluting stents who identified as female, black, Hispanic/Latino, or American Indian/Alaskan Native and compared their 12-month outcomes with that of white men. Social determinants of health data, such as

Continued

**Table 1 Continued**

Strategies	Examples in CVD research
Use existing registries to identify underrepresented participants. <sup>42</sup>	healthcare access, living conditions, socioeconomic status, exercise habits, substance use, and language barriers, were also collected. <sup>41</sup> Retrospective and prospective registries can be used to identify subgroup variation in treatment and outcome (e.g. EURObservational Research Programme— <a href="https://www.escardio.org/Research/Registries-&amp;-surveys/Observational-research-programme">https://www.escardio.org/Research/Registries-&amp;-surveys/Observational-research-programme</a> ). Insights from the global anticoagulant registry in the FIELD-Atrial Fibrillation (GARFIELD-AF). <sup>43</sup> Sex differences in AF treatment and outcomes between men and women. <sup>44</sup>

**Table 2 Examples: study conduct—recruitment and retention**

Strategies	Examples in CVD research
Using targeted recruitment strategies, such community outreach events and CVD health fairs. Having a research presence at community events. <sup>33,48,49</sup>	Community-based, RCT pilot trial of a CV mobile health intervention, demonstrating feasibility of mobile health intervention building on partnership between researchers and African–American faith communities. <sup>54</sup>
Improving cultural competency and sensitivity of all clinical trial staff through training and ongoing personal development. <sup>33</sup>	Zhu <i>et al.</i> <sup>55</sup> recommend rebuilding trust through improving cultural competency and humility in CVD clinical trial leadership and frontline teams to address the under-enrolment of Black, Indigenous, and People of Colour (BIPOC) participants.
Providing transportation or carer support for participants who may face logistical barriers to participation. <sup>33</sup>	Addressing logistical barriers to participation in research—example from the 'Getting There': Transportation as a Barrier to Research Participation among Older Adults. <sup>56</sup>

**Table 3 Data collection, analysis, and reporting**

Strategies	Examples in CVD research
Consider the impact of culturally and gender-mediated responses in your questionnaires and surveys and in study design.	Cultural and gender influences on quality of life in chronic heart failure and addressing cultural and gender-mediated responses in self-care behaviours and relationships. <sup>67</sup> Digital health tools for First Nations heart health, needed to integrate Western and Indigenous healing approaches. Importance of considering both perspectives essential for effective 70 comprehensive heart health and wellness support. <sup>60</sup>
Use weighting methods to adjust for bias in the sample.	Data from the Atherosclerosis Risk in Communities (ARIC) study demonstrate the importance of weighting methods to correct for pre-hospital mortality bias, addressing a common bias in CVD research that can exclude sicker more diverse populations. <sup>64</sup>
Use disaggregated subgroup data analysis. Include sex-specific details at all study stages. Test for interaction between sex and the intervention. Address the implication of sex on results. Explain the rationale if no sex-specific analyses were conducted. <sup>65</sup>	This review of 224 heart failure RCTs (2000–2020) with 228 801 participants (28.2% female) found none reported sex-specific screening, consent, withdrawal rates, or adverse events, underscoring the urgent need for better consideration of sex differences in trial outcomes. <sup>65</sup>
Collect both sex at birth and gender identity data. <sup>33</sup>	Disparities across several cardiovascular risk factors among LGBTQ adults have been identified, and this American Heart Association statement provides a useful glossary of terms which moves towards standardized sexual orientation and gender identity measures that can be integrated in CVD research. <sup>68</sup>
Report effect sizes and confidence intervals to help identify meaningful differences across subgroups in meta-analysis, and determine sample sizes for new studies. <sup>69</sup>	Improving the study design, analysis, and completeness of reporting of sex in cardiac resynchronization therapy cohort studies. <sup>70</sup>

