

The Italian law on gender medicine: a reality and a hope

Giovanella Baggio and Walter Malorni

Scientific Editors, *The Italian Journal of Gender-Specific Medicine*

We are proud to announce that the law regulating the implementation of gender-specific medicine in Italy has been definitively approved at the beginning of 2018.

A summary of the law and the implementation of the important healthcare plan, derived from the law released and signed by the Ministry of Health in June 2019, is briefly described below, edited by Alessandra Carè, Director of the Center for Gender-Specific Medicine at the Italian National Institute of Health, and Elena Ortona, Director of the Gender-Specific Physiopathology Unit at the same Center, where the national Observatory, which should report annually to the Parliament the state-of-art of the application of the law, will soon be established.

This Plan has been integrally published in the supplement to *The Italian Journal of Gender-Specific Medicine*.

In the era of personalized and precision medicine the dimension of gender medicine, which must be applied to all medical specialties, clearly represents the first essential step. Men and women, as this Journal continuously demonstrates, need a sex/gender specific diagnostic approach as well as a sex/gender specific therapy and different paths of prevention and cures. However, in order to realize this objective, the first step will be the training of health personnel, physicians in primis. Thus, Universities, medical and health professionals' associations, all training agencies in the field of the healthcare (biomedical and paramedical) should include training courses taking into account the relevance of gender differences. In the era of evidence-based medicine, all medical specialties are involved in developing this approach. As a general rule, and as the title of our Journal says, we prefer to talk

of gender-specific medicine instead of gender medicine since all the diseases affecting women and men in all the fields of medicine have to be studied and taught on the basis of gender differences. This attention to the differences in diagnostics, therapy and, more in general, in the clinical pathways to be followed, has to be considered as an educational background that should be spread in all university courses and fields of investigation: from cardiology to oncology, from neurology to infectious diseases, from immunology to metabolic diseases and so on. Moreover, gender-specific medicine, as described in the healthcare plan of the Italian law, should not be considered as an exclusive medical interest but, more in general, should be developed as a holistic approach that needs the contribution of pharmacologists, biologists, toxicologists, psychologists, and nurses as well as healthcare managers. The involvement of humanistic and sociological approaches as well as social players will be welcome. Therefore, all the stakeholders could contribute to improve knowledge about sex/gender differences in terms of symptoms, diagnostics and therapies. Private companies, such as pharmaceuticals, could play a pivotal role. They could certainly provide more detailed information as concern appropriate dosages and adverse effects of drugs or contribute to the improvement of gender-tailored prevention and specific screening paths for men and women. Biomedical scientific research (both basic and translational) should provide further and new evidence-based data and suggest new solutions and innovations. This will be an essential element for the development of gender-specific medicine. Italy's regional authorities, which coordinate



Obituary

On August 4th, Professor **Andrea Peracino**, a member of the Scientific Committee of the *Italian Journal of Gender-Specific Medicine* and President of the Giovanni Lorenzini Medical Foundation (Milan-New York), passed away. Since the 1990s Andrea has been a stimulus to better understand sex and gender differences in medicine. In 2009, he co-founded the National Research Center on Gender Health and Medicine.

Andrea was a great scholar, a tireless "hunter" of all national and international innovations with the capacity for continuous critical analysis. He was a man of broad culture, rigorous intellectual curiosity who in the last twenty years of his life devoted himself to the improvement of scientific education through the projects run by the Lorenzini Foundation.

But despite his rich professional life he always considered himself a physician.

His culture and personality have been a constant model for many clinicians and researchers. But, above all, Andrea was a great friend of ours who, with kindness and intellectual strength, has always pushed to improve scientific and human dimension of life.

the health system, have to organize regional networks among the various health agencies and universities with the aim of fostering training and creating gender-specific diagnostic and therapeutic healthcare pathways in their territory. Looking ahead, regulatory agencies such as AIFA (the Italian Medicines Agency) should also revise or develop some new aspects of its activity proposing new rules for drug evaluation studies that could take into account both sexes. For instance, the marketing of new therapeutic products, drugs and medical devices, should be approved only if tested in both sexes. Thus, pharmaceutical industries should expand their development plans including the sex/gender dimension and reconsidering their data by starting to stratify the results of clinical trials taking into account both sexes/genders. And, perhaps, they should understand that gender medicine could be a challenge providing new opportunities for the development and growth of pharmacology and drug discovery. The professional board and the Italian National Federation of the Medical Councils (FNOMCeO) is already strongly

committed to support the training of healthcare personnel, surgeons and dentists in this dimension and it will certainly help the Italian National Health Service in the development and implementation of the healthcare plan set out by the gender medicine law.

Finally, after about twenty years of pioneering scientific work, Italy becomes the first Country in the world with a law and a healthcare plan that promise the development of specificity and gender equity in health. This thanks to some women and some men committed in health policies: primarily the Italian senators Beatrice Lorenzin and Paola Boldrini. This is a victory for all of us who believed in the relevance of gender medicine and worked for its development.

We sincerely hope that the law and the plan for the application and dissemination of gender medicine will soon become a milestone for the European Community, a reference for all Western countries and, why not, a stimulus for those countries where diagnostic and therapeutic appropriateness is still a hope or a chimera.

Gender medicine in Italy: implementation of Law 3/2018

Elena Ortona and Alessandra Carè

Center for Gender Specific Medicine of the Italian National Institute of Health

On January 31, 2018, Law 3/2018 "*Delegation to the Government concerning clinical trials of medicinal products and provisions for the reorganization of the health professions and for the healthcare officials of the Ministry of Health*" was published in Official Gazette no. 25.

