Baim Institute for Clinical Research

Clinical Trial Leadership: Where are the Women?

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Women are Still Underrepresented in Cardiovascular Clinical Trials

Although legislation passed in the 1980s and 1990s mandated the inclusion of women in clinical trials:

Women represented less than

39%

of cardiovascular clinical trial participants between 2010 - 2017

Participation prevalence ratios are 0.48 - 0.78

for trials in heart failure, acute coronary syndrome, coronary heart disease, stroke, and arrhythmia (PPR of <0.8 indicates underrepresentation in relation to disease prevalence).

This under-representation

LIMITS THE POTENTIAL

for developing sex-specific strategies and recommendations for cardiovascular disease in women

Jin X et al., Circulation, 2020.

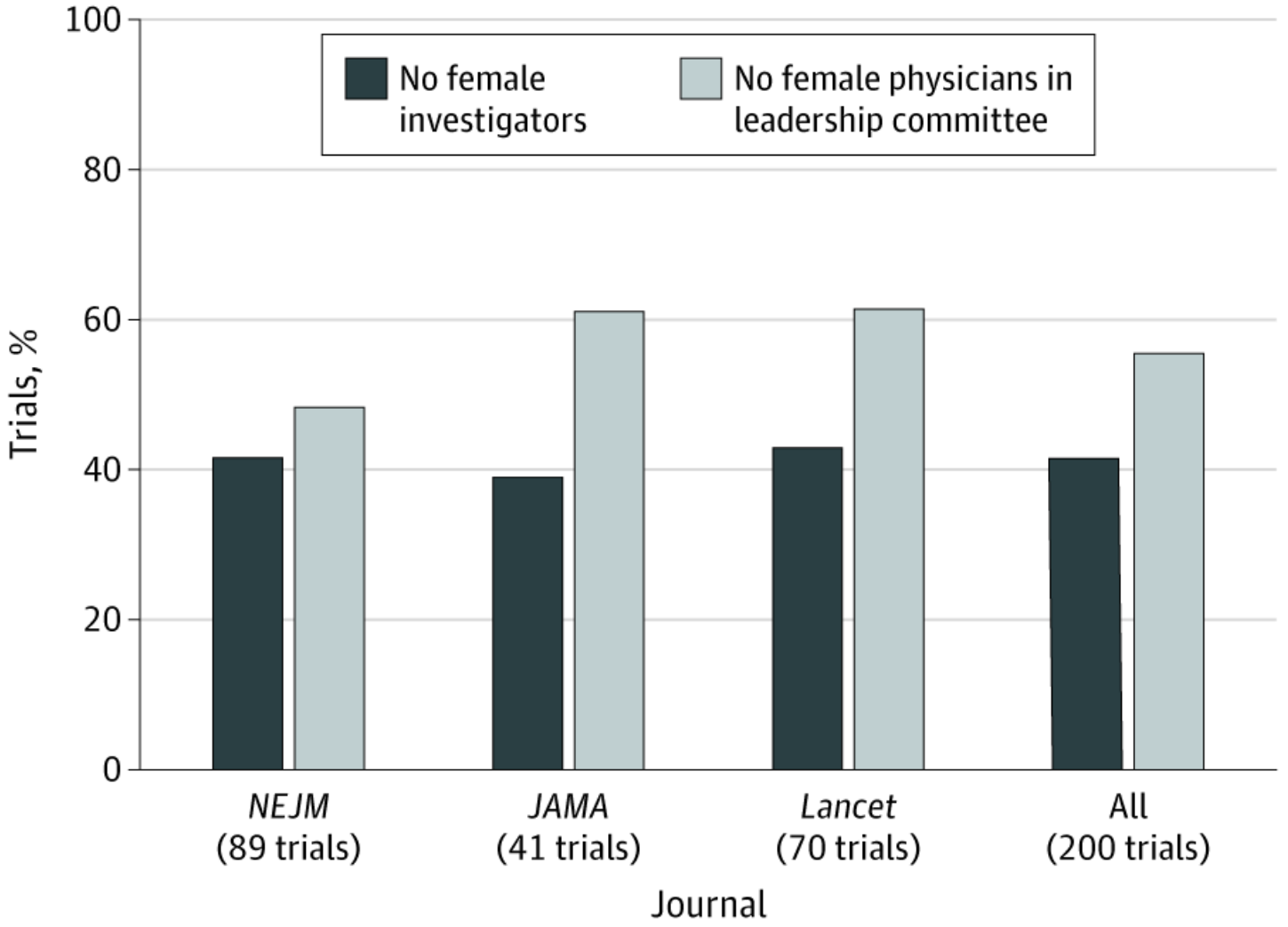
Women Are Under-Represented as Trial Leaders in CV RCTs
2014-2018, 200 RCTs, 2433 executive committee members

