

The SAGER guidelines, an editorial tool for promoting sex and gender equity in research

Paola De Castro

Scientific Communication Unit, Italian National Institute of Health. *Received 15 February 2019.*

Biomedical research does not always consider sex and gender differences when studying disease, which leads to potentially serious consequences in the applicability of the results obtained. Sex and gender differences are, in fact, important determinants of health and if they are not adequately considered when the study is designed, they can have such a negative impact on the results of research as to make it pointless, with terrible waste of both human and financial resources. To give a few examples that are easy to understand even for those who are not sector experts, suffice to think of the different effects that medicinal products have on the metabolism of men and women; of the effects of the environmental contaminants that have a detrimental effect on female reproductive health, but that are studied primarily in men; of the car safety device tests that are performed mainly on men, thereby putting women's safety at a serious risk; of the different behaviors, attitudes and perceptions of women and men as determinants of mental and physical health and welfare.

In order to provide a solution to this problem, which is undeniably not an easy one, in 2016, a group of editors belonging the European Association of Science Editors (EASE, www.ease.org.uk) published the SAGER (Sex And Gender Equity in Research) guidelines¹.

These guidelines are inspired by the results of a survey conducted in 2014 by the EASE Gender Policy Committee (GPC) that brought to light the lack of attention to gender by editors on an international level. The survey was conducted by means of both online research, on journals instructions for authors and referees, and a questionnaire. Of the 716 editors who answered the questionnaire, just 7 stated that they follow an editorial policy including the gender aspect; the majority of respondents (75%), on the other hand, expressed uncertainty or reluctance to introduce attention to gender into their editorial policy (especially regarding a correct use of terminology and the obligation to publish data disaggregated by sex and gender). The SAGER guidelines were developed precisely on the basis of this limited consideration of the gender issue by editors who, as we know, can have a direct influence on the choices of authors and referees, and consequently on research methodology. As an example of their role as the gatekeeper of research, suffice to think of the considerable

increase in clinical trial registrations since editors made it compulsory to publish the trial registration number².

A correct implementation of the SAGER guidelines will represent an efficacious strategy for guaranteeing, whenever appropriate, the presentation of disaggregated data by sex and gender, starting with the study design phase, and therefore for making it possible to obtain results able to guarantee equity in research, thereby minimizing waste of resource.

Indeed, the SAGER guidelines act primarily through the editors of scientific journals who demand that unpooled data are provided in all sections of scientific articles, including the title and abstract, whenever appropriate. As it is in the interest of all researchers to publish their work (publish or perish), and as the editors dictate the rules for the publication of articles in their journals, the SAGER guidelines are destined to have a significant impact on research. They represent a useful tool not only for editors, but also for authors and referees, as they provide general recommendations (regarding the correct use of terminology) and specific recommendation for each section of the article. They also include a checklist that helps authors to verify, for example, when the study only includes one sex, whether this is stated in the title and abstract; how sex and gender were taken into account in the study design; whether the data are presented in a disaggregated way in the results; and whether the discussion section adequately considers the implications of sex and gender.

The guidelines involve journal editors from the time they receive the manuscript and decide to start the editorial process or whether it is first necessary to ask the authors to revise the paper, by presenting the data in an unpooled manner in compliance with the SAGER guidelines. Referees will also have to consider the SAGER guidelines when reviewing articles, on a par with the other aspects evaluated.

After their publication, the guidelines were extensively discussed by the scientific community, generating an interesting debate in leading international journals³⁻⁷ and were also included in training courses on scientific writing and research methodology in a number of fields. At the current time, the SAGER guidelines have been translated into Spanish and Portuguese.

The SAGER guidelines are published on the Equator website, <http://www.equator-network.org/reporting-guidelines/sager-guidelines/>, the most important editorial guidelines portal, whose mission is to promote transparency and integrity in biomedical research.

Further information (including presentations and publications) are available on the EASE website, where it is also possible to sign the official endorsement, the first step towards the adoption of a more conscious approach to gender differences in research (<http://www.ease.org.uk/about-us/gender-policy-committee/>).

I took part in the drafting of the SAGER guidelines, as a member and, for a certain time (2016-2018), as Co-Chair of the EASE Gender Policy Committee. I hope that the work done, on voluntary basis by a professional association, may, in time, have the desired impact on the research community. We have now, therefore, submitted to the European Commission a new project that, which with adequate funding, should allow us to promote and implement the SAGER guidelines in publishing groups and amongst research institutions, in line with the development and adoption of the Gender Equality Plans⁸, which are increasingly necessary to deal with the gender differences that still exist in research institutions.

References

1. Heidari S, Babor T F, De Castro P, Tort S, Curno M. Sex and gender equity research: rationale for the SAGER reporting guideline and recommended use. *Res Integr Peer Rev.* 2016;1:2.
2. Viergever RF, Keyang L. Trends in global clinical trial registration: an analysis of numbers of registered clinical trials in different parts of the world from 2004 to 2013. *BMJ Open.* 2015;5:e008932.
3. De Castro P, Heidari S, Babor T. Sex and gender equity in research (SAGER): reporting guidelines as a framework of innovation for an equitable approach to gender medicine. *Ann Ist Super Sanita.* 2016;52(2):154-7.
4. Clayton JA, Tannenbaum C. Reporting sex, gender, or both in clinical research? *Jama.* 2016;316(18):1863-4.
5. Marsh J. Sex and gender in psychiatry. *Lancet Psychiatry.* 2016;3(11):999.
6. Lundine J, Bourgeault IL, Clark J, Heidari S, Balabanova D. The gendered system of academic publishing. *Lancet.* 2018;391:1754-6.
7. Heidari S, Bachelet V. Sex and gender analysis for better science and health equity. *Lancet.* 2018;392:1500-2.
8. European Institute for Gender Equality (EIGE) [Internet]. What is a gender equality plan? Available from: <https://eige.europa.eu/gender-mainstreaming/toolkits/gear/what-gender-equality-plan-gep>.

Conflict of interest statement: the Author declares no conflicts of interest.

Correspondence to:

Paola De Castro

Director, Scientific Communication Unit
Italian National Institute of Health
Viale Regina Elena 299
00161 Roma, Italy
email paola.decastro@iss.it