



Presenting the Gender and Health Research Group

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Second Inserm Ethics Day at ICM

Presenting the Gender and
Health Research Group

Inserm Ethics Committee

**JUNE
2015**

**Second Inserm Ethics Day at the Brain and Spine Institute (ICM), La
Pitié-Salpêtrière Hospital, Paris, France
Wednesday, June 10, 2015**

**Gender and Health Research Group
Presentation text written by Jennifer Merchant, Catherine Vidal
and Mylène Botbol-Baum**

In 2014, the Inserm Ethics Committee set up a Gender and Health Research Group (<http://www.inserm.fr/qu-est-ce-que-l-inserm/l-ethique-a-l-inserm/les-groupes-de-reflexion-thematique-du-comite-d-ethique>). The gender perspective is often neglected in biomedical research in France, as opposed to Anglo-American and other European countries. One of the objectives of this Group is to conduct ethical reflection on the influence of social and cultural factors on the differences and inequalities between the sexes in health and medical research practices.

It is important to encourage physicians to take the differences between men and women into account, not as a simple dichotomy between male and female, but as the result of intricate links between sex and gender (Fausto-Sterling 2000, 2012, Springer 2012, Krieger 2003). Such an approach can improve research practices and consequently increase knowledge about the origins of differences between women and men in health.

In the first part of this document, and in order to use concrete examples, we suggest some thoughts and recommendations for the consideration of gender in three disciplines:

- MRI neuroimaging (Catherine Vidal)
- Cardiovascular diseases (Jennifer Merchant)
- Assisted reproductive technologies (Mylène Botbol-Baum)

These thoughts constitute the beginning of the debate and have already elicited responses from the Committee that will be useful for future versions of this document which, like all Committee Memos, remains open to further development.

The second part includes a report on the Group's activities for 2014/2015, followed by its projects for 2015/2016.

1. PRACTICAL RECOMMENDATIONS AND THOUGHTS ON THE CONSIDERATION OF SEX-GENDER INTERACTION IN MEDICAL RESEARCH AND HEALTH

1.1. Recommendations for neuroimaging research (Catherine Vidal)

Principles and implications for the design, analysis and interpretation of experiments

In neuroimaging research on brain functions and cognitive skills, studies that interrogate the impact of education and sociocultural environment on gender differences in men and women are still rare (Rippon 2014). Neuroscientists are still relatively unfamiliar with the concept of gender. Yet taking it into account can only enrich research on cognitive and behavioral disorders whose prevalence varies according to sex and environment (Dussauge 2012, Fausto-Sterling 2012 a-b, Fine 2014).

In the following sections, we will present some principles that may be useful when considering the relationship between sex and gender, and give examples of how this approach is likely to improve the practices of MRI brain research in both women and men. We will also propose recommendations for the design, analysis and interpretation of experiments (see Rippon 2014 for a detailed review of theoretical and practical issues in MRI research comparing female and male subjects).

The interaction between sex and gender

For more than 10 years, MRI studies on brain plasticity have accumulated to show how experience and learning shape the brains of both children and adults (May 2011, Vidal 2009). The concept of brain plasticity provides a fundamental

neurobiological insight into the processes of social and cultural construction of gender identity. Sex and gender are not separate variables, but interact in a process of “embodiment”, a term that describes the reciprocal interactions between biological sex and the physical, emotional, social, and cultural environment (Fausto-Sterling 2012a-b, Fine 2013). Gender influences biology, and biology affects gender.

These interactions result in a wide range of personalities, cognitive skills and social behaviors, which reveal both differences and similarities between women and men (Hyde 2014). This diversity is reflected in the brain and can be detected by neuroimaging studies (Kaiser 2009, Bluhm 2013, Mueller 2013). Several principles therefore arise in MRI studies on both men and women that need to be considered.

1) There is great diversity in brain anatomy and functioning, regardless of sex.

Meta-analyses comparing the brains of both sexes show that there is no strict dimorphism that differentiates male brains from female brains (MacCarthy 2011, Joël 2011, Giedd 2012, Ruigrok 2014).

The brain volume of men is indeed greater (by about 10% on average) than that of women, even after considering the difference in body size (Cosgrove, 2007). Women also have on average slightly more gray matter, and men slightly more white matter (Hanggi 2014). These differences, however, are related to brain size, and not sex (Hanggi 2014, Jancke 2015). If we compare the brains of men and women of the same volume (around 15-20% of cases in the population), we no longer see differences in gray and white matter ratios (Luders 2014). The few studies that have shown differences after taking the size factor into account are rare, and need to be replicated (Luders 2009, Raznahana 2014).

On a functional level, meta-analyses also indicate significant diversity in brain activity (Wallentin 2009, Bluhm 2013, Mueller 2013, Miller 2014). An overview of the studies on the language areas of the brain that were published from 1995 to 2009, which together included 2,000 subjects, shows that interindividual variability is such that no statistical difference between the sexes can be detected (Kaiser 2009).

