

Sex, gender and health

2020

prospective analysis report

HAS

HAUTE AUTORITÉ DE SANTÉ

Advancing quality in health
and social care services

There are numerous definitions for terms relating to sex and gender.

This report uses the definitions indicated below.



- The term **sex** is employed to refer to the biological sex of a person or group. Used alone it covers chromosomal sex, gonadal sex, anatomical sex and physiological sex.
- The term **gender** refers to the social construction of sex:
 - sometimes the gender experience, i.e., the gender people are perceived to be by society;
 - sometimes the gender identity, i.e., the gender people perceive themselves to be.
- **Trans people** are individuals whose biological sex does not match their gender identity.
- **Intersex people** are individuals whose sex characteristics at birth do not correspond to binary norms defining males and females (people with variations in sex characteristics).
- The term **gender stereotype** refers to a social norm defining behaviours supposedly characteristic of a given gender.
- Here, the term **sex-based differentiation** relates to differentiating elements that concern both sex and gender.



EDITORIAL

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For this third edition, HAS has chosen to build its annual prospective analysis of the healthcare system around sex and gender, two factors that influence our sensitivity to diseases, their expression, our health and life paths, as well as our behavior as users and professionals.

Biology plays a key role in health, yet sex is not fully taken into account in public health strategies. Gender is also often neglected, including in social care strategies. Public policies often make little attempt to take into account the influence of these two factors; sometimes, on the contrary, they are too restrictive in the targets they aim at, at the risk of widening or even creating health inequalities.

Sex and gender are often inseparable, and act in addition to other key factors for our health. Understanding their influence requires a detailed analysis and the mobilization of new approaches to health. The findings of this report show that we must, in some cases, collectively build tools that take our differences into account. Our administrative norms, the rules for clinical trials, the guidelines drawn for professionals in the health, social and medico-social sectors, and their training must take greater account of the specificities of each individual.

Not all of these public policy instruments need to be differentiated by sex or gender, but understanding the differences that may emerge must be our common concern.

To this end, we commit HAS to act.

We will bring the concerns raised in this report to the bodies in which HAS participates. We plan to make sex and gender issues in health one of the axes of our training plan. We will soon ask manufacturers to provide results broken down by sex in real-life studies. We will be equally vigilant about the data used in artificial intelligence algorithms. The objective is to ensure that health products are made available to all users with the same guarantee of effectiveness and safety.

In the medium term, we plan to review our working methods to better integrate sex and gender issues. These issues will be systematically considered in the literature reviews that form the basis of our productions, and we will go further in the search for gender balance in our committees and working groups.

We encourage all actors in the health and social care sectors to take up this issue, and we commend those who are already undertaking this change. This report formulates ten proposals for public decision-makers and players in the field. It provides avenues for action as we are convinced that taking better account of sex and gender means improving the health of all.



T. F. Wang

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Sex, gender and health

By an Order issued on 26 January 2017, the Haute Autorité de santé (French National Authority for Health - HAS) was tasked with transmitting to Parliament and the Government each year a prospective analysis of the French healthcare system, together with proposals for improving its quality, effectiveness and efficiency. In this analysis, it considers health in its broadest sense and therefore examines the health, social and medico-social fields.

For its third edition of this report, HAS has chosen to analyse our healthcare system through the prism of two factors likely to improve the health of all and contribute to reducing certain inequalities: sex and gender.

Sex corresponds to physical and biological characteristics. While gender relates to socially constructed roles, behaviours, expressions and identities.

Why focus specifically on these two determinants of health? Because differences between the sexes are numerous, inadequately documented, too often ignored and sometimes

a source of health inequalities. These differences are linked to our biological specificities, or to our behaviours, sometimes induced by associated gender stereotypes. Although they are also induced by social inequalities that have repercussions on health, efforts must be made to ensure that sex and gender are better taken into consideration, both in formulating and implementing public health strategies.

It is for this reason that HAS is making proposals aimed at adjusting French public health policy and adapting its instruments. It also makes its own commitments with a view to incorporating sex and gender issues into its own actions and work.

Although these proposals and commitments primarily concern the French health system and are thus thought and designed for the French context, this English version aims to make the elements of reflection developed in the report available to non-French players.

Why focus on sex and gender in the area of health?

When HAS started drafting this report it quickly became clear that the realities related to sex and gender are particularly complex when it comes to health.

Hence for men, the weight of certain diseases and conditions considered to be “women-only problems” is still too often ignored and inadequately tackled. Osteoporosis is one example. Conversely, when it comes to women, until very recently the signs of a heart attack were too often confused with those of an anxiety attack. Similarly, while women are more affected by a certain degree of job insecurity despite doing better, on average, in the school system, the fact that more boys drop out of education early without undertaking any other forms of training is often overlooked. This has long-term repercussions for health, the WHO having pointed out the close links between level of education and working life, on the one hand, and health inequality, on the other.

The literature illustrates this, with numerous publications calling for a renewed look at the issue of sex in the area of health. Not only because health outcomes are positioned at the crossroads of many factors that go beyond sex alone, but also because situations outside this binary approach call for some nuance. Hence this report also looks at trans people, i.e., individuals whose gender identity differs from the biological sex assigned at birth, as well as intersex people, understood as individuals who, cannot be classified according to the medical norms of so-called male and female bodies with regard to their chromosomal, gonadal or anatomical sex. Each of these two populations provides a different perspective on health-related issues.

In this report, the analysis of health findings is conducted through a succession of themes demonstrating the influence of sex and gender on health. It highlights:

- differences in morbidity and mortality and behaviours that are risky to variable degrees, strongly linked to sex and gender identity, often at the intersection of other factors;
- too little consideration of sex and gender specificities in the medical field, as illustrated by examples in the fields of sexually transmitted infections, cardiology, mental health, osteoporosis or life after cancer;
- special needs not taken into consideration and a form of asexualisation of people with disabilities or the elderly, alongside barriers in their access to care. At the same time, the role of natural caregiver is subject to significant social pressures on women, who find themselves expected to take on this role more than men;

- particularly marked social difficulties for women in a precarious socio-economic situation, but also for trans people who often accumulate vulnerabilities, and differentiated treatment in the areas of child protection and judicial youth protection.

For each of these themes, the findings show that situations linked to people's sex or gender are often not adequately taken into account in terms of their effects on health, calling for a great degree of nuance.

These findings prompt HAS to address an initial proposal to all healthcare players and to society more broadly.

Proposal 1

Encourage greater awareness among stakeholders

Improving overall health requires a greater awareness that women's health is not limited to reproductive issues; that men's excess mortality up to the age of 65 should not be seen as inevitable; that the health of intersex people is not limited to sex reassignment operations; and that the health of trans people is not limited to sex transitioning issues.

Focusing on sex and gender at every stage in the construction of public health action strategies

An in-depth study of sex and gender reveals a complex interaction of factors and plural realities

Women and men are thus differentiated based on a whole series of biological criteria, to which is added the multiplicity of social roles, either expected or practised by people. Other determinants also come into play. Age, level of education, situation with regard to the social scale, disability, etc. are all factors that interact with one another, and also with sex and gender.

Furthermore, sex is usually expressed in binary terms: "female" or "male". Yet this biological binarity does not exhaustively cover the subject of sex and gender and is not absolute: in particular, there are many people with variations in sex characteristics. At the same time, the understanding, experience and expression of gender takes many diverse forms, although here again a binary female-male register prevails.

Examining sex and gender, from both a biomedical and sociological point of view, invites us to go beyond the traditionally accepted binary.

Although the approach based on the social determinants of health as mobilised over the last ten years provides tools for understanding, the gender criterion is still neglected despite its importance. This same approach too often fails to take into consideration the biological characteristics linked to sex, which are nonetheless major, although focusing on biology or gender alone would not be sufficient.

Faced with plural realities, sex and gender must therefore be the focus of renewed attention and be considered in interaction with the other determinants of health. Three recent scientific approaches can be mobilised:

- epigenetics, which demonstrates that the biological expression of sex combines with living conditions and environment - including social environment - to explain how the living conditions of childhood or adolescence "go deeper than the skin" and can explain diseases of adulthood in a number of fields;
- the bio-social approach, which calls for a combination of biological considerations and social roles of women and men;
- a more intersectional approach that looks at how gender interacts with other social determinants of health. It aims to identify where determinants intersect and the impact of these intersections on health status.

Reconciling universality and targeting in formulation and implementation

The public health policies implemented in recent decades present flaws, which sex and gender-based observation reveals in a new light: aimed at the population as a whole, they do not always reach everyone with the same force; specific, they inevitably have blind spots.

It is therefore necessary to propose health actions and programmes for all, but with an intensity chosen according to the needs of social groups, in order to improve the health of all, while taking care not to amplify health inequalities.

This involves the formulation of health policies, firstly, and the way that these policies are implemented, secondly.

The participation of citizens in public choices

Since considering sex and gender implies looking at the environment in which individuals evolve, as well as a combination of biological and social factors, it is necessary to encourage the greater participation of users from the public policy formulation stage.

Two tools are increasingly being used today: citizen representation in decision-making bodies and participatory approaches. France has already made a lot of progress in the first area, and is gradually opening up to the second.

Without replacing expertise and the various types of preparatory work for health policymaking, the mobilisation of public debate makes it possible to ensure better consideration of specific experience related to sex and gender, in all its diversity.

As HAS has already stated, particularly in its 2018 prospective analysis report, public debate is particularly justified when it comes to incorporating new concerns into health policies - in this case sex and gender issues - or new ways of looking at them.

The incorporation of sex and gender in impact assessments

Impact assessments associated with legislative bills are an advance assessment tool that makes it possible, firstly, to quantify the benefits derived by the various key populations and, secondly, to ensure that the measures adopted do not further reinforce inequalities. The aim is to anticipate the effects of public policies on a whole range of issues. However, in terms of its effects on health inequalities associated with sex and gender, this tool seems to be under-used in the area of health.

Thus, impact assessments associated with laws do not contain, in their health component, the information required to verify that the action is true to its intention of improving health, or that it is not likely to increase health inequalities linked to sex or gender.

The French Directorate General for Social Cohesion (DGCS) has already issued recommendations relating to consideration of sex and gender in impact assessments.

HAS proposes that this approach be continued, with a view to producing a public doctrine relating to all health, social and medico-social sectors.

When a sex or gender-differentiated measure is envisaged by a law or when a law excludes a subpopulation instead of being universal, the impact assessment associated with the law must justify the benefit of such differentiation in the light of its potential consequences.

The academic world, within the framework of public action (calls for projects, research contracts, etc.), should be mobilised to define key objectives, indicators and advance (impact

assessments) and retrospective (performance assessment) assessment methods adapted to sex and gender issues.

Towards proportionate universalism

This way of conceiving health policies with a view to proportionate universalism applied to sex and gender requires a guarantee, ensured by normative standards, that these policies treat sex and gender as determinants of health. This would also encourage greater use of studies on epigenetics, intersectionality and bio-social research in the preparatory work carried out by public authorities.

Proposal 2

Incorporate sex and gender into public policy formulation

Public policy formulation must take into account differences related to sex or gender while at the same time being underpinned by the principle of improving the health of the population as a whole. Specific measures and/or increased resources for certain groups should be made available where relevant and useful. This implies defining a new form of health policy universality that does not disregard differences, particularly those related to sex and gender.

In particular, this involves:

- the use of public debate;
- impact assessments;
- the mobilisation of the academic world;
- the reformulation of article L. 1411-1 of the French Public Health Code specifying the objective of health policies, in order to incorporate the concept of interaction between biological sex, gender identity and social determinants.

Mobilisation of the populations concerned

The people concerned and the organisations they set up are key players in health policies.

It is necessary to decide on actions and build health programmes for all, without discrimination, but also to strengthen actions aimed at target publics, through dedicated means or strategies for reaching these targets (outreach, community approach). The plurality of situations and health outcomes related to sex and gender requires that public policies move towards these grassroots approaches so that no population is left on the sidelines.

Building bridges with the populations concerned, whether in the implementation of a policy or in the collection of data, appears to be crucial to ensure effective consideration of sex and gender. All the contractualisation tools - particularly with associations - already exist, but they remain under-used at present, despite the fact that their effectiveness has been clearly established.

Proposal 3

Construct implementation with the populations concerned

It is necessary to reconcile universality and targeting in order to define social and health policies for all, while at the same time deploying specific means, where required, to reach different population subgroups.

The implementation of health policies must be constructed with the populations concerned, and the stakeholders, particularly associations. It is necessary to act for and with these populations when they are at risk of being difficult to reach without specific action, in particular due to vulnerability associated with their sex, their gender identity or any social or medico-social difficulties exacerbated by these factors.

This requires the mobilisation of partnerships and a co-construction approach: in this sense, institutional players must act in synergy with associations in order to improve the health of the people on whose behalf they are working. By contractualising the action with operators, it is possible to more effectively cater for this target, reaching out to the populations concerned and getting them involved in the action.

Retrospective assessment incorporating sex and gender

The purpose of assessment is to determine whether the policy is effective and reveal any flaws that need to be corrected by public action. Consequently, the criteria defined to set its framework are crucially important. When the public authority or its supervisory bodies conduct or request an assessment, it would be useful to include the health consequences of a public policy or action from a sex and gender point of view.

A reference model for this type of assessment has already been adopted by the World Health Organisation (WHO) and several European countries; France has not yet aligned itself with this standard. A new assessment framework would be even more relevant if it enabled the

issue of health inequalities to be incorporated into the final assessment, among which it would not be difficult to include sex and gender criteria. This would provide a basis for making the necessary corrections to our public health policies.

The assessment of the efficiency of sex-based differentiation of a policy, while desirable, is unfortunately dependent on the existence of comparative data that are often lacking. Only certain health actions meet this condition, as was the case, for example, for colorectal cancer policy in the Netherlands and the extension of HPV vaccination to boys in France.

Similarly, gender-based assessment requires complex work and specific data, and should not necessarily be carried out systematically, but only when relevant.

Proposal 4

Conduct a retrospective assessment of public policies through the prism of sex and gender where relevant

Sex- and gender-related concerns must be incorporated into the assessment of public policies according to criteria of effectiveness, efficiency and equity defined by the impact assessment.

In particular,

- an assessment of effectiveness and efficiency should be conducted whenever a sex-differentiated measure is scheduled, provided that a comparison with a universal alternative is possible;
- an equity assessment must be sought when social roles or gender stereotypes have a major impact on health, in particular to check that the policy implemented does not deepen inequalities.

Developing more inclusive public health policy instruments

Broader collection and analysis of sex data in the field of health with the aim of understanding the influence of sex and gender on health

Public statistics from INSEE (French National Institute for Statistics and Economic Studies), DREES (French Directorate for Research, Surveys, Assessment and Statistics), CNAM (French National Health Insurance Fund), CNAF (French National Family Allowance Fund) and INED (French National Institute of Demographic Studies) are a very rich source

of sex data that can be used for public health purposes.

However, insufficient use is made of sex-related differences identified by public statistics.

With a view to ensuring the correct use of these data and informing public policy in order to improve health for all, we need to be more willing to investigate the influence of sex or gender.

Proposal 5

Mobilise public statistics

Public statistics should make it possible to detect sex or gender-related differences in order to inform public policy and enable their sex-based differentiation. In order to promote the use of these already sex-differentiated data as determinants of health, it would be useful to:

- make data more accessible via open data;
- more systematically show sex-based differentiation in research work, define priorities and a work programme;
- establish coordination of this cross-disciplinary topic, a role that could be taken on by one of the French National Council for Statistical Information's theme-based committees.

The results of research in the field of health products and medical procedures are too often considered, out of habit, to be valid for both women and men. It is possible, however, that the benefit-risk ratio of treatments may not be absolutely transposable to everyone, depending on their biological specificities, in particular their sex.

While the populations recruited in the clinical validation phases for a treatment almost achieve parity, on average, in France, they are not always representative of the population to be treated. However, there is a lack of precise information on this subject.

European regulations include provisions relating to consideration of sex in clinical trials and investigations on medicinal products and medical devices. In order to pursue this objec-

tive of effective promotion of gender equality in research, public authorities and operators need to pay more attention to compliance with European requirements. More equitable representation within research decision-making structures would make it easier for research teams to incorporate this issue when defining the framework and design of projects.

The reality of financial arguments that the inclusion of more women in clinical trials (both public and private) would be too costly should not be overlooked. Firstly, to be able to conduct subgroup analyses it is usually necessary to increase the size of the study population. Secondly, the inclusion of women may involve specific insurance costs. However, the additional cost should be acceptable where a substantial health benefit is expected.

Proposal 6

Explicitly consider sex in clinical trials on health products and medical procedures

In order for potential sex-related differences to be better documented, HAS recommends that these differences be considered at every stage in the construction of a research project (in the definition of the project's objectives, in the analysis of the results, and in their presentation). This implies taking into account sex:

- in the prior literature search strategy, which should make it possible to identify the expected differences related to sex and possibly gender;
- in the definition of research questions and hypotheses in order to be able to collect sex-disaggregated data, where relevant;
- in the study population, which should reflect the patients who will be treated, including in paediatric studies.

HAS particularly recommends that ethics committees be especially vigilant in this area. This also requires that all those involved in the research ensure compliance with the rules relating to equal representation of women and men in decision-making structures and research teams.

Finally, HAS recommends that an assessment of the representation of men and women in clinical trials conducted on the national territory be carried out.

We increasingly have access to more diverse sources of data, and the amount of data is growing all the time. Most data are collected along with information on sex (although this concerns the reported sex).

This pool of data is vast and analyses need to pay much more attention to sex-related differences in the field of health than they do currently.

All stakeholders must give greater consideration to these differences, both in the collection and analysis of real-life data and, more broadly, in public health statistics.

The weight of sex and gender identity needs to be systematically considered when using data, as part of a more comprehensive multi-dimensional approach.

Proposal 7

Analyse data

Public statistics data and real-life data should be disaggregated on the basis of sex. Their analysis should go beyond a straightforward presentation in two columns (men/women). If significant differences appear, or if a difference does not appear when it was expected, explanations need to be sought, if necessary through additional studies. In all cases, the result of the analysis should be indicated.

The evolution of initial and continuous training

This report identifies numerous deficiencies concerning the initial and continuous training of professionals, both in terms of teaching and practical learning.

While students of health sciences are obviously taught about the physiology and anatomy of the human body, there appears to be little or no training in how they should adapt their care and attitudes on the basis of the sex and gender of the patient. This failing is compounded by still deeply entrenched gender stereotypes, which sometimes lead to an underestimation of health needs. In addition, study programmes do not include teaching about trans or intersex people, which impairs the caregiver-patient relationship, can lead to inappropriate behaviour on the part of some caregivers, and can sometimes be a source of stigmatisation.

The consideration of new knowledge on sex-related differences helps move towards a more personalised approach.

The use of active listening techniques and the perception of the patient as a person living with their illness within a set of social, professional and environmental interactions is given little place in the training of caregivers. Yet consideration of an individual's gender is a crucial component of their care.

While a global approach and listening to the individual also play a central role in the field of social work, with professionals trained to take into account all the components in the life of the individual being supported, the issue of sex and gender is slow to become an explicit part of social work teaching. As a result the need for help or support may sometimes be underestimated, and stereotypical visions may not always be identified.

Proposal 8

Evolve initial and continuous training

Be it in the social, medico-social or health fields, initial and continuous training needs to be supplemented in order to integrate sex or gender-related differences, and to tend towards a more global approach to individuals incorporating a gender perspective.

The battle against stereotyping in professional practice needs to begin from the initial training stage.

An appropriate methodology for drawing up guidelines

Guidelines are another lever to help change practices. Various examples testify to the fact that taking into account sex-related differences, whether in the field of prevention, screening, diagnosis or treatment strategies, makes it possible to develop guidelines differentiated on the basis of sex where relevant.

In order to achieve this, it is still necessary to always ask the question.

Other countries already include sex and gender in their methodological guidance documents for the drawing up of guidelines. That is not yet the case in France, in either the health, social or medico-social field.

Proposal 9

Adapt the methodology for drawing up guidelines

Consideration of the sex and gender of individuals in professional practices in the health, social and medico-social sectors should be encouraged by a methodology for the drawing up of guidelines that itself takes these factors into account.

The various issuers of guidelines (institutions, professionals) should define methods for systematically asking whether it is possible that the clinical or social profile, the diagnostic assessment, the care or support might have been different for each user of the healthcare system if they had been of the opposite sex.

Legal and administrative standards more effectively safeguarding the interests of individuals

Our legal and administrative standards are largely constructed on the basis of a binary female-male approach. This does not take into account the situations of trans and intersex people. Part of the answer lies in improving these standards, in consultation with the communities concerned.

In particular, the sex of a user is utilised for invoicing checks, especially for medical procedures in the French Medical IT Programme (PMSI) database. Hence it is impossible to invoice a woman for prostate ultrasound or a man for a cervical smear test. The same is true for certain aesthetic procedures, such as the treatment of baldness or surgery for an excessively prominent Adam's apple.

However, in the event of a change of sex, due to the fact that certain tissues or organs of the sex assigned at birth will persist, this blocking of invoicing is a difficulty that is generally

circumvented by entering information that does not correspond to the procedure actually performed, which is unsatisfactory, particularly in order to comply with France's willingness to pay for these surgeries.

Discrimination on inclusion in clinical studies that may not always be justified

In practice, research protocols schedule the systematic collection of information on the reported sex of study participants in the form of a binary choice (male or female), the only one proposed in trial forms. This methodological point has several consequences.

Firstly, it does not enable an individual's identity to be comprehended. Secondly, it excludes individuals who do not fit into this binary framework, either from a biological sex or gender perspective, or includes them unknowingly with the risk of misinterpretation of the study results.

It would be preferable to work with the individuals concerned.

Proposal 10

A specific concern for intersex and trans people

A reflection process should be initiated with the communities concerned in order to define one or more set(s) of values for sex and gender that can be used in health-related administrative procedures, in order to be more inclusive, and at the same time preventing the risk of re-identification when using data.

The PMSI database rules which check the compliance of a procedure or a stay against the sex of a user (in order to avoid input errors) should no longer be blocking when the coding actually corresponds to the patient's circumstances.

Intersex and trans people should not be automatically excluded from clinical trials.

As a public authority, HAS makes a commitment

From today

- HAS will bring to the table the concerns arising from this report in the national, European and international bodies in which it participates.

In the short term

- Make sex- and gender-related issues in the field of health one of the priorities in the training programme for HAS officers.
- Encourage manufacturers to incorporate the issue of women/men representation in their studies, by raising awareness during the early dialogue process and requesting these data in the post-registration studies. HAS will make this a systematic consideration in its assessments.
- In the context of requirements relating to the representativeness of training and test bases for artificial intelligence that HAS has already formulated, the relevance of the sex ratio needs to be documented.
- HAS will continue to seek balanced women/men representation in its committees and working groups.

In the medium term

- Integrate sex- and gender-related issues into HAS's methodological guidance documents and working methods (literature search, sex and gender analysis of the studies used in its work, reporting in publications, evidence reports or opinions), without systematically producing differentiated conclusions.
- HAS will monitor the impact of its commitments on its work and will review progress in its activity report.

In the long term

- Take into account sex and gender differences in its next strategic project in the broader context of the fight against inequalities.

Introduction

The legislator tasked HAS with the annual production of a prospective analysis of the French healthcare system, together with proposals for improving its quality, effectiveness and efficiency. This year, HAS has opted to analyse the formulation and implementation of public health policy through the prism of sex and gender. In reality, while these determinants have not been completely absent from reflection processes with a view to equality, they could be more extensively mobilised.

Biological sex is a key determinant of health differences between men and women since it results in pathophysiological differences and significant disparities in the prevalence of diseases that are often inadequately taken into consideration, outside the reproductive function sphere. It is therefore important to identify these differences and take them into account in order to optimise health policies and care. However, it is not only these biological differences that come into play. Male/female binarity is a key component of our social organisation. This categorisation has long been conducive to a significantly differentiated assignment of social roles that also affects overall health. This differentiation has reduced in France over the last few decades, but it has not disappeared completely. It has been known for the past ten years or so that health outcomes can be partially explained by socio-economic factors. An understanding of the observed differences can also be sought in gender-associated behaviours or stereotypes. Health usually lies at the intersection of different factors without it always being possible to differentiate between biological and social influences. Examining sex and gender, from both a biomedical and social point of view, invites us to go beyond the traditionally accepted binary approach. Biological considerations themselves call for an expanded vision in order to also include the realities of trans and intersex people.

In the first part of this report, HAS presents an observation of health differences associated with sex and gender identity. This synoptic overview, which is deliberately partial, is very nuanced.

In particular, this overview does not make it possible to consider, in absolute terms, that any one group (women, men, trans people, intersex people) is in poorer health than the others. All the groups are affected to varying degrees by different health issues. Only a detailed analysis of the findings and causes can lead to greater understanding and action.

While women's health issues have long been on the French political agenda, the actions carried out have mainly targeted their reproductive health. The objectives underpinning these concerns and the resulting advances made do not automatically become obsolete, far from it. However, this approach to putting issues on the political agenda, generally dictated by the most visible needs, naturally results in a number of blind spots, the consequences of which should no longer be ignored.

Whilst they could be justified by the particular vulnerability of the groups concerned, these exclusive approaches to one or the other have unfortunately not prevented the observations made today, and have sometimes served to reinforce inequalities. Throughout Europe the excess mortality of men is a cause for concern. And while women's health has benefited from recent initiatives specifically targeting them, such actions have only been partial. Furthermore, while there is an increasing realisation of the stigmatisation of intersex and trans minorities, their health is still inadequately addressed. Finally, a broad range of examples are provided in the following pages, which encourage the issue of sex to be looked at from a different perspective in the field of health and in the social and medico-social sectors.

The second part of this report develops the need to take sex and gender into account in public policies, and the means HAS considers necessary to achieve this.

Because the role of biology in the differences observed cannot be overlooked when talking about health, because gender has too often been used to talk only about women, because, as a society, we also still have an excessively binary vision of the concepts of sex and gender, it is time to rethink our approach to public health policy and the prism of sex and gender can help us to do so.

While they require a strong strategic impetus, greater awareness and consideration of sex and gender in our public policies cannot be achieved without translation into everyday instruments, as explained in the third part.

These instruments also need to be revised, in order to systematically integrate sex- and gender-related differences and be more inclusive: firstly the collection and analysis of data, then their use in the recommendations that guide our practices in the health, social and medico-social sectors, and finally their use by professionals, who need to be aware of these differences, whatever their level and field of action. Each and every one of us needs to understand the biases and inequalities that can result from not taking sex and gender into account; this calls for vigilance on everyone's part, something that training, as well as administrative and legal standards, can contribute to in order to reflect reality as closely as possible.

Acknowledge the findings; renew public policy; adapt instruments. This trio has prompted HAS to make ten concrete proposals aimed at public authorities and research, health, social and medico-social players. These proposals aim to improve the health of all users and promote a more inclusive healthcare system, through a focus on sex and gender.

In order to meet these objectives, HAS makes various commitments to incorporate sex- and gender-related issues into its actions and work.

Part 1

Why focus on sex and gender in the area of health?

Health findings

General indicators

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Medical field

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Medico-social field

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Incorporating sex and gender into health brings a new perspective on the state of health and its determinants in France. The omnipresent stereotypes associated with these factors create an obstacle to the acknowledgement of their influence on health; it is necessary to clarify the possible findings concerning their influence on health. This approach also makes it possible to observe the persistent presence of shadowy areas in these findings due to a lack of knowledge concerning certain populations.

Health inequalities are obviously not related to sex and gender exclusively. They are the result of a complex interaction of factors that this part attempts to reconstruct through the analysis of a few characteristic subjects. It nonetheless emerges that biological attributes related to sex, as well as factors associated more with social gender roles, have an underestimated impact that needs to be highlighted.

Here, health is understood in the broadest sense of the term, in line with the World Health Organisation's vision ("a state of complete physical, mental and social well-being"). The scope of HAS' missions are also explored. Consequently, four series of health outcomes are presented in this first part of the report: general and cross-cutting indicators, findings related to the health and medical sphere, medico-social findings and, finally, social findings. The aim is thus to identify possible shortcomings in the prevention and treatment of health problems rooted in their sex or gender-related aspect.

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General indicators

Health inequalities strongly correlated with sex and gender

Population subgroups based on sex and gender

We will differentiate between four population subgroups based on sex and gender: women, men, intersex people and trans people. This artificial separation is made so that we can describe the health indicators and outcomes that are specific to each of these populations.

Demographic characteristics and life expectancy

France has more women than men in its population. On 1 January 2019, out of a total population of 67 million, 51.6% were women, i.e., 2.2 million more women (1).

Table 1. France has more women than men in its population. On 1 January 2019, out of a total population of 67 million, 51.6% were women, i.e., 2.2 million more women (1). Scope: Metropolitan France

| Population by sex and age category on 1 January 2019 | WOMEN | MEN | F/M DIFFERENCE |
|--|-------|-----|----------------|
| Total population | 52% | 48% | 4% |
| Under 20 years | 49% | 51% | > 2% |
| 20 - 64 years | 51% | 49% | 2% |
| 65 years and over | 57% | 43% | 14% |

On average, women live longer than men. In 2018, in Metropolitan France, life expectancy at birth was 85.3 years for women and 79.4 years for men (1). This gap is tending to decrease: the life expectancy of men at birth increased by one year and ten months between 2008 and 2018, whereas it increased by one year only for women (2).

