

Q&A

Shirin Heidari

Dr. Shirin Heidari is the lead author of the Sex and Gender Equity in Research (SAGER) guidelines. In this interview with Dr. Isabel Goldman at *Cell*, she discusses her research, GENDRO, the SAGER guidelines and importance of considering sex- and gender-related variables in research, and her work on sexual and reproductive health in forced displacement.

Biography

Dr. Shirin Heidari is the founding president of GENDRO, an association dedicated to advancing gender-sensitive research and data analysis. As a senior researcher at the Gender Center, Geneva Graduate Institute, she is the principal investigator of a multi-country, multi-disciplinary research consortium on sexual and reproductive health in forced displacement. Previously, she held leadership roles at Sexual and Reproductive Health Matters and the International AIDS Society, spearheading gender-sensitive research, policy, and program delivery in HIV and sexual and reproductive health. Dr. Heidari is a feminist and human rights advocate, known for developing the widely cited Sex and Gender Equity in Research (SAGER) guidelines. She is a TEDx speaker and has served as a commissioner to the Lancet Commission on Women, Power, and Cancer. Her impactful contributions have earned her recognition as one of the influential figures shaping the future of International Geneva in 2022.

Can you tell us about your research and work?

S.H.: I am a researcher at the Gender Center, Geneva Graduate Institute, where I lead a multi-country research consortium focused on sexual and reproductive health within forced-displacement contexts. Concurrently, I hold the role of founding president at GENDRO, an international nonprofit organization in Geneva. GENDRO is dedicated to advancing the integration of sex and gender perspectives in research and data analysis across various disciplines. I also collaborate with the World Health Organization to incorporate these dimensions in technical work, working closely with the Department of Gender, Rights and Equity and the



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Can you tell us about the SAGER guidelines? What are they? Why are they important?

S.H.: The SAGER guidelines were formulated to address a significant gap in existing reporting standards for academic articles. Developed in 2016, this initiative stemmed from inadequate academic reporting of how sex and gender considerations are integrated into research methodologies, results, and interpretation of findings. This collaborative effort emerged through the Gender Policy Committee of the European Association of Science Editors, following a collective and consultative approach. Research, including systematic reviews from our group and others, had revealed the persistent underrepresentation of women in clinical trials. Studies that overlook underlying sex or gender differences may lead to significant harm for women. For instance, a 2001 report by the US Government Accountability Office (GAO) showed that 8 out of 10 drugs with-

drawn from the US market between 1997 and 2001 were removed because they caused greater harm to women. This underscored the urgent need for more inclusive and gender-sensitive research and reporting practices to ensure accurate drug evaluations and prioritize women's safety.

The SAGER guidelines provide a compelling rationale and a set of recommendations aimed at fostering improved reporting of sex and gender throughout the research process. They systematically outline how authors can methodologically enhance the presentation of their sex and gender considerations, from the initial research design and methodology selection to data collection, analysis, and the presentation and discussion of results. By offering practical insights, the SAGER guidelines help authors transparently depict whether and how they factor sex and gender aspects into their research, justify lack of such consideration, and provide a more nuanced understanding of the study's implications.

Moreover, the SAGER guidelines equip editors and reviewers with valuable tools and recommendations, enabling them to evaluate the integration of sex and gender aspects throughout the editorial process. This proactive approach contributes significantly to filling the gender-based evidence gap, fostering a more inclusive and thorough examination of research outcomes.

It is worth noting that while the SAGER guidelines primarily serve as reporting guidelines, their applicability transcends the realm of reporting. They are equally valuable at the research design and implementation stages, offering critical insights that researchers can integrate into their studies. Additionally, these guidelines function as a key resource for funders and research ethics committees, providing them with a framework

to assess the incorporation of sex and gender considerations in proposed research proposals and protocols. Thus, the SAGER guidelines play a pivotal role in enhancing the rigor and inclusivity of scientific research across domains and stages, ensuring that sex and gender aspects are adequately addressed and reported.

What's next for the SAGER guidelines?

S.H.: Certainly, there remains much room for further advancement. It is deeply gratifying to witness the widespread incorporation of the SAGER guidelines within scientific journals and academic publishers. Despite initial reluctance and slow uptake, these guidelines have now become standard practice at nearly all scientific journals and have garnered support from various research organizations, such as the Institute of Gender and Health at the Canadian Institutes of Health and Research (CIHR-IGH) and the [Drugs for Neglected Diseases initiative](#). More recently, the World Health Organization [adopted the SAGER guidelines](#) and is taking steps to implement them. These developments hold the potential to break the cycle of insufficient reporting on sex and gender, which is paramount to making research more rigorous and reproducible such that it has a lasting impact. However, there is still much work to be done.