In particular, Article 3 of this law, "Application and dissemination of gender medicine in the National Health System," required the preparation of "*a plan aimed at spreading gender medicine through dissemination, training and indication of health practices that in research, prevention, diagnosis and treatment, take into account the differences arising from gender, in order to ensure the quality and appropriateness of services provided by the National Health System in a uniform manner throughout the country.*" This Plan was drafted jointly by the Ministry of Health and the Gender Medicine Reference Center of the Italian National Institute of Health with the collaboration of a technical-scientific panel of regional experts in gender medicine and the gender medicine contact persons of the network of Italian Research Hospitals, as well as AIFA and AGENAS. The Plan includes a first part which provides a general framework of gender medicine, describing the priority areas of action and the national and international state of the art and highlighting the importance of applying a real gender-specific approach in health care.

The second part sets out the principles and objectives of the Plan and is divided into the following 4 areas: (A) Clinical pathways, B) Research and innovation, C) Pro-

fessional training and refresher courses, D) Communication and information. General and specific objectives have been set for each of the areas.

A) Clinical pathways (prevention, diagnosis, treatment and rehabilitation)

General objective. To ensure prevention, diagnosis and treatment for each person with an approach that takes into account gender differences, at all stages of life and in all living and working environments.

Specific objectives. A.1) To obtain a complete picture of the structure, organization and resources (human, instrumental, services) of gender medicine in Italy; A.2) To pursue the prevention and early diagnosis of pathologies in a gender perspective based on the epidemiological data; A.3) To develop innovative solutions for access to services, also enhancing the experiences already present in the national territory, implementing paths for taking charge of patients from a gender perspective, in order to favor greater appropriateness and personalization of prevention, diagnosis, treatment and rehabilitation pathways; A.4) To promote actions aimed at applying a gender approach to health policies and on safety in the workplace.

B) Research and innovation

General objective. Promoting and supporting biomedical, pharmacological and psycho-social research based on

gender differences and transferring innovations into clinical practice.

Specific objectives. B.1) To identify and implement gender medicine as a priority in regional, national and, where possible, international research calls; B.2) To develop basic, pre-clinical and clinical, pharmacological and psycho-social research on gender medicine; B.3) To transfer innovations arising from biomedical, pharmacological and psycho-social research on gender medicine in the fields of prevention, diagnostics, therapy and organization to the Italian National Health System.

C) Professional training and refresher courses

General objective. Ensuring adequate levels of training and update courses on gender medicine for all medical and healthcare personnel.

Specific objectives. C.1) To build, validate and use tools dedicated to training in gender medicine, which are effective and replicable; C.2) To promote awareness of gender differences in healthcare in order to transfer the knowledge and skills gained in professional activities.

D) Communication and information

General objective. Spreading the knowledge of gender medicine among all health professionals and the general population, involving the world of journalism and the media.

Specific objectives. D.1) To identify tools dedicated to the transfer of communication content to the target audience; D.2) To inform and raise awareness among health professionals and researchers of the importance of a gender approach in every area of medicine; D.3) To inform and raise awareness among the general population and patients on gender medicine, through campaigns and communication initiatives involving the press and the media.

For each specific objective, the Plan sets out the priority actions, the actors involved and the indicators useful for their monitoring. The implementation of these actions may include subsequent operational plans and national, regional and local technical documents, identifying detailed and specific operational activities and responsibilities.

Finally, a governance strategy is described to ensure effective coordination of actions at national, regional and local level.

In particular, the following actions at regional level are recommended for the implementation of this Plan:

1. identify a regional contact person experienced in gender medicine;
2. establish a regional technical group for the planning of activities for the dissemination of gender medicine;
3. identify ways for implementing the actions set out in the Plan at regional level;

4. create a network system for the advancement and development of gender medicine and health throughout the region;

5. determine indicators stratified by gender to be included in the collection and processing of information flows and in the formulation of health budgets.

On 13 June 2019, Minister Grillo formally approved the Plan by signing the implementing decree relating to Law 3/2018. With the approval of this Plan, we were the first in Europe to formalize the inclusion of the concept of "gender" in medicine, a concept that is essential to deliver the best care to every individual, respecting the differences and achieving a genuine "personalization of therapies."

Pursuant to paragraph 5 of article 3 of Law 3/2018, the implementation of the actions to advance, apply and support gender medicine provided for in the Plan will be monitored by an Observatory dedicated to gender medicine. As per the agreements between the Ministry of Health and the National Institute of Health (ISS) and as also specified in the Plan for the application and dissemination of gender medicine, this Observatory will be based at the ISS and involve other supervised bodies, such as AIFA, AGENAS and the Research Hospitals already engaged in the field. In addition to representatives of the ISS, the Ministry of Health, AIFA, AGENAS and Research Hospitals, the Observatory will include representatives of some National Federations of Professional Boards and Regions. In addition, it is envisaged that the Observatory may rely on the collaboration of external experts according to the topics on the agenda. A proposal concerning the composition of the Observatory, already agreed with the Ministry's directorates involved in drawing up the Plan (Directorate-General for Health Prevention, Directorate-General for Health Professions and Human Resources of the National Health System, Directorate-General for European and International Communications and Relations, Directorate-General for Research and Innovation in Health, Directorate-General for Medical Devices and Pharmaceutical Service), has recently been sent to the Ministry of Health. The general objective of the Observatory will be to ensure the initiation, maintenance and monitoring of the actions provided for in the Plan, updating the specific objectives over time based on the results achieved. In addition, the Observatory will have to produce data for the annual report that the Minister of Health will send to Parliament.

In conclusion, we can say that a very important result has been achieved, but now a great commitment of all professionals will definitely be needed in order to achieve the goal of including this new "dimension" of medicine based on differences in sex and/or gender, in all areas of medicine. The ultimate goal is to improve the health of all through truly personalized medicine, which we hope will be also more effective and economical.