It Is Not Only a Matter of Biases: Identifying Organizational and Institutional Obstacles to Bring Sex- and Gender-Oriented Approaches into Biomedical Research

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Abstract

An extensive body of research inspired by feminist epistemology and feminist science and technologies studies has contributed to deconstructing the supposed gender-neutrality of biomedical research by shedding light on the persistence of gender biases that threaten the accuracy of scientific results. Against this background, this research analyzes the factors hindering the adoption of a gender perspective in research by considering, as a case study, the field of oncology. To date, most literature has focused on researchers' gender blindness and stereotypes and how to enhance their awareness. In this paper, we have shifted the focus in two ways, moving from cultural to material explanations on the one hand, but also from individual (micro) to contextual (meso and macro) factors on the other. Both aspects have been under-explored so far. In order to do so, an organizational approach to the study of bioscience becomes essential in order to understand the role of work and organizing in reproducing gender biases. Based on interviews and focus groups conducted at the European Institute of Oncology, a research and healthcare organization in Italy, our results suggest that the reasons underlying sex and gender inequalities in scientific research are complex and multi-level, comprising epistemological, methodological, technical, organizational, contractual, financial and normative constraints. As such, they require complex solutions designed not only to "fix" researchers, but also to "fix" institutions, their underlying structure and culture.

Keywords

gender medicine; feminist STS; feminist epistemology; sex and gender research; work and organizations.

1. Introduction

For more than three decades, an extensive body of research within the wider field of feminist science and technology studies (STS) has cast light on the persistence of gender assumptions and biases in biomedical knowledge and practices which entail negative consequences in terms of the accuracy of results and quality of care (Martin 1991; Schiebinger 1999; Åsberg and Lykke 2010; Schiebinger et al. 2011-2020).

In these studies, the idea of science as neutral has been questioned while new critical approaches have been adopted by taking inspirations from, and by putting into practice, the idea – brought forward by feminist epistemologists – that techno-scientific knowledge is always situated (Harding 1986; Haraway 1988). In this respect, Sandra Harding's standpoint theory (1986) and Donna Haraway's theory of situated knowledge (1988) theories had a significant impact on the work of feminist scholars in unveiling the gender dimension of science. Both authors agree that the process of knowledge production is affected by two dimensions: the social, cultural, historical, and geographical location of the researcher and the culture/structure of scientific organizations and institutions.

Most of the empirical work inspired by this epistemological debate has focused on the first of the two dimensions by looking at the gendered assumptions reproduced by researchers and clinicians in their work, mostly due to internalized gender norms which can roughly be distinguished into two different types: gender blindness, which assumes gender equality when differences actually exist, and gender stereotyping, which assumes gender differences even when such differences are not present (Ruiz and Verbrugge 1997; Risberg et al. 2009; Oertelt-Prigione and Regitz-Zagrosek 2012; Marcum 2015).

Undoubtedly, less attention has been given to the second dimension, that of *contextual* obstacles embedded in organizations and institutions, namely research institutes, scientific organizations, funding agencies and the broader scientific community. This research aims to fill this gap as it sheds light not only on the role of cultural assumptions, which are reproduced by scientists in their practices, but also on more structural obstacles, including, among others, organizational and institutional constraints. Unveiling these kinds of factors is possible by adopting an organizational approach to the study of bioscience. Indeed, this approach provides the theoretical and empirical tools necessary to highlight science as the result of ordinary and routine practices which are intrinsically embedded not only into the culture but, most especially, into the materiality (Orlikowski 2007) of the workplaces in which scientists work (Latour 2005; Bruni 2024). As such, this approach makes it possible to provide a comprehensive answer to the research question at the core of this article, that is: what are the factors – at the micro, meso and macro level – that hinder the adoption of a gender approach in biomedical research? More specifically, the individual (micro) level concerns researchers' practices, the organizational (meso) level refers to organizational processes and norms, while the institutional (macro) level includes the role of institutional stakeholders, with their norms and agendas. For this purpose, we conducted a qualitative research field, based on interviews and focus groups, at the European Institute of Oncology (IEO, *Istituto Europeo di Oncologia*), a research and healthcare organization based in Milan, Italy.

Our results suggest that the reasons behind gender inequalities in scientific production are complex and heterogeneous and they cannot be reduced to individual stereotypes only, even though these continue to represent a crucial explanation. They comprise epistemological, technical and methodological issues that researchers have to face in their daily work (micro level), but also organizational constraints, from the scarcity of resources to the contractual distribution of tasks (meso), as well as institutional factors, including the role of funders, ethics committees and data protection norms (macro). Thus, if the *reasons* underlying gender inequalities in scientific production are multi-level, so too must be the solutions. We conclude that interventions aimed at gendering medicine should target not only single researchers but also scientific organizations and institutional stakeholders.