9% of first authors
10% of last authors

42% of trials = no women investigators

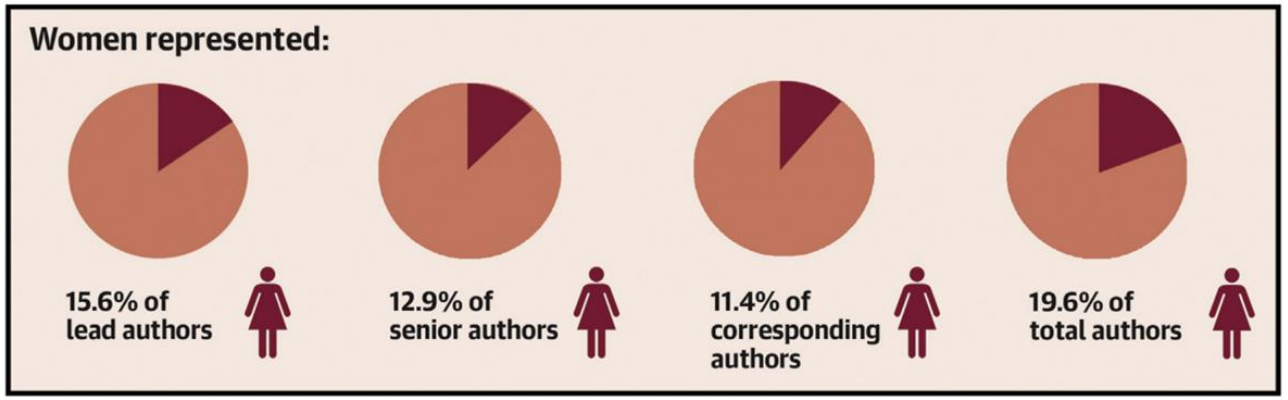
56% of trials = no women trial executive committee members

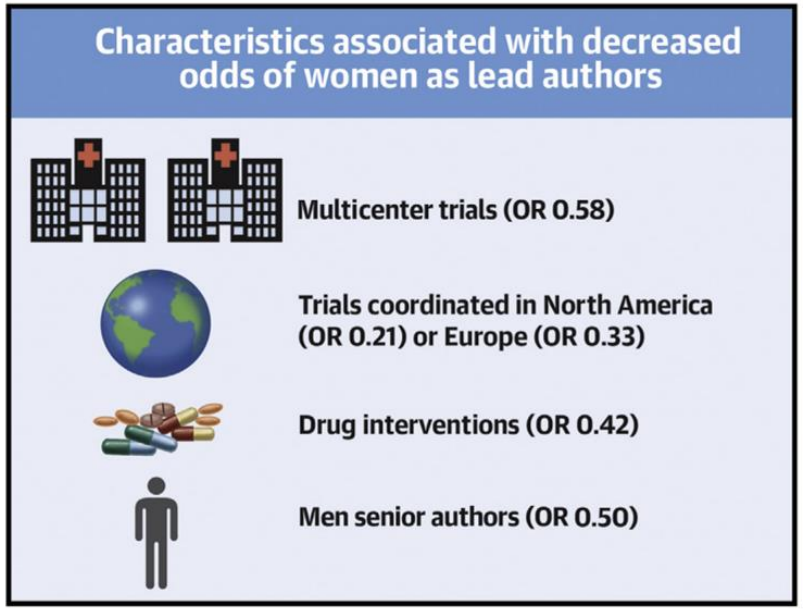
11% of trial executive committee members