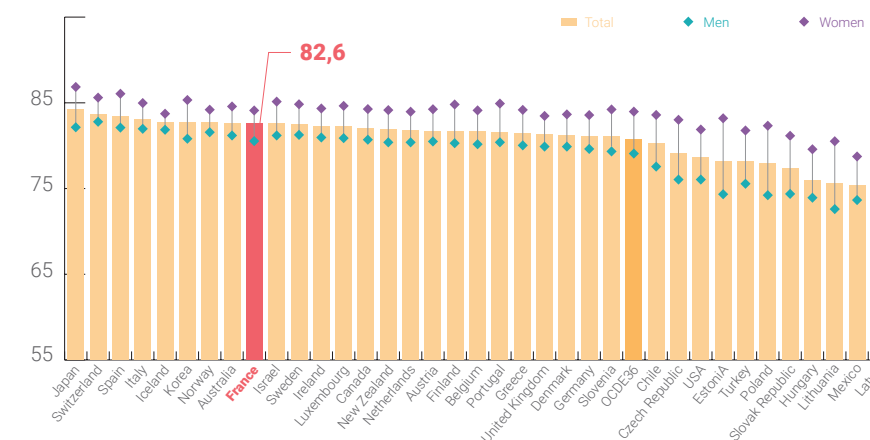
Life expectancy: situation of France compared to other OECD countries

France is one of the countries with the highest life expectancy at birth in the European Union (EU), well above the Organisation for Economic Co-operation and Development (OECD) average. This is particularly true for women's life expectancy (1, 8) for which France is the fourth ranked country, whereas it is ranked sixteenth for men. Similarly, France ranks second for life expectancy from the age of 65, again with men disadvantaged compared to women.

Thus, the gap between women and men is more marked in France than in many other countries, such as the United Kingdom or the USA for example (8), despite an overall favourable trend.

This indicator - regularly used to compare the state of health between countries - also depends on many factors: health behaviours; socio-cultural variables; economic resources; positioning of populations on the social scale, etc. Context-specific elements for each country or region of the world also come into play. Finally, the health system and the level of health spending, while important, are not the only factor in the good health status of a population (9).

Figure 1. Life expectancy at birth by sex in OECD countries in 2019 according to the Organisation for Economic Co-operation and Development, 2019(8)

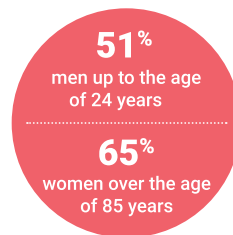


Immigrants, in the blind spot of certain life expectancy calculations

Life expectancy figures are not necessarily the same for people living in France but who were not born in the country. The immigrant population, which represented just under 10% of the French population in 2015, with a roughly similar proportion of women and men (3), may not be included in some calculations of this indicator. However, there is a lack of specific data on the life expectancy of these people; this is also the case for subgroups such as irregular migrants¹, in particular refugees whose health is nevertheless a matter for concern in numerous respects (4).

¹ In the absence of a legal definition, a migrant is defined as any person born outside France and arriving in the country for whom the process of administrative (obtaining a stable residence permit) and spatiotemporal integration (stable housing or employment) has not been completed. In particular, a distinction is made between migrants and immigrants, the latter including all people living in France but originally from elsewhere.

There are more boys than girls at birth and this remains the case until the age of 23 years (51.1% of the under 24s). Above the age of 24, the man/woman ratio is inverted, and the difference gradually becomes greater, in favour of women. Men thus become a minority at older ages, accounting for only 38.9% of people aged 75 or over. The proportion of women in the population increases with age, and they account for almost two-thirds of the over 85s and more than three-quarters of the over 95s. (1). Hence, "ageing is, first and foremost, a woman's issue" (5, 6).



At all ages, men have a higher risk of death than women(1). This excess male mortality is particularly marked between the ages of 20 and 30: the risk is up to three times higher for men than for women at the same age (7).

At the same time, the gap in disability-free life expectancy, which was 1.1 years in favour of women in 2018, is also tending to narrow. Relative to life expectancy at birth, the proportion of years lived without disability is around 79% for men and 75% for women (1, 2).

Although little epidemiological or demographic data are available, the rate of intersex births (children with visible or non-visible variations in sex characteristics²) is estimated to be around 1.7% (11, 12). These variations in sex characteristics are very diverse; some profoundly call into question the gender assignment. Hence there may be genuine hesitation in terms of assignment of the baby's sex for approximately one birth in 5,000 (13, 14).



The proportion of trans people is estimated to be between 0.5 and 2%. However, the figures vary depending on the definitions, which are more or less medicalised (or "pathologised" to use the term employed by the people concerned and relevant associations (15-17)) of transgender identity (18, 19). It is now understood that transgender identity concerns young people, including children. Moreover, in 2013, the Council of Europe highlighted the fact that the number of trans children is doubtless higher than the published estimations of 1/500 (14).

The life expectancy of these population subgroups is little documented.

A detrimental lack of data on intersex and trans people

The diversity of variations in sex characteristics, on the one hand, and in gender variation situations, on the other, has been well described by the Council of Europe. However, the absence of a consensus with respect to their definition and the slow pace of advances in knowledge contribute to a lack of understanding of these situations from both a medical and social perspective.

This lack of data reinforces:

- the invisibilisation, the feeling of being abnormal and the stigmatisation of the people concerned;
- the risk of blind spots in health and social care.

² Here, the definition of the Council of Europe Commissioner for Human Rights is used: variations in sex characteristics correspond to a variation such that individuals "cannot be classified according to the medical norms of so-called male and female bodies with regard to their chromosomal, gonadal or anatomical sex" (10).

Life expectancy differs according to sex and also according to social category, with differences that have remained stable over the past 25 years: the wealthier a person is, the higher their life expectancy (20). The differences in life expectancy at birth between the richest 5% and the poorest 5% are much greater in men (13 years) than in women (8 years) (21).

At an income of around 1,000 euros per month, an additional 100 euros is associated with 0.9 years of extra life expectancy for men and 0.7 years more for women, while the gap is only 0.3 years and 0.2 years at an income of around 2,000 euros per month (20).

The very natures of the professions exercised partially explain the differences in life expectancy. White-collar workers or managers have fewer occupational accidents, illnesses or exposures than blue-collar (manual) workers; they belong to a social group whose lifestyles are conducive to good health, while risky health behaviour, less use of and access to health care, and obesity are more common among blue-collar workers. In addition, health status can itself influence social category membership: poor health can prevent a person continuing their education or keeping their job, or make promotion and access to the most qualified jobs more difficult over the course of a career (21).

Nonetheless, regardless of their social category, women live longer than men. Even the life expectancy of a female manual worker is higher than that of a male manager. This can be at least partially explained by differences between men and women in terms of risky behaviours, and by more regular medical follow-up of women, especially during their fertile life. (21).

In addition to these demographic differences, there are diseases and vulnerabilities, sex- and age-specific health behaviours and particular life events that have a direct impact on health.

Different life paths depending on sex and gender

Different health problems emerge at different stages of life, risk-taking behaviours change, health concerns increase with age, and chronic illnesses have an impact on the everyday lives of the majority of people over the age of 50.

In the same way, the occurrence of certain events can disrupt life paths and adversely affect health and well-being: the death of a loved one, the consequences of surgery, massive exposure to environmental pollution or chemical agents, social isolation, financial insecurity, migration from one country to another, etc.

As far as the life paths of women are concerned, certain specific characteristics should be highlighted.

Women, for example, are affected by life events specific to them (pregnancy, childbirth) that bring them into contact with the health system, and by health problems related to the different stages of their lives, accompanied by significant hormonal changes.

Women of childbearing age are affected by menstruation, and almost all by contraception (22). At this stage of life, fertility management, pregnancy, miscarriage or abortion, or childbirth are major events.

In young women, the pressure to succeed academically and socially, and to conform to stereotypes, particularly with regard to physical appearance, can lead them to adopt risky behaviours (dangerous consumption, unprotected sex, etc.) (23).

“ The life expectancy of a female manual worker is higher than that of a male manager ”

The challenges of balancing work and family commitments, in particular time pressure, can have a significant impact on women's physical and mental health, especially as women continue to take on a higher share of family responsibilities. (3, 23, 24).

For women in mid-life, the symptoms of the menopause and other factors such as support for the elderly can affect health. This is a transitional period. And it is a part of their lives that is given little prominence - either in the media, in public policy or in the current feminist debate - contributing to a perception of being undervalued. Anxiety and depression, musculoskeletal conditions and breast cancer are among the most prevalent health problems (23, 25).

“Femininities and masculinities: the burden of social norms”

Women are also more frequently exposed to physical and psychological domestic violence, with significant repercussions on their mental health (anxiety, depression, suicide attempts), without this being exclusive to any particular age of life (3, 23, 24, 26).

Finally, since this stage lasts a third of their life, on average, elderly women are more likely to be widowed than men, and to live alone or in a residential care home for the elderly (EHPAD). They often suffer from financial insecurity, more numerous chronic illnesses and multiple disabilities (1, 3).

The dominant norms of masculinity are often represented by middle-class heterosexual men, which can therefore marginalise gay men, trans men, men from lower socio-economic backgrounds or ethnic minority men (27), and, more generally, any men who do not fit this social norm.

Thus boys are more likely to be either the victims or the perpetrators of bullying and physical violence, both at school and on social media, with harmful effects on victims' self-esteem. Their frequent exposure to pornography can distort their body perceptions and lead to behavioural problems (27).

In addition, these norms reinforce certain behaviours of men, which are detrimental to their health because recourse to external support would be seen as a sign of weakness and vulnerability, or of femininity. This leads to harmful behaviours: taking refuge in addictions or ignoring needs for treatment, avoiding asking for help or denying their state of discomfort (27).

The burden of social gender norms can also be a vector for the deterioration of women's health. The traditional norms surrounding femininities encourage women to conform to a set of values and behaviours. Such norms are transmitted by advertising campaigns conveying stereotypical notions of a feminine “ideal”, and supported by almost permanent exposure to these ideas, along with peer pressure through the widespread use of social media (28).

Femininity norms can have an impact on health. Social pressure to achieve unattainable standards of femininity is correlated with significantly lower self-esteem in adolescence, and, ultimately, with the early occurrence of depressive episodes (29). In addition, the remnants of an ideology of femininity, reflecting a passive role for women in sexual relations, have been linked to poorer sexual health. According to a study conducted in the United States in 2011, young women who were more exposed to this ideology had less knowledge of sex-related risks, were less confident during sex and had lower body esteem during their first sexual experiences (30).

Masculinity and rejection of care: the example of the agricultural world

Grégory Beltran studied the mechanisms of rejection of healthcare in a French rural farming population based on interviews with 14 men and 9 women, having stated that they had refused healthcare (31).

Agricultural work is described by the interviewees as hard manual labour that necessarily entails physical suffering that needs to be accepted. This description of the trade, combined with a high degree of professional or financial precariousness, reveals the socio-economic conditions favouring the rejection of healthcare in this population. A study of the discourses shows that these material explanations fit into a broader argument constructed around the figure of the worthy farm worker. This figure corresponds to the traits of a traditional masculinity characterised by valuing the ability to withstand pain, as well as a low level of concern for health. This model of masculinity applies differentially depending on sex: women want access to it, while men need to demonstrate that they are actually capable of living up to it.

Intersex people encounter health problems specific to their situation, dependent on the variations in sex characteristics concerned. In addition to these problems, health issues specific to women or men also arise over the course of their lives.

The available data report physical suffering (surgical sequelae and chronic pain) and negative psychological effects due to the consequences of operations carried out during early childhood in an attempt to “correct” certain variations in sex characteristics (hypospadias repair, vaginoplasty, gonadectomy, clitoral reduction, etc.) (32). This suffering, especially psychological, is particularly acute at puberty, due to clearer manifestations of the variations in sex characteristics, psychological conflicts related to adolescence and a school environment that is often hostile to difference (32, 33).

Then, for a proportion of intersex women, fertility becomes a priority issue (33, 34).

Throughout life, the feeling of abnormality is reinforced by invisibility and the unsaid. Many people report that they or their families were not informed that they were intersex, or that they were given incomplete information. Receiving a diagnosis of long-concealed variations in sex characteristics is experienced as a shock and is generally traumatic (14).

In 2013, the Sion conference³ demonstrated the need to specifically tackle the situation of trans and intersex children, who too often feel lost within a set of social norms that denies their existence (14). The lack of knowledge on the part of the general public and early childcare or education professionals, as well as many healthcare professionals, leads to risks of physical and psychological violence for these children. It also leads to inappropriate responses to parents (14).

The health status of trans people has long been identified as being particularly precarious. Although it is not possible to consider all situations in a uniform way, there is nevertheless a prevalence of numerous risk behaviours and significant psychological distress. (14). Finally, trans people often turn to unsafe healthcare paths, including seeking surgery abroad, buying hormones online, etc. (35).

In addition, a proportion of trans and intersex people are concerned by the taking of hormone treatments, with a risk of negative impacts on their health, side effects, contraindications or interactions with other drugs (36, 37).

³ International conference entitled “The right of the child and the adolescent to his/her sexual orientation and gender” held in Sion (Switzerland) from 2 to 4 May 2013, following which a report was submitted to the Council of Europe, co-organiser of the conference.

Furthermore, for both trans and intersex people, there can be a sense of exclusion from the health-care system, too often associated with bad experiences, with difficulties in accessing primary care.

Surveys show that a third of trans people go without healthcare “because of prejudice on the part of healthcare personnel”, and that 75% have already felt uncomfortable with a doctor for a reason related to their transgender identity. This is further reinforced by administrative incongruity, for example when individuals do not have papers or a health card matching their appearance (38-40).

A slow and partial rebalancing of socio-economic inequalities, despite the better academic success of women

Education and level of qualifications

Level of education is a determinant of health and it is a factor that favours women since they stay in education for longer and are more successful academically⁴.

Many boys do not achieve the same level of educational success as girls. In France, they more often leave education early without undertaking any other forms of training (27). A comparison between the years 1990 – 1992 and 2014 – 2016 reveals an inversion in the male/female ratio in young people coming out of initial training (42).

The level of education is more discriminating for men than for women. For example, the gap in life expectancy between those with the lowest and highest levels of education is greater for men than for women (20, 27).

“ **Level of education is a determinant of health, a factor that favours women** ”

Pre-school and school structures are not properly prepared to receive trans or intersex children

A lack of awareness and understanding on the part of professionals, bullying by other children, hurtful or clumsy comments, repeated embarrassing situations, non-acknowledgement of their gender identity, often lead to absenteeism, dropping out of school, or withdrawal of the child from the school system (14).

Paradoxically, although access to education is becoming more equal, the professional separation of male and female activities remains extremely strong. This can be partially explained by disparities between streams in secondary education (although all streams are open to everyone), and by the fact that girls more frequently choose studies leading to “women’s occupations” or jobs deemed to be more compatible with family life. Expectations related to women’s social and family roles can thus influence their career path from the outset (43-45).

⁴ In France, girls stay in school for longer (the school life expectancy at the age of 2 years is 18.6 years for girls and 18.1 years for boys). The baccalauréat (high school leaving certificate) pass rate in 2017 was 90% for girls and 86% for boys for all streams, including vocational ones (41). Many boys do not achieve the same level of educational success as girls. They more often leave education early without undertaking any other forms of training (27).

This is summed up by François Dubet when he says that “equality is increasing while separation remains and, ultimately, this tension produces inequalities since women go into jobs that are much less well paid, because the work requirements are more compatible with the family activities for which they are responsible, and because they are more willing to sacrifice their career”(45).

Income and standard of living

A major determinant of health inequalities, income differences between men and women persist, despite progress towards greater pay equity. France remains a country particularly marked by professional inequality, whether in terms of career development, contract stability, access to responsibilities or training, and pay (44).

A gradual rebalancing in favour of young women is taking place with respect to their first salaries⁵. The reduction in the gap between the average salaries of men and women is partly due to the increase in the proportion of women among managers (35.2% in 2016, compared to 34.8% in 2015), which is, on average, the highest paid category. In addition, the share of part-time work is decreasing for women, although they still make up the majority of part-time workers.

The increase in women’s level of education has therefore enabled them to access higher starting salaries (42-44, 46).

However, despite the trend towards an increase in their levels of education and work experience, there is still a wage gap that is disadvantageous to women. This gap is greater in the private sector (18% on average in terms of full-time equivalents⁶) than in the public sector (12%), but has narrowed in the private sector over the past 20 years while remaining almost unchanged in the public sector (47-49).

The pay gap is widened by having children - being a mother is still perceived by employers as a disadvantage - and increases further with age. In reality, mothers’ careers develop little in the period from two years before until ten years after the birth of a child, whereas this is a period of significant career progression for men (43).

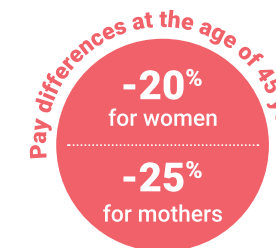
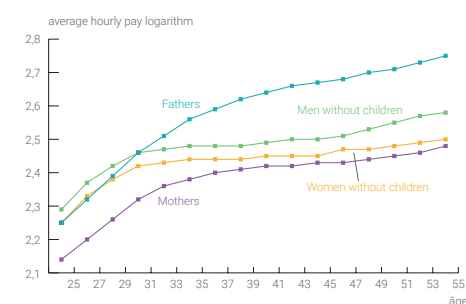


Figure 2. Average earnings by age, gender and parental status [reproduced as per Coudin et al., 2019 (43)]



At the age of 25, women earn around 6% less than men, but the difference is 11% between mothers and fathers of the same age. And at 45 years of age, the difference is 20% between men and women but 25% between fathers and mothers (43). This comparison shows that parenthood is a disadvantage for women, while it is a vehicle for wage progression for men.

⁵ The purchasing power associated with the average wage increased by 20% for women (young people in employment 5 years after graduation), while it increased by only 8% for men; between 2015 and 2016, the average wage gap (full-time equivalent) between men and women fell by 0.3 points and by 3.4 points compared to 2002.

⁶ In 2015, the average net monthly wage in full-time equivalents was €2,238; it was €2,438 for men and €1,986 for women, i.e. a difference of €452 per month to the detriment of women (46, 47).

Behaviours with respect to risk-taking influenced by numerous factors, including gender

Smoking

Across all socio-economic groups, men demonstrate greater risk-taking behaviour than women (27).

In France, 25.4% of people aged 15 years or over smoke on a daily basis, with 28.2% of men in this age category and 22.9% of women (2015-2019 figures) (50).

Men tend to smoke more, to start sooner and to inhale smoke more deeply (51). Tobacco-related morbidity and mortality are higher in men in absolute terms, but are decreasing, while they are increasing among women (52, 53).

“ **More men die as a result of smoking and alcohol...
... but women are catching them up** ”

In fact, over the past 15 years, the number of deaths attributable to smoking among women has increased by more than 5% per year on average, while it has decreased among men. These figures reflect the increase in female smoking between the 1970s and the 1990s (52).

A study published in 2020 in the European Journal of Public Health examined changes in morbidity and mortality in France related to three diseases particularly associated with smoking, which were long seen as almost exclusively male conditions (53). It reveals that:

- in women, the standardised incidence of lung cancer increased by 72% (stable in men), and mortality by 71% (whereas it decreased by 15% in men) between 2002 and 2012;
- for chronic obstructive pulmonary disease (COPD), the rate of hospital admissions for an exacerbation among women doubled between 2002 and 2015 (whereas it increased by “only” 30% in men), and mortality increased by 3% (whereas it fell by 21% in men);
- for myocardial infarction, the rate of hospital admissions was globally stable over the period 2002 - 2015, but the trend was very unfavourable in young women (an increase of more than 50% in women aged 35 to 64, compared with 16% in men).

Nonetheless the prevalence of smoking has tended to decrease in recent years. Anti-smoking policy, characterised by a ramping-up of regulatory and preventive measures may have contributed to this fall. These encouraging results need to be confirmed (51, 54).

Smoking, like alcohol use, is still very, and above all, marked by social inequalities: the least privileged people (the unemployed, people with few or no qualifications, people on low incomes) are more frequently smokers than other people (51, 55).

“ **Social inequalities and age are also key factors** ”

International comparison of smoking and alcohol use

International comparisons over the period 2015 - 2019 reveal that daily tobacco use among the over 15s in France is in the same range as in Spain, China or Turkey (21 - 30%). While these rates exceed 31% in Greece and Indonesia, they are under 11% in Sweden, Mexico and the United States.

France ranks 31st (out of 35) for the proportion of daily smokers, 34th for the percentage of female daily smokers, and 27th for the percentage of male smokers. The difference between women and men is only 5 points in France (22.9% versus 28.2%), while it is slightly higher in Spain, and as much as 27 points in Turkey (for total proportions of smokers in the same bracket) (50).

The prevalence of smoking therefore remains high in France compared to most other European countries, particularly among women, and this gap is even greater compared to the USA or Mexico (50, 55).

These differences also highlight the mixed effects of health policies implemented in the field of prevention around the world in this area, especially in France. In particular, the small gap observed in France between the percentage of female and male daily tobacco users could be partially linked to an insufficiently targeted approach to women in the policy implemented in the 1980s and 1990s.

Similar observations are made concerning the alcohol consumption of French women, which is higher than that of European women as a whole. These results are probably also related to French culture, slow to see alcohol drinking as an addiction due to the country's wine-growing tradition, resulting in higher consumption for women too. This is also the case in other alcohol-producing countries (Italy with wine, Germany or Australia with beer, the United Kingdom with whisky, Russia with vodka) (56-59).

Alcohol use

Like smoking, drinking alcohol remains common practice in France, although the overall figures mask a significant amount of heterogeneity.

Although gender does not explain all the variations in alcohol consumption, it remains an important explanatory factor. Alcohol use appears to be increasingly male as drinking frequency increases, with men three times more likely than women to drink alcohol daily (60).

Table 2. Alcohol consumption in 18 – 75 year-olds in 2017 as per Richard *et al.*, 2019 (60). Reference year 2017

| Alcohol consumption from 18 – 75 years | WOMEN | MEN | M/W SEX-RATIO |
|--|-------|-------|---------------|
| At least once in the past 12 months | 83.7% | 89.4% | 1.07 |
| At least once a week | 28% | 52.6% | 1.9 |
| Average consumption on a typical day (number of glasses) | 1.8 | 2.8 | 1.6 |
| Occasional binge drinking at least once in the year | 21.4% | 49.6% | 2.3 |
| Adult drunkenness (at least once in the past 12 months) | 13.2% | 28.6% | 2.2 |
| Occasional binge drinking in the past month | 38% | 49% | 1.3 |

Alcohol use is already higher among boys than girls during adolescence and in young adults. And this difference increases with the frequency of consumption, whether it is experimental use, regular drinking, or binge drinking (60-62).

Alcohol is currently the second cause of avoidable death in France, behind smoking, and kills three times more men than women (11 % vs 4 %) (61, 63).

The impact of alcohol on health differs depending on sex: for men, cancer is the leading cause of death attributable to alcohol (more than 12,000 deaths), while for women it is cardiovascular diseases (4,000 deaths vs. 3,500 deaths from cancer) (63).

Table 3. Estimation of deaths attributable to alcohol as per Bonaldi and Hill, 2019 (63). Reference year 2015

| | WOMEN | | | MEN | | |
|---------------------------|---------|----------------------------------|------------------------|---------|----------------------------------|------------------------|
| | Deaths | Fraction attributable to alcohol | Alcohol-related deaths | Deaths | Fraction attributable to alcohol | Alcohol-related deaths |
| Total | 288 844 | 3.7% | 10 730 | 287 198 | 10.6% | 30 350 |
| Cancers | 67 532 | 5.3% | 3 573 | 91 133 | 13.6% | 12 358 |
| Cardiovascular diseases | 76 232 | 5.3% | 4 025 | 65 651 | 8.9% | 5 872 |
| Gastrointestinal diseases | 10 935 | 16.7% | 1 829 | 12 464 | 39.7% | 4 951 |
| Suicides | 15 518 | 6 % | 870 | 22 219 | 20.5% | 4 562 |

Illegal substance use

Based on data from the 2017 *Baromètre santé* health survey, including 20,000 people aged 18 to 64 years, the *Observatoire français des drogues et toxicomanies* (OFDT - French Monitoring Centre for Drugs and Drug Addiction) and Santé publique France determined that a higher proportion of men than women use illegal psychoactive substances, irrespective of substance and type of use (64).

By way of example:

- 52.7% of men and 37.2% of women have experimented with cannabis;
- 5.4% of men are regular users, whereas the figure is 1.8% for women;
- 8% of men have already tried cocaine, and 2.1% heroin, whereas the figures are 3.2% and 0.5% of women.

This use, like all addictive behaviours, is also dependent on age. Irrespective of the substance, usage levels decrease beyond the age of 26.

Eating habits, physical activity and body weight

Diet, physical activity and sedentarism, along with nutritional status markers, are risk or protective factors for numerous chronic diseases (65).

The available data underline the influence of level of education, socio-professional category and, where applicable, situations of precariousness on the prevalence of obesity and overweight (66, 67). They also show that eating habits, physical activity and body weight depend on age, sex and level of education (68).

Studies⁷ highlight the fact that the most qualified people adopt more favourable eating habits, and reveal variable differences between men and women depending on age. For example, among children, fewer girls meet the benchmark for calcium sources, with the situation deteriorating with age. Half of men and three-quarters of women do not meet the recommended dietary intake for calcium, and the situation for women aged 55-74 is particularly worrying as almost 90% do not achieve this intake (68).

In addition to these nutritional behaviours, physical inactivity and a sedentary lifestyle are increasingly common, with women being the most concerned (71). In the space of 10 years, the proportion of women who are physically active has fallen by 16%, and more than one in five women are both sedentary and physically inactive.

Screen times have also increased significantly, as is the case throughout Europe, particularly among adolescents. This problem is particularly significant for boys, who are more likely than girls to engage in online gaming (27). Hence, the proportion of young people spending 3 hours or more in front of a screen each day is 71% for girls and 87% for boys aged 15-17 years (71).

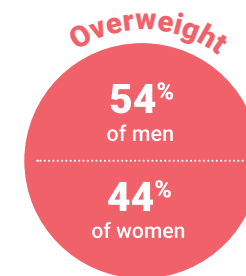
The prevalence of overweight is high in children and it increases with age. It affects men more than women of all ages (53.9% versus 44.2%).

Since the implementation of its Plan national nutrition santé (PNNS - National Nutrition and Health Plan), France has been one of the very first countries in the world to see a stabilisation in the evolution of overweight among children. This stabilisation is also gradually being seen in adults, regardless of sex (70).

At the same time, the prevalence of underweight has increased significantly, from 8% to 13% in 10 years. This increase mainly affects girls aged 11-14 years, but an analysis of body weight by gender and age shows an increase in the prevalence of underweight among men and a decrease among women (70).

Excessive thinness and its consequences remain overwhelmingly a women's health issue. This is reflected by the prevalence of anorexia nervosa, which affected 0.5% of girls and 0.03% of boys aged 12-17 years in 2008. In other words, more than 90% of those affected by this disorder before the age of 18 are women (72). In particular, this should encourage us to remain attentive to the effects of the ideals of beauty and femininity conveyed by the media and advertising.

However, this fact should not eclipse the situation in boys affected by anorexia nervosa, another specific concern (73).



⁷ In particular, we have drawn on data from two surveys conducted in France(67):

- The *étude nationale nutrition santé* (ENNS - national nutrition and health study) conducted in 2006-2007 to describe the dietary intakes, nutritional status and physical activity of adults and children (3-17 years) living in Metropolitan France (69).
- The *Étude de Santé sur l'Environnement, la Biosurveillance, l'Activité physique et la Nutrition* (ESTEBAN - national health study on the environment, biosurveillance, physical activity and nutrition), conducted in 2015 as part of the assessment of the PNNS 2 (French national health and nutrition programme), focused on three health themes: nutrition, physical activity and sedentarism (70).

Other studies (EPIFANE, ANAIS) concerned special populations, such as children under the age of 3 years and elderly people living in residential care homes.

Medical field

Some examples of insufficient consideration of sex and gender specificities

This report is not intended to be a comprehensive overview of the health status of the population by sex or gender. However, focusing on a few themes helps to illustrate the differences between men and women, and the specific situations of intersex and trans people..

Brief overview of morbidity and mortality by sex

Overall, “French people are generally in good health but there are still significant social and territorial inequalities from a very early age” (74).

Beyond this general assessment, numerous indicators of morbidity and mortality by sex (reasons for hospital admission, consultation, causes of death, expenditure items, etc.) make it possible to consider health status according to sex and gender.

Only the following are retained for this very brief overview:

- reported causes of morbidity, based on age and sex;
- the main causes of death.