2. Literature Review

The critique carried out by feminist scholars towards the supposed gender-neutrality of biomedical research and its clinical practices is part of a wider debate within the STS on the social organization of science and its relations with power structures. It is not inaccurate to say that it is thanks to the contribution of feminist researchers that STS have made substantial headway in bringing concerns about the social fabric of scientific production (Asdal et al. 2007). At the same time, feminist STS – also called, among other terms, feminist technoscience – did not stem from STS, but rather had their specific history (Adrian et al. 2018). Indeed, their genealogy can be found in feminist theories and, most especially, feminist epistemology. Originally characterized by three different approaches – feminist empiricism, standpoint theory and postmodern feminism – whose boundaries have partially blurred over time (Intemann 2010), feminist epistemology brought concerns over the relations between power structures and the production of scientific knowledge using the lenses of gender and other social categories. In its first, and most conservative, approach, that is empiricism, feminist epistemology was characterized by the uncovering of gender biases in science considered as a threat to the impartiality and neutrality of knowledge and its method, which were not put into question (Fausto-Sterling 1985). With standpoint theory (SpT), and the work of Sandra Harding (1986; 1993) and Donna Haraway (1988), the epistemological reflection went much further, driven by a sharp critique of the scientific method, the notion of objectivity and the claim that partiality is not only an obstacle but can be a resource (Wylie 2003; Tanesini 2015). More recently, postmodern feminists, feminists of color and postcolonial feminists problematized some aspects of SpT, including the risk of a unitary and essentialist idea of "woman" as the fundament of knowledge (Seidman 1994). Their position has shaped both Harding's standpoint theory and Haraway's conceptualization of situated knowledges.

All in all, feminist STS scholars today generally agree on two elements: first, the fact that knowledge and technology are partial, situated and embodied. Moreover, it is achieved from a particular standpoint reflecting the social identity of the subject (and so the intersection of his/her/their gender, class, race and other social categories) and his/her/their social roles and relations within a profession, an organization, an epistemic community (Anderson 2017; Cipriani 2020). Second, the fact that some standpoints – such as those of traditionally marginalized groups – are epistemically privileged because they have a more rigorous critical reflection towards the process of knowledge production and, as a consequence, they are more likely to maximize objectivity (Harding 1993; Intemann 2010; Medina 2013; Cipriani 2020).

Situated knowledges and standpoint feminist aspirations were put to work in many empirical studies conducted by biologists, social scientists and humanities scholars. A rich strand of contributions has focused on the ways through which technoscientific and biomedical knowledge produce biased results based on gendered assumptions (Oertelt-Prigione and Regitz-Zagrosek 2012). On this point, the literature is heterogeneous in both terminology and concepts, and several models have been proposed to account for the different types of stereotypes. A way to efficiently disentangle the scholarship is to distinguish between two forms of bias: i) gender blindness, which assumes equality between women and men; ii) gender stereotyping, which assumes gender differences (Ruiz and Verbrugge 1997; Risberg

et al. 2009). The former presumes that disease risks, symptoms, and progression are equal for men and women when they are actually different, while the latter presumes that they are different when they are actually equal.

Biases in research can be reproduced in the design of a study, the choice of included subjects (cells, animals, or humans), and the way data are analyzed, interpreted and reported. Examples at a preclinical level include studies mainly based on the male sex (Franconi et al. 2015). Likewise, at a clinical level, many drug testing protocols are still gender unbalanced (Grego et al. 2020). Stereotypes in the interpretation and treatment of pain – with physicians more inclined to read men's symptoms as biological and women's as psychological – may also occur (Samulowitz et al. 2018).

Today, the promotion of sex and gender equality in research is a hallmark of many funding schemes, including those offered by the European Commission, and dedicated programs, such as "Gendered Innovations", which was implemented in cooperation with the US National Science Foundation (Schiebinger et al. 2011-2020). Moreover, many tools and guidelines have been developed by editors, associations and funded projects to promote the reporting of sex and gender in the study design, data analyses, results and interpretation of findings, including the well-known SAGER guidelines (Heidari et al. 2016). Such efforts have certainly led to a better gender awareness among researchers across the world, as a recent study on the increasing balance between female and male subjects in biomedical testing shows (Clayton 2018).

However, there is still much work to be done. Existing guidelines usually target researchers, with the aim of enhancing their gender awareness (Heidari et al. 2016; De Castro et al. 2016; Schiebinger et al. 2011-2020). Such types of interventions parallel the over-representation, within the scientific literature, of the role of socio-cultural factors, namely internalized stereotypes and norms due to gender-based socialization (De Castro et al. 2016; Marcelin et al. 2019; Salles et al. 2019; Sukhera et al. 2020). Less attention has been given to other types of explanations, namely contextual and structural factors which go beyond the culture in which we live. This requires delving into the places where scientific knowledge is produced in order to focus on the more concrete, detailed and routine aspects of researchers' activities as well as to the relationship between such activities and the materiality of the workplace in which researchers work.

To do so, an organizational approach to the study of bioscience appears to be essential because of the attention that it gives to the understanding of how researchers' practices are performed and reproduced in the workplace in relation not only to organizational values, customs, (formal and informal) norms, and institutionalized processes, but also – as the "materialistic" turn in organization studies has recently highlighted (Orlikowski 2007) – to material forms and spaces through which scientists interact, namely artifacts and infrastructures (Latour 2005; Orlikowski 2007; Nicolini 2009; Bruni 2024). The idea underlying this is that work and organizing "shape" scientific knowledge as long as scientific knowledge is the outcome of practices which are performed not only within a situated socio-cultural set of meanings, through which scientists understand and interpret their experiences, but also within the more material forms and spaces of work and organizing (Latour 2005).