It is important to note that there is a certain degree of bias in the interpretation and media coverage of the results of some scientific studies (Guo 2014, Ionnidis 2014, Kriegeskorte 2010). When comparing the brains of women and men in studies with a

large number of subjects, differences that are sometimes observed on a smaller scale go largely undetected. However, it is the studies that show differences that are cited the most often! When going through recent MRI studies on cognitive function, one finds that out of the approximately 16,000 articles published from 1992 to 2008, only 2.6% reported differences between the sexes (Kaiser 2009).

In conclusion, and contrary to popular belief, the brains of women and men show no distinct differences, at least to the degree that they can be easily identified. Meta-analyses reveal that brain diversity is so rich that there is significant overlap (size effect) in the anatomy and function of the brains of both sexes. There is just as much variety in psychological traits, cognitive skills and social behaviors, all of which reflect both similarities and differences (Petersen 2011, Miller 2014, Hyde 2014).

Recommendations 1:

Statistics and data analysis

Given the diversity, differences and overlap between the anatomical and functional traits in male and female brains, the following measures are recommended in statistical analysis:

- Use a sample that is large enough to avoid false positives and negatives.
- If the samples are small, as is frequent in MRI studies, the results need to be replicated before they are considered valid. Use non-parametric statistical tests.
- Estimate size effects and conduct meta-analyses.

Illustrations

MRI results for each sex often undergo separate statistical analyses that are illustrated with distinct images. If these images are different, their *qualitative* comparison is insufficient. It is important to instead make a *quantitative* statistical comparison in which the differences between the sexes are represented by a *single* image.

Publications

Report the absence as well as the presence of differences between the sexes in studies.

This should make it possible to implement the consultation of databases, whose keywords currently only take the differences between the sexes into account.

2) Brain and cognitive characteristics are not fixed but evolve with time and according to the environment due to the brain's plasticity.

MRI research has amply demonstrated that learning and experiences alter both the structure (thickness of the cortex, amount of white matter, etc.) and functioning of the brain (May 2011, Fine 2013). When an MRI scan shows differences between the sexes, it does not mean that these differences have been engraved in the brain since birth, or that they will persist. MRI scans only give a snapshot of the state of a person's brain at a given moment.

Differences between the sexes in cognitive abilities are not immutable. For example, spatial orientation test scores, which often reflect better performances from boys, become the same when the girls being tested are first trained to play video games, or do not fall victim to "stereotype threats" (Spencer 1999, Spelke 2005, Wraga 2006, Feng 2007). Epidemiological surveys show that differences in performance between the sexes in math and languages vary by country and socioeconomic status (Guiso 2008, Hyde 2009, Else-Quest 2010).

In conclusion, the differences between the sexes in education, socialization and life experience are reflected in the functional structure of the brain and in behavior. These gender differences are not fixed, and can be modified, neutralized or even reversed depending on personal experience and sociocultural, economic and political environment.

Recommendations 2:

Image interpretation

- Acknowledge the immediate nature of MRI images, and keep in mind the brain's capacity for plasticity when analyzing MRI scans.

- Question the possible *origins* of the presence or absence of differences between the sexes.

Take variables other than biological sex into account when comparing the brains of women and men

- Collect bibliographical information other than sex, such as age, education, hobbies and interests (such as sports or games), occupation, ethnicity, family history, social status, and economic status.

- Incorporate these different variables when selecting subject groups, in order to form groups that could be more relevant than those which are simply classified by sex.

Writing articles

Use the terms *sex/gender* rather than just *sex* to acknowledge the complex relationships between the two.

General conclusion

Categorization by sex is a general practice that implies that biological sex is a significant factor when studying the neurobiological bases of cognitive function in women and men.

Neuroimaging studies often interpret brain-related differences between the sexes as the result of genetic and/or hormonal determinism (Jordan-Young 2010, Bluhm 2013). When a region of the brain appears to be different between the sexes, it is often seen as reflecting a difference in cognitive skills or social behavior – an interpretation which is often heavily influenced by gender stereotypes.

It is clear that despite current knowledge on brain plasticity, essentialist conceptions of the origins of gender differences persist in scientific publications. Reflection on the ethical issues has to be undertaken in order to create the intellectual and methodological conditions needed to encourage researchers to integrate gender into neuroimaging research practices (Illes 2006, Dussauge 2012, Vidal 2012). It is important to question the normal and the pathological through the lens of gender, and thus move past the simple dichotomy between the sexes. This approach will allow us to develop new models that articulate the biological and social mechanisms that may

explain the differences and inequalities between women and men in the field of health. Taking gender into account in neuroscience also has a social impact when transmitting scientific research to a large public. Explaining that societal roles assigned to women and men are not determined by a biological law hardwired into their brains will help fight against conservative prejudices and sexist stereotypes.

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1.2. Recommendations for integrating sex and gender in research on cardiovascular diseases (Jennifer Merchant)

The link between sex, gender and cardiovascular diseases ¹

Cardiovascular diseases are the leading cause of death for women in Europe. While one in 26 European women dies of breast cancer, one in three dies of cardiovascular disease. Women develop cardiovascular disease on average ten years later in their lives than men – the most commonly cited reason is the notion that menopause can lead to hypertension, diabetes, hyperlipidemia, obesity and other metabolic disorders. This hypothesis reinforces stereotypical views among doctors and researchers regarding the differences between men and women. Yet there is no conclusive research evidence to support this hypothesis. In other words, we have been too quick to decide on the dominant role of hormones as a protective factor, followed by the lack thereof as a factor explaining cardiovascular diseases in women.