Main causes of morbidity

The main causes of morbidity (diseases or health problems) reported in 2014 are listed in the table below. These are reported survey data that enable the prevalence of health problems in the general population to be assessed. According to the French Directorate for Research, Surveys, Assessment and Statistics (DREES), these data are found to be predictive of healthcare consumption, established illness or disability, as well as mortality (74).

People were surveyed based on a predetermined list of diseases and conditions. The percentages correspond to the proportion of people answering yes to the question: “In the past 12 months, have you had any of these diseases or health problems?”.

Table 4. Main causes of morbidity reported in France in 2014 based on sex and age as per the French Directorate for Research, Surveys, Assessment and Statistics (DREES), 2017 (74)

| Main causes of reported morbidity* (%) | Under 25 years | | | 25 to 64 years | | | 65 years and over | | |
|---|----------------|------|-------|----------------|------|-------|-------------------|------|-------|
| | F | H | Total | F | H | Total | F | H | Total |
| Asthma | 9.3 | 9.0 | 9.1 | 8.6 | 6.7 | 7.7 | 12.0 | 11.2 | 11.6 |
| Chronic bronchitis, COPD or emphysema | 4.7 | 2.1 | 3.4 | 4.8 | 3.7 | 4.3 | 10.7 | 10.2 | 10.5 |
| Myocardial infarction (MI) | | | | 0.3 | 0.9 | 0.6 | 2.4 | 4.1 | 3.2 |
| Coronary artery disease, angina pectoris or angina | | 0.3 | 0.1 | 0.5 | 1.3 | 0.9 | 4.4 | 8.6 | 6.3 |
| Hypertension | 0.1 | 0.9 | 0.5 | 10.5 | 9.9 | 10.2 | 35.2 | 34.9 | 35.0 |
| Cerebrovascular accident or stroke | 0.2 | 0.1 | 0.1 | 0.4 | 0.4 | 0.4 | 3.3 | 3.4 | 3.4 |
| Osteoarthritis excluding vertebrae | 0.5 | 0.1 | 0.3 | 17.4 | 10.1 | 13.9 | 57.8 | 39.3 | 49.5 |
| Low back pain or other chronic back problem | 16.5 | 9.2 | 12.9 | 31.1 | 29.3 | 30.2 | 40.6 | 35.1 | 38.1 |
| Neck pain or other chronic neck problem | 9.0 | 2.5 | 5.8 | 19.2 | 11.7 | 15.6 | 27.4 | 16.5 | 22.5 |
| Diabetes | 4.6 | 2.1 | 3.4 | 8.9 | 7.0 | 8.0 | 17.9 | 22.1 | 19.8 |
| Allergy | 16.0 | 14.3 | 15.2 | 16.9 | 11.5 | 14.3 | 15.7 | 9.6 | 13.0 |
| Cirrhosis of the liver | | | | 0.0 | 0.1 | 0.1 | 0.4 | 0.4 | 0.4 |
| Urinary incontinence, bladder leakage or bladder control problems | 1.7 | 0.5 | 1.1 | 4.8 | 1.5 | 3.2 | 16.8 | 11.7 | 14.5 |
| Kidney problems | 0.5 | 0.4 | 0.5 | 1.5 | 1.8 | 1.7 | 4.1 | 3.9 | 4.0 |
| Depression | 3.1 | 2.2 | 2.7 | 8.0 | 4.4 | 6.3 | 9.3 | 3.3 | 6.6 |
| Other chronic disease | 3.7 | 3.0 | 3.4 | 10.8 | 7.7 | 9.3 | 18.0 | 14.9 | 16.6 |
| No disease or health problem reported | 58.4 | 67.7 | 63.0 | 36.3 | 41.2 | 38.6 | 11.7 | 14.1 | 12.8 |

Proportion of people answering yes to the question: “In the past 12 months, have you had any of these diseases or health problems?”.
Scope: Metropolitan France, population aged 15 years and over in standard households - Source EHS-ESPS 2014 (DREES-IRDES).

Naturally, the number and causes of reported morbidity are closely correlated with age, and the part of the population reporting no disease or health problems is the youngest group.

These survey data also highlight many differences between women and men in terms of prevalence (74) :

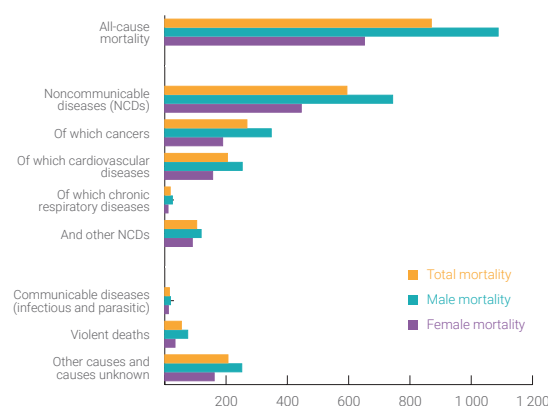
- irrespective of age group, a higher proportion of men than women do not report any of the diseases or health problems proposed in the list;
- young people aged 15 to 24 report few health problems; among the most frequent, low back pain and other chronic back problems are more common among women (16.5% for women against 9.2% for men);
- between the ages of 25 and 64, more diseases or health problems are reported, especially by women;
- 49.5% of those aged 65 and over report osteoarthritis, 38.1% low back pain or other chronic back problems and 35% high blood pressure. women report more urinary incontinence and bone and joint problems, while diabetes is cited more by men (22.1% versus 17.9%).

Main causes of death

Standardisation by age⁸ reveals a mortality per 100,000 people that is 1.7 times higher for men than for women.

In terms of premature mortality rates (death before the age of 65), France is the second highest in Europe for women. In addition, the trend for road accidents is relatively promising, with mortality ranked seventh for women and eleventh for men in Europe (74).

Figure 3. Main causes of mortality according to sex in France in 2016 as per Boulat *et al.*, 2019 data (75)



“ An excess male mortality irrespective of cause ”

Premature deaths account for 22.6% of male deaths compared to 11.3% of female deaths (75).

Irrespective of the causes of death studied, analysis of standardised rates reveals an excess male mortality:

- of 1.7 for noncommunicable diseases (up to 4.6 for airways and digestive tract cancer deaths);
- of 1.6 for communicable diseases (but 3.8 for HIV/AIDS);
- of 2.2 for violent deaths (with a factor of 3.7 for suicide).

Noncommunicable diseases (NCDs), otherwise known as “chronic diseases”, are the leading cause of death in France, accounting for almost 90% of all deaths, with, in descending order, cancers (approximately 30% of mortality depending on the sources), cardiovascular diseases (approximately 25%), chronic respiratory diseases (approximately 6%), and diabetes (approximately 2%) (74-76).

For cancer-related mortality, France ranks 9th in Europe (6th for women and 13th for men) and the trend is favourable. However, the DREES notes a significant lag in the field of breast cancer (16th place) (74).

According to the WHO, 257,900 lives could be saved in France by 2025, by implementing all of the WHO “best buys” (promotion of reduced tobacco and alcohol use and appropriate diet and physical activity) (76).

Deaths related to communicable, infectious and parasitic diseases, on the other hand, have continued to decline during the 2000s, accounting for only 1.8% of deaths in 2016, for both men and women (around 10,000 deaths in total). In particular, mortality due to Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) has fallen significantly, for both sexes (with standardised rates of 0.5 for total mortality, 0.8 for men and 0.2 for women) (75).

Violent deaths, which include all types of accidents, homicides, suicides and falls, account for some 35,000 to 36,000 deaths each year in France, i.e. about 6% of all deaths (75-77).

According to the DREES, the suicide mortality rates observed in France are higher than in most other European countries. The situation is significantly more problematic for men, but despite the large gap between the sexes, women are also much more affected by this mortality in France than elsewhere in Europe (74).

France's international ranking for a few men's health indicators

In the absence of a true comparative overview, a few of the men's health indicators reported by the WHO in its report on “The health and well-being of men in the WHO European Region: better health through a gender approach” provide a quick insight into findings in France in 2016 compared to the 53 other countries considered (27):

- healthy life expectancy: 6th place;
- cardiovascular deaths: 11th place;
- new HIV diagnoses: 32nd place;
- Alcohol use: 43rd place.

⁸ “Standardised” rates make it possible to overcome differences in the age structure of these populations in order to enable comparisons.

Table 5. Causes of death according to sex as per Boulat *et al.*, 2019 (75)

| Cause of death | Total mortality | Male mortality | Female mortality | Sex ratio |
|--|-----------------|-----------------|------------------|-----------|
| All-cause mortality (Std rates) | 869.7 | 1087.8 | 651.6 | 1.7 |
| Total number of deaths in 2016 | 579 230 | 288 926 (49.9%) | 290 304 (50.1%) | |
| Of which premature deaths (under 65 years) | 98 191 (17%) | 65 273 (22.6%) | 32 918 (11.3%) | |
| Noncommunicable diseases (NCDs) (Std rates) | 594.3 | 743.5 | 445.4 | 1.7 |
| Of which cancers (Std rates) | 268.1 | 347.4 | 188.8 | 1.8 |
| Upper airway and digestive tract cancers (Std rates) | 14.4 | 23.7 | 5.2 | 4.6 |
| Respiratory system and lung cancers (Std rates) | 52.4 | 78.9 | 25.8 | 3.1 |
| Gastrointestinal cancers (stomach, liver, pancreas, colon, rectum) (Std rates) | 66.3 | 87.0 | 45.7 | 1.9 |
| Of which cardiovascular diseases (Std rates) | 204.4 | 252.7 | 156.2 | 1.6 |
| Ischaemic heart disease (Std rates) | 50.7 | 73.4 | 27.9 | 2.6 |
| Cerebrovascular disease (Std rates) | 44.5 | 50.1 | 38.8 | 1.3 |
| Of which chronic respiratory diseases (Std rates) | 17.7 | 24.8 | 10.6 | 2.3 |
| And other NCDs (Std rates) | 104.1 | 118.6 | 89.8 | 1.3 |
| Communicable diseases (infectious and parasitic) (Std rates) | 15.1 | 18.4 | 11.7 | 1.6 |
| Of which AIDS and HIV (Std rates) | 0.5 | 0.8 | 0.2 | 3.8 |
| Violent deaths (Std rates) | 54.1 | 74.8 | 33.4 | 2.2 |
| Of which suicides (Std rates) | 14.0 | 22.0 | 5.9 | 3.7 |
| Of which accidents and falls (Std rates) | 40.1 | 52.8 | 27.5 | 1.9 |
| Other causes and causes unknown (Std rates) | 206.2 | 251.2 | 161.2 | 1.6 |

Std rates: standardised rates

Biological differences that are clearly identified and too often ignored in the area of cardiovascular disease with a detrimental impact on women

French indicators related to cardiovascular diseases reveal that the associated mortality has fallen significantly, particularly in France. Between 1990 and 2015, while OECD average figures indicated an almost 50% reduction in ischaemic heart disease-related mortality, in France the risk fell by 75%. This is the second biggest reduction, behind Denmark (-81%), and well ahead of Germany (-52%) (78).

Cardiology is probably the most advanced speciality when it comes to understanding clinically significant biological differences between the sexes.

However, cardiovascular diseases are still very often considered to be a specifically male problem, affecting men aged 50 to 60, who are smokers, sedentary and overweight. It is true that men are more often concerned than women by sudden deaths, particularly due to cardiovascular events. And cardiovascular morbidity and mortality remain higher among men.

Despite these advances in knowledge and care, and a mortality rate well below the European average for all sexes, cardiovascular disease remains the leading cause of premature death among women in France (74), mainly due to myocardial infarction or stroke (79). This is of particular concern since cardiovascular diseases are increasing among younger women (53, 79).

Cardiovascular risk factors

The classic cardiovascular risk factors continue to be the most prevalent in men and in older age groups.

At the same time, changes in women's lifestyles and the adoption of unhealthy habits such as smoking, poor diet, stress and lack of exercise have led to an increase in their cardiovascular risk over the past 30 years. The *Fédération française de cardiologie* (French Federation of Cardiology) points out that women are also less well screened due to a lack of recognition of the signs of the disease specific to women, leading to longer delays in treatment, not to mention the fact that they find it more difficult to recover from a stroke (75, 79-81).

There is a worrying increase in risk profiles, particularly among women aged 40-54.

“ Signs of cardiovascular disease specific to women ”

Myocardial infarction: differences in symptoms

Generally speaking, the general public and health professionals are most familiar with the symptoms of myocardial infarction (or heart attack) in men. This leads to poorer management of women in this indication. For example, a woman complaining of chest pain may be prescribed medication for anxiety, whereas a man will be referred straight to a cardiologist.

The warning signs can also vary depending on sex. In many cases, a heart attack is preceded by a sudden, intense pain in the chest, an agonising feeling of being in a vice, along with a burning and crushing feeling. But some warning signs are more common in women:

- unexpected weakness and fatigue;
- unusual anxiety and nervousness;
- indigestion and bloating;
- feeling of heaviness or compression between the breasts or in the sternum;
- pain between the shoulder blades (79).

For example, almost half of women under 60 years of age who have had a heart attack did not experience “classic” symptoms. This lack of awareness leads to delayed diagnosis and treatment, which reduces the chances of survival. Women should learn to recognise the atypical signs of a heart attack (79).

A higher cardiovascular risk and poorer prognosis have been observed in women than in men. Hence the risk of myocardial infarction related to hypertension, diabetes or psychosocial factors appears to be higher in women according to the INTERHEART study (81).

A higher cardiovascular disease incidence and mortality have been reported in diabetic women than diabetic men in several studies. High blood pressure causes more strokes, myocardial infarctions and heart failure with preserved ejection fraction⁹ in women than in men, and one in every two women has high blood pressure beyond the age of 65 (79).

Smoking increases the relative risk of coronary heart disease in female smokers by 25% compared to male smokers (82). In addition, women who smoke have their first episode of myocardial infarction 13.7 years earlier than non-smokers (compared to 6.2 years for men smokers) (83). Use of combined oestrogen-progestogen contraception - particularly beyond the age of 35 years - further increases this risk.

Finally, stress, anxiety disorders and low socio-economic status, which particularly affect women, play an important role in cardiovascular risk (81, 84). These factors are correlated with coronary heart disease to a greater degree in women than in men. The psychosocial factor appears to be even more important than hypertension or diabetes (81).

Specific risk associated with hormonal and reproductive factors

Sex hormones play a major role in the pathophysiology of cardiovascular disease in women. The contraceptive phase, pregnancy and menopause are ideal times for the assessment of vascular risk.

Contraception: the arterial risk linked to combined hormonal contraception is highly dependent on associated risk factors and increases with age and smoking. The arterial risk can be controlled if the contraindications of combined hormonal contraceptives are respected.

Pregnancy: pre-eclampsia, gestational hypertension and gestational diabetes are currently recognised as independent cardiovascular risk factors and early markers of cardiovascular events. It is important to investigate for and detect the presence of these conditions, which present an evolving risk that needs to be monitored. The objective of screening for these risk factors is to prevent or slow down the vascular metabolic changes associated with the menopause that lead to excess cardiovascular mortality.

Menopause: hormonal disturbances at menopause result in an increase in cardiovascular risk factors. Hysterectomy or early menopause and climacteric symptoms are aggravating cardiovascular risk factors.

The synergistic effect of cardiovascular risk factors leads to the use of scores to assess overall risk. These scores were determined on cohorts in which women are under-represented, and therefore underestimate their cardiovascular risk. The Framingham score, for example, does not take into account the hormonal risk specific to women.

Until recently, only the North American stratification enabled differentiated management of cardiovascular risk. In 2018, the Société française d'hypertension artérielle (French Arterial Hypertension Society) established an expert consensus making it possible to develop a cardiovascular risk stratification adapted to French women, to help practitioners in their management, taking into account the different phases of their hormonal life (contraception, pregnancy, menopause) (85).

“ Risk factors that are more detrimental to women ”

“ A need for specific assessment of the cardiovascular risk in women ”

Practices are evolving together with scientific progress. For example, despite pathophysiological considerations and epidemiological studies suggesting a beneficial effect of hormone replacement therapy (HRT) on blood pressure and cardiovascular risk in women having recently undergone the menopause, the first randomised trials on orally prescribed treatments have in fact demonstrated an increase in this cardiovascular risk. It seems that the effects of exogenous oestrogens on vessels depend not only on the type of product, but also on the pre-existence or otherwise of additional risk factors. This research-driven evolution in knowledge has led to recommendations for the specific management of hypertension in women (85).

Gender stereotypes resulting in inadequate care for men: examples of mental health and osteoporosis

Mental health and suicide

Mental illnesses cover a continuum of pathological conditions ranging from relatively minor disorders or those that occur for a short period only (mild depression, temporary behavioural disturbances, etc.) to serious chronic conditions (chronic psychosis) or severe acute disorders with a risk of suicide or endangering others. They also significantly impair quality of life, both for patients and their relatives (86).

In France, psychiatric disorders are the third most common registered chronic condition in adults, with 1.4 million beneficiaries of the general health insurance scheme concerned. Mental disorders thus represent such a health, economic and social burden that mental health is one of the country's main public health priorities (87).

According to a European study, anxiety disorders, depression, eating disorders and dementia are more common in women. Conversely, alcohol and drug-related disorders are much more common among men, as are conduct disorders and certain personality disorders (antisocial, paranoid, schizoid) (88, 89).

The lower self-esteem of adolescent girls than boys of the same age, combined with the anxiety generated by changes in their body image, may lead to a higher prevalence of depression and eating disorders. The “mental” burden of the family, burn-out both at work and at home (the two are sometimes linked), bullying at work and the resulting loss of confidence and violent relationships (sexual and domestic violence in particular) are greater risk factors for psychological illness in women than in men. Later on in life, new vulnerabilities emerge, for example with the loss of gender role identity in the case of infertility or at the age of menopause. Finally, the mental health of the elderly may be adversely affected in a context of stressful life events (bereavements), isolation and disabilities, which are more frequent in women because of their longer life expectancy.

“ A gender-based breakdown of mental illness ”

⁹ Heart failure with preserved (left ventricular) ejection fraction is a common condition, associated with high morbidity and mortality. Patients are often severely impaired in their everyday activities and the rate of re-hospitalisation following cardiac decompensation is high.

The prevalence of reported depressive disorders in France in 2009 was twice as high among women (13%) than among men (6.4%). Economic and social inequalities that disadvantage women put them at greater risk (90).

More specifically, national data show that being a woman, along with not working, low income levels, marital breakdowns (widowhood, divorce) and, to a lesser extent, being single, are positively correlated with the occurrence of a major depressive event in the year (90, 91).

However, the observation of a greater frequency of anxiety and depressive disorders in women, and of different and often unrecognised clinical signs, leads to an underestimation of these conditions in men, and consequently, their under-treatment. Another hypothesis is that men are less likely to admit to depression when asked, that they may express their unhappiness differently. While depression is more likely to manifest itself in women as bouts of sadness, fatigue or emotional fragility, men tend to adopt aggressive or risky behaviours such as alcohol or drug use (89, 91). Furthermore, the illness appears to be more common in men between the ages of 18 and 34, while the prevalence peaks in women between the ages of 35 and 44, which again contributes to its under-diagnosis in men (90, 91).

“ Unequal use of psychotherapy ”

A study conducted in the USA in 2013 showed that when all symptoms are taken into account (including anger, aggression, substance abuse and risk-taking), there is the same proportion of depressed women and men (30.6% of men and 33.3% of women) (92, 93). A number of initiatives, such as a series of videos by INSERM, are aimed at raising awareness of this issue in France (94).

Another differentiating factor is that, in general, women are more likely to seek help and share their mental health symptoms with their doctor, with the exception of their alcohol consumption. However, three to four women out of ten with depression do not seek specific care. At the same time, the available data show that almost half (49%) of men do not consult a health professional, make use of a facility or seek psychotherapy (compared to 39% of women), and 39% do not use any of these aids or psychotropic medication (compared to 28% of women) (90). Among those individuals treated by a therapist, women consult, on average, more frequently and for longer than men (89).

Furthermore, studies show that psychotropic drugs do not necessarily have the same effect, depending on sex. Differences between women and men are reported in the literature with respect to the therapeutic and adverse effects of these drugs (95, 96). It is also important to remember the detrimental interactions between psychotropic drugs and contraceptives.

The factors most frequently associated with suicidal thoughts are, for both men and women, having experienced a major depressive episode during the year and having been a victim of violence (threats, intimidation, humiliation, etc.). Women report more suicidal thoughts and suicide attempts than men; they are also more likely to have been hospitalised for a suicide attempt (86, 97, 98). But men account for 75% of suicide deaths, which may seem paradoxical given the much higher figures for attempted suicide among women (98).

An analysis of socio-demographic factors revealed that being widowed is a risk factor for men, but not for women; while being single or divorced is associated with suicide attempts for both men and women, as are financial or work-related difficulties. In contrast, people with a higher education qualification are less often suicidal (86).

However, according to the Observatoire national du suicide (ONS - French national monitoring centre for suicide), these risk factors do not explain why, for the same context and for similar risk factors, reactions - including suicidal behaviour - differ from one individual to another. Other studies focus on the individual neurobiological characteristics associated with suicidal behaviour, in other words investigation of specific biological vulnerabilities. This research provides additional hypotheses to explain suicidal behaviour that could help pave the way for new ways of dealing with it.

suicide
Attempts
twice
as many women
Deaths
75% men

Figure 4. Number of suicides recorded by age category in 2012 (raw figures, not related to the population)
Source: Observatoire national du suicide

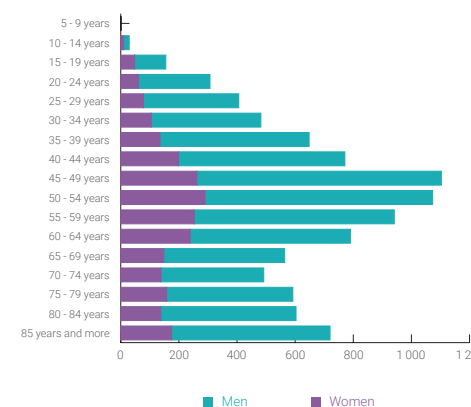
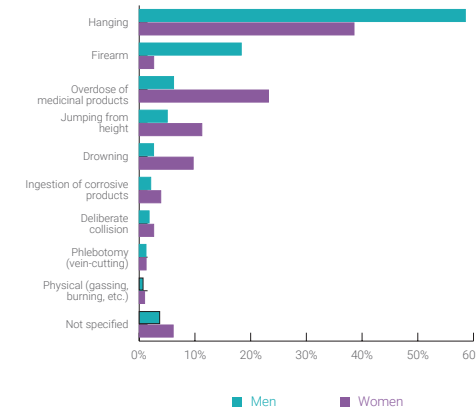


Figure 5. Methods of suicide observed in 2012 in France
Source: Observatoire national du suicide



This apparent gender paradox is systematically found in studies comparing suicide attempts with deaths from suicide. One of the explanatory factors may be the use of more lethal methods by men (firearms, hanging) resulting in more deaths than in women. In parallel, gender-associated social norms (expression of suffering, help-seeking, seeking care, social acceptance of the suicidal act) could have an impact on the modalities and intentionality of the suicidal act (86, 99).

Osteoporosis

More common in women than in men, osteoporosis has become an exclusively female disease in people's minds. Moreover, there is no threshold value for bone densitometry below which doctors can state that a man has osteoporosis, although it is accepted that the available scores (T-score and Z-score according to age) can be used by adapting them accordingly (100).

Yet 40% of osteoporotic fractures occur in men, and one in five men will have such a fracture after the age of 50. The epidemiology and pathophysiology in men present some specific characteristics. Two incidence peaks are observed in men (101):

- in young adults, with fractures secondary to sports or work injuries;
- in elderly men, with fractures due to bone fragility.

“ Osteoporosis is often unrecognised and more severe in men ”

As in women, these fractures increase with age but occur on average 5 to 10 years later. A history of fracture, long-term corticosteroid use or hormone therapy for prostate cancer are three situations frequently associated with osteoporosis. Excessive alcohol consumption and chronic smoking are by far the most common risk factors for osteoporosis in men (101).

However, mortality after a hip fracture is twice as high in men as in women: mortality in the year following a hip fracture is 30% in men while it is only 10% in women (92, 101).

In the special report entitled "sexe et genre, mieux soigner les hommes et les femmes" (sex and gender: providing better care for men and women), published in *Science et santé* in December 2017 (92), the rheumatologist Karine Biot highlights the fact that osteoporosis is rarely considered in men with fractures. According to her, rheumatologists and orthopaedic surgeons are not very aware of this diagnosis, and therefore too rarely propose an appropriate treatment⁹ (92).

Male osteoporosis: new guidelines to improve treatment

Osteoporosis is less recognised and less well treated in men than in women. A multifactorial aetiology, hitherto undefined risk indicators for fracture, and a lack of knowledge about this disease in men are the causes (104).

The American College of Physicians has produced osteoporosis treatment guidelines that are differentiated for women and men (102).

The upcoming publication of guidelines by the *Société française de rhumatologie* (SFR - French Rheumatology Society) and the *Groupe de recherche et d'information sur les ostéoporoses* (GRIO - Osteoporosis research and information group) was announced at the French Rheumatology Congress (December 2019) (105). They have yet to be published.

In addition, unlike many drugs in other therapeutic areas, a significant proportion of treatments do not have a validated indication in men¹⁰ since they have not been included in clinical trials (100, 102). As a result, very few men are properly treated, even in the event of multiple fractures or a high-risk profile, despite the fact that the effects of osteoporosis are more detrimental in men (92, 101, 103).

Men more affected by sexually transmitted infections, women more vulnerable

According to the WHO definition, adopted by France, sexual health involves mental well-being in relation to sexuality. However, it remains difficult to assess this well-being in the French population due to a lack of studies.

While it is not possible to address all aspects of sexual health here, the findings relating to several major examples of sexually transmitted infections (STIs), HIV and AIDS (106, 107), Chlamydia trachomatis infection (108), gonococcal infection (109) and syphilis, show significant differences between women and men at all levels.

The efforts made in the area of STI prevention, particularly with regard to HIV, have made it possible to stabilise new infections and even to observe early signs of a decrease (110). However, this downward trend in infections is not observed in all categories of the population, and, in particular, varies depending on geographic origin, despite initiatives rolled out to counteract these inequalities (111).

¹⁰ According to HAS' 2019 *Bon usage des médicaments* (Good practice guidelines for medicinal products), Alendronate, Risedronate and Zoledronate are indicated to treat male osteoporosis (100).

In other areas of sexual health, the implementation of a long-term national strategy in 2017 is encouraging, with particular reference to the importance of sex and gender in improving care.

Epidemiology and access to care

Monitoring of the activities of French Centres offering free information, screening and diagnosis (CeGIDD), which cater for populations at highest risk of contracting STIs (HIV, hepatitis B, syphilis, gonorrhoea and Chlamydia trachomatis infections), shows that men are more likely to attend. The rates of STI positivity, excluding Chlamydia, are higher among men than among women (although they are decreasing, probably related to an increase in the proportion of young people consulting such facilities).

As highlighted in two French parliamentary reports, women are more likely than heterosexual men to be infected with HIV and other STIs due to biological, anatomical and social specificities that make transmission easier from men to women (112, 113):

- violent or coerced sex can increase the risk of transmission as a result of injury and lesions;
- the more precarious their social situation, the less women are able to negotiate condom protection during sex;
- due to a lack of information, too many women consider HIV infection and AIDS to be a man's disease and are unaware of their vulnerability to the virus;
- the risk of HIV transmission from an infected man to a woman is twice as high as from an infected woman to a man;
- finally, few studies have been carried out examining the particular features of HIV infection in women and the specific characteristics of its treatment in women.

In addition, there has been a small increase in the number of HIV-positive women over the age of 50, which may be partially related to a recent trend for women to be tested when they start a new relationship with a new sexual partner after separation (112).

Significant disparities in HIV-related treatment side effects

In 2015, the AIDES association conducted a survey, called EVE, on the adverse effects of treatments in women with HIV. This revealed a problem in terms of consideration of women's experiences, particularly with respect to adverse effects on their sexuality. The recurrent consequence, as revealed by the survey, is a decision to reduce treatment without consulting their doctor, with the risk of ineffective treatment (114).

In addition, HIV-related clinical trials and research often include 15 to 30% women (115). While this unequal representation may be related to the epidemiology of the disease in France, the trends towards an increase in seropositivity among some women, as well as the differentiated forms of side effects, raise questions about the need to include more women in order to be able to conduct appropriate analyses among this population.

The focus on the risk of pregnancy sometimes results in more material considerations being overlooked or efforts not being made to accommodate women (e.g. facilitating childcare) to encourage their inclusion in trials. The question of adjusting treatments developed predominantly for men to the characteristics for women then arises (114).

Associations and specialised organisations thus emphasise the negative consequences for women of this inappropriate treatment. Catherine Kapusta-Palmer, coordinator of the Women and Aids programme within the French Family Planning organisation and member of France's national Aids Council, detailed a few of these consequences, highlighting, in particular, an increased cardiovascular risk "that doctors are still slow to acknowledge" (112). She also points to the body changes caused by "asexual" triple therapy, leading to premature ageing by 12 to 15 years in women, lipodystrophy and masculinisation of their bodies, with a resulting impact on their emotional life and self-image.