**Table 4 Translation and impact**

Strategies	Examples in CVD research
Seek feedback from communities and participants to help build trust and engagement with interventions and/or new therapies.	Process Evaluation of Strong Hearts, Healthy Communities: A Rural Community-Based Cardiovascular Disease Prevention Program. <sup>74</sup>
Make results accessible to communities by engaging in a two-way dialogue from planning to implementation. <sup>73</sup>	Community-based participatory research (CBPR) approach used to develop innovative cardiovascular health (CVH) and wellness digital application (FAITH! app) co-designed with African–American community members after extensive piloting. <sup>54,75</sup>
Share data via community-based means (e.g. town halls meetings, newsletters, video summaries, and social media). <sup>75</sup>	Closed Facebook groups can also be used to support ongoing dialogue. <sup>36</sup>
Publish in open-access journals	This requires funding, and care must be taken to avoid predatory journals operating in CVD research. <sup>76</sup>
Advocate for female and diverse membership of guideline development committees and writing groups.	Women hold only 10% of leadership roles in CVD research and guideline development teams. <sup>18</sup> But when women lead in these spaces, DE&I in recruitment and guideline development improve. <sup>19–21</sup>

**Table 5 Research team and research environment**

Strategies	Examples in CVD research
Increase recruitment of staff from targeted under-served groups. <sup>33</sup>	Matching research team composition with targeted populations, this study recruited equal numbers of Indigenous and non-indigenous participants to a 'pollypill' RCT. <sup>80</sup>
Research staff should receive cultural competency training and recruitment encouraged from under-served communities. <sup>33</sup>	Zhu et al. <sup>55</sup> argue that addressing diversity obstacles in CVD trials requires countering distrust from structural racism and prioritizing participant concerns. Solutions involve integrating cultural competence and humility in leadership teams, design, and implementation. Diverse, culturally competent trial leaders enhance research practices, increasing diversity in participant recruitment and co-authorship.
Provide working parents, women, and individuals from other under-represented groups additional support. <sup>78</sup>	Supporting capacity building and research funding and fostering diversity and equity for CVD researchers. <sup>78</sup>

Table 2 provides DE&I strategies and evidenced-based examples for the study recruitment and retention phases.

### Data collection, analysis, and reporting

Ensuring participant safety and comfort during data collection is crucial. This involves providing DE&I and cultural awareness training to research staff and maintaining engagement with community members to build ongoing trust and mutual respect. Special attention is needed for populations with historical grievances, such as First Nations.<sup>57–59</sup> Community voices and Indigenous knowledge should be prioritized and meaningful partnerships established.<sup>58,60</sup> Using a framework such as community-based participatory research can be used to support knowledge sharing that prioritizes lived experience and places community voices at the centre of the partnership.<sup>61</sup> Where appropriate, and under the leadership of community and/or First Nations research partners and elders, the incorporation of Indigenous research methodologies, such as Two-Eyed Seeing, Yarning, or Storytelling, can be considered for data collection.<sup>57,62</sup>

When working with culturally and linguistically diverse populations, translating study materials requires careful consideration. Colloquialisms and English terminologies may lack equivalence in other languages, emphasizing the need for briefings with translation experts and consultations

with culturally congruent community members to ensure accurate interpretation during data analysis.<sup>63</sup>

For quantitative data analysis, researchers should employ statistical techniques, including weighting methods to address sample biases<sup>64</sup> and should include analysis of disaggregated data, to help identify disparities and patterns across subgroups.<sup>65</sup> Considering the impact of multiple intersecting identities on health outcomes can require sophisticated statistical approaches to account for complex interactions between social identities and health outcomes. These might include multiple main effects, statistical interactions, and multilevel modelling, to explore the additive, multiplicative, and multilevel effects of intersecting identities on CV outcomes.<sup>66</sup> This is particularly relevant when considering sex-specific and gender-based disparities in outcomes where intersecting social determinants may be particularly impactful.<sup>12</sup> Embedding these methods early in the study design phase is also crucial.

Reporting results explicitly so that the demographic characteristics of your study participants are clearly outlined and variations in study outcomes across different demographic groups are highlighted is important. This should include recognition of intersecting identities (e.g. race, gender, and sexual orientation) and their influence on study outcomes where possible.<sup>66</sup>

Table 3 provides DE&I strategies and evidenced-based examples data collection and analysis phases.