This observation invites us to reconsider research protocols. Indeed:

- Women are underrepresented in research on cardiovascular diseases, whether in clinical trials, intervention studies or biomedical research on female animals.
- Out of all of the research protocols, approximately 33.5% of participants are women.
- This underrepresentation is particularly noticeable in research on how to reduce cholesterol, the risk of ischemia and heart attacks.

1. <http://www.fondation-recherche-cardio-vasculaire.org/>

- Because cardiovascular diseases are perceived as only affecting men, women tend less than men to consider the risk factors and participate in screening programs.
- Yet women suffering from diabetes have a greater risk of developing coronary heart disease or experiencing a stroke. Their prognosis is less encouraging than that of men following myocardial infarction and they are at greater risk of death from cardiovascular disease.

These considerations encourage both sex and gender to be taken into account in cardiovascular disease research. Doing so will enable researchers to formulate new questions, analyze symptoms differently, and as a consequence improve diagnosis and envisage new prevention and treatment strategies for the various cardiovascular diseases.

These measures have already been taken in other countries, notably by the National Institutes for Health in the USA and have consequently led to an increase in the representation of women in clinical trials, as well as increased knowledge about the influence of sex and gender on cardiovascular diseases. Another notable result of this initiative has been the launching of new public health campaigns that target women and men differently in an effort to provide more accurate information about risk factors and preventive measures.

Taking inspiration from the programs already underway not only in the USA, but in other countries as well (particularly in northern Europe), we make the following recommendations:

Recommendation 1: *Consider the various cardiovascular diseases according to sex and gender for better adaptation of the diagnostic tools*²

It had long been believed that women suffered from the same cardiovascular diseases as men, namely coronary heart disease. However, recent research in the USA has found that ischemic heart disease is particularly prevalent among women (Shaw, *et al.* 2009). Angiography, the most common technique used in the examination of patients complaining of chest pain, usually results in a diagnosis of coronary heart

2. https://genderedinnovations.stanford.edu/case-studies/heart.html#heart_ischemia_patho

disease in men but is not as effective at detecting the disease in women. Many women complaining of chest pain have "normal" angiograms, and are therefore left untreated. Many of these women have a heart attack or a stroke shortly thereafter (Robinson, *et al.*, 2008).

It is therefore important to use different tools and diagnostic techniques for women, such as coronary reactivity testing (Von Mering *et al.*, 2004; Pepine *et al.*, 2010), intravascular ultrasound (Khuddus *et al.*, 2010), cardiac MRI, cardiac spectroscopy (Ishimori *et al.*, 2011), myocardial scintigraphy, positron emission tomography (PET) (Johnson *et al.*, 2011), and stress echocardiography (Kaul, 2011).

Recommendation 2: *Take sex and gender into account in the expression of symptoms*

An international study of 26,755 patients with cardiovascular disease (only 29% of whom were women) demonstrated that the most common symptom in men (94%) and women (92%) is chest pain (Dey *et al.*, 2009). However, significant differences between the sexes are observed for more "atypical" symptoms (Chen *et al.*, 2005). Women more frequently complain of intense fatigue, nausea and jaw pain – three symptoms that are closely linked to cardiovascular diseases, but do not necessarily raise red flags for cardiologists.

Practitioners must be informed of these issues in order to improve diagnosis and determine the right treatment (Zbierajewski-Eischeid *et al.*, 2009), and researchers need to focus more on explaining these differentiated expressions in the symptoms.

Recommendation 3: *Challenge hypotheses regarding the role of hormones, particularly estrogen*

As mentioned in the introduction, the decrease in estrogen levels has long been regarded as a causative factor for cardiovascular disease in women. As a result, hormone replacement therapy has often been recommended for female patients (Khan *et al.*, 2009). However, large-scale studies have shown the opposite, namely a correlation between hormone replacement therapy and an increased risk of infarction in women (Wilson *et al.*, 1985, Hulley *et al.*, 1998). Further research is required in order to precisely analyze the potential influence of hormones on cardiovascular disease in women.

Recommendation 4: *Take gender into account in order to better prevent and reduce the risk of developing cardiovascular disease*

The risk factors for cardiovascular diseases are the same for men and women: age, hypertension, hyperlipidemia, diabetes, smoking, obesity, sedentary lifestyles, high-fat diets, and so on. However, the prevalence and impact of these factors differ according to sex (Mosca *et al.*, 2012).

For example, smoking is historically more common among men than women (WHO, 2010). However, in certain countries such as Sweden and Iceland, women now smoke more than men (Shafey *et al.*, 2009). Smoking rates among women are continuing to fall in the USA, Western Europe and other industrialized countries, but this is not the case in Central, Southern or Eastern Europe, nor in many emerging countries (Shafey *et al.*, 2009). These geographical differences must be considered in research protocols. A recent study conducted on 3,587 people in five European countries has shown that smoking increases the risk of atherosclerosis in women as well as men. However, the adverse effects are twice as prevalent in women as in men (Tremoli *et al.*, 2010).

