

Gender-specific medicine in clinical research and health policy implications

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Gender-specific medicine is undoubtedly a sector undergoing rapid growth and development, a sector that is becoming more and more multidisciplinary and pervading not only all fields of medical sciences, but also ethics, economics, and political and social planning. Looking at health through this particular lens opens up new perspectives, in some ways surprising due to their novelty even in fields – such as, for example, that of occupational medicine¹ – in which a gender-specific approach should have been thought of a long time ago. We are aware that this is only the beginning of an extraordinary journey that we hope will lead us to a better and more equal world.

It is clear that the emergence of precision medicine has contributed to an increasing – and it is to be expected that it will continue to do so – interest in gender-specific medicine, which is one of the foundations of individualized patient-centred care. Gender-specific medicine, like precision medicine, is therefore becoming more and more important for health professionals, who sometimes suffer from still imperfect training, even with regard to the essential aspects of the new discipline².

Signs of an awareness of the need to define a gender-specific training program have, however, been strongly expressed in Italy. We only have to look at the document drafted by the Permanent Conference of the Presidents of Councils of Specialist Degree Courses in Medicine and Surgery (12th December 2016), which encourages all medical schools to include gender differences as multi-disciplinary teaching in all subjects. In the same way, we are witnessing the growth of gender-specific postgraduate training offers and of attention to this aspect in the design and conduct of research activities, in parallel with the production of in-depth materials, guidelines, and online tools.

Outside of Italy, a recent initiative launched in Germany is particularly interesting. An online exchange platform on gender and sex aspects in medicine, 'GenderMed-Wiki' (www.gendermed-wiki.de), funded by the German Federal Ministry of Education and Research, has been developed. The aim is to facilitate sex and gender mainstreaming in all areas of medicine³.

Returning to Italy, the first chair of Gender Medicine was established at the University of Medicine and Sur-

gery in Padua, while the University of Ferrara, in collaboration with the Local Health Authority in Ferrara, started an initiative similar to the German one by creating an online structured environment to share basic knowledge, which contains seven thematic areas with a wealth of documents and references, which may be used to help university professors implement courses that integrate gender medicine⁴.

Things are thus on the move and, despite the difficulties, all of this, over time, will increasingly and profoundly change the entire Italian national health regulatory system, as well as the economic and production system of reference: with strong implications for hospital management and, more generally, for the planning of the entire healthcare chain and therefore, above all, for the relationship between the health service and patients.

How will all this affect the current ethical and legislative framework? What about the relationship between health and disease? And what will it ultimately mean for the Italian national health system in terms of sustainability and management of economic and human resources? What financial assessments and what clinical research can we look forward to for the development of new drugs that are more innovative and at the same time more effective and safer?

This last question has complex implications that the scientific community has been discussing about for some time now. Particularly intriguing is the reading of a viewpoint published in *JAMA*⁵: "Two common questions asked by clinical researchers are (1) Should the sex or gender of the study participants be reported? and (2) What is the correct term for designating males and females or men and women? The answers depend on whether biological or psychosocial factors are under study. Sex and gender are not mutually exclusive. They are integrally related and influence health in different ways. According to the National Institutes of Health (NIH) and the Canadian Institutes of Health Research (CIHR), sex is considered a biological component, defined via the genetic complement of chromosomes, including cellular and molecular differences. (...) The terms male and female should be used when describing the sex of human participants or other sex-related biological or physiological factors. Descriptions of differ-

ences between males and females should carefully refer to 'sex differences' rather than 'gender differences'. The authors go on to say the following: "Gender comprises the social, environmental, cultural, and behavioral factors and choices that influence a person's self-identity and health. Gender includes gender identity (how individuals and groups perceive and present themselves), gender norms (unspoken rules in the family, workplace, institutional, or global culture that influence individual attitudes and behaviors), and gender relations (the power relations between individuals of different gender identities)".

It is therefore quite clear that there is still a long way to go in terms of the importance we now attach to research and gender-specific healthcare and to the cultural and cognitive tools we have to respond to such a complex challenge. "At present, there are no agreed-upon, validated tools for assessing gender", admit the authors of the above mentioned article, but all researchers designing and conducting clinical trials "should consider appropriate use of the words sex and gender to avoid confusing both terms". In order to understand and compare clinical trials in an attempt to achieve truly personalized medicine, it is essential to use the terms sex and gender appropriately when reporting and discussing biological, psychosocial and cultural factors. It is also essential to disaggregate demographic and all outcome data by sex, gender or both; to report the methods used to obtain information on sex, gender or both; and to always note all 'limitations' of these methods.

As we can see, there is no shortage of food for thought on the subject of gender medicine in the broad debate underway in the scientific community as well as in civil society and more generally in the political sphere. New

horizons are therefore being opened up, which we will have to explore on the basis of a culturally renewed outlook. That is why we think that *The Italian Journal of Gender-Specific Medicine* should no longer only encourage and spread the culture of gender-specific medicine through the publication of reviews and original articles as a result of research activities, but should gradually give more space to testimonies, interviews, and opinions on these issues. We will thus attempt to contribute to the debate underway with the hope of involving our readers and the desire for this journal to be useful and interesting for society.

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