The inclusion of the SAGER guidelines into [information for authors](#) and other publication policies marks a pivotal initial step, yet it is inadequate on its own. Effective implementation necessitates additional measures. For example, journals could make adherence to these guidelines a prerequisite during the submission process, peer reviewers could be encouraged to assess the extent to which authors have followed the recommendations, and editors could actively encourage authors to provide necessary information either prior to or during the revision process. Vigilant monitoring of progress and evaluation of journal outputs are imperative to ensure that enhanced reporting continues to bridge knowledge gaps.

Moreover, it is essential to harmonize the recommendations across key gatekeepers in the research ecosystem, including funding agencies, research

ethics committees, regulatory bodies, and publishers and editors. Additionally, we extend an invitation to researchers and stakeholders to adapt the SAGER guidelines to their specific scientific disciplines or research areas. A noteworthy example is a project underway to create SAGER guidelines for integrated outbreak analytics (SAGER-IOAs), which is an initiative that emerged from the Gender, Evidence, and Health Network, facilitated by GENDRO. Such initiatives underscore the growing acknowledgment of the significance of these guidelines.

Looking ahead, our vision includes the development of SAGER guidelines tailored specifically for research ethics committees (RECs). We are also considering developing SAGER+ tools and resources to offer guidance on how to reflect the intersection of sex and gender with other critical variables and dimensions within the research process, such as age, race, ethnicity, migration status, sexual orientation, and gender identity. This holistic and comprehensive approach to research holds the promise of elevating the quality and depth of scientific outputs to make them more accurate and precise.

Why is considering sex- and gender-related variables in research important? How does it lead to better science?

S.H.: There is compelling evidence demonstrating that both sex and gender influence various aspects of our health, encompassing exposure to risks, disease susceptibility and vulnerability, response to treatment, and overall healthcare experiences. This influence extends beyond biological differences, incorporating gender-related factors such as norms, roles, relationships, and identities, which can shape behaviors like health seeking, medication adherence, and vaccine acceptance. Furthermore, it involves complex issues such as affordability, availability, accessibility, and quality of healthcare services, as well as interactions within the healthcare system and engagements with providers. It is crucial to underline that there is also an interplay between sex and gender that merits further investigation.

Overlooking the impact of sex and gender perpetuates gender disparities in healthcare. A common misconception is that integrating sex and gender perspec-

tives into research exclusively benefits women. While historically disadvantaged groups, including women and individuals with diverse gender identities, can benefit from rectifying past inadequate research, understanding the underlying mechanisms of potential sex differences and addressing gender-related concerns can also yield substantial advantages for men.

For instance, men often face shorter lifespans and exhibit poorer health-seeking behavior. Additionally, their access to specific health services, such as in areas like sexual and reproductive health or addressing sexual violence, can be compromised when historically we've focused these areas on women. Where women exhibit biological advantages or better treatment responses, understanding the underlying mechanisms and the influence of both sex and gender can pave the way for interventions that improve outcomes in men as well.

By recognizing and examining these differences, we can develop a more nuanced, tailored, comprehensive, and equitable approach to healthcare that ultimately benefits everyone, regardless of gender.

What are the major barriers that exist to incorporating sex and gender into research? And what are the solutions?

S.H.: The significance of sex and gender in research has often been underestimated, partly due to a lack of awareness of and limited insights into their roles. Additionally, resistance to acknowledging their importance has persisted in our patriarchal society, where maleness and masculinity have been historically considered superior to femaleness and femininity. The field of science, like the rest of society, has operated within these patriarchal hierarchies, leading to the assumption that insights gained from research conducted on men can be extrapolated to women with similar results.

Another reason for the underrepresentation of women in research and the limited attention to their specific health issues has been well-intentioned measures aimed at protecting women of child-bearing potential and their fetuses, which also occurred in response to the Thalidomide tragedy. However, the risk of pregnancy does not justify excluding women from research given ample effective

measures to prevent unintended pregnancies. Moreover, pregnant women face a variety of health risks and diseases. Excluding them from research leaves them without treatment or with treatment that does not have sufficient evidence regarding safety, efficacy, and effectiveness during pregnancy.