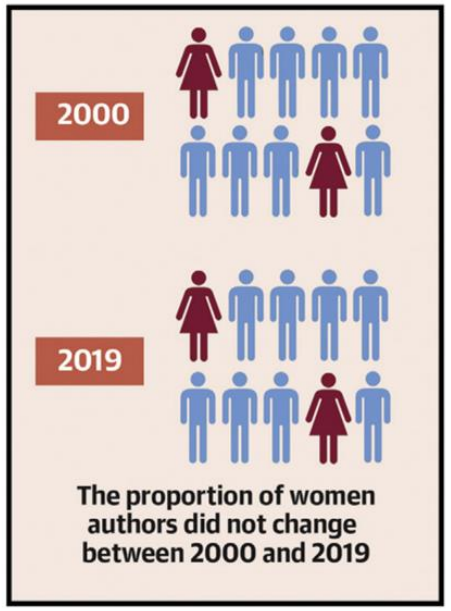


Denby, Szpakowski, Silver, et al. JAMA Intern Med. 2020;180(10):1382-1383.

Women Are Under-Represented as Trial Leaders in HF RCTs 2000-2019, 403 RCTs



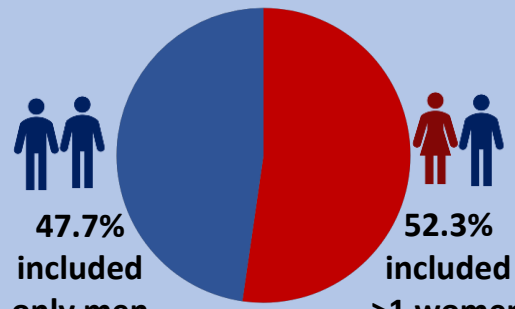




Whitelaw S, Thabane L, Mamas M, Reza N, Brethett, K, Douglas PS, ***Van Spall HGC****. JACC 2020.*

Women Are Under-Represented as HF Trial Steering Committee (TSC) Members 2000-2020, 127 RCTs, 1213 TSC members

107 TSCs reported TSC member names



Women had greater odds of TSC inclusion in RCTs led by women

aOR **2.48** 95% CI, 1.05-8.72

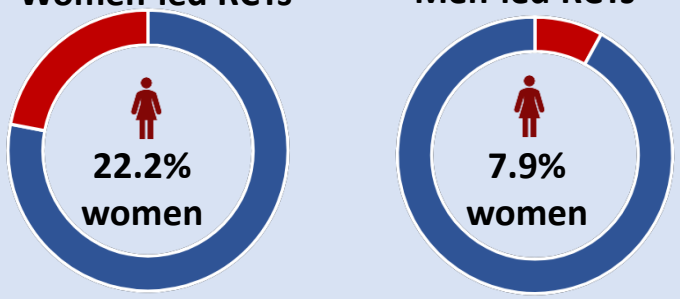
This association was not significant when TSCs restricting women to RCT leaders were excluded

aOR **1.46** 95% CI, 0.43-4.91

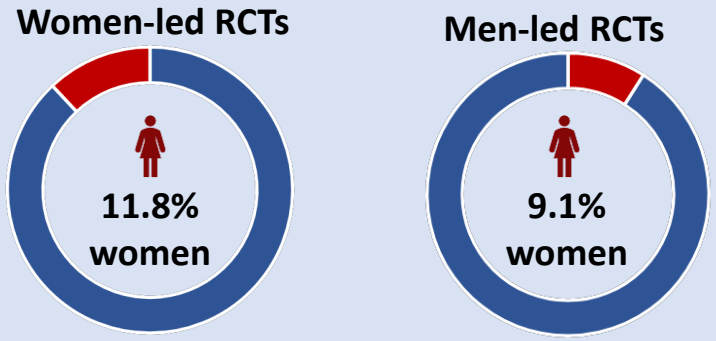
Women comprised 11.1% of 1213 TSC members