These studies on smoking have shown that societal gender roles have an impact on the behavior of men and women who smoke or decide to start smoking. Factors related to biological sex also contribute to the differences between men and women in the susceptibility to and expression of the symptoms related to cardiovascular diseases. In other words, anti-smoking programs must incorporate both sex and gender factors.

General conclusion

For the last twenty years in North America, the introduction of the factors of gender and sex into research on cardiovascular disease has undeniably improved knowledge surrounding diagnosis and treatment. Prevention campaigns that take sex and gender into account have also helped to more accurately target at-risk populations and encourage them to adopt preventive behaviors.

In 2005, the European Society of Cardiology (<http://www.escardio.org/>) launched the “Women at Heart” initiative, which aims to improve awareness and understanding of cardiovascular diseases in women, among both doctors and the general public. The European Medicines Agency has also made recommendations to include more women in clinical trials, and to collect data on gender in order to better assess the effectiveness of treatments for women and men (European Medicines Agency, 2006).

The medical research community in France is gradually becoming aware of the importance of including the factors of sex and gender in research on cardiovascular diseases. The Foundation for Cardiovascular Research, for example, has recently launched the “At the Heart of Women” campaign, <http://www.fondation-recherche-cardio-vasculaire.org/coeur-de-femmes/la-recherche-pour-le-coeur-des-femmes/lancement-programmes-de-recherche-coeur-de-femmes/>.

While these initiatives are encouraging, there is still much work to be done, and Inserm researchers will have a key role to play here.

Integrating the factors of “sex” and “gender” in their cardiovascular disease research protocols can only enrich the knowledge of these diseases and benefit the health of both women and men.

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Prendre en charge le cœur des femmes, <http://www.fondation-recherche-cardio-vasculaire.org/assets/Prendre-en-charge-le-coeur-des-femmes.pdf>

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1.3. Gender bias in human reproductive research hypotheses and its social impacts (Mylène Botbol-Baum)

Descriptions and recommendations for a gendered approach to research ethics

Introduction

No other issues are said to affect women's health more than reproductive health, procreation, contraception, IVF, etc. ... and their consequences. How can we reduce gender prejudice and bias in assisted reproduction, which many studies³ have shown to impact health and contribute to the growing inequalities in access to research and healthcare? While the Inserm has produced many in-depth reports on "fertility disorders", the impact in terms of sex and gender on the inextricable link between sex and reproduction for women – despite the advent of the pill – are barely touched on by these texts, as if the societal and gendered consequences of the research go beyond its scientific dimension and become minimized. But does such minimization of the social effects of research not help to reinforce gender bias in a research field in which the links between sex, reproduction and female/male infertility, generate inevitable ethical questions on gender relations^{4,5}?

It is therefore important to update how these gender relations biases are presented in the research hypotheses, even when the latter aim to be objective, in order to question the conditions and effects of this aim and its communication in the social sphere, and to take into account the gender-dimension of this research without challenging women's equality under the law to make individual decisions on their choices of procreation⁶.

Gender studies began to critically challenge reproductive research in the 1990s. Such heterogeneous studies lead to dialog and debate that rarely permeate the scientific world but raise ethical issues regarding the reproductive rights of women and

3. See Mikkola, Mary, *Feminist Perspectives on Sex and Gender*, Stanford Encyclopedia of philosophy, May 2011.

4. Les troubles de la fertilité, état des connaissances et pistes pour la recherche, 2012. The report focuses on the biological causes of infertility and only addresses the social issues in the final pages, without mentioning the sex-differentiated issue of research consequences.

5. In the wake of the World Conference on Women held in Beijing in 1995, the French daily *Le Monde* pointed out that over forty Catholic and Muslim states had expressed reservations on the passages of the declaration recognizing for the first time the right of women to control and freely decide their sexuality. How does this right of women to control what happens to their bodies apply in the face of "fertility disorders", if decisions are made as a couple?

6. Novaes Bateman, Simone, *Biomédecine et devenir de la personne*, Collection Esprit, 1992.

the quality of biomedical research.

They require researchers in human reproduction to confront the subjective aspect of reproductive rights, as set out in the Cairo Declaration⁷ and since implemented in international regulations, insisting on the autonomy of women in controlling their sexual and reproductive lives, as well as the anthropological representations that they help to alter through the reproductive techniques themselves. Techniques which, paradoxically, open up new possibilities for women but restrict their freedom of choice through regulations that make procreation a biopolitical issue that weakens their acquired reproductive rights: techniques where a critical dialogue between the human sciences and biotechnologies is established.

Gender studies generally reject the idea of scientific neutrality when it comes to research on women's bodies and question the lack of consideration given to the gender dimension of medical research participants in terms of the consequences of the risks and benefits of research.

While feminist studies agree on the fact that reproductive techniques increase the procreation options open to women, they also question the proportion of risk assumed by women in the development of these techniques.