“ Women are at higher risk from sexually transmitted infections ”

Vulnerable populations particularly at risk of infection

The report on France's 2017-2030 national strategy for sexual and reproductive health presents the particularly vulnerable female populations (116).

Migrant women, who are infected with HIV in greater numbers than migrant men in France, have poorer sexual health. This status is dependent on conditions in the country of origin (genital mutilation, forced marriages) and factors related to their migration path (rape, human trafficking). This poorer sexual health status may be reinforced on arrival in the host country, as the period of settlement often corresponds to a period of health and social insecurity; for example, more than a third of migrant women with HIV are contaminated after they first arrive in France (117).

Furthermore, of the women diagnosed with HIV in France in 2018, 81% were born abroad (compared to 43% among men), usually in sub-Saharan Africa. Foreign-born heterosexual women are also the only population in whom the number of HIV-positive diagnoses did not decrease between 2010 and 2018 (110).

Women working in prostitution have a Chlamydia trachomatis infection prevalence of between 4.8% and 10% according to a series of studies covering the period from 2003 to 2014; they are twice as likely to have chlamydia as women in the general population (the prevalence of Chlamydia infections in young women under 25 years of age is over 10% in the Paris region). The same is true for human papillomavirus (HPV) infection, for which the prevalence was ten times higher than in the general population (118).

The situation of trans people in France is also a source of concern. The literature points to a lack of data and its poor consistency to study the vulnerability of this population to STIs. However, several studies indicate an increased risk of infection for trans people, especially where HIV is concerned. It is also noted that this risk increases when other risk factors are associated, such as drug use, belonging to an ethnic minority, precarious migratory and socio-economic status or working in prostitution (119). In the latter scenario, for example, the HIV prevalence is 44% (19, 39, 40).

All these observations indicate the need to better protect women - particularly the most vulnerable - from the risk of STIs. They demonstrate the value of structures and programmes that provide screening and treatment for STIs, and the value of rapid diagnostic tests and screening.

However, as men remain a population at high risk of infection and transmission of STIs due to risky behaviour and unprotected sex, they must also be the target of mass prevention and awareness-raising measures, in particular to increase their uptake of screening.

A different degree of impairment of everyday life for women and men living with cancer

L Cancer is a leading cause of death in France. Social determinants explain a large proportion of the risk factors. Consequently, cancer is a major public health issue, with three successive plans implemented up until 2019, and the creation of a specific agency.

There is a downward trend in the standardised incidence and mortality rates¹¹ for men, and in the mortality rate for women; for women, however, the standardised incidence rate continues to increase slightly, due to a rise in the incidence of lung cancer and breast cancer.

In this brief overview of health through the prism of sex and gender, only questions related to living conditions five years after the diagnosis of cancer are indicated, in order to report on the differences noted in the VICAN5 study (120).

¹¹ Here "standardised" rates make it possible to overcome demographic changes in order to enable comparisons.

Numerous blind spots as regards the health of trans people; the case of cancer

Meidani *et al.* highlighted that, for trans people, health issues in general are not given sufficient consideration. The subject of cancer, in particular, tends to be eclipsed by pathological or pathologised gender issues.

These data from the literature are confirmed by a survey of trans people and professionals involved in transition processes.

Trans people are excluded from preventive practices, especially female-to-male (FtM) individuals, who report that they do not go for gynaecological screening, or have never had a mammogram, even if they have a family history. In addition, medical follow-up does not appear to mention the risk of cancer, despite the fact that the hormones administered to trans people are associated with an increased risk.

Although it is the leading cause of death in France, cancer is not a central concern for health professionals caring for trans people (35).

Taking all cancers together, almost two thirds of the respondents to the VICAN5 study¹² (63.5%) reported that they suffered from after-effects of their disease or their treatment five years after their diagnosis. Pain and fatigue are the two main sequelae spontaneously cited as responsible for adversely affecting daily life, more often by women than by men (120).

The report produced by the Institut national du cancer (INCa - French National Cancer Institute) provides statistical analysis results that are differentiated between women and men and, for some data, sex is studied as a potential explanatory factor. Thus, sex is a factor independently associated with a significant level of fatigue, 5 years after cancer diagnosis ($p < 0.001$). This is not the case for the perception of a global activity restriction, for example, whereas the level of education is a determinant. Fatigue levels are also related to age and socio-economic level (they are higher among younger people and those in precarious situations) (120).

“ Cancer: women are more likely to complain of after-effects ”

Hearing impairment is more common in men (50.7%) than in women (33.1%, $p < 0.001$). The rate of hearing aid use is also significantly different, with 19.1% of men with hearing loss wearing a hearing aid, compared to 9.2% of women in the same situation (120).

Memory problems affect more women than men (70.5% versus 61.1%, $p < 0.001$), and women are more affected in their daily lives (31.1% versus 26.7%). The same is true for attention disorders. In both cases, women are

significantly more likely to think that these problems and disorders have increased since their cancer diagnosis (120).

Women were significantly more anxious than men (55.1% versus 31.2% with suspected or definite anxiety disorders, $p < 0.001$), and more often thought about the possibility of recurrence 5 years after their cancer diagnosis. However, the prevalence of depression is no different between men and women (120).

The impact of the disease on body image is also greater for women: 36.1% report that they are bothered by their appearance versus 17.5% of men ($p < 0.001$).

¹² VICAN5 is a national survey on living conditions five years after diagnosis, which provides information on the daily lives of people with the disease at the time of the survey, but also on their journey since diagnosis. The aim is to gain a better understanding of people's needs in order to guide public action and that of all those involved in the prevention and treatment of cancer (120). This broad survey covers adults at the time of diagnosis; it does not cover children or adolescents..

They are more likely than men to report social difficulties related to their appearance and dissatisfaction with their bodies (unhappiness with scars, feeling less whole because of the disease) (120).

Contrary to common misconception: more men than women stop smoking after a cancer diagnosis

The majority of people who (re)started smoking after their cancer diagnosis were women (69.4% versus 30.6% of men), under 50 years of age at the time of diagnosis (62%) who had had a cancer with a "good prognosis" (78.7%).

In the five years following their cancer diagnosis, more than half of male smokers stopped smoking, compared to one third of female smokers (51.9% versus 33.0%).

In the VICAN5 survey, having had lung or upper aerodigestive tract cancer increases the likelihood of quitting (120).

Medico-social field

Specific needs that are not taken into consideration and asexualisation of disabled and elderly people

Both sex and gender play a role in medico-social issues. In addition to the few examples given in the medical field developed above, several situations experienced in everyday life are strongly marked by a sex-based distribution and gender stereotypes with a not insignificant impact. Elderly people and people with disabilities, especially women, experience a corresponding deterioration in their health. When dealing with people in need of support, the influence of gender is also felt in the exercise of the role of natural caregiver.

Disability: barriers to access to care, in addition to socio-economic difficulties for women

Recognition of disability and specialised care

While women account for 54% of the disabled population, 65% of children cared for in medico-social facilities and services are boys, and 59% of adults are men. This is particularly true between the ages of 8 and 20 (121). In children, mental or behavioural difficulties are the most common, with these being found more frequently in boys than in girls.

The proportion of men with a recognised disability is higher than that of women. The only benefit that does not reflect this trend in France is the disabled adult allowance (AAH), for which the male/female distribution does not differ from that of the general population aged 20-59. This pattern of male over-representation is particularly pronounced for individuals receiving a disability pension (67%) or employed as a disabled worker (63%). These high male prevalence rates in the two above-mentioned categories could be explained by a higher rate of men working and by their greater exposure to physical pressures in the workplace (124).

Autism spectrum disorders

Autism spectrum disorders (ASD) are significantly more common in boys than in girls. The most comprehensive analysis of the sex ratio of autism, published in 2017, extracted data from 54 prevalence studies around the globe. This analysis estimated around **4.2 boys with autism for every girl**. This unbalanced sex ratio has been recognised since the first cases of ASD were described in the 1940s (122).

The exact reasons remain unclear. It may be rooted in a biological difference between the sexes, or, as some experts argue, it may be an artificial construct in the way ASD is defined and diagnosed. Girls and women with ASD may go undiagnosed because doctors, teachers, parents and others believe that ASD primarily affects boys. ASD may also be expressed differently in girls than in boys (123).

There is little research that focuses directly on gender differences in the area of disability enabling a clearer understanding of the differences between women and men (125).

Difficulties specific to disabled women

However, this type of research is more developed in the English-speaking world. Gender inequalities affect girls and women with disabilities in all areas, including health, marriage and parenthood.

Being a woman with a disability entails specific difficulties, as was acknowledged by the United Nations Convention, ratified by France in 2010 (126). Women with disabilities are subject to stereotypes about their sex and gender, and about their disability. On the one hand they are seen as eternal children, asexual, dependent and fragile, (127), while on the other, they are subject to social pressure to look after children, and to prejudices about their incapacity to do so (128).

In addition, disability is an aggravating factor in exposure to violence, whether it occurs within the family or in specialised facilities (129). The lack of statistical data on this phenomenon is an obstacle to targeted public policy (130).

People with disabilities have a lower rate of access to care than the general population. For example, one in three women with disabilities is not screened for cervical cancer. Although few data are available, it appears that disabled men also have poorer access to preventive healthcare. Yet, in the absence of a specific recommendation justifying a higher frequency of screening for people with disabilities, screening should be as frequent in the disabled population as in the non-disabled population. Barriers to access to screening present an implicit risk of increasing gender inequalities, given the vulnerability of women to certain specific diseases. A recommendation of the Jacob report (2013) stressed the need to “make a disability component mandatory in all national prevention campaigns” (131).

“ Disability: more women affected, but more boys and men in receiving specialised care ”

Behind a longer life expectancy, a degree of precariousness affecting elderly women

Retirement pensions

Until the 2000s, gender and ageing remained two totally separate subjects of study. However, recent research analysing inequalities and differences between the sexes at retirement generally reveals disadvantages for women in terms of economics, health or loneliness (132).

At the end of their career, in a context of high unemployment, the majority of people that fall into the grey area between their last job and entitlement to a pension are women (people with neither a job or a pension) (133).

Although they are tending to decrease due to an increase in the amount of women working, pension gaps persist and men's direct pensions are on average 39% higher than those of women. After adding derived rights, the pension gap is 25% (133).

A **25%** pension gap to the detriment of women

Participation in social life

Elderly women are slightly more present than men on social media (42% use social media at least once a month compared to 38% of men), but they report feeling lonely slightly more often. This feeling is reported by 30% of women and increases with age, whereas it stagnates at 21% for men even as they get older (1).

Social participation, i.e. the involvement of an individual in activities interacting with other people in society, is a determining factor in ageing and quality of life (1). The study conducted by Bae-riswyl focusing on voluntary sector commitments during retirement shows that women have more limited access than men to involvement in the public sphere and are less likely to assume a role of power. Socio-economic disadvantages or health status do not explain this phenomenon; the hypothesis put forward is that gender-based power relations are also at work in old age (134).

“ A feeling of isolation that is stronger in elderly women ”

This lack of participation also highlights the social invisibilisation of older women. As they enter old age, they experience a sort of erosion of their femininity, and therefore of their specificity as women. This may be rooted in a gendered division of activities inside and outside the home. For some observers, this form of asexualisation may also begin with the menopause. Hence Camille Froi-

devaux Metterie explained to the French National Assembly that, with the menopause, women are no longer able to fulfil the reproductive role assigned to them by society, and are thereby erased from it (5).

Loss of autonomy

Secondly, if the dependent elderly are mainly women, it is, of course, because they live longer and are therefore older, but also because, at a given age, they more frequently describe themselves as dependent (1).

In contrast, the likelihood of being under legal protection appears to be higher among men in early old age, before the majority of women among the elderly counteracts this trend. Hence in 2012, 53.3% of protected people aged 60 to 74 years were men. However, above the age of 75 years, 70.6% of people under legal protection were women (135).

The predominance of female carers over male carers and variations in caring practice

Women are also primarily affected by the loss of autonomy of others, since they are the ones who care for dependent elderly people in the vast majority of cases. Hence 57% of natural caregivers are women, and women account for 56% of carers of one person, 61% of carers of two people and 72% of carers of more than two people (136).

The relationship between the person being cared for and their carer is strongly gendered. When the person being cared for is a man, the sole carer is a woman in 87% of cases (partner 50%, mother 17%, other woman 14%, daughter 6%). In contrast, when the person being cared for is a woman, the sole carer is a man in 58% of cases (partner 40%, son 10%, other man 7%, father 1%) (139).

In certain specific configurations, however, and in particular in the case of partners of adults with disabilities, male carers are more numerous (136).

Defining and determining the demographics of natural caregivers

A natural caregiver, or carer, is a person who helps, in a partially or totally non-professional capacity, a dependent individual from their family, perform activities of daily living. This assistance may be provided on a more or less regular basis, for shorter or longer periods, or on a permanent basis. These crucially important people suffer from significant invisibilisation and limited recognition.

The natural caregiver category is very diverse. The generally accepted breakdown is that 57% of this population is female (137). However, this proportion conceals other realities: according to the Haut conseil de la famille (French national council for the family) in 2011 62% of those receiving the carer's allowance (APA) in France were women (138), with the figure reported by another survey conducted the same year being 59%. These discrepancies, although slight, reflect a difficulty in precisely identifying who makes up the natural caregiver population. However, the over-representation of women remains a constant.

The unequal involvement of men and women is well documented and the differences in style, practices and difficulties encountered are widely described. However, the reasons are less clear and are not unanimously agreed upon. Three hypotheses are put forward in the literature:

- one related to the norms of care, which are experienced differently by men and women;
- one related to a difference in availability, with women more often not working;
- one related to divergences in skills, with women more used to caring for others.

The PEGASE survey examining the weight and effects of gender on care for the elderly compared the involvement of men and women in the care of dependent elderly people. It describes the reality of practices on the ground, in terms of care provided by partners or children, the process of designation (or self-designation) of the carer, the (non-)delegation of certain tasks, and the experience of the care. The aim was to describe the mechanisms of quantitative involvement, on the one hand ("who takes responsibility and for which tasks?"), and those related to quality of care, on the other ("what quality of life for the person being cared for and the carer?") (136).

The “caring partner rule” seems, in principle, to be respected without making any distinction between the sexes, but it does not prevent the care being experienced in a gendered way. Thus, the survey suggests that when a man cares for his wife, the caring relationship seems to be better perceived than in the opposite case. This situation is not experienced as a reversal of roles, but as a continuation: the man continues to protect his wife. And while maintaining this traditional role, the man is seen, and can see himself, as special (136).

In contrast to marital care, gender plays an important role in the designation of child carers, both in terms of the form of their involvement or in its meaning. When the dependent person does not have or no longer has a partner, when he or she lives alone, a process of designation (or self-designation) applies, usually resulting in an unequal distribution of care between sons and daughters. Just as mothers appear more often than fathers in terms of those receiving filial care, more daughters appear to be primary carers than sons (136).

However, it is rare for the person being cared for or the carer to mention gender as a factor of designation (or self-designation). Other factors are mentioned: individual availability (professional, emotional), geographic and, above all, emotional proximity to the person being cared for and a feeling of debt or obligation. While care is objectively gendered and dependent on historically constructed positions, subjectively, the commitment is perceived more often as a result of “circumstances” rather than a matter of choice (136).

“ Differences in caring practices ”

Social field

More marked difficulties for certain subgroups due to their gender

Beyond the strictly medical field, there are also differences in the social field, which is a major focus of HAS. A study of socio-economic differences as well as living conditions highlights possible variations between women and men. While women are undoubtedly still more affected by socio-economic insecurity, the gaps are tending to narrow. It would appear to be important to investigate the origin of this narrowing, more particularly to see whether it is due primarily to an improvement in the condition of women in France or to a deterioration in that of men.

A threefold socio-economic vulnerability of women, despite redistributive policies in their favour

Career and employment

The occupational segregation between women and men is gradually being reduced, although not all inequalities in this area have been eliminated. Women are still more likely than men to be unemployed in the population as a whole, and also to be less well paid.

Young women start their first job slightly later than young men. A survey conducted in 2013 among women and men aged from 25 to 35 years (1978-1988 generation), reveals a median age at the time of first employment (for at least three months, including apprenticeships) of 20 for women and 19 and a half for men (42).

The conditions for access to the labour market for young men and women have converged: it is becoming more difficult for young men to get jobs, while it is getting easier for young women.

This can be explained by an increase in the proportion of jobs in the service sector (predominantly female) and a decrease in jobs in the industrial sector (predominantly male) (42). However, highly educated women still seem to have more difficulties than men in finding highly qualified jobs (140).

“ Women's job insecurity, a source of dependence ”

“ Access to employment more difficult for young men ”

With regard to employment, while the quantitative findings have already been discussed among the general indicators, it is useful to take a closer look at the social roles they reveal.

The development of women's paid work has led to a reconsideration of the distribution of

household resources. From a logic of a single income positioning the man as the pillar supporting the family, we are moving towards a democratisation of the double income, even if the man's contribution still tends to be greater, on average: 56% when both partners are in full-time employment, 66% when the woman has a part-time job, and 87% if only the man has a job (27, 141).

This should not mask the fact that unemployment among women remains higher, and that the dynamics linked to hiring or promotion in the best paid sectors still favour men (27, 142).

Finally, four times more women than men work in a part-time job, which is still often synonymous with insecurity (44). This insecurity is clearly financial, because of lower pay compared to full-time jobs, but it is also social. As far as the acquisition of social rights is concerned, particularly with respect to retirement, the rights granted to part-time workers remain lower than those acquired by full-time employees. In addition, women working part-time regularly have to cope with poorer working conditions than full-time employees.

Yet this part-time work is often not a choice (44). Some 1.1 million women report working part-time because they have not found full-time work, compared to about 400,000 men (143). When part-time work is a choice, the reasons are very different depending on the sex. For women, it is mainly a question of better combining family and work life, and for men, it is a question of doing another job, studying or training at the same time, or of health-related reasons.

An example of particularly gender-biased professional insecurity: prostitution

Around 85% of prostitutes are women (144). Prostitution and precariousness are linked from both a safety and legal point of view, with the vast majority of prostitutes being of foreign origin and victims of human trafficking networks (144), but also in terms of health. A report drawn up by the General Inspectorate of Social Affairs points to the recurrence of sexual health problems for prostitutes, in addition to the difficulty of accessing rights and care for this population, which is described as precarious and significantly concerned by STIs (145).

Socio-economic situation

The poverty rate for women in 2017 was slightly higher than for men. However, the figures were relatively similar, with a maximum difference of one percentage point among 18-29 year olds, the age group most affected by poverty (146).

Women make up 84% of single parents. More than a third of them live below the poverty line, compared to about a quarter of male single parents. In addition, it should be noted that women are, on average, slower to begin a new relationship after a break-up than men, especially when they have children. Re-forming a couple takes longer for parents, especially for mothers: three years later, 29% of mothers have re-formed a new couple compared to 43% of fathers (1).

“ A third of female and a quarter of male single parents live below the poverty line ”

Family and social insecurity also affect intersex people, regardless of gender.

Although the demographics are difficult to assess, a major European study suggests that intersex people have a significantly lower quality of life than the population as a whole in terms of social relationships. These cover family relationships, intimate relationships and friendships, more broadly, the rate of satisfaction with these relationships was found to be lower than in the rest of the population, including people with health problems. The testimonies and advocacy of associations defending the rights of intersex people also suggest this, reporting recurrent difficulties as regards self-esteem, relationships with loved ones and engagement in intimate relationships (147).

Precariousness in access to housing and homelessness

In contrast to common perceptions associated with the homeless, which remain largely focused on the experience of men ("tramps"), in recent years there has been a shift towards the feminisation and "familialisation" of this very precarious situation (148).

Table 6. Housing situation of the adult population in 2012 according to sex as per Yaouancq et al., 2013 (149)

| Housing situation | WOMEN | MEN |
|--|-------|-----|
| Homeless | 38% | 62% |
| On the street | 5% | 95% |
| in collective accommodation only open overnight | 9% | 91% |
| in collective accommodation also open during the day | 36% | 64% |
| in a hotel | 63% | 37% |

Interpretation: among homeless people, 5% of those living on the street are women.

Scope: French-speaking people aged 18 years or over in cities with more than 20,000 people in Metropolitan France.

Source: INED, INSEE, survey among people using accommodation or meal distribution services, 2012 (149).

However, because women have specific needs (in terms of personal hygiene in particular), are more vulnerable to sexual, physical or psychological violence, and are sometimes accompanied by children, they benefit from better care, whereas men stay longer on the street.

Hence women account for 38% of homeless people but are still very much in the minority (5%) among people living on the street (146). They are faced with specific difficulties. For example, 62% of homeless women living on the street of childbearing age do not use any form of contraception, and every year more than 80 women are forced to give birth on the streets without going to hospital. Fewer than 10% of pregnant women seen for a medical consultation in a care and referral centre (CASO) had active health insurance rights on the day of their first visit; and 45% had a delay in monitoring their pregnancy (150).



In the absence of support and care, women living on the street become "invisible". They disguise themselves "as men" so as not to be recognised and raped, and often live in hiding (car parks, basements, squats, etc.).

Homeless women and men are also different when it comes to the construction of intimate relationships, something that the example of young people experiencing homelessness demonstrates quite clearly. This situation tends to create relationships based on traditional gender roles that result in unequal relationships between women and men.

While among young women, intimate relationships are often seen as a necessary strategy to ensure safety and survival, including by resigning themselves to violence, young men disengage themselves, either partially or totally, from these relationships in favour of a quest for a privileged status, often by investing in criminal activities (151).

In 2017, three quarters of migrant women¹³ living in a hotel stated that they had been exposed to a form of relatively or very serious violence during their lives. Of these, 44% had been subject to violence in their country of origin, 16% during their migration and 46% in France. Hence the extent of the violence, often cumulative, experienced by migrant women in situations of administrative insecurity needs to be recognised and lead to appropriate medical and social care (152).

In France, access to healthcare for foreigners in an irregular situation has been guaranteed since 2000 via a free state medical aid mechanism (AME). However, this system does not guarantee application of these rights and only 51% of those eligible actually benefit from it. While the most significant variable remains the length of stay, women are more likely to be covered than men (153).

“ **In response to precariousness, redistributive policies tend to favour women** ”

These data reflect the idea of an accumulation of vulnerabilities to the detriment of women, but a degree of nuance is required. In fact, women appear to benefit more from redistributive policies. That does not mean that it is easier for them to get out of their precarious situation than it is for men, but it does at least imply that situations of extreme precariousness affect them less and for less time (146).

rious situation than it is for men, but it does at least imply that situations of extreme precariousness affect them less and for less time (146).

In a related area - that of housing - it appears that women benefit more from family and/or institutional safeguards, which slow down the move into temporary accommodation systems. These safeguards are also promoted by the gender-based perceptions of professionals (149).

An accumulation of vulnerabilities among trans people

It is important to highlight the fact that trans people, regardless of their gender identity, are particularly affected by different forms of precariousness (professional, economic, family and social). They are the target of discrimination, rejection and physical aggression and have significant social integration difficulties. According to a 2014 study, 8 out of 10 trans people have experienced transphobic discrimination in their lifetime, 37% of them more than 5 times in one year. Yet 96% of the victims surveyed did not file a complaint (154).

This transphobia leads to a cascade of discrimination and exclusion in terms of education, starting at school age (155), employment and housing. Transphobia therefore has a serious impact on the quality of life and health status of trans people, leading to a higher risk of precariousness, with all the negative repercussions that this can have. Finally, transphobia is a source of isolation, with 40% of respondents saying they had lost contact with a family member (154).

¹³ Here, the term “migrant women” refers to women from a different country who have arrived in France and are in an irregular situation or are awaiting official papers authorising their presence in France.

Child protection: treatment and inclusion in systems clearly differentiated according to gender

In France, approaches incorporating sex-related differences are not widely envisaged in the child protection sector or in the judicial youth protection service (PJJ)¹⁴. However, these approaches are very present in the context of support services (types of difficulties encountered, group effects, mixed or non-mixed groups, particularly during adolescence, etc.).

There are slightly more boys than girls in the care system, with girls accounting for 43% of the population in child welfare service facilities (ASE) and 10 to 15% of the population in the care of the judicial youth protection service (PJJ) (158).

“ **Different places and reasons when it comes to placing children in care: to protect girls, to supervise boys** ”

Table 7. Breakdown of children and adolescents cared for in a child welfare service facility as per the French Directorate for Research, Surveys, Assessment and Statistics (DREES), 2017 (159)

| Breakdown of children and adolescents under the care of the child welfare service | GIRLS | BOYS | F/M DIFFERENCE | SOURCE YEAR |
|---|-------|------|----------------|-------------|
| By the AEMO and AED services ¹⁵ | 45% | 55% | - 10 | 2008 |
| By residential care structures | 38% | 62% | - 14 | 2017 |
| Social care institutions for children (MECS) | 39% | 61% | - 14 | 2017 |
| Children's homes | 34% | 66% | - 16 | 2017 |
| Nurseries | 46% | 54% | 12 | 2017 |
| Children's villages | 51% | 49% | 12 | 2017 |
| Small child welfare residential care facilities | 36% | 64% | - 34 | 2017 |
| By specialised prevention clubs and teams | 36% | 64% | - 28 | 2008 |

Interpretation: On 15 December 2012, 43% of the children in care in social care institutions for children (MECS) were girls. Scope: Whole of France, excluding Mayotte, on 31 December 2008 or on 15 December 2012.

Source: DREES, ES survey on children in social difficulty, 2012.

¹⁴ According to a report produced by the Cour des comptes (French court of auditors) in 2009, child protection is “a set of rules and institutions, the purpose of which is to prevent the dangers to which a minor may be exposed” (156). The judicial youth protection service (PJJ) is defined by the French Ministry of Justice as a service intended to ensure “educational action within the penal framework. The aim is to educate, protect and integrate minors in conflict with the law, with a view to effectively combating recidivism” (157). The child welfare service (ASE) concerns all minors requiring protection. Its nature and missions are stipulated in article L221-1 of the French Code for social action and families - CASF (https://www.legifrance.gouv.fr/affichCodeArticle.do?jsessionid=79DBC7269DE7DF2B89DACC8A4BD14C3.tpdjo08v_1?idArticle=LEGIARTI000006796782&cidTexte=LEGITEXT000006074069).

¹⁵ Community-sector educational support services (AEMO) and home-based educational support services (AED) are services that are deployed in the home (administrative or judicial measures).

As stated in a 2009 INED file, "Girls and boys do not enter the child protection system at the same age (boys: 10.4 years and girls: 11.2 years), or for the same reasons". Girls are more likely to enter services after having been victims of abuse or as a result of family conflict. For boys, the reasons for being placed in care are more likely to be related to school problems or delinquent behaviour (160).

The types of placement differ depending on age and sex. While boys are more likely to be referred to collective facilities such as children's homes, girls are more likely to be referred to foster care. The "mixing" of genders is dependent on early childhood and siblings up to the age of 12 or 15 years. Thereafter, the separation of girls and boys is instigated by teams.

Sixteen percent (16%) of facilities only take in boys, and 9% only girls (161). Thus, officially, a quarter of child welfare facilities declared that they were not mixed in 2012 (162). However, it is probable that this proportion is under-estimated.

Facilities that take in ex-offenders who are likely to be incarcerated with "significant" behavioural problems will have an educational programme adapted to this type of public. Consequently, if the facility is advertised as being mixed, the prescriber (judge or child welfare inspector) will probably not send girls there. In addition, professionals will primarily reserve these places for young people whose "social" - and especially judicial - profiles, correspond to the facility's programme, without abandoning the facility's mixed profile (161).

Since equal treatment of girls and boys is the rule in France, approaches incorporating sex-related differences are rarely considered and taken into account in the initial and continuous training of child protection workers.

“ Sex-based perceptions of professionals that have an impact on practices ”

Are girls more often the victims of sexual abuse and exploitation?

More often the victims of abuse, sexual exploitation and forced prostitution than boys, girls suffer from a poorer self-image and have a greater need for respect and safety than boys. However, although girls express themselves more than boys and at an earlier age, abused boys find it more difficult to see themselves as victims, and there is a clear under-reporting of abuse, particularly sexual abuse, among male victims. This makes their support and the whole process of personal reconstruction more complex (160).

Yet research concerning the criminal justice treatment and perception of women offenders shows that they are treated very differently by judges and the administration than young male offenders (163). In this respect, events to promote the research conducted by France's national school for judicial youth protection (ENPJJ) were organised on the theme of "socio-educational work from a gender perspective" (164).

The various studies carried out among child protection workers show that many professionals are reluctant to work with delinquent girls and women, who are perceived as being particularly difficult and demanding.

Various reasons are put forward by professionals, including the verbal aggressiveness of girls due to their greater expression of emotions. This uneasiness with respect to their support is also rooted in a lack of experience and knowledge of working with women and girls with deviant behaviour (161).

Prison environment: a very unbalanced sex ratio, detention conditions that are more detrimental to women

The very unbalanced ratio in the prison environment (3.8% women) can be explained in two ways. A lesser expression of violence, on the one hand, but also a different treatment of women. Hence, women may receive preferential treatment from the police and the judicial system because they are women, and they may be referred to alternative disciplinary channels to men (165).