No change in % over time

Gender composition of TSCs



Gender composition of TSCs excluding RCT leaders



*Eliya Y, Whitelaw S, Thabane L, Voors AA, Douglas PS, **Van Spall HGC**..Circulation HF 2021*

Enrollment of Female RCT Participants is Greater in Trials Led by Women 2000-2019, 317 RCTs

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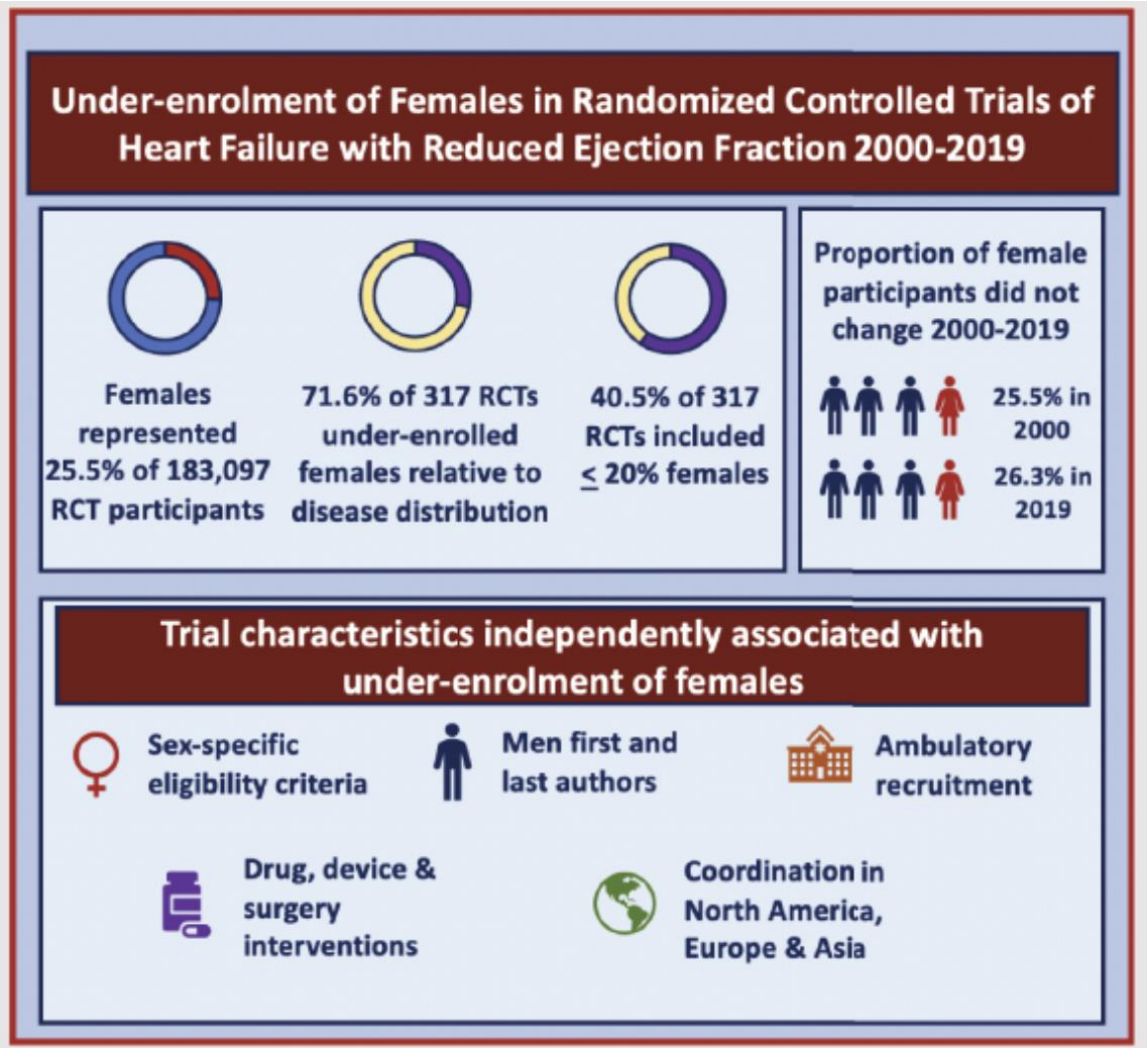
Under-enrolment
= 20% below F : M distribution of HFrEF