This concerns the medical procedures themselves, embryo transfers, and the invasive techniques involved: donation of gametes, cryopreservation, preimplantation genetic diagnosis. The risks of these techniques, which for women involve multiple pregnancies and their associated pathologies, had rarely been considered prior to their inception. Thanks to the French National Consultative Ethics Committee (CCNE) report and feminist studies, this regulation progressively improved – without forgetting the ethical issues raised, creating a conflict of interest between female reproductive freedom and the status of the embryo. It is therefore essential to consider, prior to carrying out the research and from the gender perspective, the consequences of this

7. Déclaration du Caire 1994, intégrée par l'ONU en 1998 : « les droits reproductifs peuvent être vus comme ces droits, possédés par toutes les personnes, leur permettant l'accès à tous les services de santé reproductive... Ils incluent aussi le droit de prendre les décisions reproductives, en étant libre de toute discrimination, violence et coercition... Les droits reproductifs sont intimement liés à d'autres : le droit à l'éducation, le droit à un statut égal au sein de la famille, le droit d'être libre de violence domestique, et le droit de ne pas être marié avant d'être physiquement et psychologiquement préparé pour cet événement » [ONU, 1998 a : 180] (repris de http://horizon.documentation.ird.fr/exl-doc/pleins_textes/pleins_textes_7/autrepart/010023309.pdf)

research in order to minimize risks and increase benefits for women.

While the issues raised by *assisted reproductive technologies* have been the subject of many national and international bioethics committee opinions, they have above all become a means of *acclimatizing* the public to these technologies without reaching a sharable consensus on what makes or does not make them legitimate. Gender studies have refused to submit to a social signification of these technologies to the biological facts of reproduction and have produced an impressive body of critical literature on these technologies, all too often ignored by researchers in the field.

I will therefore concentrate here on the ethical and scientific reasons for taking seriously gender bias and the confusion between sex and gender in this debate, so as to improve the perception and quality of the research on present and future reproductive techniques which would include a gendered perspective of these techniques. We might ask ourselves why the numerous feminist studies on the subject have not seriously impacted the methodological *a priori*s of reproductive research. We might naively suggest that the hierarchy between the sexes has difficulty being challenged by disciplines, or that men – who are in the majority – have difficulty negotiating their privileges around a social egalitarianism they consider to challenge the coherence of the neutrality of their epistemological model by introducing anthropological and social data that go beyond the realms of their expertise and seem too empirical to be verifiable.

To consider, for ethical reasons, that the integration of these two epistemological discourses implies an alternative and more egalitarian biopolitical model, driven by the research institutions and the researchers in a context in which the institutional hierarchy often confirms existing gender privileges, privileges which must be undone, which research ethics requires us to challenge. It is therefore about questioning – in reproductive medicine and in general – the myth of the axiological neutrality of the natural sciences.

For that we will need to challenge the resistance to the gender perspective in science and propose recommendations for the improvement of scientific excellence through the introduction of a gender perspective, hitherto perceived as incompatible with the hypothetico-deductive approach because, we are told:

- either neutrality towards gender would deny male/female biological determinism,
- or positive discrimination skews the objective data from research on biological determinism through a belief in unalterable universals, or in an irrational relativism of the cultural values.

Biotechnologies: redefining the reproduction players

Recent developments in assisted reproductive technologies have led women to question the purpose of the reproductive technologies in the redistribution of the roles of the procreation players.

The field of reproductive research as laboratory for changing gender categories and power struggles

The field of reproductive research is one of the most illustrative of this methodological bias and of the power struggles involved from a heterosexual research perspective, as the work of many sociologists and feminist biologists (Haraway, Fausto-Sterling) has shown.

Indeed, men for a long time remained the principal players and women the subjects of research, without implementation of ethical rules of research, until the bioethics law in France in 2004. Reproductive technologies straddle multiple disciplines in the domain of therapeutic innovation, faced with women made vulnerable by sterility that deprives them of their traditional social role and for which they demand therapeutic solutions which did not require very clear informed consent protocols as they were the ones calling for those solutions – a situation which has evolved thanks to recent bioethics opinions and work. Feminist studies first criticized the seizing of power over women's bodies, in an area that was the only recognized social role of women. Science was going to make children with and for women. The situation in France, as the 2011 report by the French Biomedicine Agency shows⁸, is more nuanced. It states that sustained research efforts will be needed to improve infertility treatments, particularly assisted reproductive technologies, and highlights genetic or

8. *Les troubles de la fertilité, état des connaissances et pistes pour la recherche*. Rapport remis au parlement le 18 décembre 2012.

constitutional factors among the causes of impaired reproductive health, but above all the behavioral aspect of delayed procreation for women and smoking. The servitude concerns the biological markers of male and female fertility. It is about “controlling fertility” and it is added in the introduction that social choices must be justified in order to harmonize the advances in knowledge in fundamental research, population research and surveillance. Nevertheless, the part devoted to societal challenges appears only in a few pages of the third section of the document which reports the evolution in knowledge on human reproduction, but only mentions the question of “individual aspirations”, while noting that faced with a wide variety of demands, the legislator is led to make difficult choices and observes that faced with the restrictive regulation of assisted reproductive technologies, the reasons for which are not analyzed, increasing numbers of men and women go abroad to benefit from methods that are forbidden in France, without addressing the societal or gender issues, even the democratic dimension of the respect for “individual aspirations” beyond biological and gendered determinations⁹.