This low proportion of women in prison masks harsher prison conditions for women (166). In fact, there are only two prisons exclusively for women in France today. In 55 other facilities, women prisoners are kept in separate quarters with no contact with the male population.

In mixed-sex prisons, access to communal facilities is automatically reduced by the requirement to separate women and men. This results in poorer access for women to all activities and work opportunities, but also to care (166).

In terms of family and partners, the situation in prison is also described by the French section of the International Prison Observatory (OIP) as more detrimental to women, who are more likely to be imprisoned far from their partner or family (167). In addition, the sociologist Corinne Rostaing, cited by the OIP, explains that it is harder to maintain relationships with an incarcerated woman: "Unlike female partners, who maintain long-term ties with their imprisoned male partners, very few men stay with their imprisoned wives. Either because they themselves are in prison, or because they prefer to end the relationship" (167).

All these findings prompt HAS to present a preliminary proposal aimed at encouraging greater awareness among stakeholders.

This requires the construction and dissemination of tools (awareness-raising campaigns, training, access to educational material, etc.). Some are already available. A few of these tools have been identified through this analysis and are provided for information in the annex to this report (annex 2.1).

Preliminary proposal

Proposal 1

Encourage greater awareness among stakeholders

Improving overall health requires a greater awareness that women's health is not limited to reproductive issues; that men's excess mortality up to the age of 65 should not be seen as inevitable; that the health of intersex people is not limited to sex reassignment operations; and that the health of trans people is not limited to sex transitioning issues.

Part 2

Focusing on sex and gender at every stage in the construction of public health action strategies

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The findings based on health outcomes in France in terms of sex and gender reveal significant differences depending on health areas and issues, and an unequal matching of care and support with respect to women, men, trans or intersex people. Health data in France, examined through the prism of sex and gender, illustrate diverging situations and variable outcomes. However, it goes without saying that other factors impact health outcomes and France's position on an international level: level of qualifications and education, socio-professional category, culture and age are also factors that influence behaviour in response to risks, and health outcomes more generally, whether in terms of access to care, precariousness or morbidity and mortality, in particular.

The French situation is not bad in comparison with other healthcare systems in OECD countries, but the gaps between women and men in terms of life expectancy at birth, for example, are wider than elsewhere, and although France is fairly well positioned in terms of cardiovascular deaths in men compared with other countries in the World Health Organisation (WHO) euro zone, it is much less so for other indicators.

Since there are disparities in the magnitude of these differences, or in impacts on supposedly protected populations, public action in France must take ownership of sex and gender issues in the field of health. The first step is to incorporate them in health policies, which provide impetus and objectives.

To achieve this, HAS wants sex and gender to be taken into account at every stage in the construction of public health policies, including in the social and medico-social field: their formulation and implementation could give greater consideration to these factors. Retrospective assessment should also examine the effects observed on the basis of sex, and sometimes gender. Without ignoring the progress already made, the aim here is to draw up a rapid assessment and then to present, step by step, avenues and examples designed to enable a greater focus on the role of sex and gender in health.

.....

Analysis of public health policy through the prism of sex and gender

Before proposing tools that can be used to more effectively incorporate sex and gender into health policies, it seems important to look back at what has been done in the past. By observing health policy in the broad sense (health and social) in recent years, the influence of sex- and gender-related factors can be seen. The avenues presented thereafter will aim to override any potential unintended effects of this influence and to take these factors into account in a fairer way.

The compartmentalisation of women's health policies

Legislative and operational advances focusing on reproductive health

Women's health has long been part of the political agenda in France. Indeed the issue is often linked to health questions in the political architecture, as reflected, for example, by the existence of the combined Ministry of Social Affairs, Health and Women's Rights from August 2014 to February 2016.

Women's health has been the focus of specific attention, linked to overprotectiveness on the part of the legislative authorities, who for a long time banned women from certain activities based on a philosophy designed to protect mothers (labour law, clinical trials, conscription, alcohol, etc.). Today, this focus is no longer legally possible in the name of equality, but it can be reflected in other ways. As a result, women's health issues have often been limited to certain specific aspects.

Hence, the main legislative measures applied in the country are related to reproductive health. The development of contraception, monitoring during pregnancy and the prevention of complications before and after childbirth, as well as voluntary termination of pregnancy (abortion), represent the core of women's health policies. In general, and in particular with regard to access to abortion, the findings are positive and waiting times are being reduced, despite persistent geographic inequalities (168).

These developments are part of a liberalising movement aimed at enabling women to have unrestricted and healthy control over their own bodies.

French legislation reforming the health system enacted in early 2016 is an example of how women's health is focused on reproductive issues. Prior to this legislation, two parliamentary reports from each of the chambers were published, proposing advances in women's health.

Both the Senate and National Assembly reports present sexual and reproductive health issues separately from other women's health issues and are quite succinct on these other issues in their proposals. The January 2016 law incorporated the great majority of the points relating to reproductive issues, which were, furthermore, those that were the most highlighted following its publication¹⁶. Conversely, many of the measures proposed in other fields (training of professionals, clinical trials, increased involvement of women in assessments, cardiovascular diseases, occupational health, smoking, etc.) were not incorporated.

The focus on women's reproductive health can itself be compartmentalised. While the progress made in terms of reproductive rights is to be welcomed, the focus has tended to be on a few key issues. However, there are also other situations that merit public policy attention. Endometriosis is one example. Until very recently, this exclusively female disease affecting around 10% of women had been the focus of very little public policy attention. This lack of interest has been pointed out by patient associations who explain it by the continuing taboo surrounding menstruation (170). However, measures presented in 2019 (increased training, creation of dedicated structures, development of research) (171), accompanied by a greater focus on the issue by the Ministry could change this assessment.

Sex-related biological differences obviously explain some of the specificities of women in terms of reproductive issues. But they are not limited to this. However, in other areas of women's health related to biological factors but not linked to childbearing, public policy attention is more limited.

In addition, gender-related representations also have an influence on whether or not a condition or disease is linked to women's health. This was the case for cancer, for example. Initially seen as a primarily female disease up until the mid 20th century, because available diagnostic methods mainly made it possible to identify breast and uterine cancers, cancer has gradually "changed gender". One example of this is the diagnosis of lung cancer, the seriousness of which was initially realised in men. However, even today cancer in women is still mainly considered in terms of its specifically female locations (172). This is partly reflected in the policies implemented in this area (cancer plans, etc.), although this gap to the detriment of women is tending to narrow, as demonstrated by recent colorectal cancer screening campaigns.

Finally, health policies in France, apart from the elements specifically related to women's health, generally adopt the widespread traditional view that assumes human health is universal, resulting in public actions that do not take into consideration both sexes¹⁷.

Therefore, apart from reproductive issues, is women's health sufficiently targeted by public action?

The distance between the most vulnerable women and health policy persists. The progress and positive changes mentioned above do not seem to affect all women everywhere and to the same degree, suggesting that their effectiveness needs to be qualified (173).

Taking social and biological factors together, being a woman increases the risk of precariousness over the course of a lifetime. Without going into detail situation by situation, it appears that public health is struggling to achieve a real improvement in the health of all women despite targeted measures for this population (174).

A number of vulnerabilities have been identified that may exclude some women from non-specific women's health policies: old age, disability, irregular migration status, trans-identity, homosexuality, incarceration or prostitution (175).

¹⁶ A ministerial document summarises the main advances of the law. Of the measures directly related to health intervention, only eating disorders are mentioned alongside sexual and reproductive health issues (169).

¹⁷ And the converse is also true, resulting in a lack of specific actions focusing on men's health. This point will be examined in detail later on.

The exclusion of particularly vulnerable people from the health system also encourages a focus on the inclusiveness of public action, an idea affirmed by the WHO. In a recent report, the organisation discussed the barriers to achieving universal health coverage, irrespective of sex. This social justice-based report examines the links between gender, disadvantage and health, and the distribution of power in public health processes, from policymaking to programme implementation (176).

Omissions detrimental to the condition of other populations

Outcomes unfavourable to men given little consideration by public policies

The universal approach of public policies has tended to exclude specific actions targeting women's health outside of reproductive issues. However, it has not had the hoped for positive effects on men's health, and this has not been corrected by specific actions either.

The 2016 French health law stipulated gender equality as one of the guiding objectives in its opening remarks. However, apart from two provisions that do not directly concern the health of populations¹⁸, this objective is not supported in any way and is not the subject of any other measures.

Hence, although men's health outcomes are empirically worse, related considerations are absent from a health law that aims, among other things, to reduce health inequalities.

As the comparison between France and the rest of the world shows, the alarming state of men's health is highlighted by transnational sources (WHO, OECD). This holds true in France and elsewhere in Europe, where there are few national policies that truly acknowledge this imbalance. However, when health outcomes in France are compared with the rest of the European Union, it appears that the indicators for men rank much lower than those for women (74).

Obviously France is not exempt from public initiatives aimed at highlighting risks to men's health, especially when these risks are ignored due to stereotypical views. For example, INSERM has produced short videos designed to challenge perceptions of osteoporosis or depression, which are often considered to be an exclusively female problem, with the aim of improving their identification by men and caregivers (94). These academic and university initiatives remain insufficient in view of the public health issues described above, due to the lack of widespread implementation driven by public action.

A start when it comes to addressing the needs of trans people, intersex people still invisible

In 2016, France became the fourth country in the European Union to no longer require a sterilisation procedure to allow a person to have their sex changed on the civil status register. People wishing to make this change can do so by going before a judge. The relatively advanced position in France shows that trans people are gradually being taken into consideration, although this could be further supplemented by the adaptation of public policy instruments.

However, people with variations in sex characteristics (intersex people) are still an invisible population when it comes to health policy.

¹⁸ Articles 163 and 169, relating, respectively, to the collection of sex and gender statistics by the Caisse nationale de l'assurance maladie des travailleurs salariés (French National health insurance fund for salaried workers) and parity on the boards of directors and supervisory boards of various health institutions and bodies, including HAS.

The social and medical difficulties they face in France, which are greater than for the general population, show that health policies are failing to fully meet their needs (147).

Their situation was addressed in 2017 by a Senate report, which set out a series of recommendations hinged around three priorities: ensuring respect for their fundamental rights to privacy and physical integrity; improving physical and psychological care associated with the variation; promoting the recognition of intersex people and combating their stigmatisation (177).

At present, there is no legislation that incorporates these points. Associations defending the rights of intersex people deplore the detrimental impact on the physical and psychological health of these individuals that may result from this.

The bioethics law, under discussion since July 2019, did not include provisions concerning variations in sex characteristics in its original draft, a shortcoming greatly criticised by associations. Yet this was an anticipated issue, new in the context of bioethics, with an opportunity to re-highlight issues that had been observed for some time by public players such as the Council of State (178). Parliamentary debates have raised the situation of intersex people, but in a very limited way: an amendment approved in the National Assembly provides for the referral of children affected by a variation to one of the four reference centres for rare genital development diseases, in Lille, Lyon, Montpellier and Paris.

Other countries, including Malta and Portugal, have gone further in terms of supporting and recognising intersex people, in particular by reinforcing their right to self-determination and safeguards against non-consensual sex assignment.

Without necessarily designing public health action specifically targeting intersex people, knowledge of their situation and their problems should make it possible to more effectively formulate appropriate health policies. The development and dissemination of official documents and reports relating to intersex people help give greater insight into their needs in all areas of health.

Furthermore, trans and intersex people are implicitly included in health and social policies, and are subject to specific measures concerning the Lesbian, Gay, Bisexual, Trans, Intersex (LGBTI) community.

More generally, the formulation of health policies must ensure that they are sex- and gender-inclusive; this requires a systematic study of sex- and gender-related effects in all their diversity.

Social policies in which gender inequalities persist

The inadvertently gendered effects of certain social mechanisms

The social arena can also present public action strategy that is influenced by sex and gender issues. A broad and multi-dimensional sector, social policies cut across many areas where sex- and gender-related inequalities persist: employment, pensions, social benefits, medico-social concerns. Traditionally, social policies have been oriented towards women in a compassionate, or even slightly paternalistic way. **Although sex, and more particularly gender, are gradually being obscured within the scope of these policies as legal equality develops, women are omnipresent, whether as actors or as beneficiaries** (179).

Social benefits are an effective means of combating income inequalities between women and men. However, they are not specifically targeted at women, but help to prevent the socio-economic gap widening.

Hence, the collection of taxes and the redistribution of wealth through benefits reduce income inequalities between men and women by half (180).

Redistribution acts in two different ways: inequalities can be reduced because men pay more taxes due to their higher average income (181), but also because fewer of them appear to receive benefits. The Complement de libre choix d'activité (CLCA), a benefit aimed at families with children under 3 years of age, where one or other of the parents does not work or works part-time, is an example of the underuse of a benefit by men. This compensatory income can be claimed by both fathers and mothers, but in practice fathers account for only 3.5% of recipients. They also receive the benefit for a shorter time than mothers. One of the reasons for this low take-up is a refusal to depart from traditional social expectations of fathers in terms of working time and career commitment (182).

Beyond family policies, broader redistribution tools such as the Revenu de Solidarité Active (RSA - a "top-up" benefit for low-income workers) can also have differentiated effects. According to a study on the average earnings of a household depending on circumstances, the requirement to return to work in order to receive the benefit is, in fact, an incentive primarily for men living with their partner and who have children, who are on average better paid than women in the same situation, who are therefore less inclined to take up employment. It has been shown that the benefit, calculated on the basis of household income, reinforces the traditional family model (the man works, the woman plays the role of housewife). On the other hand, women again become the targets of activation policies when they separate from their partner (183).

One of the symbols of reflection processes relating to the future of social policies in France, the implementation of a universal minimum income paradoxically raises the same question of a gender-unbalanced benefit. Examples from other countries provide a partial - but not unequivocal - answer to this question. Hence, the experiment in Japan seems to have helped stabilise income inequalities and improved the situation of many women, often confined to traditional gender roles. However, transposing this finding to other countries is not as easy as all that, as demonstrated by another mechanism in Finland, for which there is no specific assessment of the effects of the benefit on gender inequalities (184).

In the medico-social field, policies governing old age and dependency also have gendered effects despite their apparent neutrality. This gendered aspect is inherited from the composition of the populations concerned, since the majority of participants, whether lay or professional, in the resulting programmes are women, and the majority of beneficiaries are also women. In both cases, the status is a source of a certain amount of precariousness. **Thus, social policy, even if it is not differentiated on the basis of sex, will first of all have the effect of either reducing or increasing this precariousness for women** (185).

The persistence of inequalities within subpopulations despite the quest for equity

Behind gender inequalities - often between women and men because they are better documented - there may also be other disparities that social policies do not address and may even accentuate. For example, successive family policies have exacerbated certain inequalities between wealthy and working-class women. Thus, the average decrease in the time spent on domestic tasks can be explained by a set of social transformations linked to the development of other domestic norms, firstly, but also to mechanisms for delegating various tasks, facilitated, among other things, by tax reductions for the employment of people to carry out domestic services (French law of 26 July 2005 relative to the development of personal services, known as the "Borloo plan"¹⁹). However, this capacity to delegate work is unequally shared socially, resulting in a deceptive reduction in inequalities between women and men (186).

19 www.legifrance.gouv.fr/jorf/id/JORFTEXT00000632799/.

Furthermore, although the efforts made by the public authorities to promote working equality between women and men have improved the situation for some women (the most highly qualified and the best integrated), women who are the most excluded from the labour market (less qualified, relegated to poor-quality jobs, forced into under-employment or not working) seem to have been forgotten (187).

Even more directly, redistributive policies, as well as policies designed to reduce the family burden, have differentiated effects. While mothers from working-class backgrounds are encouraged to withdraw from the labour market in order to benefit from parental education allowances and to look after their children, women from more affluent backgrounds are the ones who make the most use of daycare facilities and childminders or home childcare in order to continue working, thus benefiting more from this segment of family policies (186).

It appears that social policies in France regularly give rise to different effects depending on the gender of the beneficiaries, and thus have an impact on the associated inequalities. As is the case of health, it is therefore essential to put in place measures to prevent an increase in inequalities. Furthermore, while gender inequalities may be reduced, there is a risk that social policies may underestimate other factors and have unintended effects. This shows that while policies appear to be formulated as universal, they have targeted effects that need to be better anticipated. It is therefore essential to adopt a universal approach - which, in particular, means ensuring that no situation is left out - that is weighted on the basis of needs from the outset.

A medical research policy that requires fine-tuning when it comes to sex and gender issues

In France, as elsewhere in the world, there is considerable room for improvement in terms of more effectively considering differences between women and men for the diagnosis and treatment of certain diseases. Research is a crucial part of this process, since it both forms the foundations of knowledge and data on which public policies can be built, and is an essential step in the development of new diagnostic or therapeutic alternatives.

At the symposium on "Sex and gender in health research, an innovative joint approach" organised by INSERM in 2017, Hervé Chneiweiss, Chairman of the Institute's Ethics Committee, pointed out that one of the committee's objectives was to analyse the origins of the lack of consideration of sex and gender in French research (188). An inventory of this type would make it possible to implement specific actions, targeting the problems detected, and thus to rationalise the resources used, act with greater relevance and undoubtedly obtain more conclusive results.

Without denying the progress made, the aim here is to present and analyse the causes of the persistent shortcomings in the way sex and gender are taken into account by medical research in France.

A lack of awareness of the importance of sex-related differences

D There are societal and structural reasons underpinning the lack of awareness of the importance of addressing sex and gender differences in medical research (113, 189).

It was long considered that women were no different from men, except in terms of their repro-

ductive organs. Consequently, it was assumed that data obtained from research involving male subjects could be extrapolated to women (190). Some authors also point out that the male sex was long seen as being representative of the human species and that anything different was considered to be atypical or abnormal (191).

Fortunately, that assumption is no longer accepted today, which means that the gender dimension of medical research should not be overlooked. This guiding principle needs to be taken on board in knowledge-generating research, in order to improve both women's and men's health.

Moreover, it is studies conducted on the basis of this analytical approach that have led to the identification of specific characteristics for women with respect to cardiovascular diseases, or for men as regards osteoporosis, for example.

Preclinical research

The predominant use of male animals and cells in preclinical research is widely reported internationally. In 2009, a bias in favour of male specimens was observed in 8 out of 10 biomedical disciplines, particularly in the field of neuroscience (ratio of articles reporting results in male animals only compared to those in female animals only = 5.5:1) (191). This is partially due to a widely-held belief that female animals are intrinsically more variable than males owing to their oestrous cycle. However, a recent meta-analysis has challenged this assumption by showing that, in the majority of cases, female mice, when tested throughout their oestrous cycle, are no more variable than males (192). Moreover, testosterone-associated variability has also been documented in the recent literature (193).

Now, different studies have shown that the results can be different in male and female animals or cells, justifying the performance of preclinical studies in both sexes, in order to guide clinical trials (194, 195). Examples of this include: sex-related effects in the function of certain receptors in our immune system were discovered in 2011 following a study in mice (196), and in 2013 sex-related differences in predisposition to type 1 diabetes were discovered in mice (197). This knowledge could not have been gained without including animals and cells of both sexes.

Clinical trials are the part of the medical research process aimed at developing new therapeutic or diagnostic tools and demonstrating their efficacy and safety.

It is crucially important to take sex into consideration when developing treatments. Doing so provides better information relative to differences between the sexes and helps avoid a series of pitfalls. In fact, there is a risk that treatments developed without incorporating this variable might:

- only be effective in one sex - or be effective at different dosages - without this being detected, due to a lack of representation of both groups or a sex-differentiated analysis of the results (e.g. withdrawal by the Food and Drug Administration (FDA) in 2001 of eight drugs carrying a greater risk of arrhythmia for women than for men) (198);
- be dropped when they may work in men or women only, because the study protocol was limited to a combined analysis of the data or one of the groups was not sufficiently represented (198).

Furthermore, some countries sometimes opt to take into account the strength of scientific evidence in their policy on the reimbursement of health products. For example, up until 2019 in Belgium, breast cancer treatment was only reimbursed for women and not for men, who are less often affected by this disease and not included in trials. A male plaintiff and the Institute for Gender Equality recently won a case in court, which found that this was direct discrimination.

France, which is strongly committed to the principles of equality, has generally resisted this type of decision.

Why focus on sex and gender in COVID-19 research?

The data collected very quickly showed that COVID-19-related mortality was higher in men than in women, partly for biological reasons, probably combined with behavioural factors or comorbidities.

Moreover, pandemics can exacerbate existing inequalities related to sex and gender, as well as those related to other factors (e.g. socio-economic). It is therefore essential that these different subpopulations be taken into account in the studies conducted, in order to implement efficient and fair health policies and interventions.

In Canada, the Canadian Institutes of Health Research published a guide in April 2020 containing recommendations for researchers conducting or analysing studies on COVID-19, in particular (199):

- preclinical research: include both male and female cells and animals and disaggregate results by sex (since the cell receptor appears to be X-linked and sex hormones may influence the immune response);
- vaccines and treatments: efficacy, safety and toxicity may vary depending on sex, as is the case for some drugs; randomisation should be stratified by sex in clinical trials;
- medical devices and personal protective equipment: incorporate sex-specific anatomical differences and gendered user preferences;
- social and behavioural observational and seroprevalence studies: consider identity characteristics such as sex, gender and age in the population observed and the survey questions; consider gendered behaviours (such as smoking and use of healthcare) and social roles (gendered professions, relations between the sexes, etc.);
- implementation of interventions and public policies: include and target different communities, if necessary, according to sex and gender (and other specific characteristics that may also influence the effectiveness of implementation);
- public policy: the unintended outcomes of all COVID-19 policies, especially economic recovery policies, should be considered for groups such as sexual and gender minorities, single parents, immigrants, unpaid workers, individuals with a precarious work status, people with disabilities, the homeless and those living in rural and remote areas (199).

Multifactorial causes for the under-representation of women in clinical trials

As has already been indicated, historically women were not represented in clinical trials.

A relative under-representation of women in trials still persists today, as highlighted in various parliamentary reports in 2015 (112, 113), by INSERM, in particular, at a symposium on "Sex and gender in health research, an innovative joint approach" held in Paris in November 2017 (92, 188), as well as numerous international organisations, such as the European Union (200), the European Institute for Gender Equality (201), the European Gender Medicine Network (202), the US Food and Drug Administration (203) or the NIH Office of Research on Women's Health (204), to mention but a few²⁰.

According to the FDA, the reasons for the predominance of men in clinical trials are threefold (205):

- knowledge-related: a lack of understanding of the importance of differences between men and women in terms of the aetiology and pathophysiology of diseases or their reactions to treatments, making sex-differentiated clinical trials essential;
- biological: the need to protect pregnant women and fetuses from the potential risks of studies;
- economic: perception of investigators and sponsors that it takes more time and money to recruit women.

²⁰ Detailed figures will be outlined in the next section of this report (chapter 3.3.1).

But according to the European Institute for Gender Equality (EIGE), there may be other systemic reasons for this situation (201):

- the lower number of women working in scientific research (in 2012, 33% of researchers in the EU-28 were women);
- the barriers facing women seeking to climb the career ladder in university settings and their under-representation in the most senior academic positions;
- the low proportion of women on boards, R & D commissions and within various authorities with a significant influence on the orientation of scientific research (in 2010 in the EU-27, 36% of such board members were women).

According to the EIGE, a better gender balance would help encourage consideration of female representation in research studies and the potential sex-related variability of findings.

Ambitious international examples contrasting with a lack of political drive in France

D Back in 1994, the FDA created the Office of Women's Health in the USA, the role of which was to help protect and advance women's health via policies, science and awareness-raising. Consequently, the Office advocates for the inclusion of women in clinical trials and seeks to increase scientific knowledge through advanced professional training in subpopulation analysis (206). The FDA has also published guidelines enabling the inclusion of women of childbearing potential in phase I and II clinical trials, providing that they use effective contraception (207). It has also required pharmaceutical companies seeking a Marketing Authorisation (MA) to submit clinical trial data covering both women and men.

In Canada, an Organization for the study of sex differences (OSSD) was founded in 2006 by the Society for Women's Health Research (SWHR). One of the objectives of this society is to advance knowledge of sex and gender differences by bringing together scientists and clinicians from a variety of backgrounds and raising awareness of these differences.

In Europe, since the 2000s, a number of countries (Germany, Belgium, Netherlands, Sweden, Ireland) have set up research institutes focusing on the theme of "Gender and Health", with the support of the European Commission (208).

The European Union also tries to ensure the effective promotion of equality between women and men and full consideration of the gender dimension in the content of research and innovation, including in the field of biomedicine (200). In 2014, a regulation of the European Parliament and of the Council legislated on the consideration of sex in clinical trials of medicinal products for human use, notably making it compulsory to indicate this information in the protocol and the study synopsis (209). This regulation specifies that the subjects participating in a clinical trial should represent the population categories, for example the sex and age group, that are likely to use the medicinal product investigated, but the regulation is not fully applied, as highlighted by a French National Assembly report in 2015, which specified that the Minister of Social Affairs, Health and Women's Rights at the time - Marisol Touraine - had pointed out that, according to the terms of the European regulation, clinical trials must be conducted on a representative sample of the population, i.e., in men, women and children. She did not support the introduction of new components into the law, on the grounds that the legislation already provides that trials should also concern women (113). In addition, this regulation does not require that results be analysed on the basis of sex.

In France, one of the recommendations of a 2015 Senate report was that "studies and research in the field of biology and medicine consider the differences between women and men" (112). Taking this route would make it possible to better consider sex and gender disparities in health, in order to make medical research a strategic tool in the implementation of public policies.

To our knowledge, in France, only the *Agence nationale de la recherche* (ANR - National Research Agency) is listed by the University of Stanford's "Gendered innovation" project (210) as requiring the consideration of sex and gender in its calls for projects.

In France, given the observation of the "under-representation of women in health research", an evaluation mission on clinical drug trial conditions and the representation of women in these trials was recommended in a report to the National Assembly in 2015 (113), but to our knowledge, this has not yet been carried out.

Formulating health strategies: the philosophy and tools to address sex and gender issues

Mobilising new approaches better tailored to sex and gender issues in health

Fully mobilising sex and gender as determinants of health

- **Social determinants of health: levers that are frequently mentioned but little used together**

Social and territorial health inequalities are central to public health thinking. Since the beginning of this century, they have also been integrated in preliminary recommendations and reports preparing legislative actions related to health, in France as elsewhere.

Determinants of health have been at the forefront of public health thinking since the early 2000s, and particularly since 2010 in France, following a report by the *Haut conseil de la santé publique* (HCSP - French National Council for Public Health), contributing to the debate on health inequalities. They are therefore incorporated in a large proportion of the preparatory studies produced in the field of public health since this time (211).

Social determinants of health are also cited by the public authorities as a means of acting on these inequalities, which have themselves become a key issue in health policy. This is reflected in the 2016 legislation reforming the French health system, with the reduction of social inequalities in health through action on determinants of health cited as its main objective in article 1²¹.

On an international level, in 2018, the WHO verified the impact of many factors on health inequalities across the life-course, including societal factors (levels of national wealth and income inequality, gender equality, cultural adherence to traditional gender norms) and individual factors related to access to economic resources, sexual orientation, and having an ethnic minority or migrant status. Each of these factors can be considered to be a determinant of health (27).

However, the interest in determinants of health does not appear to persist beyond the preparatory stage. Rarely a focus of debate, and therefore of the health policy agenda, this issue is regularly relegated to the background as a concern of experts (211).

Alcohol use, a risk factor typically associated with determinants of health

Although the decline in alcohol use among adolescents observed between 2014 and 2017 is encouraging, the persistence of major disparities in use, particularly as a function of educational status and family environment, calls for prevention actions and initiatives to give greater consideration to these survey findings in order to better adapt and target them. The determinants mobilised here thus go beyond social level alone and demonstrate the value of a multidimensional study of alcohol consumption among young people (62).

- **The limited role of gender as a social determinant of health**

At the same time, it is regrettable that gender, a concept deeply rooted in societal issues, has nonetheless not received any real attention in the area of public health. Although it is often cited, it is in reality given little consideration in policy formulation work. The incorporation of gender-related concerns within public health policy strategy would therefore be desirable, in addition to other social determinants.

The WHO regularly explores the relationships between sex, gender and the socio-economic determinants of health. To understand how gender combines with gender-related behaviour, it is useful to consider gender as a system of social organisation, a set of attributes historically and culturally constructed through the activities of everyday life. These activities are themselves determined by the conditions in which people are born, grow up, live, work and age (212).

Gender can therefore be seen as a factor that generates health inequalities, insofar as it leads to differentiated behaviours, expectations and interactions.

The use of masculinities to understand certain behaviours in the area of health

A large body of health research indicates that traditional stereotypes of masculinities are related to worse health outcomes in men, that develop across the life-course, their effects accumulating with age (27).

A recent report on suicide in Ireland, for example, highlights the fact that dominant norms of masculinities are often represented by middle-class heterosexual men. It is therefore important to understand how these norms may further marginalize gay men, transgender men, men from lower socioeconomic backgrounds and ethnic minority men (27).

