

## **Statistical and Political Power: Utilizing Research to Transform Health Innovation for Women<sup>1</sup>**

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Understanding disparities is critical to health innovation. And yet, scientific inquiries are often underpowered, both statistically—with insufficient study sample to detect effects across sex and gender differences—and politically—lacking the will or opportunity to include women throughout the generation and adaption of evidence. Addressing sex and gender differences in health innovation is not only imperative from a social justice standpoint but also for improving the health of all by achieving improvements in population health. The gap between the expected effects of health innovations and real-world results is hindering progress toward health for all. Funders, policymakers, researchers, and implementers can drive the demand for the representation of women in health innovation.

### **The Power of Data**

Successful innovation requires representative and comprehensive evidence. To achieve statistical power, health innovation research requires disaggregated data, including by sex and gender. Research that is not powered for disaggregation by design precludes the opportunity to safely and effectively generalize findings to women. For example, a recently approved HIV prevention medication, the PrEP drug Descovy, was not tested in cisgender women because, according to manufacturer Gilead Sciences, including such women in the clinical trial would have “required too many resources.” Thus, although women compose more than half the population living with HIV globally, lack of inclusion in this trial prevented Food and Drug Administration approval of this medication for cisgender women. The inclusion of transgender women, who have a particularly high risk of HIV infection, is even more limited. Out of seven clinical trials analyzing the efficacy of the HIV prevention medications, trans women composed only 1.2 percent of one trial and 0.2 percent of total trial enrollments. This failure to test health innovations across sex and gender strata may explain why evidence-based innovations fail to achieve expected outcomes in real-world populations composed of 50 percent women.

Even when they are included, it is important to understand the hurdles that may limit the participation of women participants in studies, including cultural, linguistic, and economic factors, among others. A better understanding of these dynamics may be addressed during the design phase of research, including participant recruitment and retention strategies, as well as in adaptive methods during implementation. Statistical power is a necessary component of effective health innovation.

### **The Power of Politics**

Second, political power drives the inclusion of women in the health innovation agenda. Decisions about research funding, such as the conditions examined, the populations included, and the individuals and institutions carrying out the investigations, are inherently political. Over two decades have passed since the inclusion of women in clinical trials was mandated by U.S. federal law, yet there is inadequate progress toward remedying the underrepresentation of women and the lack of attention to sex and gender differences. For example, women remain underrepresented in clinical trials in cardiovascular disease and cancer—the leading causes of death among women in the United States. Among studies

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inclusive of women, the influence of sex or gender is not widely nor rigorously analyzed, such that our understanding of the etiology of health in women is limited for many conditions.

Gender bias across the research enterprise, from decisions about funding for health innovation research to the publication of findings, further demonstrates the political nature of the inclusion of women in health innovation. For example, applications submitted by women investigators are less likely to be funded by government health research institutes in the United States and Canada. This gendered bias carries forward through to academic publishing.

Beyond sex and gender, true health innovation requires an intersectional approach—an understanding of the interaction of the multiple identities that shape risk and protective factors—to address political and institutional biases. For example, despite dedication to a health condition specific to women, until recently, the field of maternal health has largely failed to examine differences across race and ethnicity, to the detriment of the health of black mothers and infants. Intersectionality recognizes the complex interplay of sex and gender with other identities, and political and institutional biases, and represents the melding of social justice movements in health innovation. As an underrepresented and yet numerically equivalent population, inclusion of women in health innovation may serve as a rallying point to advance intersectional approaches for improving the health of all.

### **Beyond “One-Size-Fits-Men”**

Together, statistical and political power have the potential to advance health innovation. Recent progress has been driven by demand—for example, the *Lancet* journal encourages correct use of the terms *sex* (when reporting biological factors) and *gender* (when reporting identity, psychosocial, or cultural factors), as well as stratified reporting of results. Efforts to quantify gender bias across research activities, led by academics and publishers, is driving change in the composition of editorial boards toward the overall goal of more diverse authorship and thus more diverse contributions toward health innovation. Advocacy efforts around the detrimental effects of gender-blind research include criticisms of the “one-size-fits-men” approaches to innovation—from seatbelt configurations designed for men who sit further back in their seats to protective gear designed for men’s bodies.

A multi-sectoral approach is needed to continue to advance an inclusive agenda for health innovation. Funders can set inclusivity requirements for the evidence base of health innovations. Policymakers can develop regulations for the statistical representation of women in research. Implementers can insist on inclusive interventions. Researchers can develop new methodological approaches to analyze barriers to women’s participation.

To go the “last mile” in development by achieving global commitments to the goal of health for all, health innovation must be statistically and politically powered to include women. This approach will leverage the triple gender dividend by closing gaps in health, gender, and development.