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Gender medicine: the role of Institutions

Sandra Zampa

Undersecretary of the Minister of Health

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We have been hit by a virus that is disrupting the way of life not only of the Italian people, but of the entire world population. This virus often forced us to ask ourselves unprecedented questions about our health, our way of life, our health system, but it has also made it clear to everyone that men and women get sick and respond differently to diseases. Coronavirus infections, including Sars-Cov-2, have in fact a higher lethality in men, and the Covid-19 pandemic made everyone – including the decision makers – aware of the importance of biological and gender differences in health and in sickness.

With this, and not only this, in mind, on September 22 I signed the decree establishing the Observatory dedicated to gender medicine: an act long awaited and envisaged by Law 11 January 2018, no. 3, which governs the application and dissemination of gender medicine within the National Health Service.

In this regard, I would like to thank all those who worked before me and with me to reach this goal and, in particular, the Senator Boldrini, first signatory of the bill; the Honourable Lorenzin, who has done so much for gender medicine; and the President of the Senate, Senator Casellati, who as Undersecretary for Health set up a working table to formulate guidelines on clinical and pharmacological trials with a gender approach.

The establishment of the Observatory is an essential step to implement the four areas of intervention envisaged by the Plan for the application and dissemination of gender medicine: 1) clinical pathways of prevention, diagnosis, treatment and rehabilitation; 2) research and innovation; 3) training/education and professional updating; 4) communication and information.

The Law, the National Plan and the institution of the Observatory emphasize the critical role played by Italian Institutions in anticipating changes in society. Indeed, as Nelson Mandela argued, "*Safety and security don't just happen, they are the result of collective consensus and public investment*".

With these premises, I would like to retrace with you the long journey that allowed all this, because only in this way this great accomplishment by the Institutions becomes evident.

The first Italian Institution that addressed the issue of gender medicine and health is the today's National Agency for Regional Health Services (AGENAS), at the time Agency for Regional Health Services (ASSR), which under the direction of Dr. Laura Pellegrini set up a working group in 2003 to develop recommendations on the conduct of gender-related pharmacological studies. In those years, also the Women's Health Committee was born at the Ministry of Health, which – chaired by Minister Livia Turco – had gender medicine among its objectives. Subsequently, several initiatives and activities were implemented, both at national Institutions – such as the Italian Medicines Agency (AIFA) (with special study Committees), the National Institute of Statistics (ISTAT), the National Institute for Insurance against Accidents at Work (INAIL) and the Italian National Institute of Health (ISS) (first with the establishment of a dedicated Division and then with the national Center for Gender-Specific Medicine) – and at Universities (Padua, Sassari, and later Rome Tor Vergata). On a national level, the National Study Centre on Health and Gender Medicine and the Italian Health and Gender Group (Giseg) organization were created, with specific training and research promotion activities. In addition, the territorial Center for Health and Gender Medicine in Tuscany and the University Study Center in Ferrara were born. Nor should it be forgotten the essential contribution of the Scientific Institutes for Research, Hospitalization and Health Care (IRCCS) during this journey. The number of national and international courses and congresses on gender medicine has then deeply soared. Finally, in many Scientific societies specific working groups have been created, aimed at developing this issue within their field of expertise.

The Standing Conference of the Presidents of the Council of the Degree Course in Medicine and Surgery included gender medicine among the Elementary Didactic Units (UDEs) of the core curriculum within the educational offer of many Courses, in order to train a doctor who knows how to treat and take care of the person.

The Italian National Federation of the Orders of Surgeons and Dentists (FNOMCEO) also set up a working table, which organized several conferences and prepared a remote course, together with the Italian National Federation of the Orders of the Nursing Professions (FNO-

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PI) to promote the training of doctors, essential for the development of gender-specific clinical practice.

Obviously, a more than important role was played by Parliament, which attempted to systematize what was happening in the Country. In fact, in 2011 the "Omnibus" Law Decree mentioned the topic of gender medicine; in March 2012, the Joint Motion on Gender Medicine was approved in the Chamber of Deputies and, in 2013, two Bills with the same title, "Regulations on gender medicine", were also filed in the Chamber of Deputies.

In February 2016, the Bill "Provisions to promote the application and dissemination of gender medicine" was presented (first signatory Paola Boldrini), which then merged into Art. 3 of Law 11 January 2018 no. 3.

We must not forget the great work carried out by the Regions, which proved to be sensitive to the subject. Some of them, in fact, have already introduced gender medicine in the regional health plans, while others included it in the objectives of the general directors of the Local Health Authorities. At the beginning of 2020, in order to promote gender medicine, a technical-scientific table of regional representatives appointed by the respective Regional Departments was set up, with the aim of building, activating and sharing training and dissemination paths and health policies from a gender perspective. Furthermore, on the part of the regional reference persons, working groups are being set up within each local reality, in order to share the gender approach in the individual territories.

In this context, the stimulating role played by international organizations (United Nations, World Health Organization - WHO - and European Union - EU) – which anticipated and promoted the cultural and political changes necessary to apply gender medicine to health – was extremely important. In 1998, in the World Health Report, WHO launched a '*gender challenge*' to states and international organizations. These are the words that perfectly summarize the thought of the WHO:

"There is now a growing body of evidence to indicate that medical research has been a profoundly gendered activity. The topics chosen, the methods used and the subsequent data analysis all reflect a male perspective in a number of important ways. (…) Gender bias is evident not only in the selection of research topics but also in the design of a wide range of studies. Where the same diseases affect both women and men, many researchers have ignored possible differences between the sexes in diagnostic indicators, in symptoms".