Analysis of coping mechanisms shows that men (more than women) tend to cope with their problems and dilemmas by taking refuge in addictions or ignoring needs for treatment. Consequently, depression symptoms in men often remain undiagnosed (27).

Besides the fact that men avoid asking for help or deny their state of discomfort (as doing so would be seen as a symptom of weakness and vulnerability), diagnostic criteria for depression are often polarised around signs of a traditionally feminine disease (27).

Men report that they would seek help less often when faced with a serious emotional problem and believe that they would be more embarrassed than women if friends knew about professional help received for their mental health (27).

Recognising that there is insufficient focus on the interactions between masculine norms and men's health within public health systems, the WHO's regional office for Europe published a strategy for men's health in 2018, which has so far not necessarily had a significant impact in France or in the rest of the European region. Whether through the production of reports or public action, as will be detailed below, this factor has not been given the attention it deserves, demonstrating the inadequate consideration of gender as a determinant of health in French public health (213).

Yet there are ways of taking this factor into consideration. While neither sex nor gender have been a major theme in the area of health and health promotion, a theoretical and practical guide on "la promotion de la santé au prisme du genre" ("health promotion through a gender lens") published by EHESP sought to demonstrate that "these two concepts are intrinsically linked on a theoretical, militant and professional level". This guide "highlights the importance of taking gender into consideration as a determinant of health inequalities. [Its objective] is twofold: to raise awareness among public and association sector healthcare professionals of the stereotypes they can convey and the impact of this on healthcare provision and to provide professionals with a set of guidelines" (214).

In this respect, it is useful to have a systematic approach to gender with respect to health promotion, assessing all the stages involved in the formulation and implementation of a project (structure sponsoring the project, context, objectives, resources, implementation on the ground, population targeted by the planned action, principles of inclusion, participation and ethics). At the end of this analysis, the synthesis needs to be discussed collectively by the team responsible for the formulation and implementation of the health promotion project. This systematic approach is also useful at public policymaking level, provided policies consider gender as a real social determinant of health.

- **A lack of consideration of sex as a biological determinant of health**

The health outcomes outlined in the first part of the report suggest that determinants - all determinants - can have an impact on the health status of an individual. Yet they are not all given equal consideration.

However, social determinants - including gender - cannot themselves explain all health inequalities.

A public health strategy also needs to take into account the existence of biological determinants, primarily influencing the severity or treatment outcome of a disease. To illustrate this need, it is necessary to identify situations where biological factors - in this case sex - have a reasonable probability of being an important determinant in differences in health outcomes.

Biological factors affect survival rates of boys and girls from the first years of life, over and above social and healthcare factors. Despite the overall improvement in mortality in children under 5 years of age, the gap between boys and girls has remained constant. This suggests that, despite advances in the field of perinatal health and in the first year of life for both sexes, the biological differences that make male babies more vulnerable persist. Thus, on the one hand, biology plays a decisive role in early childhood, but, on the other, it is not sufficient to explain morbidity and mortality rates at older ages (27).

It is not only a question of binary considerations separating the female and male sexes but, more broadly, of an increased reconsideration of all sex situations. The case of people with variations in sex characteristics (intersex) or that of trans people needs to be taken into consideration, both in terms of their specific characteristics, and also in relation to the general health issues that concern them but from which they seem to be excluded. This less binary understanding of sex and gender does not exclude the biological component: on the one hand, intersex people are biologically different, and on the other, some of them live with levels of male and female hormones that will have an impact on their health throughout their lives (in the same way as for trans people having had treatment to align their sex and gender identity).

While behavioural explanations can provide a better understanding of the differences that are observed between women's and men's health than biological explanations alone, this is not enough given the structural gap, present for almost all diseases. Hence, gender should be considered more clearly as a determinant of social health inequalities, but not without also making sex a central consideration in public health strategies.

New approaches can help to accurately account for this gap, drawing on available data.

Sex as part of a causality chain: epigenetics

The life-course epidemiology approach highlights the importance of the continuum that exists between people's early environment and the development of chronic diseases in adulthood. Studies demonstrating the influence of the early years of childhood on cardiovascular diseases and cancers in adulthood, or overall mortality, have major policy implications, particularly for children.

Epigenetics looks at the influence of the environment on gene expression, and hence on the evolution of this expression over the life-course. This discipline sheds new light on the link between health and the environment, including the social environment. The traditional distinction between genes and environment is therefore no longer pertinent (215).

Recent biological discoveries and advances in the field of epigenetics can be useful for public health policymaking. They show that the early-years environment of individuals is likely to be reflected in their gene expression and to promote diseases in adulthood, establishing an explicit link between biology and environment.

Reasoning on the basis of a chain of causal links helps in terms of choice of interventions, between those that address biological, societal and social causes and those that target proximal, purely biological or even pharmacological causes.

This approach obviously conflicts with the time-frames of public policies since it aims at results over several decades. However, at the very least, epigenetics can help provide a better understanding of health situations and outcomes, and pave the way for the necessary complementary consideration of the biological and contextual factors leading to these outcomes. Examining chains of causality, and therefore multiple mediations, implies accepting a long time-frame.

Social inequalities in health at the crossroads between a number of variables: the intersectional approach

Numerous health studies tend to explain health differences between different people on the basis of their individual behaviour. In recent years, these behavioural explanations have been considered as part of a broader range of factors determining health. A greater understanding of the importance of gender on health has led to the gradual introduction of notions such as sexism or masculinity into the debate on the social determinants of health.

For example, in the field of gynaecology, significant differences in health can be observed between French women born of French parents, French women with an immigrant background and women who are immigrants. These differences persist after taking into account the variety of socio-economic situations, even among those who are regularly monitored (216). Hence, neither social level alone, nor sex or gender alone, can clearly explain the variety of situations.

Another example relates to the higher levels of intolerance to men who are migrants, from minority ethnic populations, as well as gay or trans men, leading to exclusion and discrimination, in areas where normative models of hegemonic masculinity prevail. Such discrimination can have a serious impact on the health of the men affected (27).

When it comes to social inequalities in health, the issues of gender inequalities must therefore be analysed in terms of multiple variables at the intersection of different groups (men/women, workers/managers, naturalised/foreigners, etc.). A strictly biomedical or behavioural approach is insufficient.

Originally introduced to observe the specific difficulties of African-American women in the USA and to show the cumulative discrimination suffered by certain groups, the principle of the intersectional approach can also be applied to rethink the link between gender and health.

In this respect, a growing body of scientific work argues in favour of an intersectional approach, which is characterised by an in-depth examination of the factors that contribute to gender-based health patterns: socioeconomic factors, marital status, relationships with the world of healthcare, differential experiences in medical care treatment, masculinity, social support, migratory status, ethnic minority status, and health behaviours (217).

Intersectionality theory explicitly encourages the investigation of intersections of multiple inequalities (including, but not limited to, gender), not only on an individual level, but also on a structural level. By using intersectionality in their studies, various researchers have illustrated innovative approaches to examining the link between health and gender.

Health as a product of interactions between biological and social factors: the biosocial approach

L Biosocial research refers to approaches, theories and analyses that examine health as a product of intersecting biological and social phenomena. Health and illness are thus the result of interactions between psychosocial and biological factors.

As demonstrated by Springer et al in 2012 in a special edition of the Social Science & Medicine journal, two lines of research on gender-related health inequalities have dominated: empirical studies on differences between the sexes and their impact on disease, on the one hand, and research on gendered diseases and their translation into “men’s health” and “women’s health” policy on the other (218).

Both approaches reinforce a binary construction (male versus female) and treat sex and gender as easily separable.

To understand how to go beyond this construct, several examples of uses of the biosocial approach can be mobilised.

Example 1: research focusing on gender and bones proposes a biosocial research model, showing how bone health is shaped by sex-based and cultural norms, as well as biological processes. For example, the author shows how play activities in childhood and adolescence, which are significantly gendered, influence bone development and bone strength in adulthood, with women at greater risk of fragility (219).

Example 2: a biosocial analysis was applied in a study on congenital adrenal hyperplasia, a variation in sex characteristics that causes the overproduction of androgens. Jordan-Young uses congenital adrenal hyperplasia to disprove the widely accepted theory that high prenatal exposure to androgens permanently “masculinises” the brain - a theory used to explain a wide range of health and psychosocial development outcomes. More broadly, his article uses congenital adrenal hyperplasia as a case study to demonstrate a basic principle of biosocial research - that physiological phenomena (e.g. height/weight ratio or mood dysregulation) have specific meanings and effects within a particular gender regime and must be seen as a simultaneous product of biology and the social environment (220).

Example 3: In the 1990s, analysis of psychological links was able to reveal that psychosocial factors affect the biological system in ways that can weaken bodily functions and alter vulnerability to infectious agents (221, 222). In addition, health habits have a significant impact on psychological and physical well-being. Numerous chronic disorders are partially due to a combination of harmful behaviours and a detrimental environment. As health economists have amply demonstrated, medical treatments are no substitute for habits and environments that are favourable to health (218).

In order to understand the gendered dynamics of health, and more specifically, the dynamics of men’s health, it is necessary to move away from a strictly biomedical or behavioural approach that tends to homogenise the group of men and the group of women, and to take into account living conditions, working conditions, the differential assignment of care tasks and the differential effects of public health policies on men and women (223).

Incorporating sex and gender into public policymaking

The approaches developed in the academic world, and primarily the intersectional and biosocial approaches, make it possible to increase the consideration of health inequalities in the preparation of public policies. These approaches call for more sex- and gender-inclusive health policies, and for biological and social considerations to be combined in order to better address them.

The need to mobilise public debate in order to fully integrate sex and gender

Public debate corresponds to the mobilisation of the community before a public decision is taken in order to solicit the public’s opinion. It can be mobilised to different ends.

First of all, to inform decisions and give health issues the necessary societal basis, taking into account the diversity of situations.

Secondly, establishing a deliberative procedure goes some way towards addressing the issue of defining fairer allocation of resources, a central issue when seeking to more effectively take into account factors of inequality, whether biological (such as sex) or social (such as gender). Indeed, in a field where social expectations and opinions can take precedence over the initial objective of improving people’s health, recourse to expertise alone may not be sufficient. This has been seen in interventions concerning bioethics-related topics (224) and further encourages the mobilisation of public debate.

Whatever the perspective, public debate makes it possible to define areas for vigilance, but also to develop proposals.

When talking about sex and gender, public debate is essential because expertise alone is limited. Without replacing expertise and the various types of preparatory work for health policymaking, public debate makes it possible to ensure better consideration of specific experience related to sex and gender, in all its diversity and closer to the realities on the ground.

Given the diversity of situations and issues related to sex and gender, and to health more generally, a participatory component is useful. This is particularly true since this consideration implies looking at the environment in which people live, as well as the combination of biological and social factors.

In this field of public action, the need to involve the population is nothing new and widely accepted (225). A report by the WHO Commission on the Social Determinants of Health indicates that the input of civil society, greater representation of health needs based on gender and the encouragement of citizens to propose alternative solutions combine to reduce gender inequalities in the field of health (226).

While there is no doubt that public debate is necessary, it is now a question of defining good implementation methods to more extensively consider sex- and gender-related factors in health.

Experiences in other countries demonstrate ways of incorporating sex- and gender-related issues, corroborating the need to give room to public debate in health policy formulation.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) has set up a citizens council, broadly representative of the various components and cultural identities of UK society to address the principle of “Inclusiveness” sought by the institute, and which corresponds to involving all the stakeholders concerned (healthcare professionals, pharmaceutical companies, patient associations, researchers, etc.) in studies. This council led to the emergence of “Social Value Judgements”, which are now incorporated in all public health strategies. One of these judgements is combating social health inequalities and preventing discrimination on the basis of sex or gender (227).

Public debate is therefore useful to set strong rules and requirements for taking into account certain personal characteristics rather than others. Moreover, the characteristics of the people consulted influence the way they set priorities, hence the interest of a plural consultation process (228).

In France, health is publicly funded, with 76% of spending covered by the compulsory health insurance system (229). Consequently everyone is concerned by the allocation of health resources as a potential beneficiary and as a funder. Consulting the public about its preferences with respect to the fairness of health resource distribution seems to be entirely legitimate in this context (230). This question of prioritising the allocation of resources according to sex may seem incongruous. However, it is a fact, for example when health products are paid for by public funding with sometimes more limited information on the benefit/risk ratio for women than for men, or when social or health policies are aimed at a specific group, entailing a risk of failing to meet the needs of other groups.

This is food for public debate, which could help define values that might be lacking in the formulation of a public health strategy by emphasising the importance of sex, gender and their interactions with other determinants.

Other public debate formats can be envisaged, with examples in France²². Each of these presents advantages and disadvantages, depending on what is expected (230).

²² These formats include participatory democracy (e.g. national health conference, opinion on health democracy); the involvement of expert user groups in decision-making (e.g. representatives involved in a dedicated council and at HAS working group level); états généraux round-table talks (e.g. implemented within the framework of the bioethics laws); public enquiries, aimed at identifying the values of society and translating them into deliberative criteria.

Awareness-raising with respect to the need to make choices as a prerequisite for debate

People are not necessarily familiar with sex and gender-based health outcomes, as well as the interactions between biological factors and social determinants and so awareness-raising is required. The incorporation of public debate into policy formulation works towards this. However, other health policymaking elements are still essential, including in citizen participation mechanisms.

Making choices relative to the allocation of health resources - especially when it is a matter of funding new treatments - is a complex exercise for public opinion. In addition concepts such as opportunity costs and rejection of funding for other health products in order to fund a given treatment are not easy to understand.

Engaging civil society could also help raise awareness and increase individual responsibility when it comes to making choices. This awareness-raising, like that concerning sex- and gender-related issues in the field of health, is a prerequisite in terms of obtaining a citizen opinion that can be applied via public action. In addition, this is a necessary step to enable a better match between the decision and the principles or values that are approved by the public.

The still partial incorporation of sex and gender into impact assessments (ex-ante)

Following a circular in 2012, the French Ministry for Women's Rights encourages the advance assessment of the effect of a public policy on gender inequalities²³. This advance assessment requires an impact assessment, a step that has been mandatory for all legislative bills since 2009. Despite this progress, the place of gender equality within impact assessments is still inadequately institutionalised and is very variable depending on the policies conducted and the way in which these concepts are understood; it is therefore difficult to really assess their consideration in the short term (231).

Yet there is little focus on sex and gender issues in health policy formulation, despite the fact that inequalities exist. It therefore seems preferable to ensure these factors are taken into account by decision-makers from the preparatory work and impact assessment phase. This thinking is not new, and refers back to the development of an “integrated” approach encouraging gender mainstreaming in areas related to public action, in order to better reduce such inequalities. Other fields, such as urban policies, have been able to adopt such an approach, through the mobilisation of actors from civil society²⁴. In health, gender mainstreaming is still struggling to find its place.

Sex, gender and impact assessments: the DGCS methodology

In 2014, the French Directorate General for Social Cohesion (DGCS) produced a guide presenting the benefits and methods of incorporating sex and gender in impact assessments (233). The methodology can be broken down into four steps:

1. “Know the sex and gender composition of the groups of people directly and indirectly affected by the bill and identify the differences that exist between women and men in the area concerned by the bill, and whether these differences pose a problem;
2. Assess the direct effect of the measure envisaged taking into consideration these differences;
3. Assess the indirect effect in terms of behaviours, time-frames and multiple discriminations;
4. Propose corrective measures, if necessary, to eliminate these differences.”

²³ www.legifrance.gouv.fr/jorf/id/JORFTEXT000026310492/

²⁴ We are thinking here of the work of the Centre Hubertine Auclert, which promotes the renewal of urban policy and has produced a methodological guide on gender mainstreaming at local level (232). This centre has produced tools to help incorporate gender in public policy formulation, presented in annex 2.2.

The DGCS details each of these steps in its report, which followed the release of another document on gender in the field of social work. However, health and its gendered component make up only a very small part of the reflection process. When listing the different ministries for which the impact assessment incorporating the issue of gender inequalities would apply, the absence of health is again striking (233).

Criteria such as gender can be difficult to handle, and a series of tools must be available to provide a robust methodology for both the ex-ante impact assessment and the ex-post performance assessment of measures that are decided upon. In this sense, the mobilisation of the academic world, within a public action-defined framework (calls for projects, research contracts, etc.) could make it possible to define key objectives, indicators and assessment methods adapted to sex and gender issues in health. It would also enable public action to more fully incorporate the approaches outlined above.

Rethinking health policy in France in response to inequalities: proportionate universalism

Public policy in France is traditionally based on the idea of universalism, in other words, policy formulation without upstream targeting of any particular identified group. But this idea is sometimes abandoned in favour of more targeted policies, as a one-size-fits-all approach risks ignoring the needs of vulnerable populations, especially in the area of health.

However, access to these targeted interventions depends on selection criteria (income, education, health status), which can lead to the exclusion of populations that do not meet these criteria, making them invisible. In addition, targeted actions have the disadvantage of stigmatising particular groups of people.

It is to address these pitfalls that the strategy of proportionate universalism is justified in public health. The aim is to offer health actions and programmes to all (universalism), but with an intensity that varies according to needs (proportionality). What that means in concrete terms is that health actions and programmes are decided upon and built for all, regardless of social affiliation, but that the actions are differentiated depending on the target audiences, in terms of their strategy or the amount of additional resources allocated.

This adaptation of impact assessments fits squarely with the concept of gender mainstreaming when it comes to health policy formulation. Impact assessments must make it possible, firstly, to quantify the benefits derived by the various key populations and, secondly, to ensure that the measures adopted do not further reinforce inequalities. When a sex-differentiated measure is envisaged by a law or when a law targets a subpopulation instead of being universal, the impact assessment associated with the law must justify the benefit of such sex-based differentiation in the light of its potential consequences.

In order to firmly establish this principle, it is undoubtedly also necessary to support it with normative standards in order to provide all the necessary foundations for taking these factors into account right from the preparatory phases of health policy formulation. If it is to be exhaustive, this consideration needs to go beyond equality between women and men solely, which is already included in Article L. 1411-1 of the French Public Health Code. This article could therefore be consolidated, in order to highlight the importance of sex and gender in the field of health, but also the need to combine these factors with other determinants.

New methods for the implementation of public policies

Acting with the populations concerned: the inclusion of actors from civil society

In its constitution, the WHO laid down a participative vision of health: “informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people”²⁵.

The effectiveness of this approach is widely recognised internationally, and it is included in many WHO statements and in the theoretical and practical corpus of public health teaching. However, this integration is still limited to certain sectors and certain historically targeted populations. It would be useful to extend programmes and partnerships via contractualisation. This idea of community mobilisation could, for example, be targeted to help men take greater care of their health by working with predominantly male groups or groups making little use of the healthcare system. An adaptation and action drive of this type, working alongside these groups, is now recommended by studies conducted in men focusing on socio-economic level (234) or ethnic minorities (235).

Within Europe, thinking hinged around the community approach is embodied by the *Secrétariat européen des pratiques de santé communautaires* (SEPSAC - European secretariat of community health practices). The organisation focuses particularly on the development of this approach in Belgium, France and Spain (236).

France’s universal culture does not favour the formulation and implementation of health actions based on a criterion of community difference, as has sometimes been the case in North America.

However, the *Société française de santé publique* (French public health society) has developed a theoretical and technical framework for action of this type, grouped under the term “community”. Such actions are made up of three components: community, participation, mediation (237).

In fact, numerous health actions rely on an approach that directly involves specific populations, based on various differentiating criteria: gender identity, in particular, but also sexual orientation, drug use, immigration, geographic area, etc.

In this context, the community should be recognised as a stakeholder to be consulted by decision-makers, in order to redefine health objectives (237). In view of the health outcomes presented and the important role that sex and gender may play in these outcomes, there is a need to better identify groups composed by taking these factors into account.

²⁵ Constitution of the World Health Organisation, 7 April 1948.

When determining the target populations, but also when choosing actors within civil society capable of mobilising these populations.

A population-based approach of this type is not included in any French normative texts. However, it is incorporated as a public health and health promotion tool.

This approach does not have strongly supported levels of evidence, especially since it was initiated by associations and has not been the subject of publications supporting its effectiveness or efficiency. However, there are documents of note describing the intervention processes (238).

The case of intersex people is a good example of the beneficial effects of concerted action. Health professionals may refer the parents of a child with a variation in sex characteristics, and the children themselves, to representative associations offering psychological and administrative support, in order to break the solitude often felt in this situation. This coordinated action also makes it easier for intersex people to access care and speak freely, thereby facilitating dialogue with the medical profession and support for research (239).

This is also true for trans people, who, as the primary parties concerned, can help raise awareness among healthcare personnel. The experience and health inequalities faced by trans people call for more collaborative work, and a shift away from a rather paternalistic approach towards this population with specific needs (240).

It is in reaching the target populations that the approach is most effective since the actions are designed by and with the populations concerned. In France, the approach has been shown to be useful to support women in vulnerable psychological and social situations, where collaboration between the initiating associations and health professionals has proved to be particularly effective (241). Therefore, the community approach provides a framework that offers the flexibility needed to ensure the effectiveness of this type of intervention: participation of citizens in the development of projects, the renewal of such projects based on needs, detailed evaluation of the actions carried (242).

While civil society, via associations in particular, can be mobilised in the implementation of public health policies, the importance of mobilisation on other subjects, particularly that of clinical trials and data collection, should not be overlooked.

The trans community, for example, has worked hard to ensure that the results of clinical trials are applicable to trans people.

It is surprising how little interest there is among women's movements in the subject of women's representation in clinical trials, and the greater uncertainty there is surrounding the results for women than for men.

At a round table held in May 2016, the co-founder of Organisation Intersex International (OII) expressed the wish that “studies be implemented focusing on the experiences of intersex people, particularly with respect to suicide rates, risk-taking, addictions, the exclusion of the people concerned and their life expectancy” (177). To this end, the involvement of intersex people in the collection and analysis of health data is essential and should help to identify areas for improvement. And this needs to be explored along with the intersex community, in a way that balances the benefit sought with the protection of people's rights in terms of discrimination and privacy.

Community action assessment models are under construction, mostly based on recent North American studies. The stabilisation of one or more models should enable comparisons to be made, something that is currently lacking. Thus, French public action strategy should probably draw inspiration from the findings that can be anticipated from the examples cited, in order to develop a more ambitious community action that reaches out to people who are both vulnerable because of their sex or gender identity and because of another precariousness factor (migrant women or prostitutes, for example) (243).

Outreach

While working with civil society groups to ensure that it is relevant to the people concerned, public health action must also be able to reach more excluded populations, who are often the most vulnerable. Outreach is an approach that consists in designing and implementing actions that literally reach out to the populations concerned, initially people excluded from the healthcare system, in the places where they happen to be or live. It is supported by health professionals and leaders from the user community depending on the field.

Several examples illustrate the value of this approach in the implementation of public health policies, even if they are designed on a principle of universality.

One of the earliest experiments was conducted in Chicago, from 1968 to 1974. With the support of municipal and community leaders, it was able to achieve significant results in terms of reducing the use of psychoactive substances. One of the keys to the success of the Chicago experiment was the recruitment of a respected leader among substance users for the initiative. This example is also relevant as far as gender is concerned, as indicated in a United Nations report highlighting the problem of stigmatisation of women substance users by the healthcare system, hence the difficulty in access to care and treatment (244).

In France, this approach echoes initiatives to combat tuberculosis, whereby social workers knocked on the doors of disadvantaged families. The fight against HIV/AIDS has revived old methods under the umbrella of outreach, sometimes supplemented by approaches to mobilise the people concerned. Hence, actions aimed at populations excluded from the healthcare system due to various, and sometimes multiple, vulnerability factors have been implemented in France. Examples include the work of free information, screening and diagnosis centres (CeGIDD) for women and men who are vulnerable for sometimes different reasons, which require adaptations, health mediators and mobile intervention teams focusing on infectious diseases or mental health, for example.

A vaccination campaign carried out by *Médecins du Monde* in 2011, in partnership with the health authorities, against the measles epidemic in Europe, demonstrated the value of an outreach approach targeting Roma populations living together in camps in Marseille. Feedback from this campaign reveals, among other things, the importance of adapting to the different needs and care requirements of women and men, when reaching out to populations (245).

Finally, targeted interventions (age-based, for example) or universal interventions for groups in difficulty have been deemed promising or have been approved by *Santé publique France* in certain areas, such as the prevention of STIs or unplanned pregnancies. There is a particular focus on these types of interventions in assessments in North America, where they originated (246).

Since people with employment difficulties have a much poorer health status²⁶ and make less use of health services than the general population, health policy must respond by targeting actions towards these groups (247). Moreover, it appears that women and men may face different forms of precariousness, which implies that adaptations should be made according to the population to be prioritised. Considering that health policy can be improved by concepts that combine biological and social vulnerability factors, its implementation via an outreach strategy becomes essential.

More generally, **cost-effectiveness assessments show that an outreach strategy is often more costly to implement than totally universal methods**, which are closer to the French model. **However, assessments also demonstrate a long-term saving through outreach**, the effective use of which could avoid substantial healthcare costs in certain situations (245).

²⁶ 50% worse than that of the general population of the same age.

In order to formalise strategies of this type, contracts with associations make it possible to more effectively reach the people concerned, but also to ensure greater engagement, enabling joint work on prevention and care.

Outreach strategies are therefore a good way of making sure that public policies are implemented where they are most needed. From a sex and gender perspective, it seems essential that the implementation of public action should target, but not be limited to, the people identified as being the most vulnerable. More generally, the different groups should benefit from these efforts to ensure improved health for all. Action of this type would counterbalance universal policies that are as inclusive as possible, in order to leave no situation excluded, with targeted and accentuated application to the populations most in difficulty. In this respect, the engagement and awareness of healthcare professionals is absolutely essential. This also implies that such a strategy should be planned at an upstream stage.

Retrospective performance assessment of health policies: effectiveness and efficiency through the prism of sex and gender

The purpose of assessment is to determine whether the policy is effective and reveal any flaws that need to be corrected by public action. Consequently, the criteria defined to set its framework are crucially important. Each criterion reflects a vision of what an effective health policy is, and the absence of certain criteria thus raises questions. In the light of the above, it is necessary to consider not only the value of integrating sex and gender into policy strategy, but also the possibility of assessing the value of differentiating policy according to these factors, both before and after the fact.

The formulation of health policies is increasingly considered alongside their assessment, both prospectively and retrospectively. Legislative bills increasingly schedule impact assessments to prepare for the application of a public health measure, as well as verification of its efficiency afterwards.

Evaluating the effectiveness of policies on gendered health outcomes

From health policy assessment to consideration of inequalities in France

With a view to improving health by combating sex and gender inequalities, the assessment phase is essential to verify that an action - especially when it targets certain populations - does not, in fact, create or increase inequalities when it is supposed to reduce them by improving the health of all.

In this respect, the assessment should be based on reliable and comprehensive data on the populations in question. However, some data are unavailable, especially for trans and intersex people. Collecting and updating these data is an essential prerequisite in order to be able to assess the effectiveness of health policies in relation to sex and gender.

In 2019, 20 indicators were defined to measure the effectiveness of public policies in France, as part of the country's National Health Strategy (SNS) 2018-2022 (248).

On this subject, the National Health Conference, consulted within the framework of the strategy, pointed out a failure to take into account several factors, such as precariousness or loss of autonomy, significantly impacted by the presence of inequalities. Furthermore, according to these indicators, there is no provision for monitoring the improvement of health with regard to sex and gender, e.g. by assessing health inequalities between women and men. Hence, despite the significant interest in these issues in France, the assessment of health policies in terms of health inequalities is relatively incomplete (249).

Ambitious international advances

In the field of health, the recognised model for evaluating the effectiveness of policies is the WHO's Health System Performance Assessment (HSPA) method, first implemented in Belgium in 2010.

An HSPA primarily aims to:

- set health system objectives and priorities;
- serve as an interface for public policy formulation and coordination of actions within the health system;
- measure progress towards the attainment of objectives;
- form the basis for comparison with other health systems;
- promote transparency and accountability with respect to citizens and other legitimate stakeholders in terms of how financial resources are spent.

In 2011, the Council of the European Union initiated a reflection process aimed at harmonising and revising health system assessment. Of the 17 respondents, 13 indicated that they had introduced an HSPA framework, in one form or another, on a national or regional scale. Assessment of the effectiveness of these systems is seen as an essential tool for making them more effective. The absence of France among these initiators is noteworthy.

The French Social Protection Committee (SPC) and its "Indicators" subgroup have been exploring the possibility of adapting the Joint Assessment Framework methodology to health systems (Social Protection Committee, "Indicators" subgroup, 2013). This quantitative methodology is envisaged as a first check to detect possible health system failures (250).

On the issue of inequalities, the degree and form of consideration varies. In the UK, the development of indicators and targets to quantify the reduction of inequalities was quickly put in place. This can also be done at the experimental stage, as in the Netherlands, in order to define the impact of different forms of intervention on social inequalities in health. Finally, Sweden, guided by the promotion of equity rather than the reduction of inequality, has produced a series of indicators targeting this objective via dedicated expert groups. The strategies defined in these three countries include components aimed at acting on the social determinants of health inequalities, at an upstream stage, and actions that mobilise the health system, downstream (251).