The domain of reproductive technologies is also paradoxically that in which gender biases have been displaced by the opening up of new reproductive possibilities, circumventing the biological determinations of individuals, to be better confirmed by genetic sex, bringing us back to an idea of the generalized plasticity of the living which minimizes the dimension of individual and social choice of the subjects of norms, which is not without raising fundamental ethical issues regarding the legitimacy of medical or political decisions that affect the private body.

The question being: how do the scientific and/or social norms that define human reproduction and filiation reconstitute and question the limits of subjects in what has become their reproductive choice? There again, the limit of legitimacy will depend on the political and institutional context of the subject, which questions the conditions of the universalization of scientific data. But also the normative capacity of States faced with reproductive tourism in a world of free movement of information and in a Europe of free movement of people.

Assisted reproductive technologies challenging the ability of biological determinism to infer social roles

9. [Idem conclusion page 106.](#)

Assisted reproduction was indeed the first biomedical technique to challenge gender roles, while practically displacing the monopoly of the heterosexual model and opening up the possibility of homosexual reproduction using surrogates, even fantasies of an artificial uterus erasing all biological determinism¹⁰. Although these questions are regulated by law, the latter is always late when it comes to the normativity inherent to the practice of research and to its developments in healthcare.

Indeed, reproductive biotechnologies, which have displaced the embryo from its “natural” setting to the petri dish, have as a consequence modified the social representations of filiation and gender roles, and have had an unsuspected social impact, altering the anthropological representations of the gendered role of men and women since the dawn of humanity, there again confusing male and female, social roles of men and women.

The science of reproductive technologies has become an actor of social modifications and therefore cannot claim neutral epistemology on the definition of the supposed natural character of reproductive roles. It highlights the limit of the natural character and as a consequence the contingency of reproductive roles as inferring immutable social roles. Paradoxically, the refusal of procreation also became an option for women and not a failure of their social role predetermined by an androcentric society which had medicalized sterility. Motherhood could still be chosen despite biological sterility. Science therefore brought complexity to anthropology and opened up to the interpretation of these new possibilities. Reproductive medicine became empowering (giving additional capacities) or alienating for women, depending on the place it gave the right of people to express their subjective choice, to accept or refuse the application of certain research to their person.

The specificity of gender studies involves not submitting social signification to biological facts.

However, the purpose of assisted reproductive technologies is to compensate for the failure of natural human reproduction processes. French bioethics laws, for example, define assisted reproductive technologies (artificial insemination, IVF and embryo transfer) as having two purposes:

10. Atlan, Henri, *L'utérus artificiel*, Seuil, Paris, 2005.

- to remedy medically diagnosed sterility in the man or woman or
- to avoid transmitting a particularly severe disease to the child.

The social conditions of assisted reproductive technologies are more or less strict depending on the national culture and the representation of the family, and often exclusively concern married couples or couples which can supply proof of at least two years of living together.

We see that the social regulation of assisted reproductive technologies unconsciously reproduces the traditional social patterns which are here regulated by politics and medicine and withdrawn from the judgment of women by technical mediation.

It is therefore important to analyze the ethics of reproductive technologies, from a gendered, non-naturalist viewpoint, which defines the difference in sexual roles as social construction; this does not mean that the woman does not exist as a social reality, but precisely that she is determined by social structures that she should be able to help modify, but which often she can only confirm.

It would be useful to challenge the idea by which the technosciences are neutral and necessarily beneficent, when referring to this major biotechnological and biopolitical challenge which medicalized reproduction has become.

The critical view of assisted reproductive technologies by feminist sociologists

The epistemological and political problems related to this issue have been concealed and masked by the vague term of human reproduction, as if the issue of gender equality was already resolved. We wish to show that power issues between the sexes are fundamental around this technique whose protagonists are insidiously not the man and the woman but “the couple” and “the embryo”, two new and particularly unclear legal entities¹¹.

The questions asked by gender literature are: for which women are the assisted reproductive technologies intended? Why is the woman transformed into a “uterine supply system”, serving the embryo and scientific research?¹² How does medical and

11. See here the French Bioethics Laws of 1994.

12. Duden, Barbara, *Disembodying Women. Perspectives on Pregnancy and the Unborn*, Harvard University Press, 1993.

political expertise in procreation as quality production become a justified extension of the familial and private decision?

The debate is all the more complex in that it brings back into play the dichotomies between vitalism and materialism, public and private, corporatist rights of the mothers and the right of women to control their bodies, etc., and raises major power issues.

Faced with these phenomena, the need to rethink the bioethical concept of women's reproductive rights and responsibilities in the face of men re-emerges, but essentially feminist movements, too much in a minority to have political representativity, or women isolated in the face of the disappointments and suffering that these techniques often cause, even though they address a biologically determined **and** socially constructed desire to fulfill their womanhood through maternity. Because reproduction has become "assisted", the concepts of freedom and reproductive rights have been weakened and are perceived by some women as the price to pay for their sexual liberation. To this "personal tragedy" of infertility said to concern only five percent of women, contemporary biomedicine responded with a succession of IVF techniques. While their initially doubtful efficacy has continued to increase, they have helped to radically change our social perceptions of filiation, of the person, of the concept of birth and even the natural character of conception – the representations of which have gone from reproduction to production, even if common parlance refers to assisted reproduction. This concept of assisted reproduction is problematic from the gender viewpoint, because it hides from everyone that biotechnology in human reproduction takes the reductive and essentialist place hitherto held by the concept of natural reproduction, from the point that it comes an obligatory step and reimbursed by French state health insurance.