The '*difference*', therefore, is not a "*fact*" to contrast with, but a value to be preserved, that allows the full implementation of the value of equality.

Therefore, I want to thank once again the Institutions, the people and the whole Italian network which for years, through an intense didactic and popular scientific activity and the cooperation with specialized journals and conferences, have developed gender medicine in our Country. However, we are still halfway, and the goal is not near. Among other things in order to reach it, it is necessary to promote the following actions.

Putting the person at the center

The health and well-being of individuals is primary assets. The person as a whole must be placed at the center of the care path by the health services; must be placed in the best conditions to be able to reach his/her full health potential, having the right to be treated regardless of his/her economic and social condition, gender, ethnicity, language, religion and opinions. Health systems, including ours, must be based on everyone's needs and be proportionate to the advances in science, which has clearly highlighted that women and men have significant differences in all areas of medicine, even in the response to treatment. Drug trials are carried out without taking these differences into account. From *in vitro* experiments, in which the male or female cellular chromosomal makeup is not taken into account, through the experimentation on animals – usually made on males only – up to the clinical studies, where women are enrolled in a minimal part: the entire development of a drug does not take into account the differences, including the metabolic ones, between women and men. Yet the Italian Medicines Agency (AIFA) on several occasions has promoted the development of a gender-specific medicine. Something is now changing, at least in the later stages of research, but women are still underrepresented in crucial areas, such as cardiovascular disease – which is the first cause of death among women – or in many chronic diseases. This lack of attention to gender differences then determines the high frequency of adverse drug reactions found in the female gender. Obviously, pharmacology is just one example. Diagnostics should also take into account such differences. And the very pathogenesis of diseases should be studied taking into account biological and gender specificities. In short, as reported by the journal *Nature*, for women "medicine is less based on evidence" than for men.

Prepare the Italian National Health Service to welcome the gender health and medicine paradigms

To achieve the goal of the person "at the center", the Institutions are necessary, because in order to promote health, as already mentioned, actions are needed to modify the social and environmental conditions; that is, the system must acquire the ability to govern the health social determinants, such as gender. The Italian health system must prepare itself to accommodate both

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an increasingly greater mass of elderly people, especially women, and severe disabilities. Paradoxically, in fact, the woman, who has taken care of others for a long time, having a longer life expectancy, has a greater risk of being disabled, alone in old age (over 65,38% of women and 15% of men live alone) and poor, because among the elderly the risk of poverty is concentrated on the single individuals. Therefore, a universal National Health Service, such as ours, must find new resources through technological, pharmaceutical, managerial and organizational innovation, through a more effective collaboration between the healthcare and the social sector. As we know, technological innovation is constantly accelerating, with breath-taking effects on health, society and economy. It is therefore increasingly crucial to be able to anticipate the future evolution, as well as foresee the changes and the emerging trends, by investing in research and development.

In particular, in the short term it appears essential to:

a. **implement measures to improve relations between healthcare professionals and patients**, for example through a gender-specific medical record, to be studied and implemented from scratch, which could improve therapeutic adherence and reduce adverse reactions. Anatomy, biochemistry, physiology, genetics are fundamental elements that should be integrated with the psychosocial aspects, so that each person is considered as a whole and we can move towards a precision, personalized medicine. Gender medicine is indeed the first step towards this goal;
b. **promote territorial gender medicine**. At the beginning of 2020, a technical-scientific table of regional reference persons appointed by the respective Regional Departments was established, with the aim of building, activating and sharing training and dissemination paths and health policies from a gender perspective. The regional reference persons, in turn, formed a working group within their own territory, to introduce the gender approach into the individual contexts;
c. **use the Recovery Fund** to promote a gender-specific vision and health planning, in order to create an interaction between the multidisciplinary research system, the pharmaceutical-biomedical industrial fabric and Public Institutions in the healthcare sector. In this way we will be able to give a concrete impulse to the research (in its widest possible sense) and to the innovation in our Country, where pharmaceutical and medical companies are world leaders in many areas and contribute greatly to our gross domestic product. Gender-specific medicine can not only improve the appropriateness of the healthcare costs – and even reduce them – but also become an engine of development for the Country, involving institutions, scientific societies, the pharmaceutical and medical equipment industry, patient organizations, and all citizens, for a National Health Service ever closer to their problems;
d. **include new drug registration rules**, considering gender balance in clinical trials. It should be stimulated a new culture that encourages the industry to implement gender-specific research in drug development through a policy of obligations and incentives (for example, by extending the expiry of patents for stakeholders who take into account gender specificities).

It is obvious that all this requires a great cultural change, one which cannot take place without a close collaboration between all the Institutions, health professionals and civil society. Therefore, I will strive to promote such a collaboration, so that our Country – the first in the world to have an *ad hoc* law and health plan – can be a leader in this area.

Conflict of interest statement: the Author is Undersecretary of the Minister of Health

Correspondence to:
Sandra Zampa
Ministero della Salute
Lungotevere Ripa 1
00153 Roma, Italia
email segreteria.zampa@sanita.it