Following Attila Bruni's introduction to a recent special issue published in this journal advocating the need to renew the interest of STS towards work and organization issues (Bruni 2024), this paper aims to shed light on the work and organizing embedded in scientific phenomena

while adopting an approach that seeks to overcome the dichotomy between socio-cultural and material explanations (Orlikowski 2007). Work and organizing are often invisible to STS phenomena, even when they are essential (Bruni 2024). The aim of this paper is to make them visible.

3. Methodology and Research Field

This research aims to identify the factors that hinder the adoption of a gender perspective in biomedical research by focusing on three different levels: the individual (micro), the organizational (meso), and the institutional (macro). It does so by means of a qualitative fieldwork carried out at the IEO in Milan, Italy, based on semi-structured interviews and focus groups[1].

The research was funded by the Cariplo Foundation within the Science and Technology Studies 2019 Call for Proposal (grant number 2019-3283)[2]. The funding was awarded to the IEO-CCM Foundation – a non-profit organization supporting research activities at the IEO – as leading organization and the University of Milan as partner organization. As IEO was both a member of the research project and the organization in which the research was conducted, this certainly facilitated access to the field. Moreover, from a methodological standpoint, the study followed a participatory approach (Borda 2006; Israel et al. 2019) aimed at identifying obstacles and some possible solutions to promote the adoption of gender-oriented practices together with the IEO participants (researchers, clinicians, HR professionals, research managers) and other stakeholders (e.g., funders). This collaborative process involved mutual learning between the members of the research group and the research participants, with the ultimate goal of facilitating organizational change.

IEO is a health organization that conducts basic and clinical research and provides patient care. As such, it represents the institutionalization of the increasing interconnection between scientific research and clinical practice considered as one of the recent features of biomedicine (Neresini and Viteritti 2014). The institute employs 1,649 individuals, including 325 clinicians and 214 researchers (IEO 2021). The remaining staff includes administrative personnel, technicians, nurses, and professionals including biologists, physicists, chemists, psychologists, and pharmacologists. This type of organization is known in Italy as IRCCS – *Istituto di Ricovero e Cura a Carattere Scientifico*, in English: "Scientific Institute for Research, Hospitalization and Care" – and is distinctive for facilitating collaborations between clinicians and researchers. Focusing on this unique "hospital" model allowed all phases of biomedical research to be explored while observing the direct impact on patient care.

The IEO has long been at the forefront of gender medicine within the national landscape. In 2016, it activated its first Gender Equality Plan (GEP) at the Department of Experimental Oncology. The plan was developed as part of LIBRA, a European project financed under the Horizon 2020 Framework Program that was carried out from 2015 to 2019 (GA. 665937) to promote sex and gender equality in research and innovation. After the project, the Department of Experimental Oncology established the WoMen in Science program, which aims to advance the results obtained in LIBRA.

The research took place from June 2021 to February 2023, during which eighteen semi-structured interviews and four focus groups were carried out. Out of the eighteen persons interviewed,

seven were researchers (two men and five women) and eleven clinicians (six men and five women). As for the focus groups, two of them were conducted, respectively, with researchers and clinicians, and the remaining two with some key figures, including unit directors, HR professionals, research managers and funders. More specifically, the first focus group – on fundamental and preclinical research – included five researchers (one man and four women), while the second one – on clinical research – included four clinicians (three men and one woman). All participants were selected from the Department of Experimental Oncology (IEO) or a clinical division of the IEO, according to the logic of theoretical sampling (Glaser and Strauss 1967).

Both the interviews and the first two focus groups were concerned with bio-scientists' practices and their daily activities within the workplace, with its norms, customs, processes and infrastructure. The third focus group was conducted with three key figures within the IEO, namely two unit directors (one man and one woman) and a research manager (a woman). The fourth one was conducted with four experts (three women and a man) in the field of research funding, three of whom were from different local funding agencies and one from the IEO. These two focus groups were held to investigate the point of view of institutional actors, namely human resources managers (third focus) and the institutional funders (fourth focus), with the idea of identifying obstacles while discussing some possible solutions to overcome gender biases in biomedical research. Coming back to the aforementioned multi-level framework of analysis, we can say that if the interviews and the first two focus groups aimed at grasping the mechanisms hindering the adoption of a gender perspective in research at the micro (individual) and meso (organizational) level, the third focus group focused more directly on the meso level while the fourth and last focus group clearly addressed the macro (institutional) level. Of course, this methodological distinction did not prevent, for instance, micro-level and meso-level aspects from emerging during the focus group dedicated to the macro level or, vice versa, macro-level elements from emerging in interviews and so on. It should therefore be understood as a theoretical framework intended to "guide" the empirical research, without in any way constraining it within a deductive approach.