**Table 6** Guidance on diversity, equity, and inclusion principles in research development

Organization	Resource name	Web page	Description
National Institute for Health and Care Research (UK)	Improving inclusion of under-served groups in clinical research: guidance from the INCLUDE project	Improving inclusion of under-served groups in clinical research: <a href="https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#for-the-nihrinclude-guidance-general">https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#for-the-nihrinclude-guidance-general</a>	Definitions/examples of barriers to inclusion/questions to inform research design and conduct.
National Institute for Health and Care Research (UK)	INCLUDE Ethnicity Framework	Ethnicity Framework: <a href="https://www.trialforge.org/trialforge-centre/include/">https://www.trialforge.org/trialforge-centre/include/</a>	Improving recruitment and retention of people from diverse ethnic and cultural backgrounds.
Multi-Regional Clinical Trials (The MRCT centre of Brigham and Women's Hospital and Harvard) (USA)	Achieving Diversity, Inclusion, and Equity in Clinical Research	Guidance and Toolkit: <a href="https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/">https://mrctcenter.org/diversity-in-clinical-research/guidance/guidance-document/</a>	Provides practical and actionable ways to improve diverse representation of participants in clinical research.
Multi-Regional Clinical Trials (The MRCT centre of Brigham and Women's Hospital and Harvard) (USA)	Using plain language in research documents	Plain Language in Clinical Research: <a href="https://mrctcenter.org/health-literacy/tools/overview/plain-language/#readability">https://mrctcenter.org/health-literacy/tools/overview/plain-language/#readability</a>	Guide to using plain language in clinical research including tool to test the readability of trial documents.
European Patients' Academy on Therapeutic Innovation (Europe)	Patient engagement	Enhanced European Patients' Academy on Therapeutic Innovation Guide for Patient Engagement: <a href="https://toolbox.eupati.eu/resources/patient-toolbox/enhanced-eupati-guide/">https://toolbox.eupati.eu/resources/patient-toolbox/enhanced-eupati-guide/</a>	Checklist designed to help teams in planning patient engagement activities.
American College of Cardiology (ACC) (USA)	ACC Diversity and Inclusion Initiative	<a href="https://www.acc.org/About-ACC/Diversity-and-Inclusion/Resources-and-Tools">https://www.acc.org/About-ACC/Diversity-and-Inclusion/Resources-and-Tools</a>	Diversity and inclusion tools and educational materials.
National Health and Medical Research Council (Australia)	Actions taken towards gender equity	Gender equity: <a href="https://www.nhmrc.gov.au/research-policy/gender-equity">https://www.nhmrc.gov.au/research-policy/gender-equity</a>	Timeline of progress on gender equity in research funding.
National Institute of Health (NIH) (USA)	Diversity matters	Promoting diversity in the research workforce: <a href="https://extramural-diversity.nih.gov/diversity-matters">https://extramural-diversity.nih.gov/diversity-matters</a>	Building pool of talented scientists from diverse backgrounds who will help to further NIH's mission.
Equality, Diversity and Inclusion in Science and Health (UK)	Diversity and inclusion survey question guidance	Diversity and inclusion survey question guidance—working draft V2: <a href="https://edisgroup.org/wp-content/uploads/2022/05/DAISY-guidance-current-updated-May-2022-V2.pdf">https://edisgroup.org/wp-content/uploads/2022/05/DAISY-guidance-current-updated-May-2022-V2.pdf</a>	Guidance to improve the quality of quantitative survey data collected relating to equality, diversity, and inclusion.
US Food and Drug Administration (USA)	Enhancing the diversity of clinical trial populations	Eligibility criteria, enrolment practices, and Trial Designs Guidance for Industry: <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial</a>	Practical advice on inclusive trial design and trial practices to increase diversity in clinical trial populations.
Australian Clinical Trials Alliance and CT:IQ (Australia)	Consumer Involvement and Engagement Toolkit	<a href="https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/">https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/</a>	Guidance on authentic partnership with patients and community members in clinical research.