The impact of excluding pregnant women from research was demonstrated during the COVID-19 pandemic when vaccines were rolled out for the general population. Due to insufficient evidence about vaccine safety and efficacy in pregnant women, they were denied access to potentially life-saving protection, even though they were at a higher risk of severe disease and death with COVID-19. As a result, numerous initiatives have emerged, advocating for the development of safe, ethical, and evidence-based approaches to conducting research in pregnant and lactating women, with the aim of informing effective interventions.

Do you think peer-reviewed research journals have a role to play in how sex- and gender-based analyses are reported? If so, what is their role?

S.H.: Journals play a pivotal role in the dissemination of scientific knowledge. Research findings are widely acknowledged as part of the body of evidence only after undergoing rigorous peer-review and being published. Throughout history, journal editors have been instrumental in shaping scientific standards, fostering transparency, ensuring accountability, and promoting ethical considerations in scientific research.

Several international standards and guidelines have been established to mandate transparent and comprehensive reporting of scientific findings. One notable example is the registration of clinical trials. An eloquent illustration of this practice can be found in the work of Zarin and colleagues published in the *New England Journal of Medicine* in 2005. In the US, the Food and Drug Administration (FDA) introduced the Modernization Act, section 113 (FDAMA 113), which mandated the registration of all private and public trials testing effectiveness for

“serious or life-threatening” conditions submitted to the FDA under investigational new drug applications (INDs). Consequently, the ClinicalTrials.gov registry was established in 2000. However, the number of clinical trials registered in the database remained minimal until 2005. It was during this year that the International Committee of Medical Journal Editors (ICMJE) policy made the registration of clinical trials a prerequisite for publication consideration. This crucial policy change led to a rapid increase, with registrations **surging by more than 70%** by October of the same year, primarily attributable to the ICMJE policy.

I firmly believe that requiring the consideration and inclusion of sex- and gender-based analysis when applicable and meaningful (or its absence justified) as a condition for consideration in academic journals, as well as reporting of all data by sex and/or gender during publication, could significantly advance our understanding.

What do you think are the next big scientific questions about sex and gender that researchers should focus on moving forward?

S.H.: As our understanding of the intricate interplay of sex and gender—along with their interactions with other determinants of health—advances, new questions inevitably arise. A significant concern in the contemporary landscape is that, despite remarkable progress, we are still in the early stages, and significant gender data gaps persist.

With the rapid development of artificial intelligence and the increasing use of digital technologies across various domains, including healthcare, if we fail to expedite our efforts to bridge these data gaps, there is a genuine risk of amplifying existing biases, which would lead to more harm and greater disparities.

You've worked on sexual and reproductive health in forced displacement. Can you tell us about that work?

S.H.: Our research initiative emerged from a critical gap identified in studies focused on humanitarian and forced-displacement

contexts. We know that gender inequalities are exacerbated at times of crisis. Our primary objectives are to examine the drivers and patterns of transactional sexual practices in forced-displacement situations, including those with exploitative components, and comprehend the gendered patterns and subsequent consequences on sexual, reproductive, and mental health. To the best of my knowledge, our research stands out as one of the first endeavors in this area, encompassing not only women but also men and individuals with diverse sexual orientations and gender identities.

Our preliminary findings shed light on the role of structural elements such as migration policies, asylum processes, and humanitarian aid systems. These factors contribute to prolonged periods of uncertainty, fostering conditions of vulnerability, housing precarity and food insecurity, and limiting livelihood options, and result in marginalization. Within this environment, exploitation, abuse, and survival strategies adapted by refugees emerge, adversely affecting their health and well-being. Refugees with diverse sexual orientations and gender identities or modalities face particularly harsh conditions, often enduring stigma and discrimination from both fellow refugees and host country citizens. Their unique needs often go unmet. Crucially, our research points to the existence of gender-related dimensions within subgroups under the sexual orientation, gender identity, and expression (SOGIE) umbrella. These differences lead to varied and, at times, invisible experiences and differential health outcomes.

As global displacement continues to rise, it is imperative to emphasize gender considerations when conducting research in such challenging settings. Understanding these nuances is vital to informing targeted interventions and policies that can truly address the unique needs of diverse populations in forced-displacement situations and ensure health equity, gender equality, and social justice.

DECLARATION OF INTERESTS

The author declares no competing interests.

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