Men trial leaders and under-enrollment of F aOR 1.34 (95% CI 1.12-3.54)

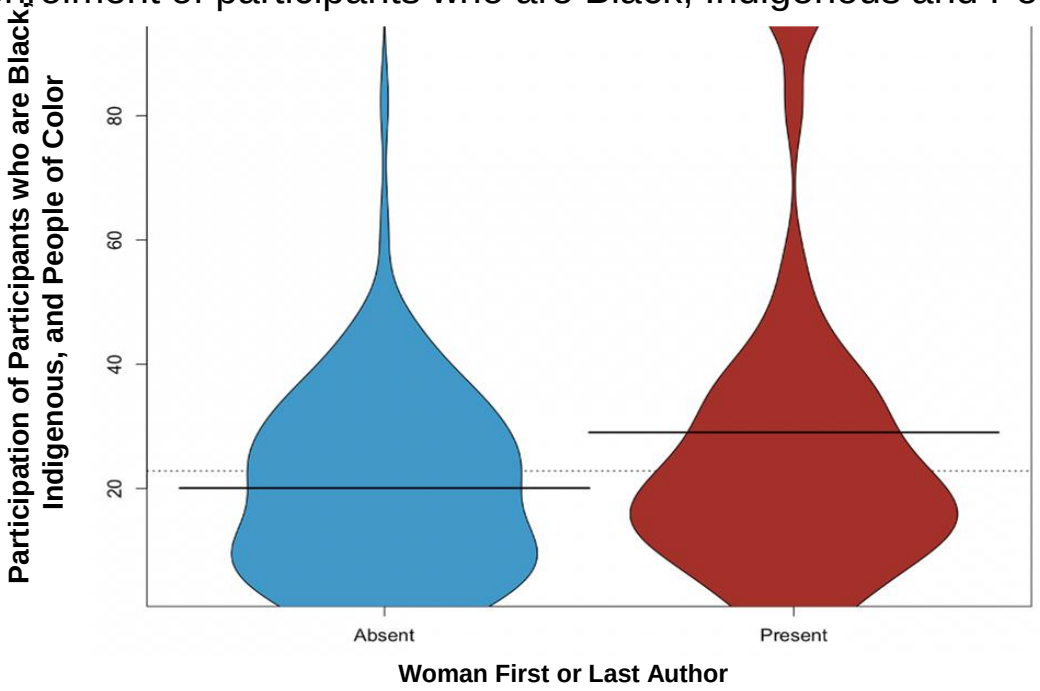
Whitelaw S, Sullivan K, Eliya Y, Alruwayeh M, Mehran R, Yancy C, Mamas MA, ***Van Spall HGC.*** *Eur J Heart Fail 2020.*

Enrollment of Black, Indigenous, People of Color is Greater in Trials Led by Women

157 RCTs, 158,200 participants 2000-2021

Univariate Analysis	Adjusted Analysis
8.9% (95% CI: 2.5-15.5%) p=0.007	8.4% (95% CI: 1.9-15.0%) p=0.0125

*No significant association between funding source, trial size or number of countries of participant enrolment and enrolment of participants who are Black, Indigenous and People of Colour