The data from the interviews and the focus groups were collected in pseudonymized form. Each participant was assigned a fictional name, which is the same name reported at the end of each excerpt in this article, along with their professional role. The collected material – comprising interviews and focus groups' transcriptions – was analyzed through a qualitative content analysis. The Atlas-ti program was used to code, compare and conceptualize the data following the coding procedures suggested by Strauss and Corbin (2008[1990]) in the framework of grounded theory.

4. Results

Our research aimed to identify the factors hindering the adoption of a gender perspective in biomedical research by focusing on three levels of analysis that differ for the subjects involved in the practices under consideration: the micro level refers to researchers, the meso to organizations, and the macro level refers to external institutions. The distinction between micro, meso, and macro is purely analytical, as the three levels influence each other, with the micro affected by the meso and the meso affected by the macro, within a circular process.

Moreover, the distinction is based on the practice itself – whether it refers to researchers' (micro), organizational (meso) or institutional (macro) practices – and not on the basis of the reasons behind that practice. This explains the cases in which a micro-practice is due to meso or macro factors, or the case in which a meso practice is due to a macro reason. We'll come to this point later on.

4.1 The Micro Level: Epistemological, Methodological, and Technical

Our research field identified three types of obstacles to the adoption of a gender perspective in biomedical research at the micro level: i) the lack of gender-oriented evidence, which we refer to as "the vicious circle of research" (to paraphrase one of the interviewees); ii) statistical methods; and iii) laboratory practices.

4.1.1 The Lack of Gender-Specific Evidence and the Vicious Circle of Research

The first obstacle is related to an epistemological issue, namely the absence of prior evidence upon which to construct new research questions that focus on sex and gender differences. This lack is often attributed to the relatively young age of molecular oncology, but it can also result from sex and gender biases in how the studies that form the basis for subsequent meta-analyses are conducted. The absence of prior evidence reinforces skepticism within the scientific community, hindering the initiation of gender-oriented research initiatives, which therefore struggle to secure funding:

> It's a bit of a vicious circle because, obviously, since the question "Are there gender differences?" is not planned a priori and, therefore, as it was not prospectively verified, all analyses you do become retrospective in nature. This reduces the strength of the evidence you produce, and any results you generate are met with skepticism because the methodological approach is not the most accurate. However, on the other hand, prospective evidence cannot be produced precisely because this skepticism exists, and there is not enough to convince someone to conduct prospective studies... it's a bit of a vicious circle. [Stefano, clinician, man]

There is a lack of evidence from prospective studies (designed to include a cohort of patients to be observed repeatedly over time from the beginning), which are considered to provide more robust evidence than meta-analyses. The absence of gender-specific prospective evidence can have direct implications for clinical practice; for instance, it can result in oncological therapies that do not take into account sex or gender differences.

> In my clinical practice, the sex dimension is of little relevance, because in these pathologies, there are no different diagnostics or therapeutic algorithms for males and females. I would like there to be sex-tailored therapeutic algorithms, but I believe that there is not enough strong evidence to support differentiated algorithms. So, the question of whether sex can modify the effectiveness of treatments has never been prospectively investigated, and the existing evidence is too weak to warrant different algorithms in clinical practice. For the gender dimension, it's even worse. There is no prospective literature – there is retrospective,

> hypothesis-generating literature, but it's not strong enough to convince the scientific community to produce different algorithms. [Stefano, clinician, man]

4.1.2 Influence of Sex/Gender Measures on Sample Size and Statistical Methods

Since the establishment in the 1990s of the evidence-based medicine paradigm (Sackett et al. 1996), systematic literature reviews and meta-analyses have become the tools through which medicine aggregates the results of studies conducted over time on the same pathology. Despite being a retrospective technique, meta-analysis has the strength of data due to the size of the sample: by combining even small studies, larger populations can be created, thereby permitting robust evidence to be collected. However, the problem is that sex and gender stratification can reduce the sample size and, consequently, the statistical power:

> If you don't have sufficient statistical power, you can't find the differences. We primarily deal with randomized trials and observational studies, meaning patients, populations... so, large samples [...]. For example, we analyzed head and neck cancer... two large population samples, and we wanted to examine a series of biomarkers... and when you perform stratified analysis, the samples become small [...] and you can't see the differences... maybe they exist, but you just can't see them at all. [Carlotta, researcher, woman]

Moreover, it would be advisable to stratify by age as well, a circumstance that risks further reducing statistical power. Hence, there is a need to develop new methodologies. In the words of a clinician:

> For example, women, unlike men, have biological differences related to age that need to be taken into account. This creates additional challenges, because recruiting a pre-menopausal woman is not the same as recruiting a post-menopausal one. So, all these variables should be considered in the study design, which, in my opinion, would require the development of an appropriate statistical methodology. [Stefano, clinician, man]

In addition to the sample size, another aspect concerns how to measure and distinguish between sex and gender:

> For example, in my research on diseases such as melanoma, we know that both sex and gender play a role in prognosis. So, it's a problem with older men, for instance, who check their skin less frequently and consequently have worse prognoses. There's also the issue of tanning beds, which serves as a different risk factor between young men and young women. [Carlotta, researcher, woman]

