

## Gender medicine: where does Italy stand?

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**Summary.** Gender or gender-specific medicine is a relatively new discipline that enables to pursue an innovative approach to healthcare. In Italy, it has been gaining importance from both the clinical and policy point of view. The aim of this study was to evaluate events, policy interventions and governance action plans by comparing quali-quantitative data with those of a previous review (dated 2013) so as to identify topic and quality evolution. A detailed assessment of draft laws and regional regulatory measures was undertaken. Policies related to gender medicine, other than healthcare, were also investigated to identify individuals who actively got involved in this issue, i.e. the "true innovators" as defined by Everett Rogers. This analysis provides useful information to lay the conceptual and methodological foundations for the development of national regulations that should take into consideration the wealth of research, knowledge and practice accumulated in Italy over the last decade. This will ensure that continuous and targeted attention is given to gender issues with acceptance of subsequent interventions.

**Key words.** Gender medicine, gender policies, diffusion of innovations theory.

### Introduction

This paper will not analyse international gender inclusion policies in health and healthcare; we will only mention, by way of example, that the "gender" theme is established as part of the World Health Organization's 2014-19 action plan, on which the different countries' implementations should be based<sup>1</sup>.

The orientation to take into account sexual and gender differences in diagnosis and care, i.e. gender medicine, is an innovation that began to spread in Italy in 1998, with a more noticeable development in recent years, particularly since 2008, as a result of the events that we will analyze below, along with the progress that has been made from 2013 – year of a previous survey, to the present<sup>2</sup>. The way in which gender medicine is spreading deserves some considerations linked to what Everett Rogers describes as the "Diffusion of innovations theory", intentionally adapted, in this case, to health projects<sup>3</sup>. According to Rogers, innovation can be defined as "an idea, practice or object that is perceived as new by an individual or other unit of adoption", which is taken essentially on the basis of two motivations. The first one is related to the benefit arising from profitability in terms of actions (or money) derived from the innovation itself, following "fashion", the current customs or a novelty. In the case of medicine in general, the benefit would be a possible increase in appropriateness in the biomedical application, attentive to fairness of the right to health. The second motivation relates to consistency with the behaviours and system of values already instilled in the individual. In the case of gender, we can relate the motivation to respect for differences, to which some people are more attentive and sensitive than others, with all the difficulties that this involves for a health professional who wants to make this orientation concrete, in the presence of healthcare practices that are not yet *gender oriented*. In order to learn a new point of view on a subject that has long been established, one needs to be willing to experience a "situation of temporary incompetence" on the new subject, which is not always met with openness and approval by healthcare professionals. Rogers identifies five different types of reaction, corresponding to an equal number of roles: the precursors of the

orientation, in our case the *gender oriented* individuals, are the pure “innovators” who, by promoting the diffusion of the innovation, interest and persuade the “early adopters”, who in turn will involve an “early majority”.

There will always be a “late majority” as well as the *laggards*, whose presence must therefore be regarded as normal in any innovative process<sup>3-5</sup>.

### Survey methodology

The survey was based on the search for information available on the web, with “core drillings” conducted at different times from 2012 to October 2015. The following keywords were used in Google and Yahoo search engines: health + woman (as is known, in its early stage gender medicine was confused with the “women’s medicine”); medicine + woman + gender; medicine + gender + University; center + gender + university; medicine + gender + law; medicine + gender + motion; medicine + gender + healthcare company. In some cases the searches have taken their cues from news reports, subsequently supported by official documents. For the specific analysis of “projects or bills”, reference was also made to Parliament websites, with some difficulties in recovering the wording of “motions”, which are not easy to retrieve. For the Regions’ actions, the search was performed using the key words: medicine + gender + Region’s name. A first “census” of 2013, carried out following the same methodology, provided the basis for a comparison with the current situation<sup>5</sup>. Any information gaps should be attributed to the lack of a national observatory on gender medicine for the monitoring of the various political actions and awareness raising, training and research good practices.

### Gender medicine milestones in Italy

The spread of gender medicine in Italy is due to organizations and people who have played and are playing the role of “innovators”, while an “early majority” of clinicians, professional, women’s and feminist associations, and healthcare volunteers are showing a keen attention to this specific innovation.

**Significant advances made in Italy.** In 1998 the Ministers for Equal Opportunities and Health launched a project named “Una salute a misura di donna” (Healthcare Fit for Women) with a report that highlighted lack of attention, inappropriate responses, across-the-board inadequacies, and underestimation of women’s problems in all the areas observed.