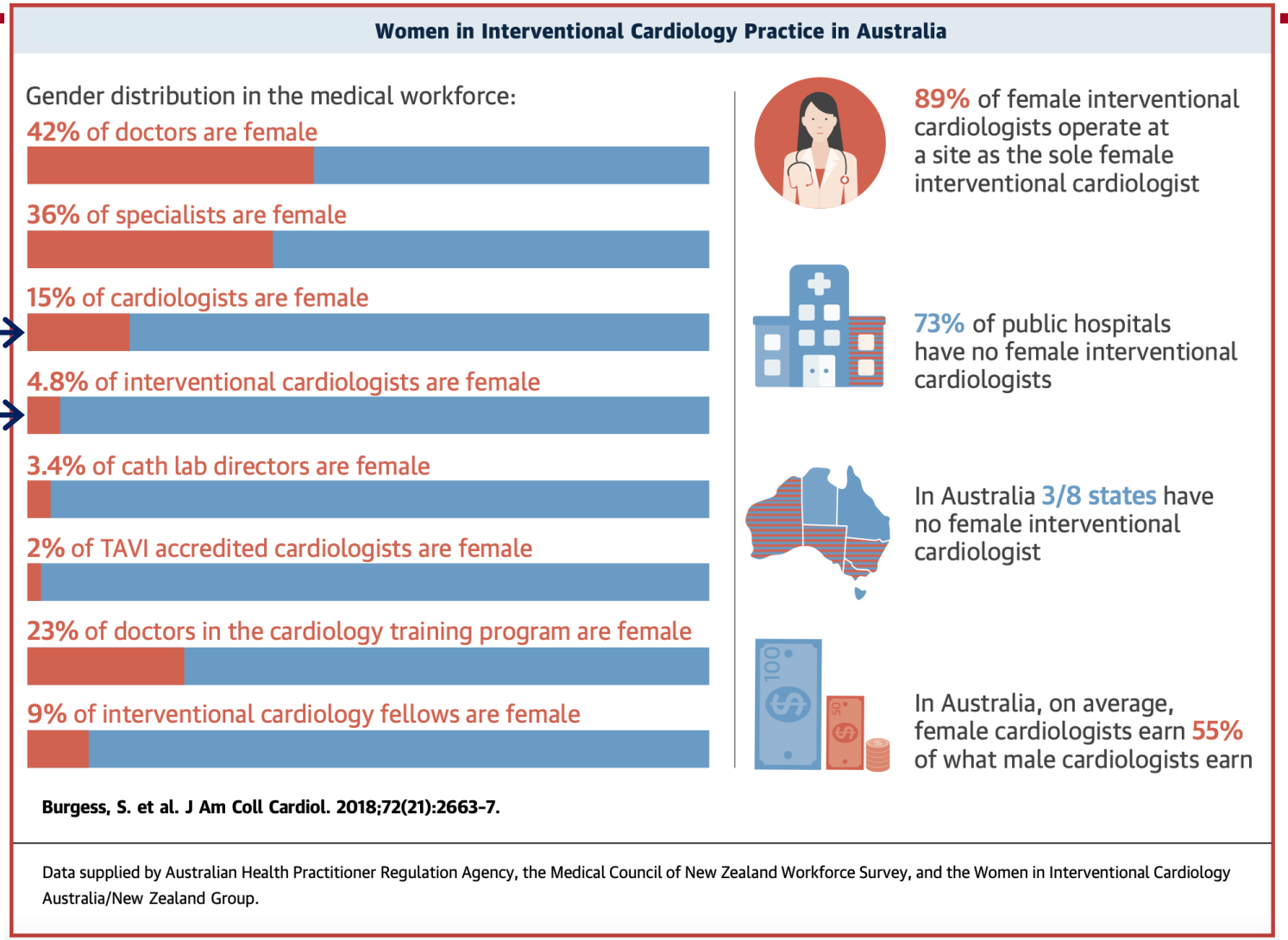
Wei S, Le NN, Zhu JW, Greene S, Breathett K, Mamas M, Zannad F, ***Van Spall HGC****. 2021. Circulation HF*

We Need to Increase the Number of Women Entering Cardiology

Few Women in Cardiovascular Medicine

Example: Interventional Cardiology

Striking similarities in the US and UK



Burgess S et al., J Am Coll Cardiol, 2018.