Carlotta's statement points to two important issues: on one hand, how to distinguish between biological (sex) and cultural (gender) dimensions, and on the other hand, how to measure the gender variable, independently of the biological factor of sex. On the first aspect, the scientific debate regarding the possibility of separating sex and gender and considering the

biological dimension as independent of the cultural one is highly contentious (Butler 1990; Krieger 2003; Legato 2015; Risberg 2004). As for the second aspect, it points out the need to overcome the gender binary divide by acknowledging that gender is a social construct varying over time and across cultures that exists in a multiplicity of forms, including transgender and gender-fluid identities (West and Zimmerman 1987; Butler 1990). Such positioning – stemming from research within the field of Gender Studies in the field of human and social sciences – has now entered into the biomedical debate as well (Springer et al. 2012; Mauvais-Jarvis et al. 2020). Indeed, transgender people have generally been underrepresented in clinical studies to date, although this underrepresentation is now changing (Mauvais-Jarvis et al. 2020). Furthermore, attempts have been made to think about gender as a continuous, rather than a binary, variable, so as to provide a more inclusive measure Finally, and although this is beyond the scope of this work, it is also important to consider that regarding health and disease, gender intersects with race, ethnicity and – as Carlotta has pointed out – age (Assari et al. 2018; Kanchi et al. 2018; Mauvais-Jarvis et al. 2020).

4.1.3 Laboratory Practices: The Sex of Cells and Mice

A further micro-level obstacle concerns pre-clinical research, and more specifically the sex of cells and mice. Researchers are not generally in the habit of questioning the sex of these:

> I don't know the sex of the cells I'm using in the laboratory, except for the HeLa cells. At the moment, we are screening tumors in mice, and I have no idea whether they are all male or all female.[Alessandro, researcher, man]

This statement is in line with many studies demonstrating that in preclinical research, the sex of the cells and mice is not known in the majority of cases (Ortona et al. 2016) and is therefore not stated in publications. This lack of knowledge about sex is not always due to a lack of gender awareness on the part of researchers who reproduce, without much reflection, long-established practices. Sometimes, the reason is technical in nature. This is the case – as some interviewees have pointed out – of the so-called "immortalized cell lines" which were derived from tumor tissues or from genetic modifications and then made immortal for use over time in experimental models. This process – known as "loss of sex chromosome" (LSC) – risks compromising the possibility of identifying the sex of the original donor, as over time these cells may lose chromosomal characteristics, meaning it may no longer be possible to attribute a sex to the cell (James et al. 2021; Shohat and Shifman 2022).

In the case of mice, the custom was to predominantly use male animals, motivated by the assumed greater hormonal variability in females compared to males, a characteristic that would make the investigative process longer and complex (Beery and Zucker 2011; Franconi et al. 2015). However, this assumption is increasingly considered problematic and baseless, based on gender stereotypes, especially in light of the results of an important meta-analysis published in 2014 that demonstrated the opposite (Prendergast et al. 2014).

Similar to cells, the use of male mice is not only driven by habits ingrained in gender stereotypes (reflecting the individual, micro level) but is also underpinned by structural

considerations engrained in research customs. More precisely, this choice is associated with the reduced expenses of maintaining a single-sex colony as compared to a mixed-sex colony, which requires doubling the units. Referring to the vicious circle of research, and the need to have previous gender-related evidence to access funding, Valentina says:

> I believe that there is no possibility of being granted an in vivo project by the Ministry of Health by saying "I doubled the number of mice because I want to see if there is a difference if I inoculate that tumor, and I still don't know if there will be differences at all, but I will use twice as many animals because I want to see what happens in males and females". [Valentina, researcher, woman]

One reason for Valentina's pessimism is that, without preliminary results or prior evidence, it is challenging to persuade funders of the need to double the colonies and thus the costs. Indeed, a justification for doubling the subjects used must have compelling reasons to secure a grant, despite being a recommended methodological practice by various experts.

4.2 The Meso Level: The Organization

At the meso level, the culture and the organizational structure encourage gender-neutral practices, often with the involvement of other actors, such as administrative staff. Our research identified two types of obstacles at this level: i) the role of research office, and specifically its limited involvement in project writing, and ii) the lack of time dedicated to clinical research due to: a) the non-distinction, at the contractual level, of time to be allocated to different job tasks; b) staff shortages; and c) the lower profitability of research as compared to clinical work.

4.2.1 Planning: The Role of the Research Office

At the IEO, the research office (known as the Clinical Trial Office, CTO) helps grant applicants to write their projects. If consulted, the CTO sends researchers its own protocol to fill out, which facilitates their project development. However, the problem is that the CTO is often involved after the project has already been written. At that point, it becomes challenging for the CTO to intervene and incorporate a gendered approach.

> For spontaneous studies, we receive the protocol [completed, note]... I'm not saying it's already in a final version, but it's when the game is already over [...]. So what comes to us, even if it's not in a final version, especially if there's a grant or a pharmaceutical company involved, it becomes difficult to make adjustments of this kind. A different situation would be to work together from the beginning with the team of clinicians, trying to build the protocol already oriented in this direction. It is feasible; we need to change the working methodology. [Sara, research manager, woman]

As Sara suggests, a change in methodology is necessary to bring greater visibility to the office within the organization and, consequently, to facilitate its early involvement in the planning phase.