We can see, from the emergence of these new issues, that the "flip side" of this efficacy, from the viewpoint of our largely-patriarchal-remaining societies, is the intrusion or disruption of the symbolic representations in relation to *the nature* of reproduction¹³.

We read an underlying conflict between the social order of the biotechnologies

13. Chesler, Phyllis, *Sacred Bond. The Legacy of 'Baby M'* (publ. Crown, 1st ed. 1988) opposes a surrogate mother to her adoptive parents. The book reiterates the old belief that maternal filiation is more biological than paternal filiation, and this in a moment when legislators are trying to establish either biologically or genetically the role of the father (Vandelac 1990).

and the natural order. It is all as if the social order was disrupting the natural order. Scientific realism is no longer content with describing what is real. It modifies it, thereby becoming an anthropological player, which requires ethical reflection on the legitimacy of these modifications, which affect couples seeking medical help for infertility, but do not mention the fact that the treatment is much more invasive for the woman, even when it is the man who is infertile. The complex links between scientific possibilities and the need to re-evaluate our social choices, as to the limits of the field of expertise to give to these sciences, once sociocultural issues are involved, oblige the sciences to assume a major biopolitical role: communicate and dialog in order to undo representations founded on partial knowledge or vectors of ideologies.

These issues, which seem remote from the research itself, have a major impact in terms of ethics or legitimacy of some studies, particularly on embryos and the place of the representations of the role played by women in technical decisions: implantation of a specific number of embryos, selection of the embryo under the microscope, etc. which erases the dimension of chance. The responsibility caused by such embryo displacement has granted power and responsibility to research, which has often been criticized by women, and has given rise to the creation in Europe of national bioethics committees, meant to arbitrate these power struggles based on both scientific and ethical criteria, but again without the sex/gender perspective being incorporated in the majority of the European regulations. It gives women, particularly with the famous Perruche case in France, the impression of being dispossessed of the control over their bodies because the decision gave less space to sex-gendered representations than to “scientific” criteria.

Challenging the harmful effects for reproductive medicine of the hierarchization between the social and biological sciences

The concept of gender must be introduced into science reflectively in order to avoid supporting or reinforcing, through genetic jargon, social prejudices relating to reproductive roles and their biological determination.

It can be seen in the scientific literature that the terms sex and gender are often used interchangeably and still do not modify research practices to a sufficient extent.

It is important to promote the awareness of biomedical science researchers within the context of their respective fields, as requested by the European Commission

since 2010. The plasticity of the living already renders researchers particularly sensitive to these social and contextual dimensions, but tools of non-discrimination must be developed in order to transform this sensitivity into a capacity to resignify the impact of these techniques in relation to existing social norms and the hierarchization between men and women, which prevail over the topics and the priorities of research issues. Introducing the concept of gender into research must involve critical training on its relevance and on the knowledge of research regulations that the international bodies produce.

Does sexual division remain a relevant normative marker?

The status of the gender concept in the biological sciences was not the feat of the biological sciences themselves, even though they have helped challenge the social biases of gender through the reproductive possibilities that they have opened up. It was done by social sciences without always being able to establish a genuine dialog with biomedical research and assisted reproductive technologies. Nevertheless, the methodological decision to reduce sexual difference to masculine and feminine is a bias whose effects are both social and scientific. Among the scientists themselves, biological sex is inferred by simple observation, and the majority of scientific publications consider these categories as evident. The role of ethical reflection is precisely to question these unshakeable inferences by firmly showing the harmful effects they induce on the mental and physical health of those who do not recognize themselves in these *a priori* categories.

It is the ability to challenge the criterion of sexual difference in biomedical research which, out of prejudice, continues to attribute some diseases to women rather than men.

This gender perspective is a critical perspective, which challenges the biological difference of the sexes and the legitimacy of inferring normative knowledge on others from an observation. If this challenge is not effective in the upstream stages of research, new biotechnologies will only contribute to reproducing social biases in the name of a hypothetico-deductive approach.

Recommendations for the inclusion of gender in assisted human reproduction

- ***Train researchers in the issues of the social consequences of scientific research.***
- ***Take seriously the polysemy of the biological sex concept from the gender viewpoint, and do not be afraid to embrace uncertainty.***
- ***Face the challenge of the normativity criteria to be adopted for the incorporation of new reproductive technologies.***
- ***Consider women rather than couples as decision-making agents in reproductive medicine.***

It is therefore not just about promoting research policies in terms of gender equality, because research increases rather than eliminates differentiation.

By incorporating the complexity of the gender dimension in research, in the very name of research excellence, our aim must be to shed light on the gray areas and biases in research provoked by unconceived presuppositions upstream of the research protocol, which involves:

- assuming social equality between men and women in research institutions,
- assuming biological differences between men and women without challenging the equality of opportunity and decision in terms of gendered reproduction,
- avoiding invalid inferences by using critical thinking to update implicit gender bias in research practices¹⁴,
- paying upstream attention to gender bias in disease research and classification by raising researcher awareness of gendered variables,
- not presenting opposing methodologies between science and gender but promoting complementary epistemological models for the sciences that have a social effect.