In 2005, the then Minister of Health organized a discussion table with the participation of the National Institute of Health, Agenzia Italiana del Farmaco (AI-

FA), the Regional Health Services Agency (AgeNaS), the University of Sassari and the Italian Pharmacology Society, with the aim to formulate guidelines on clinical and pharmacological trials based on a gender approach. 2007 saw the establishment of the Ministry of Health’s Women’s Health Committee. The Ministry of Health issued the first calls for Targeted Research studies focused on gender medicine.

2008 was rich in events that showed greater attention to women’s health, in the direction of gender medicine: three reports were published by the Ministry of Health and the Women’s Health Committee; the third national seminar on women’s health organized by the National Institute of Health and the Italian Pharmacology Society hosted a roundtable on “Gender medicine, an opportunity not to be missed”; the National Committee for Public Bioethics published a report titled “Pharmacological Trials on Women”. Most importantly, the project “Gender medicine as strategic goal for public health: Appropriateness of care for the protection of women’s health” started that same year. These events created the conditions for the current development.

In 2009 Giovannella Baggio, Director of the General Medicine Unit of the Padua Hospital and President of the newly founded National Research Center for Gender Health and Medicine, along with Giovanni Lorenzini Foundation, organized the first National Conference on Gender Medicine in Padua (at its fourth edition in 2015). In the same year Flavia Franconi, Professor of Molecular Pharmacology at the University of Sassari and Coordinator of the Gender Pharmacology Team of the Italian Pharmacology Society, organized in Sassari a meeting on “Genes, Drugs and Gender”. In 2010 the National Agency for Regional Health Services (AgeNaS) published a special issue of its journal *Monitor* dedicated to gender medicine, and subsequently formed work committees to develop gender-oriented guidelines by disorder.

In 2011 the National Institute of Health appointed Walter Malorni to lead the Degenerative Diseases, Aging and Gender Medicine Department, whose objectives are to adopt a gender approach in the study of the main pathologies with a view to optimizing diagnosis and treatment, and to study gender differences in cardiovascular, immune, degenerative and cancer-related diseases. In 2015, the Institute’s Regulations provided for the establishment of a specific “National Reference Center for Gender Medicine”.

Again in 2011, the Board for the Evaluation of the Program Agreements of Agenzia Italiana del Farmaco (AIFA) introduces “gender equity” among the evaluation criteria and formalizes the “Working Group on Drugs and Gender” to review the issues relating to the regulatory and pharmacological aspects of gender med-

icine; in 2013, AIFA encouraged pharmaceutical companies to develop sex-disaggregated data and gender-oriented study designs.

In the last few years, nearly all the conventions of the various medical specializations have featured at least one presentation on gender medicine, and Committees have been set up in various clinical networks to investigate the influence of sex and gender in the different disorders. This leads to the creation of the Gender Hepatology Committee, the Gender Diabetology Committee, etc. The National Federation of Physicians' Associations (FNOMCeO) established the National Gender Medicine Committee, while the provincial offices demonstrate significant activity<sup>7</sup>; in particular, in 2015 the Bari office launched the pilot project "Gender Medicine Observatory".

Several associations, still active today, were also founded in those years: the National Observatory for Women's Health – ONDa (2005, President: Francesca Merzagora, who was also a member of the Ethics Committee of the European Institute of Oncology); the Italian Group for Health and Gender – GISEG (2009; in 2015 the president is Anna Maria Moretti, pneumologist). Other proactive entities in the area of health and gender include the Fidapa associations; Soroptimist (the 13-15 program specifically envisages the topic); the Women Physicians Association; the Physicians' Wives Association; UDI, the Union of Italian Women; the CGIL Trade Union, and for the specific area of occupational medicine and psychology, bodies like the CUGs, Unified Committees for the Preservation of Well-being, active within public entities.

In 2015, on the occasion of the Milan EXPO, ONDa proposed the "2016-18 Manifesto on Women's Health" which, in addition to expanding the network of Pink Stamp hospitals (an initiative that has been ongoing since the association was founded) and focusing attention on maternity centers and on sexual and reproductive health, intends to pursue efforts, on the one hand, to reduce mortality from cardiovascular diseases, incidence of tumors and depression in women, and on the other to improve the quality of life of women also in cases of chronic disease, as well as to combat violence against women<sup>6</sup>.