4.2.2 The Space and Time of Clinical Research

Several clinicians were dissatisfied with the lack of dedicated time and space for clinical research. In an organization characterized by an intense pace of work, the time clinicians allocate to research is limited; often, it is relegated to evenings or weekends, outside the hospital, to avoid constant disruptions from emergencies or colleagues. This is due to various reasons, ranging from the absence of a clear delineation of duties at the contractual level to staff shortages and the lower profitability of clinical research, as briefly described below.

Unlike other international contexts, where various activities scheduled throughout the week are well-defined and contractually distinct, in Italy (and at IEO), there are no contracts or agreements with social partners that organize working hours:

> If we have a meeting to plan a study, they have to call you ten times because you have to go to the outpatient hospital or to the ward because something is happening here and there. Each of us has tried to organize this as best as possible, mostly by taking on a huge amount of overtime over the years. [...] We held scientific meetings late at night. They were all after-hours. Another important point is that the various departments of a research institute should speak a common language, in my opinion [...]. In other words, if I schedule a scientific meeting after working hours and I'm still clocked in at the institute, this may not be acceptable for the Human Resources office because they have to justify my presence. So, they should set up a schedule for the scientific commitment, but they haven't figured out how to track it yet. In contrast, it's easier for them to track the operating room or the laboratory when they are occupied by me. These are all interconnections that should be made natural in a research institute [...]. The type of schedule for a clinical researcher should simply be defined at the outset, and all of us should try to adapt to it as best as possible. [Matteo, clinician, man]

The lack of formalization of the distinction between various tasks at the organizational level reflects an absence of regulation at the national contract level for private healthcare physicians in Italy:

> We who work in a privileged context should have a perfectly structured balance between clinical work and research. In reality, we struggle, and even we manage research irregularly. Speaking for myself... it's challenging to have an American-style division of the week, where you only do research when engaged in research and only do clinical work when engaged in clinical practice. [Matteo, clinician, man]

The issue raised by Matteo concerns the statute of the IRCCS in general. As an IRCCS, the IEO is called upon by its region of affiliation (in this case, Lombardy) to carry out activities that are purely clinical. The dominance of clinical work over research appears as a structural characteristic specific to IRCCS, as they must play their part in providing healthcare services in the region. Given that the IEO, as many interviewees have pointed out, faces a shortage of clinical staff, the lack of regulations distinguishing research time from clinical

time results in a lack of time available for research. Therefore, not only regulations and rules ensuring autonomy for clinical research are needed but also adequate resources. Otherwise, research risks being stifled by care commitments and incurring very high individual costs, such as unpaid overtime workloads.

The limited availability of time for clinical research is also due to the lower profitability of research compared to clinical work. This latter aspect is related to the corporate nature of IEO: despite being an affiliated structure with the Lombardy healthcare system, it remains a private-type organization, with its cost management logic and a focus on return on investments. From this perspective, the research activity conducted by clinicians may become a management cost for the company, not only because it does not bring immediate profits but also because it takes time away from care, which is more lucrative.

> When you talk to the Human Resources, they tell you that we... the labor cost depends entirely on us, the employees. The costs go this way, the revenues go that way, and when the two curves intersect, there is a moment of stagnation, and so we are essentially seen as costs rather than resources. [Paolo, clinician, man]

> For those who control you in terms of income and expenses, costs and revenues, naturally, if you go to them and say that you have ideas that could produce a certain amount [of research output, *ed.*] but over an extended period of time and could bring prestige to the institution but don't generate immediate revenue, well... the management control officer struggles to understand how to fit in that chapter. [Matteo, clinician, man]

Importantly, none of the participants said that they had received explicit instructions from HR personnel to focus more on clinical activities. However, knowing that research is, in fact, a cost for the organization creates expectations – even if not explicitly communicated within the organization – that are internalized by clinicians. In this way, clinicians end up reducing the time dedicated to research.

4.3 The Macro Level: Institutions and Policies

At a macro level, the focus widens to encompass stakeholders, these include public and private funders, pharmaceutical companies, and Italian and international legislators. Field research has identified four types of obstacles: funding for spontaneous research, funding for commissioned research (including the role of pharmaceutical companies), regulations on patient privacy, and the gender-neutral editorial standards of publishers.

4.3.1 Funding for Spontaneous Research: Studies from a Gender and Exploratory Perspective

For nearly two decades, the European Commission has increasingly implemented policies aimed at promoting the genderization of science through its framework programs (Palmén et al. 2020; Gaiaschi et al. 2022). However, these are practices that few other funders replicate. At the national, local, and private levels, funding for gender research is sporadic. For example,

the Gender Medicine Implementation Plan proposed by the Italian Ministry of Health in 2019 does not include mandatory recommendations on the topic.