14. Ruis, Thereza & Verbrugge, Lois, « A two way view of gender bias in medicine », *Journal of Epidemiology and Community Health*, 1997, 51, 106-109.

More generally

- In medical research, take into consideration both the differences between males and females and the social norms concerning men and women, which do not obey the same epistemological models.
- Fight the effects of sexism in the teaching of biomedical research.
- Associate social science researchers with innovative medical research.
- Take gender aspects into account in sex-specific medicine. They are not contrary to the equality of rights of access to research and healthcare.¹⁵
- Incorporate gender issues in the internal and external evaluations of research institutions.
- Implement at institutional level a strategy to promote gender equality and not positive discrimination, which would call into question people's real abilities.
- Continuously train researchers, by addressing the new technologies and their social impact, by involving human science researchers in the laboratories.
- Improve communication on biotechnological innovations, incorporating the gender perspective into the social consequences of research.
- Do not oppose social egalitarianism and gender-specific medicine.

General conclusion

The aim of these recommendations is to promote a culture that is more inclusive of gender issues, which can only improve the quality of and public receptivity to therapeutic innovations, rendering researchers more accountable for the social implications of their research in terms of the gender and sex aspects.

While assisted reproductive technologies have considerably modified the possibilities for women and men suffering from sterility, they have also modified our

15. See *Structural Change in Research Institutions. Enhancing Excellence, Gender Equality and Efficiency in Research and Innovation*. Report of the expert group on structural change, EUR24905, 2012.

anthropological perception of procreation and filiation. It is crucial that new biotechnological advances affecting procreation do not remain closed to research concerning conflicts of social perception of these technologies.

This also implies devising a more integrative and interdisciplinary epistemology and reducing opacity in decisions and in the choices of biomedical research subjects.

Further reading:

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2. “GENDER AND HEALTH RESEARCH” GROUP 2014-2015 ACTIVITY REPORT

2.1. International Gender and Health Colloquium, held by the Emilie du Châtelet Institute in partnership with the Inserm, June 8-9, 2015, Amphithéâtre Buffon, Paris Diderot University

The objective of this multidisciplinary colloquium is to analyze how societal gender roles tend to influence how women and men (i) are exposed differently to health problems, (ii) perceive their health problems, (iii) use or do not use the healthcare system, and (iv) how healthcare professionals respond differently depending on the sex of their patients.

The colloquium looks at the links between gender and health in various disciplines: psychological disorders, cancer, cardiovascular diseases, HIV, sexual and reproductive health, health and work, aging.

Plenary conferences

- Prof. Kristen Springer, Rutgers University: Gender and health: questions of research
- Prof. Donna Mergler, Université du Québec à Montréal: Gender and environmental health
- Prof. Rebecca Jordan-Young, Columbia University: Gender and mental health
- Prof. Sara Arber, University of Surrey: Gender and Aging
- Prof. Rayna Rapp, New York University: Gender and globalization

2.2. The morning of the second Inserm Ethics Day, devoted to Gender and Health Research, June 10, 2015, ICM, La Pitié-Salpêtrière Hospital

Guests of honor:

- Rayna Rapp: Director of the Anthropology Department at New York University
- Francine Ntoumi: Chair of the Congolese Foundation for Medical Research
- Geneviève Chêne, Director of the Aviesan Public Health Research Institute, and Director of the Public Health Unit of Bordeaux University Hospital, will attend as guest speaker.

2.3. Initial contacts for organizing Gender and Health training with Inserm researchers

The primary objectives of these training sessions are to:

- Raise researcher awareness of the fact that biology must not mask the role played by social constructs in health behaviors.
- Develop novel methodological approaches to research with the gender tool in understanding the normal and the pathological.
- Challenge the clinical methods of management, healthcare, screening, follow-up... through the lens of gender.

Contacts and resolutions:

- Jean-Yves Barthe, manager of the Inserm Training taskforce

We agree to apply to hold a Science and Health meeting in 2016

- Claire Levy-Marchal and Sonia Gueguen, managers of the Clinical Research Training unit, Inserm Public Health Institute.

For clinical research, a document summarizing the recommendations of this Memo will be sent to the project leaders for consideration regarding the links between sex and gender in the design, analysis and interpretation of experiments.

3. “GENDER AND HEALTH RESEARCH” GROUP PROPOSED ACTIONS FOR 2015/2016

- **Gender and Health training** for Inserm researchers:

Realization of the resolutions agreed upon with the managers of the Inserm Training taskforce and Clinical Research Training unit.

- **General public communication project:** production of a short video (2 min) to promote the consideration of gender in health research.

See the video produced by the Canadian Institute of Gender and Health

<https://www.youtube.com/watch?v=LCiSytha55U>

- **Recommendations to the Ethics Committees (CPPs) and Regional Ethical Think Tanks (ERREs)** to introduce the issue of gender in the examination of clinical research protocols in accordance with the recent European regulations.