## Translation and impact

The translation and implementation of research into practice is a critical part of the research process with the persistent 17-year gap between research and translation further entrenching DE&I deficits in CVD outcomes.<sup>71,72</sup> To address this, a flexible research dissemination plan might include developing tailored presentations to participating community groups, establishing a point person to serve as a community liaison, and a continuing dialogue with community members after the study.<sup>73</sup> The principles of co-design and community participation discussed earlier

can accelerate community uptake of research findings through feedback and consultation processes. Communicating research findings back to key participants and community leaders helps build trust, accelerates uptake of evidence-based research findings, and sets the scene for future collaborations.<sup>73</sup> Fostering this dialogue, particularly with populations that are historically mistrustful of research, aids in both developing culturally relevant interventions and improving uptake of relevant research findings.

Table 4 provides DE&I strategies and evidenced-based examples for the reporting, translation, and impact phases.

## Box 2. Adapted from the National Institute for Health and Care Research, Guidance from the INCLUDE project (2020).<sup>81</sup>

### Checklist to Guide Research Teams in Designing and Delivering Inclusive Research:

- (1) What are the characteristics/demographics of the population which your research looks to serve?
- (2) How will your inclusion/exclusion criteria enable your trial population to match the population that you aim to serve?
- (3) Can you justify any difference between your projected trial population and the population you aim to serve?
- (4) How will your recruitment and retention methods engage with underrepresented groups?
- (5) What evidence have you that your intervention is feasible and accessible to a broad range of patients in the populations that your research seeks to serve?
- (6) Are your outcomes validated and relevant to a broad range of patients in the populations that your research seeks to serve?
- (7) Who are the underrepresented groups within your study catchment area? (e.g., geographical areas that the delivery team operates in)
- (8) What are the barriers to including these groups in research in our area?
- (9) What actions can we take to overcome those local barriers?
- (10) What tools, training and resources does your team need to implement these actions successfully?

## Research team and research environment

A key driver of diverse, equitable, and inclusive research is the makeup of the investigator team.<sup>77</sup> Recent findings from a systematic bibliometric review highlight that trials led by women are more likely to enrol diverse participants and report race and ethnicity.<sup>21</sup> But tackling the DE&I climate within a research team or institution requires an active stance from senior leadership and mentoring of staff from underrepresented groups, along with the promotion of ally behaviours amongst existing staff.<sup>78,79</sup> As clinician–researchers, practical steps to promote diversity and inclusion in our workplaces include engaging in DE&I training, staying informed about research on organizational diversity and discrimination, endorsing ally behaviours (such as advocating for and attending DE&I events), reflecting on personal biases, and cultivating diverse social support.<sup>79</sup>

Table 5 provides DE&I strategies and evidenced-based examples regarding the research team and environment.

## Additional resources

Table 6 provides a summary of available resources from international peak bodies and organisations that support a greater understanding and adoption of DE&I strategies in research. Box 2 provides a practical checklist researchers can use when designing and delivering inclusive research.

## Conclusion

Addressing persistent deficiencies in DE&I in CV research requires action across the entire research continuum, from the inception of study

concepts to the dissemination of findings. In the pre-planning and study design phase, early engagement with patients and community stakeholders helps to ensure research objectives are aligned with real-world healthcare needs. During the execution of studies, meticulous attention to eligibility criteria, the inclusivity of study materials, and the implementation of targeted recruitment strategies, such as forging partnerships with community organizations and employing culturally tailored communication approaches, becomes pivotal. Finally, advocating for sufficient resources to implement DE&I practices, prioritizing funding for research initiatives explicitly dedicated to DE&I, and improving diversity in journal peer review processes and editorial boards will enhance the translation and impact of research outcomes. Underpinning success is also the cultivation of diverse and inclusive research teams and environments to support the effective recruitment and retention of underrepresented participants. In summary, the advancement of DE&I principles at every stage of the research cycle is a responsibility shared by researchers, institutions, and funding entities alike. This collective commitment is essential for substantial progress towards achieving equitable CVD health outcomes.

## Supplementary material

Supplementary material is available at *European Journal of Cardiovascular Nursing* online.

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## Data availability

All data are incorporated into the article and its online supplementary material. The data underlying this article are available in the article and in its online supplementary material.

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