> ... Because clearly science is not neutral, and we can't do everything, because we don't have the money. The moment the agency issues a tender... With the exception of ERCs [...] the money reserved for this type of research, I'm talking about basic research: zero [...]. How many gender grants exist? Who has ever seen them... And this is a cultural fact, it is due to everyone... it is not true that it is only the scientist's fault. It's the fault of a system that evolves culturally much more slowly than we would like... [Alessandro, researcher, man]

Funding for gender research is limited also because gender research is still in its early stages and has not consistently generated relevant scientific evidence that can justify new, gender-focused research projects eligible for funding. This is the previously mentioned vicious circle of research: it is challenging for a funder to support a research project that lacks prior evidence. However, accumulating such evidence is difficult without specific grants:

> Because if you say "we don't know", I put myself in the shoes of somebody organizing a panel for a grant, because money needs to be sought after. If I say, "out of curiosity, I want to know if sex is relevant to this question", the standard response from the reviewer panel is, "show me something that indicates it could be relevant, otherwise we won't give you money to satisfy a general curiosity". [Mauro, researcher, man]

Such a vicious circle could possibly be overcome by promoting short-term exploratory or discovery-type funding, which would be economically less risky for the funder:

> It must be said that [...] it is also difficult to carry out exploratory projects if you don't have funding... the cycle is about that, the inability to conduct experiments. Perhaps it's easier to have preliminary data on the patient... because at that point, you have the clinical justification that allows you to perform an in vivo experiment and to convince those who have to grant permission. Going the opposite way, from my experience, is very difficult... practically impossible. [Camilla, researcher, woman]

Exploratory studies would represent a valid tool for promoting gender medicine. However, not all funding agencies provide *ad hoc* funding schemes for this type of short-term research, but rather often favor grants with broader scopes.

4.3.2 Commissioned Research: The Role of Pharmaceutical Companies

In contrast to independent studies, which are initiated by a research group and are usually funded by public entities or foundations, commissioned studies are funded by private entities, such as pharmaceutical companies. This type of study aims to address a specific question of interest to the sponsor or to test diagnostic and pharmacological tools on patients – as in the case of clinical trials. Until the 1990s, drug trial protocols allowed the recruitment of only

men, because women were considered unsuitable to meet experimental standards due to their hormonal variability related to their sex (e.g., menstrual cycle) or their gender role within the family (such as caregiving work) (Epstein 2007; Grego et al. 2020).

The absence of women in trials prevented drugs from being designed to take into account specific characteristics for women, with stark consequences for their health: of the 10 drugs withdrawn from the market in the United States between 1997 and 2000 due to their potential lethality, eight were more harmful to women than men (Schiebinger et al. 2016). From this perspective, the role of pharmaceutical companies – who are among the main sponsors of non-independent clinical studies – has been crucial, as it is up to them to establish inclusion criteria.

> The pharmaceutical company, for profit reasons, prefers to consider a group, achieve statistical significance, and obtain market authorization regardless of stratification by sex, for example, even just to assess toxicity. The pharmaceutical company employs these strategies because regulatory agencies such as the EMA impose rules for registration. If the EMA said, for instance, "I want to see toxicity separated by male and female or by age for drug registration"... However, this is a regulatory problem... [Alessandro, researcher, man]

If pharmaceutical companies lack the economic interest to test drugs on both men and women, as it would entail carrying out longer experimentation protocols, drug regulatory bodies could do more. As Alessandro points out, if the European Medicines Agency (EMA) were to demand inclusive gender recruitment criteria, perhaps more equitable experimentation futures could be envisioned.

4.3.3 Legislation for Patient Privacy

Faced with a lack of funding for exploratory research, meta-analyses allow for a gender-based, retrospective approach, even when it is based on studies for which such an approach was not used. However, conducting a meta-analysis can also have an additional problematic aspect relating to patient data management regulations, as Camilla observed:

> I try to dive into what is published or deposited... sequencing data, genetic or microbiome data... there is no male–female label on a sample that has been deposited! You have the sample but you don't know to whom it corresponds. Maybe you have the paper with a cohort of 200 patients. In the paper, it says there are 100 and 100, but when you check the repository, it doesn't say who they are. There is only a list of samples with a progressive number... [Camilla, researcher, woman]

Similarly, the following interviewee noted:

> Let's say that we have clearly anonymized data for individual patients – this greatly limits the understanding of the impact of sex on disease outcomes. [Mauro, researcher, man]

The anonymization of patient data aligns with the guidelines of the Italian Ministry of Health regarding data treatment in the context of medical trials. The "Guidelines for the

processing of personal data in the context of clinical trials of medicines – July 24, 2008" allows demographic information, such as biological sex at birth, to be deposited only for specific studies. In other words, if the collected and deposited data do not come from studies specifically investigating the sex and gender dimensions, this information is unlikely to be in the repositories. The recent European privacy regulation – the GDPR (Regulation 2016/679) – has only confirmed the provisions of the Italian legislature, preventing the identification of the sex of samples deposited in biomedical databases.