Progressive integration of sex and gender issues into effectiveness

Multiple HSPA framework formulations make reference to the issue of impartiality, or equity, in the way the attainment of objectives is distributed among different population groups. Similarly, several health systems in Europe directly include health inequalities among effectiveness objectives. Sex and gender issues could therefore be incorporated.

An extension of the effectiveness criteria therefore appear to be preferable. An assessment from the perspective of gendered identities should include both:

- an assessment of health outcomes
- an assessment of inequalities: have they been reduced, or, at the very least, not exacerbated?
- an assessment of the efficiency of the policy envisaged and of sex-based differentiation.

Obviously, this implies specifying the aspect of sex- and gender-related inequalities. Are we talking about inequalities in access to care or to social and medico-social services? Are they related to the quality of interventions or support? Those observed in terms of health outcomes?

Sex- and gender-disaggregated health outcomes provide many pointers for assessing the effectiveness of the health system from this perspective. To target an objective, any unequal situation is a starting point: the evaluation could, for example, assess access to primary care for intersex or trans people; gauge the inclusion of women in clinical trials; or examine access to gynaecological consultations for disabled or homeless women.

University research could help define efficacy indicators. In the social and medico-social field, as in many health fields, the difficulty of making comparisons still makes efficiency calculations too unreliable. As a result, the evaluation of policy effectiveness, with a more thorough characterisation of gender inequalities, would make it possible to establish more uniform paths and criteria for improvement.

Questioning the efficiency of sex-based differentiation

If health policies are envisaged as being broadly inclusive but sex- and gender-targeted from their implementation stage, the targeting should be evaluated with a view to their improvement or redesign, if necessary. Health assessment criteria include economic factors. Therefore the sex-based differentiation of a policy needs to be able to demonstrate its efficiency.

Economic evaluation makes it possible to compare different medically relevant health interventions. It enables them to be ranked against each other in terms of their costs and impact on health outcomes. This ranking eliminates options that are both more expensive and less effective. Two scenarios illustrate how the sex-based differentiation of a health policy can be assessed. These scenarios show that, depending on the policy methods and objectives, sex-based differentiation appears to be more or less efficient compared to the maintenance of universal implementation.

Two examples of sex-based differentiation effectiveness assessment

- **Medico-economic analysis of sex-differentiated screening (252)**

Studies conducted in the Netherlands on colorectal cancer screening raise the question of whether there is a need to differentiate between women and men.

In the Netherlands, colorectal cancer screening strategies are based on a single approach regardless of age and gender, despite differences in prevalence and life expectancy (and therefore screening time).

With evidence to support the fact that a differentiated faecal occult blood test (FOBT) strategy might be of value, Dutch researchers conducted a medico-economic analysis to assess the efficiency of potential sex-based differentiation of screening strategies. This study simulated the creation of separate strategies according to sex, taking into account the differences arising from this characteristic (prevalence, age of incidence, test sensitivity).

This analysis shows differentiated benefits between men and women, but the differences were ultimately marginal. In the strategy for women, screening proved to be less costly, but shifting the screening age also resulted in a loss of life expectancy for those affected. In contrast, for men, an earlier screening strategy is more effective but considerably more costly: €6,300 to gain an average of one year of healthy life.

In view of these results, the relevance of a sex-differentiated screening strategy in the Netherlands is debatable. The elements that can support this choice are:

- the small health gain or even loss of opportunity for women, depending on the strategy tested, associated with sex-differentiated screening;
- the potential impact of sex-based differentiation on participation: this is a major parameter of screening efficiency, and sex-differentiated recommendations could confuse the message to the population and decrease participation, thereby leading to a loss of efficiency rather than a gain. Indeed, the value of such a policy is probably counterbalanced by the difficulty of communicating the message linked to a sex-differentiated policy, with a potential loss of uptake of a portion of the population.

Finally, the average costs and health outcomes on an individual level (relatively low in the proposed efficiency analysis) need to be set against the size of the target population likely to benefit from screening. The latter is generally efficient at lower costs, but extended to very large populations these gains and costs take on a different proportion. Once again, assessment of the sex-differentiated policy makes it possible to visualise the efficiency and budgetary impact with regard to the empirically reached population, and the sex distribution of this population.

In this example, sex-based differentiation in colorectal cancer screening policy does not appear to be an unequivocal solution for the Netherlands. It is conceivable that the recommendation of male- and female-specific screening methods, in the context in which they are developed here, is of less value than their combination, which could improve the efficiency of the strategy by making it fit the realities. Such a combination can only exist if the message sent out to the population is clear and it participates.

This study highlights the fact that a sex-differentiated assessment of health policies is essential to ensure the success of efforts to reduce gender inequalities in health for a given issue.

In France, the French National Cancer Institute (INCa) has also examined this issue of a sex-differentiated cancer screening strategy. Its conclusions are more qualified, suggesting that a large-scale differentiated programme would generate only marginal gains but would be complex to implement in practice (253).

- **HPV vaccination: moving from a sex-differentiated policy to a universal policy**

In a number of countries, consideration is being given to HPV vaccination in adolescent boys, and thus to a universalisation of the prevention policy, initially reserved for young women.

Assessments have been carried out to examine the benefits and limitations of universal strategies of this type in order to guide health strategy choices. They provide contrasting results in terms of cost-effectiveness and demonstrate the need to take into account other criteria in public decision-making processes.

The assessments initially demonstrate that vaccinating boys as a complementary strategy to the vaccination of girls is not cost-effective, if considered solely from a cervical cancer prevention perspective. The health outcomes need to be considered more broadly, in both girls and boys (prevention of cancers of the anus, vulva, vagina and penis, genital warts, etc.) in order to observe a potential efficiency of universal vaccination. However, data on these broader health gains are not always available or consistent with the Marketing Authorisations (MA) of vaccines (254).

Secondly, cost-effectiveness results are highly dependent on vaccination coverage for both girls and boys.

For example, according to a study in the USA, it is more cost-effective to increase vaccination coverage among girls (from 30% to 45% coverage) than to bring boys up to the same level of coverage as girls (30%). Sex-based differentiation therefore remains more useful, including when vaccine coverage has the capacity to be increased (255).

A New Zealand study also shows that increasing vaccination coverage among girls from 47% to 73% is more efficient than a 47% coverage for both girls and boys (over the status quo) and that the cost-effectiveness of vaccinating boys increases when the vaccination rate for girls increases. The assessment therefore points to a decreasing returns to scale effect: as the level of vaccine coverage increases, the benefits associated with its increase decrease (due to herd immunity, for example) and the associated costs increase. (256).

In conclusion, increasing vaccination coverage for girls remains the most cost-effective strategy compared with vaccinating both girls and boys; however, the cost-effectiveness ratio of the latter is more favorable when vaccination coverage for girls is low (as is the case in France).

In France, in 2018, only 23.7% of girls born in 2002 had received all the doses corresponding to the complete vaccination schedule at 16 years of age. This low vaccination coverage among girls raises the question of whether the vaccination of boys would be useful. In this context, the question of the effectiveness of a sex-differentiated policy was raised by the Ministry of Health, which referred the matter to HAS.

The clinical and medico-economic interest of switching to a universal policy was studied, and ultimately this policy was recommended in the light of the medico-economic data, but also based on the perception by professionals of the leverage effect of vaccinating boys, and of the ethical issues, since a policy that places the burden of vaccination solely on girls may appear to be discriminatory, as may the targeting of young men according to their sexual orientation (254).

For HAS, this extension of the vaccination programme is aimed both at protecting vaccinated boys and reducing transmission in the population as a whole. Universal vaccination would also make it easier to reach men who have sex with men (MSM) without stigmatisation, at an age when their sexual preference is either not known (by the individual and those around him) or not stated.

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The importance of synergy between impact assessments and evaluation to see the benefit of sex-based differentiation in a given health system

In the literature, the incremental cost-effectiveness ratios (ICERs) of a vaccine strategy extended to boys versus a strategy targeting girls were highly variable, and highly dependent on the parameters taken into account in the model (types of health outcomes considered) and the context (initial vaccine coverage rate, types and costs of vaccines used, etc.). Depending on the studies, extension of anti-HPV vaccination to boys was or was not more cost-effective than its alternatives (254).

Although the cost-effectiveness of moving from a sex-differentiated to a universal policy cannot be transposed without taking into account the specific context in which it is evaluated, these studies confirm the value of assessing the cost-effectiveness of vaccine policy formulation choices (universal or sex-differentiated).

No budget impact study, i.e. a prior evaluation of the financial amount to be disbursed to fund the vaccination policy according to the chosen method compared to the one rejected, including the subsequent costs avoided, if applicable, has been conducted. However, given the size of the target population, an analysis of this type would have been useful.

Finally, a policy may be efficient but difficult to sustain on a population level (in terms of the number of beneficiaries, its implementation is not compatible with budget constraints).

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Proposals for better consideration of sex and gender at every stage in the health policymaking process

(proposals aimed at public decision-makers)

Proposal 2

Incorporate sex and gender into public policy formulation

Public policy formulation must take into account differences related to sex or gender while at the same time being underpinned by the principle of improving the health of the population as a whole. Specific measures and/or increased resources for certain groups should be made available where relevant and useful. This implies defining a new form of health policy universality that does not disregard differences, particularly those related to sex and gender.

In particular, this involves:

- the use of public debate;
- impact assessments;
- the mobilisation of the academic world;
- the reformulation of article L. 1411-1 of the French Public Health Code specifying the objective of health policies, in order to incorporate the concept of interaction between biological sex, gender identity and social determinants.

Proposal 3

Construct implementation with the populations concerned

It is necessary to reconcile universality and targeting in order to define social and health policies for all, while at the same time deploying specific means, where required, to reach different population subgroups.

The implementation of health policies must be constructed with the populations concerned, and the stakeholders, particularly associations. It is necessary to act for and with these populations when they are at risk of being difficult to reach without specific action, in particular due to vulnerability associated with their sex, their gender identity or any social or medico-social difficulties exacerbated by these factors.

This requires the mobilisation of partnerships and a co-construction approach: in this sense, institutional players must act in synergy with associations in order to improve the health of the people on whose behalf they are working. By contractualising the action with operators, it is possible to more effectively cater for this target, reaching out to the populations concerned and getting them involved in the action.

Proposal 4

Conduct a retrospective assessment of public policies through the prism of sex and gender where relevant

Sex- and gender-related concerns must be incorporated into the assessment of public policies according to criteria of effectiveness, efficiency and equity defined by the impact assessment.

In particular:

- an assessment of effectiveness and efficiency should be conducted whenever a sex-differentiated measure is scheduled, provided that a comparison with a universal alternative is possible;
- an equity assessment must be sought when social roles or gender stereotypes have a major impact on health, in particular to check that the policy implemented does not deepen inequalities.

Part 3

Developing more inclusive public health policy instruments

Operational application

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A new approach to the formulation of public action, more closely reflecting sex and gender realities, can guarantee better care for all and trigger a reduction in health inequalities. Making policies and strategies more universal, then adapting them on the ground by means of targeted actions, are two complementary ways of achieving this.

Policy commitments must be translated into significant and ambitious changes in terms of the incorporation of sex or gender issues. Operational implementation is central to this reflection process. Whether it is in the field of health or in the social and medico-social spheres, a number of levers exist to improve the sex- and gender-inclusive nature of the system. This means making sure that nobody is excluded by adapting the system's tools: administrative standards, clinical trials, guidelines or training of professionals.

These instruments are developed below. The national and international analysis applied to each of them makes it possible to examine the benefit of integrating sex- and gender-related issues. A quick look at practices through the lens of sex and gender also reveals the stereotypes that come into play and the imbalances that these create.

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A regulatory arsenal that is not adapted to certain contemporary realities

Room for improvement in the formulation of legal standards

Legitimate grounds for differentiation in the eyes of the law

The principle of equality is firmly anchored in the French Constitution. Indeed, it is indicated in article 1 of the Declaration of human and civic rights, which is included in the preamble to this Constitution: “Men are born and remain free and equal in their rights.”

However, this principle does not preclude a difference in treatment, which is provided for in the same article, which states that “Social distinctions may be based only on common utility”.

There may therefore be legitimate grounds for differentiation that are legally acceptable. One well-known example of this is public service pricing. It is accepted that two people who are not in the same situation can be treated differently: for example, residents of a municipality may thus be given a preferential rate for access to municipal services (theatre, swimming pool, media library, etc.) compared to non-residents.

Sex, physical appearance, state of health and genetic characteristics are listed in Article 225-1 of the French Criminal Code as criteria that, if used to differentiate between individuals, would constitute discrimination. Thus, these elements, which are central to the issues examined in this report, cannot justify a difference in treatment in terms of access to a right or a service.

With regard to the French Code of Medical Ethics, Article 7 indicates the same criteria that may not be used as differentiating factors: “A doctor must listen to, examine, advise or treat all patients with equal care and attention, regardless of their origins, their customs, their family situation, their ethnic group, nationality or religion, their handicap, their state of health, their reputation or his/her personal feelings towards them. He/she must provide assistance to them in all circumstances. He/she must at all times show an appropriate and caring attitude to the person he/she is examining.”

In the health field, it is also accepted that a vaccination campaign may target a population at particular risk rather than the whole population. This was recognised in 2006 by the *Haute autorité de lutte contre les discriminations et pour l'égalité*²⁶ (HALDE - French Authority against discrimination and for equality) in the case of targeted screening for tuberculosis, for example (257).

²⁷ Now part of the Défenseur des Droits institution (French institution for the defence of human rights).

Similarly, women are frequently legally excluded from early cancer trials by reason of their specific protection. Other groups may also be excluded from the trials, either to protect them (elderly people, children) or to reduce inter-individual bias (intersex people, trans people). Today, this approach is the subject of debate (258, 259).

Relative neutrality in legal standards

The extension of the battle against sexual discrimination to include gender discrimination in France was summarised in three main stages by Morgan Sweeney at a symposium organised in 2018 under the auspices of the Défenseur des droits institution, entitled “*Multiplication des critères de discrimination. Enjeux, effets et perspectives*” (Multiplication of discrimination criteria. Challenges, effects and outlook”) (260).

In 1992, France had to abandon certain paternalistic provisions providing specific protections for women, censured by the European Community, which requires neutrality with respect to sex (261)²⁸.

Later, European judges moved away from a rationale of discrimination based on “biological sex” towards a rationale of gender discrimination.

After imposing an amendment of the civil-status register for a trans person following a change of sex, the European Court of Human Rights then allowed trans people to marry a person of the opposite sex to their new gender, and the European Court of Justice ruled in favour of a trans person who had transitioned in order to receive the social benefits conferred by their new sex.

According to Morgan Sweeney, this judgement gives primacy to “social” sex over “biological” sex (262), in contrast to certain fields such as sport, where today the provisions reserved for women are still based on their biological sex (with the difficulty of defining what a woman is biologically, and the question of the legitimacy of the sports authorities to decide this) (263).

Some discrimination, which is systemic in nature and part of the organisation of a society, is legally acceptable.

From this point of view, the law can then be considered to itself be a vector of sex-based differentiation, which some authors question (264, 265).

Through a dedicated research programme, several authors have used gender as an analytical concept in order to sift through French law and identify legal norms that explicitly distinguish between the sexes and those that, although semantically neutral, help perpetuate historically dated gender stereotypes (266, 267).

Thus, despite a stated political will to promote gender diversity and gender neutrality, there are still provisions in the law that establish unequal or stereotyped relationships assigning gendered identities and binary roles, most often in the name of the individual's interest. This is the case, for example, with the rules relating to the attribution of surnames, or family names, which, although they have no longer systematically included the father's name since 2002, nevertheless remain favourable to the transmission of the latter as a matter of principle in the absence of a specific decision by the parents (268).

The value of research focusing on these issues was highlighted in the information report on gender studies submitted to the French National Assembly (269). Indeed, while the law can be an instrument for combating inequalities (and in this respect the inclusion of the term “gender” in non-discrimination law is an important step forward), it can also have unintended effects in terms of social relations.

²⁸ It should be noted, however, that the provision relative to night work continued to be included in French labour law until 2001. www.legifrance.gouv.fr/codes/id/LEGIARTI000006647328/1987-06-20/.

That is why the Delegation for women's rights and equal opportunities for men and women recommended in 2016 (recommendation No. 20) that it was necessary to “ensure greater consideration of gender equality issues in impact assessments in order to improve the drafting of legal standards, for example, by entrusting the Secretariat General of the Government with the role of monitoring the analyses prescribed by the circular of 23 August 2012²⁹ in impact assessments, so that the inclusion of bills in the subsequent legislative process be dependent on their existence and quality”, as proposed by the Court of Auditors (269).

Still incomplete adaptation of the law in terms of sex and gender

In France, birth certificates are required to indicate the child's sex³⁰ (without specifying whether it should be indicated as “female” or “male”). The declaration must be made within 5 days of the child's birth.

The law does not define the notion of “sex”. However, the binarity of the sexes (“male” / “female”) is found in numerous legislative provisions, stipulating “of either sex” (e.g.: article 388 of the Civil code defining minority)³¹.

For national identity cards in France, the circular of 10 January 2000 indicates that “The sex indicated on the birth certificate (article 57 of the Civil code³²) must be indicated by the letter M (male) or F (female)” on the card, introducing the notion of binarity of sex.

Therefore French law does not allow any sex other than male or female to be indicated on civil status register documents. Yet scientific data contradict this binary conception of sex, just as social sciences conceive a variability of social roles and gender identities. Hence a series of situations reveal certain limitations.

For example, **the time limit for the declaration of the sex at birth is difficult to apply in the case of intersex infants.**

Therefore article 57 of the Civil code is supplemented by a 2011 circular³³ that specifies that: “Where the sex of an infant is uncertain, the use of the term ‘undetermined sex’ should be avoided on the birth certificate” and “the sex that appears most likely” to the doctor should be indicated.

Hence if uncertainties exist, the French Supreme court has issued a negative opinion to the question of creating an identity other than female or male on grounds that are open to debate³⁴:

- “(...) given that French law does not allow any sex other than male or female to be indicated on civil status register documents”;
- the risk with the recognition of a neutral sex of “profound repercussions on the rules of French law constructed on the basis of the binarity of the sexes [which] would imply numerous legislative changes of coordination.”

²⁹ www.legifrance.gouv.fr/jorf/id/JORFTEXT000026310492/

³⁰ Article 57 of the French Civil code stipulates that “the birth certificate shall indicate the day, time and place of the birth, the child's sex, the first names given to the child, the family name, [...] as well as the first names, surnames, ages, professions and places of residence of the father and mother”.
www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006420911/2006-07-01.

³¹ www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000032207650/2016-03-16.

³² www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006420911/2006-07-01.

³³ Circular of 28 October 2011 on the rules specific to various civil status records relating to birth and filiation. Sex of the child - Where the sex of an infant is uncertain, the use of the term ‘undetermined sex’ should be avoided on the birth certificate”. Parents should be advised to seek advice from their doctor as to which sex appears most likely, taking into account the expected outcome of any medical treatment. This sex will be indicated on the certificate, and the indication will be legally rectified afterwards, if necessary, in the event of an error. If, in certain exceptional cases, the doctor considers that they cannot immediately give any indication of the probable sex of a newborn infant, but if this sex can be definitively determined within one or two years, following appropriate treatment, it could be accepted, with the agreement of the procureur de la République, that no mention of the child's sex be initially entered in the birth certificate. In such an event, all necessary steps should be taken to ensure that the birth certificate can subsequently be completed by a legal decision.

³⁴ Order No. 531 of 4 May 2017 (16-17.189) - Cour de cassation (Court of Appeal) - First civil chamber.

- a parliamentary report (177) advocates an extension of this time limit; however, it does not question the binary form of the civil status register. The Council of State questions the legality of the 2011 circular (270).

Other issues concern, firstly, the seeking and formulation of the person's consent to treatment during a gender reassignment process, and secondly, the question of the relevant age for treatment. These two issues, which fall within the scope of general law relating to the expression of consent, are not covered in this report.

There is no state in Europe that allows “neutral sex” or “intersex” to be indicated on birth certificates. In Germany, it is possible to declare an undetermined sex and to have birth certificates issued with no indication of the child's sex. The Constitutional Court has demanded the introduction of a neutral sex in birth registers. In the UK, birth certificates can be issued with the indication “unknown sex”; individuals can then, in the course of their lives, either choose to be male or female, or keep the sex indication blank.

Outside Europe, some States have accepted the creation of a third category in civil status documents (neutral sex or other cases), in particular Australia, New Zealand, India and Nepal (271).

Civil status error at birth in intersex children: no change possible on the full birth certificate

Civil status errors are relatively common following the birth of a child with a variation in sex characteristics. For example, some children with complete androgen insensitivity (one of the variations, in particular) are sometimes declared as being male on the basis of an XY karyotype, yet these children will be female for life. And these women do not have a gender identity problem. The Chairwoman of the Surrénales (Adrenals) association indicated to the Senate that “this situation is extremely difficult psychologically speaking” (177, 272).

Unfortunately, it is impossible to alter a full birth certificate without going through a legal procedure. All their lives, an indication in the margin of a change of sex (which is not true because it was an administrative error) will appear on the full birth certificate of such individuals. Similar difficulties are encountered when some girls are born with such marked signs of virilisation that they are sometimes declared to be boys.

Such errors are not unusual. The Défenseur des droits institution has suggested that some legal changes should be made with respect to this point, especially concerning minors, in accordance with the recommendations of the United Nations (UN) Committee on the Rights of the Child (273).

Administrative standards to be adapted to the realities of a change of sex or gender identity

The need to recognise a person for who they are in administrative processes

In addition to the legal recognition mentioned above, new attitudes and administrative adaptations of the health system are needed.

Firstly, the various administrative forms could be more inclusive than they are: binary in design (women - men), they do not take into account the possible mismatch between the sex and gender of people, nor the possibility that people do not recognise themselves in these “boxes”. A reflection process could be initiated with the communities concerned in order to define one or more set(s) of values (possible choices for sex and/or gender) that could be used, at the same time limiting the risk of re-identification during data use.

Secondly, medical and non-medical staff should make sure that they use pronouns and/or nouns that match the person's preferred gender, whether in administrative processes or in care and support practices (274).

Administrative and medical records should include this information in a visible way to facilitate its use.

Conversely, information related to a sex or gender transition should only be accessible to professionals who need this information to care for or support these individuals.

This is what has been done in some hospitals treating trans people: at the request of these individuals, their medical files are marked to indicate their trans identity in order to obtain better medical care and administrative recognition.

Risks related to identification of the user in the event of a sex or gender transition

Ensuring the reliable identification of users³⁵ in relation to the documents concerning them during their interactions with the health system is essential in order to be able to provide the right care or offer appropriate support.

Identity monitoring is aimed at ensuring all patients are correctly identified throughout their healthcare pathway in medical and administrative data exchange processes. The objective is to link user-specific information to an individual user, particularly when stored in a computer system. This may include, for example, medical records held by a healthcare facility or entitlement to 100% reimbursement in the case of a long-term illness (ALD).

A person consulting a professional, or attending a hospital or other facility is usually identified by means of their family name, their first name (as defined in Article 57 of the French Civil Code), their sex and their date of birth. This information constitutes their identifying details.

Computer systems will be based on these details, but will operate by means of an “identifier”, i.e. a number or combination of digits and letters which will be unique to each user and which can be retrieved by means of the details.

The identifier, linked to the details, may vary depending on the information system but, in France, the Identifiant national de santé (INS) is the national health identifier³⁶ for the health and medico-social care of individuals. This is their “social security number”, sometimes also known as their “INSEE number” (*Institut national de la statistique et des études économiques* (French National institute for statistics and economic studies) – INSEE). The other user identifiers must be aligned with this identifier and linked to it.

The computer system administered by the French national health insurance system allows healthcare providers both to know a user's identifier from his or her details, and to verify a person's details (surname, first name, sex, date and place of birth) from the identifier, on presentation of their Carte Vitale (health card), in particular.

These details are considered to be permanent, which is why they can be used as identifiers. However, none of them are perfect: the date of birth may be uncertain for users themselves, particularly if their early childhood included periods of nomadism; the surname and first name may have been defined in non-Latin alphabets whose transliterations are not clear-cut and, above all, with definitions that are not those of French culture and law.

³⁵ Identification issues need to be differentiated from authentication issues, which consist in demonstrating that users are indeed who they claim to be, for example in order to access rights or to access information via a computer system

³⁶ French decree No. 2017-412 of 27 March 2017 relative to the use of the registration number in the national registry for the identification of natural persons as a national health identifier.

Similarly, the sex may have been changed, either in the event of difficulty determining it at birth or in accordance with the user's wishes. If the user's sex is changed, the national health identifier (INS) will also be changed, because the French national health insurance system's computer system is aligned with the civil status registry computer system.

There is therefore a risk of creating two medical files for the same user, in a hospital, for example. If these two files remain separate, there is a risk that information entered in the first file is not taken into account (for example an allergy to a medicinal product or full cover of healthcare costs for a long-term illness). Conversely, if two medical files for different users are “merged” by mistake, there is a risk of blood group confusion (and hence a risk in the event of a blood transfusion) or patient qualification for a disease that they do not have (for example, cancer in the palliative phase).

Querying the French national health insurance system on the basis of a given National Health Identifier should make it possible to find out which previous identifiers have been generated with a different sex, for example, and thus enable the cross-referencing of different medical, social and administrative data. Although it is already possible to reconcile the different files of the same user for beneficiaries of France's general health insurance scheme, it is not yet possible for everyone. Moreover, for reasons of confidentiality, the successive national health identifiers (INS) of a user will only be provided by the French national health insurance system if the query is made with the user's Carte Vitale (health card), which is not necessarily possible in emergencies or situations of distress, for example. Finally, even when these successive identifiers are provided by the French national health insurance system, it should be noted that the computer systems of the various social and medical players vary significantly in terms of their performance when it comes to merging files.

As a result of this technical and legal environment, **the reconciliation of the medical, social and administrative data of a user whose sex has changed usually represents a specific difficulty, exposing this user to a risk of loss of medical, social and administrative data.**

Furthermore, the loss of medical, social and administrative data linked to a change of sex or gender in the medico-administrative databases does not allow for detailed and exhaustive analyses, particularly of the pathways of intersex and trans people. Without a change in coding to allow high-quality linking of files and appropriate information on the hospital procedures and stays of the people concerned, the creation of new data is therefore necessary to better identify and follow-up these individuals.

The cause of this difficulty can be found in the way the national health identifier (INS) is constructed. The social security number (or INS) is composed of 13 digits and a two-digit control key. The first digit represents the sex (1 for males and 2 for females), followed by the year of birth, the month of birth, the département of birth, the number of the commune (municipality) of birth, a chronological number of birth registration (to differentiate between people born in the same place at the same time).

There have been calls to add an additional value for sex, as the first digit of the identifier. However, the legislator has refused, on the grounds of gender binarity, and the risk of discrimination linked to the possible identification of a minority group of people. In addition, this would not provide a solution to the risk of loss of information in the event of a change of sex as explained above.

Another possibility, rarely mentioned, in terms of overcoming problems related to issues of a change of biological sex or civil status, would be to dispense with sex in the construction of the INS.

Indeed, insofar as the national and European courts have confirmed the right to change one's sex, the question of retaining this characteristic as an identifier must be raised, as well as that of its retention in the construction of the national identifier.

This solution could usefully be studied by INSEE (French National Institute for Statistics and Economic Studies), in liaison with all the relevant stakeholders (*Caisse nationale d'assurance vieillesse* (French national pension fund) - CNAV, *Caisse nationale d'assurance maladie* - CNAM (French national health insurance fund), *Commission nationale de l'informatique et des libertés* - CNIL (French data protection authority), *Agence technique de l'information sur l'hospitalisation* - ATIH (French technical agency for information on hospital care), and *Agence du numérique en santé* - ANS (French Digital healthcare agency)), in order to examine both the number of collisions (risk of allocation of the same INS to two separate individuals), the impact this could have on information systems, and the methods to be implemented to compensate for this deletion of information in the national identifier, while maintaining information relative to sex, which remains useful for the very large majority of users.

Sex-related administrative incompatibilities in billing systems

LA user's sex is also used for billing checks, particularly for medical procedures (whether it is part of the identifying number, or collected elsewhere).

Consistency and safety controls exist in healthcare (or dispensing) software, for example in order not to prescribe combined oestrogen-progestogen contraception to a man, or not to prescribe Depakine® to a woman of childbearing potential. However, professionals can always override this control if they consider it inappropriate.

Conversely, in the control process for coding in the *Programme de medicalisation des systèmes d'information* (PMSI - medical IT Programme) and the billing of procedures in the *Classification commune des actes médicaux* (CCAM - joint classification of medical procedures), the sex rule is blocking. And this provision is not compatible with the possibility for a patient to change sex or gender.

