# Where are the women? Fixing the broken pipeline in cardiovascular research

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# For most of history, Anonymous was a woman. – Virginia Woolf

In this well-known quote from her 1929 essay, Virginia Woolf reflects on why women were absent among authors of influential works. While her words refer to the historical erasure of women's voices in literature, they remain relevant a century later to the field of cardiovascular research, where women continue to be under-represented.<sup>1</sup>

Enrolment of women in major cardiovascular randomised clinical trials has increased over time, from 21% in 1986-1990 to 33% in 2011-2015.2 While this represents progress in the right direction, it remains inadequate, as enrolment continues to fall short of the proportion of women in the disease population-a disparity quantified in the literature as the participation-to-prevalence ratio. For example, women with heart failure constitute 55% of the disease population but account for only 28% of trial enrolment.<sup>2</sup> Women have also been under-represented in certain areas of cardiology, including research related to ischaemic heart disease, arrhythmias, valvular heart disease and procedural interventions.<sup>1</sup> An analysis of research presented at major cardiovascular meetings in 2021 demonstrated that low female inclusion persists for late-breaking clinical trials, with 30% of trials enrolling fewer than 25% women.<sup>3</sup> Outcomes from these male-dominated cohorts influence the cardiology clinical guidelines globally, yet there is a lack of evidence regarding their applicability to half of our patient population.

Kunadian *et al*<sup>4</sup> put forward a consensus statement on behalf of the British Cardiovascular Societies and the British Heart Foundation Clinical Research Collaborative with the aim of (1) describing the current state of female participation in cardiovascular research across the

Correspondence to Dr Martha Gulati; martha.gulati@csmc.edu disease spectrum, (2) identifying barriers to research participation by females and (3) proposing actionable strategies to enhance female participation in cardiovascular research. The authors discuss female representation in research related to cardiovascular risk factors, female-specific conditions, coronary artery disease, valvular heart disease, heart failure, cardio-oncology, arrhythmias, congenital heart disease, inherited conditions, cardiac surgery, cardiac rehabilitation and cardiovascular imaging. Across all of these domains in cardiology, the question remains: where are the women?

Previous statements have postulated that contributors to limited participation of women in research exist at multiple levels, ranging from individual patients and clinical care teams to local research team, clinical trial infrastructure and broader societal factors.<sup>56</sup> Similarly, Kunadian *et al* describe the complex barriers related to socioeconomic, psychological and biological factors and propose actionable strategies with a focus on several key areas, including partnerships with community organisations, awareness via public health campaigns and structural-level interventions.

Barriers at the individual patient level may include a lack of research awareness, transportation challenges, caregiver responsibilities and external influences on decision-making to enroll in a study. Addressing these challenges requires reducing logistical barriers and exploring novel recruitment and retention strategies, including the use of digital technologies and artificial intelligence. Providing flexible or remote visits, offsetting hidden costs, incorporating pragmatic follow-up and offering education in a linguistically appropriate and culturally sensitive manner are some potential solutions.<sup>7</sup> Overall, understanding the factors that influence a woman's willingness to participate in clinical trials, which may be influenced by cultural and societal norms, is essential to effectively address each of them.

Partnerships with primary care practices, community organisations and public health campaigns can help broaden outreach efforts as these are often the first point of contact for patients. Raising awareness at the provider level can facilitate appropriate referral for clinical trials. Furthermore, meeting patients at local community sites and developing strong relationships with community leaders who can serve as ambassadors can cultivate trust in the research enterprise and improve engagement.<sup>8</sup>

The lack of representation of women at the clinical trial leadership level remains striking and contributes to the low enrolment of female participants in research. Studies have shown that clinical trials led by a woman as first or senior author are associated with a higher proportion of enrolled female participants.9 To address this disparity, greater diversity is needed in trial and site investigator leadership, requiring systemic changes at the level of funding agencies, industry, government sponsors and regulatory bodies. These entities, which hold significant influence, must step up and mandate diverse trial leadership. They also need to hold trialists accountable for reporting sex-specific results and ensuring a proportional level of female enrolment. Increasing diversity in leadership can foster trust among participants, help address cultural barriers and provide a degree of familiarity and comfort that enhances retention. To have more representation of women in trial leadership, institutions and professional societies must take on the obligation to support mentorship, sponsorship, compensation and career advancement.

Representation of women in clinical research is also influenced by age and sex-specific factors such as pregnancy. Older adults are often under-represented in trials,<sup>10</sup> which exacerbates the under-representation of women, who are more likely to be older when developing certain cardiovascular diseases. Women of childbearing age are also frequently excluded from studies, creating a barrier to understanding sex-specific conditions. Addressing these barriers requires the design of more inclusive criteria and eliminating sex-specific exclusion criteria.<sup>11</sup>

Kunadian *et al* also provide perspectives from a diverse range of stakeholders involved in the scientific enterprise, including trainees, nurses and cardiac physiologists. This highlights the philosophy that research and the advancement of knowledge are not solely controlled by one domain but require team effort from the entire healthcare community. A diverse research staff can significantly contribute to recruitment and retention efforts. To improve female representation in cardiovascular studies, awareness



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**Figure 1** Central illustration highlighting the broken pipeline in cardiovascular research and solutions for the broken pipeline that span changes at the level of trial design, trial recruitment, trial reporting, trial team and trial retention.

and involvement from all stakeholders are essential. In this consensus statement, the authors also include a section on incorporating the patient perspective; this is important as including the patient voice through the research process can be influential, and soliciting feedback from women participating in trials can inform future efforts.

Only by including women in studies can we effectively extrapolate results to half of the population we care for on a daily basis and enhance our understanding of sex-specific pathophysiology. Moving the needle on female participation will necessitate collaborations and transformative changes across all levels of the research process, from trial design to trial recruitment to trial reporting and to the trial team (figure 1). Kunadian et al should be applauded in their collaborative efforts to challenge the status quo and propose a multifaceted approach to address disparities. However, recognition alone is not enough-without decisive and bold actions to implement these solutions, we risk continuing to render women anonymous in cardiovascular research.

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