5. Discussion and Conclusions

This research has aimed to shed light on the factors that impede the integration of the sex and gender dimension in biomedical research by considering, as a case study, the field of oncology. Most existing literature has predominantly focused on cultural assumptions – gender blindness and stereotypes of the researchers, together with proposals about how to enhance gender awareness through education and training. In this paper, we have double-shifted the focus: moving, on one hand, from cultural assumptions – whose role in engendering biases is of foremost importance but which has been extensively explored so far – to material constraints – which deserve more attention, but also, on the other, from individual practices to contextual factors – that of scientific organizations and institutions. Thus, even when micro-practices were at stake, reasons going beyond the gender stereotypes of individual scientists were emphasized, such as epistemological, methodological or technical obstacles characterizing the research process.

This double shift – from the culture to the material structure, from individual to contextual factors – allows us: i) to gain a better understanding of the underlying reasons for resistance to incorporating a gender perspective in medicine, and ii) to design more comprehensive and effective strategies to promote it.

Indeed, we find that the obstacles exist at three different levels: the micro level, encompassing researchers' practices; the meso level, involving organizational practices; and the macro level, which concerns institutional practices and norms. Micro-level obstacles include: 1) a lack of preliminary gender-based results, leading to a vicious circle characterized by the scarcity of further funding for a sex- and gender-oriented research (epistemological issue); 2) the lack of statistical robustness when samples are stratified by sex or gender in meta-analyses, coupled with uncertainty on how to measure the gender variable (methodological issue); and 3) the neglect of sex differences in cells and mice due to factors such as i) researchers' lack of sex and gender awareness; ii) the sex chromosome loss in immortalized cells (technical issue); and/or iii) the difficulty of obtaining funds for duplicating mouse colonies and allowing both sexes to be analyzed (institutional issue).

Meso-level obstacles include: 1) limited involvement of the grant office (here, the CTO) by researchers when writing proposals, due to the office's low visibility in the organization; and 2) clinicians' struggles to find time for clinical research due to factors such as i) contracts with unclear task distinctions; ii) an insufficient number of clinicians; and iii) lower (short-term) returns of research as compared to care activities.

Finally, macro-level obstacles include: 1) low funding for spontaneous sex- and gender-oriented research and for preliminary studies by institutional funders; 2) limited funding for sex- and oriented- research commissioned by pharmaceutical companies; 3) international and national norms related to patient privacy, which can obscure the sex of research participants and the quality of collected data used for meta-analyses.

It is important to underline that the three-level model is based on the practices themselves – whether they concern researchers (micro), the organization (meso) or institutions (macro) – rather than the reasons underlying these practices. This complexity explains why many lower-levels obstacles can be due to higher-level factors, within a concentric structure, showing how a micro-practice can stem from meso or macro factors, or how a meso practice can be influenced by macro reasons. For example, the sex-neutral use of mice – which is a micro practice – can be due to the lack of SGR awareness of the researchers (that is a micro factor) and/or to more institutional (macro) reasons, such as the difficulties of obtaining funds for doubling the mouse colonies. The lack of a distinction of the different tasks in the work contract (at the meso level) reflects the lack of bargaining at the national level (and thus the macro). Finally, the low amount of time dedicated to clinical research (meso) is due both to a shortage of staff among clinicians (at the organizational, and so meso, level again) as well as to the nature of the IRCCS and its role within the Lombardy healthcare system (at the institutional, and thus macro, level).

All in all, this research underscores that obstacles are multi-level and show a high degree of complexity. Certainly, these findings are based on a field study conducted within a single biomedical research institute located in Italy and are therefore context-specific, especially those related to the meso level and thus to organizational constraints. At the same time, and also considering the intrinsically "global" nature of scientific practices and communities, they may still offer valuable insights into broader patterns, dynamics, and challenges that could be relevant to similar settings.

If obstacles are complex and multi-level, so should be the solutions. Beyond actions envisaged to enhance researchers' gender awareness, for example by offering them training sessions on the topic and by promoting the use of guidelines for the inclusion of sex and gender in research, efforts should be driven also towards the institutional actors at stake. The third focus group highlighted the need for a clear distinction between research and clinical activities which should be included in the contract, a circumstance that involves – at the meso level, that of the organization – HR and the worker representatives. At the macro level, the request to promote and institutionalize a national network to foster gender equality policies in science has emerged in the fourth encounter. This would involve funding agencies, research foundations, the ethical committees of research institutes, and gender equality officers. This type of network could foster fund-raising events to provide seed funding for explorative studies, and support women's careers by envisaging specific grants dedicated to early-career female researchers.

In summary, this research underscores that obstacles are complex, multi-level, and embedded into organizations, and so should be the interventions for gendering biomedical research. That is, actions should transcend individual practices and target the context in which these practices are carried out. To cite a well-known refrain among gender experts and policymakers

who strive to reduce gender inequalities in academia and science, and therefore inequalities among the *subjects* of knowledge (Burkinshaw and White 2017), gender biases in medicine – and thus in the *object* of knowledge – should be tackled not only by "fixing" researchers (that is by enhancing their gender awareness) but also – and most importantly – by "fixing" institutions – in other words, by changing their culture and their structure.

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Notes

[1] The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy and ethical restrictions. The study was approved by the Ethical Committee of the University of Milan on June, 15th, 2021. (Reference number: 63/21)

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