Recommendations for Career Advancement of Women Cardiologists

During Training & Early Career

Recommendations for fellowship program directors and accreditation agencies

Work with ACGME to provide clear FMLA policies and flexible training pathways

Recommendations for academic divisional and departmental leadership

Develop mentoring programs and increase women applicants to fellowship programs

Sharma G et al., JACC, 2019.

Recommendations for Career Advancement of Women Cardiologists

During Training & Early Career

Recommendations for employers, institutions, and practices

- *Develop programs that support career flexibility and work–life integration*
- *Recognize implicit bias and adopt zero tolerance for workplace harassment*
- *Provide clear parental leave policies, radiation safety, and lactation rooms*

Sharma G et al., JACC, 2019.

We Need More Women Cardiologists

But

We Also Need to Increase the Number of Women Becoming Clinical Trialists

TABLE 2 Strategies for Academic Institutions to End the Gender Inequality in Research Leadership

1. Purposeful recruitment, retention, and promotion policies that reduce barriers to entry and advancement of women
2. Implicit bias training for all selection committee members for recruitment, leadership, and research awards
3. Mentorship and leadership training programs for and by women and under-represented groups
4. Flexible promotion policies to account for life circumstances (e.g., "stop the clock" policies so faculty members do not fall behind in achieving promotion metrics during parental leave)
5. Fair distribution of internal research funding awards to ensure equal opportunity in external funding competitions
6. Open calls for leadership positions, funding opportunities, and research chairs
7. Leadership training and development for those from under-represented groups
8. Equal pay for equal work
9. Transparent reporting of gender-disaggregated metrics on recruitment and advancement
10. Zero tolerance policies for discrimination, sexual and gender harassment, implementation of gender, race/ethnicity trans-formative policies to achieve excellence in diversity and equality

***Van Spall HGC**, Lala A, Deering T et al. JACC 2021*

TABLE 4 Strategies for Industry Sponsors to End the Gender Inequality in Clinical Trial Leadership

1.	Establish internship and sponsorship programs for women and underrepresented groups to engage in protocol development, leadership selection meetings, trial executive committees, data safety monitoring boards
2.	Create open calls for applications and implement transparent, merit-based processes for the selection of clinical trial leaders and executive committee members
3.	Assess current status of gender inequity, develop policy and commitment to diversity, equity and inclusion in clinical trial leadership processes
4.	Report gender-disaggregated data on composition of trial leadership committees, including principal investigators, steering committees, data safety monitoring boards, and event adjudication committees
5.	Offer equal remuneration for equal work and report remuneration schemes transparently
6.	Develop networking programs and break the pattern of mentorship and sponsorship along gender lines
7.	Collaborate with catalyst organizations that focus on gender and racial equity
8.	Close the diversity gap on industry boards and leadership teams

***Van Spall HGC**, Lala A, Deering T et al. JACC 2021*

Two Broad Pathways of Clinical Trial Leadership

Key / Digital Opinion Leader / Spokesperson Model

- Present results of a study largely designed, executed, analyzed and summarized by the sponsor
- N of 1

Clinical Trialist

- Design study, statistical analysis plan, write protocol & present it to FDA
- Constitute an executive & steering committee
- Identify sites & contract with them to do study
- Write CEC & DSMB charters & contract with members
- Manage safety reporting in 50 countries
- Perform analysis
- Prepare end of study report for the FDA & go before the FDA
- N of 100s

Recruited Eight Women to Join Baim Faculty

Carolyn Lam

Harriette Van Spall

Cecilia Bahit

Martha Gulati

Suzanne Baron

Rasha Al Lamee

Vijay Kunadian

Malissa wood