### Gender-oriented actions in Regions and Healthcare Units

Under the appropriate governance procedures, the Regions implement gender-oriented actions by:

- a. including gender medicine in the Regional Social and Healthcare Plan (in Apulia, Veneto, Piedmont, Lombardy, Umbria, Tuscany, Marche, and Autonomous Province of Trento), in the Regional Preven-

- tion Plan (in Piedmont), or in an integrated action plan (in the case of Abruzzo);
- b. assigning the objective of implementing gender medicine to the General Managers of healthcare units (in Lombardy and Basilicata);
- c. setting up a regional Group or Committee for Gender Medicine (in Puglia, Tuscany and Veneto);
- d. promoting gender-oriented research (with specific actions envisaged by the regulations of Veneto and Marche);
- e. training of health professionals (e.g. in Apulia, Veneto, Emilia Romagna, Marche and Tuscany);
- f. publishing a regional report on gender health and establishing a Regional Center and Gender Medicine Centers in every healthcare unit (Tuscany);
- g. entering into an agreement to disseminate information on gender medicine (Marche).

Lastly, we should mention the law enforced by the Emilia Romagna government in 2014, containing two articles aimed at the implementation of gender medicine. Other regions (e.g. Campania and Basilicata) are working to adopt a similar legislation.

Several healthcare units promote training programs. Examples worthy of mention are those of the Healthcare Units (ASLs) of all Tuscan cities, of Foggia (in cooperation with the local University) in Apulia; the ASL2 of Lanciano-Vasto Chieti in Abruzzo; of Nocera Inferiore in Campania; of Varese, Monza-Brianza and Mantua in Lombardy; of Nuoro in Sardinia, the ASL 1 of Naples in Campania; in Emilia Romagna, the ASLs of Parma, Ravenna, Forlì, Imola and Ferrara; since 2009, the latter has involved about a thousand healthcare providers in training initiatives and supported the implementation of improvement actions, based on the "Silent Revolution of Gender Medicine" model, with a working group composed of members from the Healthcare Units, the National Institute of Health, the Emilia-Romagna Region and the University of Ferrara.

### Training and health policies

In the Decree of the Ministry of University and Research dated 4 October 2000, the gender-sensitive perspective is placed among the learning objectives in six three-year degree classes (including Exercise and Sport Science) out of twenty-six, and in eleven five-year degree classes (including Medicine and Surgery and Exercise and Sport Science) out of fifty-two<sup>8</sup>.

In 2013, a research study on "Gender-sensitive university and post-university education in Italy" was presented during the National Conference on "Gender, Sociology and University" sponsored by the University of Roma Tre. Based on data relating to the academic year

2011-12, out of a sample of 57 public universities, it was found that only 16 universities had set up courses "on gender" (0.001% of all university education offered in Italy), 20% of which in the area of medicina<sup>9-10</sup>.

With regard to medicine in general, a phenomenon that is becoming quite common is the creation of optional degree courses: after the Chair of Gender Medicine at the University of Padua, organized as of the academic year 2013-14 as a series of interdisciplinary seminars, a similar one was started in Siena from 2014-15, while the University of Ferrara approved a specific course starting from academic year 2015-16. University Research Centres on gender, usually interdepartmental and often oriented towards health and healthcare, are being set up in these years (notable examples are Milan, Bologna, Trento, Sassari, Novara, Pavia, Naples and Bari).

As regards public health policies, during the hearing before the Hygiene and Health Committee of the Senate on 26 June 2014, Minister of Health Beatrice Lorenzin in reporting on health policies during Italy's six-month EU Presidency, focused on the theme of prevention, recalled the importance of "women's health, because of gender-specific characteristics" and the importance of "promoting healthy life styles and prevention (...) also considering gender differences". During Italy's EU Presidency, a European Ministerial Conference on "Women's Health – A Life Course Approach" was organized to affirm the need to evaluate health, disease symptoms and treatment with a careful eye to sex and gender differences<sup>11,12</sup>.

### Motions, Decrees and Bills

Three motions on gender medicine were presented to the Senate in 2007 (nos. 45, 87, 89), all based on the contradictory statement that "while acknowledging that situations of blatant discrimination do not exist in our country, still a number of factors does determine a substantial disadvantage for women with regard to the protection of health". These motions simply requested the creation of a specialization course in gender medicine.

In 2010, Motion no. 1 – 00384 proposed the strengthening of already existing structures dedicated to gender medicine (the National Institute of Health in addition to the ONDa Association and the Lorenzini Foundation), highlighting the usefulness for the NHS to adopt this approach.

In 2011 the Law Decree called "Omnibus" introduced an important innovation.

For the first time, the subject of gender medicine was included in a legislative text to specify that clinical trials should be conducted on an equal number of male and female volunteers.

That same year also saw the creation of the Parliamentary Intergroup "Supporters of gender medicine", which in 2012 signed the "Manifesto for gender medicine" promoted by GENS, a "goal-oriented" alliance for gender medicine formed by the associations Donne in rete, Equality Italia and GISEG, to raise awareness of the need for medical science and research to be attentive to the specificities of women as well as of men<sup>13</sup>. Based on this, the Intergroup developed a "Unified motion on gender medicine" (approved by the Chamber of Deputies but never discussed by the Senate), which defines gender medicine as an "interdisciplinary approach between different medical areas" and recalls article 32 of the Constitution, the right to health and the appropriateness and personalisation of care.

We analyzed the text of this Motion, which in the first part mentions as many as nineteen diseases, including the incidence rates in one sex compared to the other

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|---------------------------|---------------------------------|
| 1. allergies              | 12. thyroid diseases            |
| 2. Alzheimer's disease    | 13. autoimmune diseases         |
| 3. anxiety                | 14. heart disease               |
| 4. rheumatoid arthritis   | 15. neurodegenerative disorders |
| 5. arthritis, arthrititis | 16. osteoporosis                |
| 6. renal stone disease    | 17. chronic diseases            |
| 7. cataract               | 18. osteoarticular disorders    |
| 8. headache migraine      | 19. varicose veins              |
| 9. depression             |                                 |
| 10. diabetes              |                                 |
| 11. arterial hypertension |                                 |

The text lists the major steps that have led to the initiation of research studies, which are providing evidence of an increasing number of differences or confirming often unexpected similarities.

The Motion continues with details that commit the Government to: include gender medicine in the National Health Plan; promote gender medicine applications with "consistent" strengthening initiatives throughout Italy; promote "gender medicine" as a subject of medicine, nursing and other healthcare-related degree courses, in order to foster interdisciplinarity and awareness of the importance of gender medicine; identify healthcare pathways that take gender into account. The Motion stresses the importance of prevention and early diagnosis, suggests tax incentives for research studies that take into account sex and gender differences; encourages information campaigns to increase knowledge on sex and gender differences.

Lastly, the motion promotes the creation of a National Observatory for Gender Medicine in collaboration with the National Institute of Health.

In 2013, two bills with the same title, "Regulations on Gender Medicine", were filed with the Chamber of Dep-



uties. The texts of the two bills, whose first signatories were Delia Murer and Pierpaolo Vargiu, respectively, were very similar and introduced few changes from the Motion mentioned above. The stated objective is to identify provisions aimed at “recognizing gender medicine” in an appropriateness perspective, with applications (integration into the National Health Plan, University training courses, information campaigns, National Observatory, research funding) similar to those already mentioned in the unified Motion and with the Ministry of Health playing a guiding role. Both proposals have not completed the parliamentary process.

## Conclusions

The comparison with the 2013 survey brings to light several interesting developments: the active Regions have almost doubled in number. They also make efforts to develop models whose effectiveness will become visible in a few years; the healthcare units involved are increasingly numerous, and those that do take action continue to do so over time; universities have started to establish departments devoted to gender medicine, even though for the moment the number of courses is much smaller than provided by law; the number of women's, feminist and professional associations is growing at a fast rate; initiatives are constantly taken by the national regulatory bodies, in particular the National Institute of Health and AIFA.

The fact that none of the Motions and Bills (the latter presented in 2013) have completed the parliamentary process suggests that some reflections on the disproportion between ends and means are in order. The various texts focused excessively on biomedical descriptions and the presentation of data, with the more or less overt intent to convince of the benefits of gender medicine.

A future legislative text that pays attention, on the one hand, to the positions of international regulators who already confirm the scientific validation of gender medicine and, on the other, to the assignment of roles to the different players, both old and new, and to the setting of deadlines and binding milestones, will probably succeed in reaching past the enunciation phase and to constitute a concrete and effective tool for ensuring an equitable and appropriate right to health.

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