In fact, in the case of sex reassignment surgery, some tissues of the birth sex will remain and must be able to be investigated and treated. However, it will not be possible to invoice a trans woman for a prostate ultrasound, despite the prostate having been preserved by sex reassignment surgery, or to bill a man for a cervical smear test (275). The only option for the health professional is to waive payment for the procedure, or declare a different procedure. In both cases, the trace of the procedure left in the patient's electronic medical record will thus not be consistent with the reality and will expose the patient to a risk of incorrect decisions or to a recurrence of prescription of the procedure.

Administrative incompatibilities: billing problems and patient stigmatisation

I Cases of trans women having obtained a change of their civil status prior to surgical sex reassignment have been reported to HAS.

Hence, following a request for funding, a trans person whose civil status had already been changed from "male" to "female" (INS starting with 2) at the time of her orchiectomy received a response from the French national health insurance system indicating "procedure code CCAM JHFA005 is not compatible with your sex", because this funding is reserved for men only. This led to the person being required to supply proof of male biological sex at the time of the procedure, in parallel with the female sex in terms of civil status.

A few years later, this person was prescribed a "prostate volume study". The same problem arose: administrative incompatibility (a prostate examination is impossible in a woman). The simplest solution to avoid administrative procedures was to transform the examination into a pelvic ultrasound...

This situation relates to the billing control system, firstly, and, secondly, poses the problem of the stigmatisation of those who suffer as a result, who must justify their civil status, sometimes publicly.

These problems with PMSI coding and CCAM billing are not uncommon in situations of a change of sex or identity, which may seem to run counter to France's decision to fund sex reassignment treatments and hormonal treatments for trans people.

That is why the PMSI and CCAM rules which check the compliance of a procedure or hospital stay against the sex of a user (in order to avoid input errors) should no longer be blocking when the coding actually corresponds to the patient's situation. Cross-referencing the procedure or stay, with the sex and existing information relative to a change of sex would avoid blockages at the time of the compliance check.

Use of gendered data: promoting analysis, protecting individuals

Public statistics: male/female data extensively collected, but under-used

In 2013, in a report entitled “L’information statistique sexuée dans la statistique publique” (Gendered statistical information in public statistics) submitted to the Minister for Women’s Rights, Sophie Ponthieux (Insee) (276) made the observation that progress had been made, particularly in the area of:

- the production of gendered male/female data, including in the health and social fields;
- collection as part of public surveys in order to increase knowledge;
- publications relating to differences between the sexes.

Public statistics group together all the statistics produced from:

- statistical surveys, the list of which is determined each year by order of the Minister for the Economy;
- the use, for general information purposes, of data collected by administrations, public bodies or private bodies with a public service mission (276).

This report highlighted a concern about sex-based differentiation, which is still uncommon.

Unfortunately, there seems to have been little change in 2020: it is most often the distribution by sex within a situation or status that is described, without there necessarily being any differentiated analysis or investigation of the influence of sex or gender on the statistical data.

Three institutions govern public statistics, as part of a tripartite organisation: the *Conseil national de l’information statistique* (CNIS - French National Council for Statistical Information), the *Service statistique public* (SSP - Public Statistics Department) and the *Autorité de la statistique publique* (ASP - Public Statistics Authority). Consultation between users and producers of public statistics takes place mainly within the framework of seven theme-based committees.

The “Demographics and social issues” and “Public services and services for the public” committees are those concerned by the majority of the issues raised in this report:

- the first focuses on the themes of demographics, living conditions and social statistics;
- the second examines the themes of health, social protection, education and training.

- the many primary producers of public statistics concerned are detailed on the CNIS website (www.cnis.fr).

The data and analyses already available highlight the biological, behavioural, social and structural factors surrounding the health of people according to their sex and gender. They underline the need to explicitly consider sex in statistical and public health studies, when the data is available.

Collection and - above all - appropriate use of the data could help to highlight differences in health outcomes according to the sex and gender characteristics of patients or individuals receiving support, or professional practices.

To do this, it is not enough to simply introduce the sex variable at the time of collection, and then cite the example of women or men to analyse sex and gender specificity and genuinely modify the analysis perspective (276, 277).

In order to improve the use of these already sex and gender-specific data as determinants of health, it would be useful to:

- make them more visible and more accessible, alongside sex-differentiated analyses where these exist;
- identify gaps that still need to be filled;
- more systematically show sex-based differentiation in research programmes, and define priorities and a work programme;
- establish coordination of this cross-disciplinary topic, a role that could be taken on by one of the French National Council for Statistical Information’s theme-based committees.

Big data: what secondary use of sex or gender-related data?

By definition, Big data allows the reprocessing of data to answer new questions using new analysis technologies. Consequently, this mainly involves secondary use of the data, often not intended at the outset. Moreover, Big Data allows data from different sources (clinical trials, real-life data, public statistics, personal data, etc.) to be processed together.

In the field of health, Big data corresponds to a data set that is potentially much larger than public statistics: medico-administrative data (SNIIRAM (health insurance scheme reimbursement data), data from the French technical agency for information on hospital care (ATIH), pension funds, etc.), data from cohorts (data from the follow-up of a group of people with common characteristics) and data from clinical trials.

To this can be added data from connected health objects, but these are usually stored and managed by the internet giants.

There are many potential uses for Big Data in the field of health, including uses focused on knowledge (for example, identifying risk factors for disease), scientific or technological monitoring, improving care or support, steering health policies, or even helping to recruit patients for clinical trials.

37 INSEE’s Department of demographic and social statistics, the statistics departments of the French Ministries of the Interior, Culture, Sport, and Justice, the Ministry of Solidarity and Health’s Directorate for Research, Surveys, Assessment and Statistics (DREES), the Ministry of the Ecological and Inclusive Transition’s Department of data and statistical studies (SDES), the French National Institute of Demographic Studies (INED), the French Monitoring Centre for Drugs and Drug Addiction (OFDT), as well as the Ministry of Education’s Directorate for evaluation, forecasting and performance (DEPP), the Ministry of Higher Education’s Sub-directorate for information systems and statistical studies (SIES), the French national fund for family allowances (CNAF), the French national health insurance fund for salaried workers (CNAMTS), the French national pension fund (CNAV), the French national observatory for delinquency and penal solutions (ONDRP), among others.

A significant proportion of the data that feeds into Big Data in the field of health is gendered data. In particular, medico-administrative data are routinely collected along with information on the user's sex. Sex-based analyses are therefore eminently possible.

Generally speaking, the secondary use of sensitive data (including data on sex) raises the issue of the principles of transparency and fairness, and of the individual's capacity to exercise his or her rights, since by definition this use was neither foreseen nor sometimes foreseeable at the time of collection, regardless of the initial purpose.

The five broad principles of personal data protection rules (278)

- The principle of purpose: the data controller may only record and use information relating to natural persons for a specific, lawful and legitimate purpose;
- The principle of proportionality and relevance: the information recorded must be relevant and strictly necessary for the purpose of the file;
- The principle of storage limitation: it is not possible to keep information on individuals in a file for an indefinite period of time. A precise storage period should be set, depending on the type of information recorded and the purpose of the file;
- The principle of security and confidentiality: the data controller must guarantee the security and confidentiality of the information it holds. In particular, it must ensure that only authorised persons have access to this information;
- The rights of individuals, in particular to transparency and fairness regarding the use of their data³⁸.

However, for the vast majority of Big Data, the "sex" variable is collected in a binary way (woman or man), and its reuse is, in principle, authorised by the French data protection authority (CNIL), subject to compliance with personal data protection rules.

In the field of health, Big data therefore offers significant potential for sex-differentiated analysis that could be more effectively harnessed with the aim of improving the health of men and women, through the statistical detection of differences in their health status, their response to treatment, their care, their use of healthcare, etc.

Use scenarios for the Health Data Hub platform that can incorporate sex/gender-related questions (279)

- "Predicting individual patient trajectories and improving prevention actions".
- "Improving the understanding and transparency of the healthcare system".
- "Providing answers to patients with rare diseases" "Caring for patients as early as possible".
- "Offering patients the best treatments over the long term".
- "Supporting healthcare professionals in an increasingly complex clinical context".

³⁸ The rights of individuals relating to information, objection, access, erasure, delisting, portability, human intervention, restriction of processing, and the right to request rectification.

A lack of data that is detrimental to intersex and trans people

Both in France and internationally, there is a scarcity of data concerning intersex and trans people (13, 14, 177, 280-282). Little information is available concerning their life expectancy, their quality of life, their living conditions, their access to health and social services, the illnesses that affect them, etc.

There are several obstacles that need to be overcome, which make it difficult to conduct research and follow-up projects throughout the lifetimes of these individuals:

- their relatively small numbers and the heterogeneity of the groups covered by the terms "trans" and "intersex", raising questions concerning identification and representativeness;
- the reluctance expressed by patients to take part in studies which, firstly, have no direct individual benefit for them and are seen as an additional constraint in a life that is already highly medicalised, and, secondly, are considered by some as a form of record-keeping;
- cohort follow-ups that cannot obtain funding because they are not clinical trials per se, and because research is focused on scientific discovery and new drugs.

Public health data concerning trans people: an international review

A review of the literature published in The Lancet in 2016, identified 116 studies concerning trans people in 30 countries (including 16 studies conducted in Europe, none of which in France). The authors allocated points to the various subjects studied on the basis of their occurrence (282).

The subjects of interest in these studies are, in order of importance: mental health (30.9% of points), sexual and reproductive health (22.3%), drug and alcohol use (19.7%), violence and experience of victimisation (10.7%), stigmatisation and discrimination (9.5%). General health (mortality, diabetes, hormone use, metabolic diseases, cancer) only represents 6.9% of points and studies in this area are very disparate (282).

Two types of real-life studies can enable the collection of data relating to intersex or trans people:

- a survey or dedicated study, including these people only;
- collection of data from a more diverse population, with the possibility of identifying the data relating to these individuals.

The collection and use of these data is associated with some major challenges.

Contrary to certain misconceptions, the current legal standards do not prevent the collection of data relating to sex, gender or sexual preferences as part of a research project. The legal framework for the protection of personal data provides for the collection of sensitive data by way of exception, provided that a number of conditions are met, in particular that such collection is justified (which would most certainly be the case for studying health inequalities, for example).

It is first and foremost the purpose of a study that determines whether this can be done. It is therefore necessary to consider the benefit/risk ratio of research studies. Attention should always be paid to the appropriateness of a "neutral" versus a "gendered" (differentiated on the basis of sex) treatment of an issue or phenomenon in the formulation of a data research project.

With regard to sex and gender minorities, the central issue is the value set to be used to collect sex and gender information. And this issue cannot be separated from the risk of re-identification.

In fact, sex data is even more sensitive when there is a potential risk of re-identification of the person.

So should we stick to a binary male/female choice? At first sight, this appears to be the simplest value set; but it necessarily incorporates a bias in terms of interpretation between biological sex and social sex.

Does this mean that we need to make a distinction between sex and gender? And in this case, what choices should be proposed?

Does one or more value sets need to be standardised?

The finer the value set, the more respondents will recognize themselves in the choices. But the more the statistical analysis on each value lacks power (unless categorical groupings are made), the more the risk of re-identification of individuals will increase.

The precision of the value set for sex and gender data should therefore depend on the need with respect to the study objective, the size of the cohort, and the rarity of the value in this population.

These are the principles of “proportionality” and “relevance”: the information recorded must be relevant and strictly necessary for the purpose of the file (278).

Life-long follow-up studies in intersex people

Since the number of people affected by each variation in sex characteristics is very small on a national level (for example, 50 patients have been identified in France in the last five years with androgen receptor mutations) (12), it is particularly difficult to conduct studies including enough patients to draw conclusions.

The international dsd-LIFE study (standing for life with disorders in sex development) is an exception (283). Funded by the European Commission's Directorate General for Research, this follow-up study looks at the results of surgical and hormonal therapy and possible psychological support. It aimed to overcome the problems of representativeness of small samples, by studying the quality of life of 1,040 intersex people across six European countries. A French reference centre is participating in this study, which remains the most ambitious carried out to date despite certain limitations (35% non-respondents, exclusion of certain variations, etc.) (284). It should help improve healthcare in intersex people.

There are many benefits to be gained from collecting and analysing data on intersex and trans people, in terms of knowledge about the health of these populations, the appropriateness of treatments and their life courses, from a medical, psychological, economic and social point of view.

This cannot be done without risk, and must be discussed with the people concerned.

In primary use, the right of individuals to transparency and fairness regarding the use that will be made of their gendered data is well controlled, since this use is described in the information sheet issued to individuals agreeing to the collection of their data by the study sponsor.

The secondary use of such data raises the question of the rights and principles of personal data protection rules, since, by definition, this use was neither foreseen, nor sometimes foreseeable, at the time of collection.

This benefit/risk ratio of using gendered data collected in a non-binary way must be estimated for each study. This balance is different for primary and secondary use.

The conditions for collection and use need to be defined collectively.

In the longer term, consideration could be given to fine-tuning the routine collection of public statistics and moving beyond the current binary mode that does not correspond to a proportion of the population.

Artificial intelligence and sex or gender-related biases

Artificial Intelligence (AI) algorithms are increasingly present in the field of data analysis; they open up new opportunities in terms of improving knowledge and understanding in the field of health (285). These algorithms also make it possible or will make it possible to identify weak signals, or to formulate new hypotheses, related to sex or gender. **The promise they hold means that it is necessary to act now to ensure that the digital world also takes into account differences related to sex and gender.**

While, on the one hand, artificial intelligence opens up research avenues to reduce disparities or inequalities in health (286), or to detect selection bias in the populations enrolled in clinical trials, (115), on the other hand, it raises the question of sex-related bias.

The issue of bias, which is not exclusive to sex or gender, first and foremost concerns source data. If source data is biased, this will have an effect on the results. For example, a given population may be over-represented in relation to another, or a variable or group may be omitted. However, selection bias, or the omission of a variable, can reproduce and amplify phenomena of both biological and social normalisation, and generate discriminatory effects. Depending on whether these biases are corrected or not, and also depending on the rules given to the algorithm, it will be more or less discriminating.

The subject of “gender bias” has been the focus of a growing number of publications since 2016 (Pubmed bibliometrics) (287-291).

Various associations are working to ensure fair algorithms in different fields. In Paris the new artificial intelligence centre, opened recently at La Sorbonne, incorporates the study of sexist and racist biases. There are conferences dedicated to these issues, as well as a growing number of studies.

There is not yet a perfect and universal solution to guarantee the absence of sex and gender bias in algorithms. Consequently, to a certain extent it is necessary to trust the players working in this field, whose interest is not (generally speaking) to develop gender-biased technological solutions, while maintaining the general principles of explicability and auditability, representativeness of training and test data.

In parallel, and without delay, it is necessary to develop an ethical framework for the use of data by these new technologies, to have flexible copyright rules on a European level, adapted to the extremely rapid developments in this field, and to reflect on standards that could guarantee a certain level of gender equity.

In this regard, HAS recalls the recommendations it made in 2019 concerning artificial intelligence (285), which are transposable to the issue of sex and gender.

Furthermore, considering the costs of developing algorithms on the one hand, and quality controls on the other, it is likely that it will be up to the funders of digital solutions, and in particular the public authorities, to demand guarantees that sex and gender bias is controlled in data analyses.

Users should also be vigilant and report any sex or gender bias they observe.

It is essential that all stakeholders (civil society, healthcare and social work professionals, industry, digital players, institutions, politicians, publishers of scientific journals, cultural and educational players) be made aware of this issue. (288). The players the most closely involved in data collection, analysis and presentation should be trained in the implications of sex and gender bias so that they remain alert to the problem.

There are calls to encourage the presence of women in these fields, this being seen as crucial to address gender bias in data collection and analysis, prevent inequality and discrimination, and break the vicious circle whereby machines perpetuate an obsolete model (287). That is why the Laboratoire pour l'Égalité ("Laboratory for Equality" association) wants to "make AI a driver of gender equality" and proposes a Pact to this end, unveiled on 27 May 2020 (292) and supported by the government (see annex 2.3).

Clinical trials: understanding sex-based differences, promoting the inclusion of women and minorities

Male – female representation in clinical trials: an international issue

Sex in clinical trials: reported data

In the majority of clinical trials, demographic data are reported by participants. It would therefore be more appropriate to use the terms "reported sex" and "reported age". Indeed, in the vast majority of research protocols, it is not possible to carry out a detailed sex assessment to determine the genetic make-up of all participants (293). For this reason, Sex and Gender Equity in Research (SAGER) guidelines indicate that authors should explain in the methods section whether the sex of participants was defined based on self-report, or assigned following external or internal examination of body characteristics, or through genetic testing or other means (294).

When sex is based on self-report, it will be incorrect for a very small percentage of individuals, who are XX or XY, or who have reported their civil identity or gender identity rather than their biological sex.

Proportions of women and men in trials: a quasi-parity that conceals significant disparities

As already indicated in the second part of this report (A medical research policy that requires fine-tuning when it comes to sex and gender issues, page 75), when seeking to assess the participation of women in clinical trials on an international level, it is evident that progress has been made in recent years - for clinical drug trials, in any case - although there is still room for improvement (92, 112, 113, 188, 190, 191, 200-204).

More detailed quantitative data are provided below, supporting this observation.

The representation of women varies a great deal from one clinical trial to another, and depending on the diseases considered:

Feldman *et al.* developed an algorithm to extract sex data from articles listed in PubMed. While overall female representation is 49% in this retrospective study conducted over a 25-year period, it varies greatly depending on the trial. A significant under-representation of women is observed in 7 out of the 11 disease categories explored, especially HIV/AIDS, chronic kidney diseases, and cardiovascular diseases. More rarely, these sex ratios can also be unfavourable to men in certain therapeutic fields, such as musculoskeletal disorders (115).

As concerns medical devices, a review conducted in 2014 of all the phase III clinical trials registered in the USA reported that average female representation in clinical trials was 50%, but that it ranged from 18% to 100% depending on the trials and fields studied. Irrespective of sex ratio, very few studies (less than 6%) reported or analysed results or adverse events by sex (295).

A moderate under-representation of women is found in clinical trials on new drugs:

- in 2019, the FDA analysed trials on new medicinal products approved between 2015 and 2016 (154 pivotal studies for 66 new products). Women represented 43% of the people enrolled in these trials, with the figure falling to 41% once seven trials for sex-specific indications were removed from the analysis. Female representation was 49% for trials conducted in the USA (45% for mixed indications), with this country alone accounting for a third of female participants, and 40% outside the USA (39% for mixed indications), with each individual country accounting for 5% or less of study participants;
- France was the ninth-ranked country in terms of the total number of participants in trials, and in second position behind the USA for the proportion of women (46.1% overall for all the trials analysed);
- in Europe (nine countries out of the 20 having included the most participants), the proportion of women was 39% (203).

This study also confirmed that the proportion of women varied substantially depending on the therapeutic area: from 0% in trials conducted on diagnostic imaging products to 76% in ophthalmology. The authors concluded that the situation was relatively satisfactory, particularly based on the percentages observed in the USA (203).

While the situation does not appear to be alarming on the basis of these figures, a comparison of the sex ratios of trials relative to real-life epidemiology is nonetheless required before we can be confidently satisfied about the representation of women in clinical trials.

In France, male and female representation in clinical research was the subject of an information report produced by the country's National Academy of Medicine in June 2016, entitled "Parité en santé, la recherche scientifique et la médecine ne peuvent plus ignorer les différences biologiques entre les sexes" (Parity in health, scientific research and medicine can no longer ignore the biological differences between the sexes") (296). In this text, the Academy points out that "Men and women are not equal when it comes to illness and must therefore be treated differently". It warns that France is lagging behind in terms of acknowledging the differences between men and women, sometimes to the detriment of their health, and makes six recommendations, including the revision of established principles relative to fundamental and clinical research, as well as routine medical practice.

Male-female representation: an issue that is not limited to sex ratio

BAAlthough it is preferable that the sex ratio of the trial population matches that of the target population, there is more to the issue of female representation in clinical trials than that. The statistical analysis that may or may not be conducted on the data collected by sex is a key issue. In fact, to achieve the objective of having evidence of efficacy, safety and, thereafter, cost-effectiveness, with a sufficient level of confidence irrespective of sex, the latter needs to be considered at the various stages of a research project (198, 297, 298):

- the definition of research questions and hypotheses should, in principle, take sex into account (unless the science has shown that this is not useful), which implies designing the study such that it is possible to collect sex-disaggregated data;
- if the trial population cannot reflect the patients who will be treated and women and men cannot be matched on the basis of factors identified as having a potential influence, this should be measured and controlled;
- a trial that includes women and men should use statistical tests to determine the confidence with which similarities or differences can be asserted, and analyse whether any differences found have medical implications.

The reality of financial arguments that the inclusion of more women in clinical trials (both public and private) would be too costly should not be overlooked. Firstly, to be able to conduct subgroup analyses it is usually necessary to increase the size of the study population. Secondly, the inclusion of women may involve specific insurance costs. However, the additional cost should be acceptable where a substantial health benefit is expected.

For example, the data presented several times in this report concerning HIV/AIDS highlight the fact that trials in this field often include only 15 to 30% women (115). This unequal distribution is mainly due to the under-representation of women in the infected population in France (299).

Since efficacy markers in HIV are very stringent (viral load is one such marker), this proportion of women is generally sufficient to demonstrate equivalence in terms of efficacy between women and men (although this clearly depends on the total study population).

Treated and monitored patient cohorts confirm these findings.

However, tolerance and teratogenic risks are much more difficult to assess: since these adverse events are rare, their analysis requires much larger numbers of subjects than those enrolled in trials.

This raises the dual question of women's tolerance to these new treatments (studies have shown, as pointed out in the first part of this report, that women often tolerate these drugs less well), and the potential foetotoxicity of these products.

However, solving this problem is hampered by complex barriers:

- the high risk of foetotoxicity limits the enrolment of women of childbearing potential in trials;
- a large proportion of HIV-positive women are disengaged from the healthcare system, especially in Europe.

In order to anticipate as well as possible the negative effects and risks of treatments to the foetus, data observed in pregnant women having taken the treatment before discovering they were pregnant, or data collected in countries where more women than men are infected with HIV (in Africa the sex ratio is reversed) and are given new drugs, including during pregnancy, are used. The risk is therefore not avoided in reality: it is simply displaced, and less well anticipated.

This calls for consideration of the appropriateness of including more women in clinical trials, weighed up against the risks to research organisations and female participants.

It remains important to note that the objective of parity of representation in clinical trials can constitute a disproportionate barrier in terms of the quest to find a treatment in some cases. For example, clinical research concerning rare diseases involves an extremely small study population that it is already difficult to achieve. In this case, a requirement for sex-based representation would then be perilous, as it would lengthen the duration of the trial, but without enabling any in-depth study of the effects of the treatments based on this factor.

Women also under-represented in surgical research

A team of researchers from Northwestern University in Chicago, analysed 1,303 original studies conducted between 2011 and 2012 in five journals dedicated to non-specialised surgery. Studies concerning sex-specific surgeries (ovarian, testicular, etc.) were excluded from the analysis.

The majority (78%) included men and women, but fewer than half included a third women or more.

When the information was supplied, it was inadequately analysed:

- sex-disaggregated results were reported in 38% of cases;
- these results were the subject of an analysis taking into account sex as an independent variable in 33% of cases;
- and a discussion of results on the basis of sex was found in 23% of the publications.

Finally, a wide variation in sex-based inclusion, matching and data reporting was demonstrated depending on the surgical specialities (and the journal) concerned, with colorectal, thoracic, endocrine and oncological surgery having the best scores and cardiac, bariatric, and breast surgery having the worst (300).

The director of this research team, Melina Kibbe, has since become editor-in-chief of the JAMA Surgery journal.

What about the clinical trials submitted to HAS as part of reimbursement applications?

HAS examined the files submitted to it in the context of requests for funding by the French national health insurance system. An analysis of trials based on product indication, for both medicinal products and medical devices, was conducted over a short period. The details are provided in the annexes (annex 3.1).

For medicinal products, a retrospective analysis of the preparatory documents analysed by the Transparency Committee using a complete examination procedure was conducted from 8 January 2020 to 19 February 2020, over four Transparency Committee³⁹ sessions. During these four sessions, 25 applications for medicinal products were presented for a complete examination procedure (first application for reimbursement, re-evaluation with new supporting data, indication extension).

In these 25 files, 49 trials were analysed and detailed in the preparatory documents; for 36 of them, information concerning the sex ratio was reported in the document submitted to the Committee.

In these 36 studies:

- The average proportion of women for all the studies was 43.5%;
- the percentage of men was higher than the percentage of women for 22 of the 36 trials (i.e., in 61% of cases), and exceeded 65% in seven trials;
- the percentage of women was higher for 12 of the 36 trials (i.e., in a third of cases), and exceeded 65% in five trials;
- two trials had a 50-50 ratio.

Interpretation of these female-male proportions needs to be related to the prevalence of the diseases under consideration per sex. This comparison was performed for the clinical trials in which the proportion of one sex was over 65%:

- this substantially higher percentage of men had an epidemiological rationale for five out of the seven trials and four out of the five diseases;
- this substantially higher percentage of women had an epidemiological rationale for two out of the five trials and two out of the four diseases.

The three diseases in which the over-representation of one sex cannot be explained by prevalence are allergic rhinitis (more men in the trial despite the fact that more women are affected by the condition), beta thalassaemia and Wilson's disease (significantly more women in the trials although just as many men affected by the disease).

Furthermore, analysis of the trials demonstrated a much lower representation of women compared to men in clinical trials conducted in HIV in the two submissions concerned (four studies).

This issue is regularly highlighted by HAS, since it raises a problem of transposability (301-304).

A similar analysis of the trials examined by the *Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé* (CNEDiMTS - National Committee for the Evaluation of Medical Devices and Health Technologies) was also conducted prospectively between 20 January and 20 February 2020. This analysis concerns all the medical device applications studied by the committee over this period.

A total of 26 files were analysed.

Among these 26 files, 66 clinical trials were presented in the preparatory documents submitted to the Committee; 64 included information on the sex ratio.

Two files relating to a device with an exclusively female use (suburethral bands for the treatment of urinary stress incontinence) were extracted from the analysis.

The final analysis of this study therefore concerns 24 files, and 60 trials for which information on the sex ratio was available.

In these 60 trials:

- the total mean proportion of women was 37.5%;
- the percentage of men was higher than the percentage of women for 51 of the 60 trials (85%), and exceeded 65% in 38 trials;
- the percentage women was higher for 9/60 trials, and exceeded 65% in four trials.

As for medicinal products, the sex ratios were compared to the prevalence by sex of the conditions considered only for trials in which the percentage of one sex exceeded 65%:

- this substantially higher percentage of men had an epidemiological rationale for 37 out of the 38 trials and five out of the six conditions concerned (cardiovascular diseases and Parkinson's disease);
- this substantially higher percentage of women had an epidemiological rationale in all the trials in question (three conditions concerned).

³⁹ The Transparency Committee is the body tasked with assessing medicinal products in France when the marketing pharmaceutical company wishes to submit an application for their funding by the French national health insurance system.

Only one clinical trial presented over-representation of men that could not be explained by the prevalence of the condition. This was a trial on a treatment for chronic sinusitis. No data were identified that could justify this over-representation.

Overall, although this sample is not necessarily representative of the applications submitted to HAS, it provides a snapshot on the date of its collection.

This quick study of the clinical trials analysed by the health product assessment committees of HAS is consistent with the international literature on the topic (92, 113, 115, 203, 295, 305):

- major progress has been made in the past ten or so years with respect to the sex ratio and average proportion of women in clinical trials, particularly in drug trials;
- however, there is still significant disparity depending on the trials and diseases or conditions.

An analysis of representativeness with respect to the target population was only performed on trials in which one sex represented 65% or more of the patient sample. The proportions observed are usually related to the prevalence of the disease (without always being the same, however).

But, in the absence of a threshold for determining whether the difference between the sex ratio of the sample of patients enrolled in the trial and the proportion of women and men in the target population is detrimental to the representativeness of the sample, it is difficult to know whether the patients included in the trials available to HAS committees are reflective of those who will be treated in real life with the health products.

Furthermore, it would be interesting to carry out further analysis to check whether the results were reported by sex, and if statistical analyses were carried out to see whether any differences observed should have been taken into account.

The question of the representativeness and transposability of results in HAS opinions: a question that is not exclusive to sex and gender

The question of the representativeness of the population enrolled in clinical trials, and the transposability of the findings observed, is regularly raised with a view to helping the public authorities reach decisions for the funding of health products.

In fact, the elderly (who are mostly women over 65 years of age), children and pregnant women, etc. are generally excluded from trials, and women and men are still too often represented in trials in proportions that differ from the population to be treated. This question of the representativeness of patients enrolled in clinical trials in relation to the intended use of the product is mentioned in various documents issued by HAS or its committees (285, 301-304, 306-308).

Hence, in some opinions, the committees indicate reservations about the interpretation of the results of certain trials because of the possible non-representativeness of the group of treated patients due to the low participation rate and a lower than expected average age of the patients in the trial.

Post-market follow-up: a crucial clinical research tool

As already indicated in this report, sex and gender differences can have an impact on observed results of health interventions. Thus, even if simply because of differences in average weight between the two sexes, a “standard” dose of a drug for a man might be too much for a woman. Likewise, the concomitant use of oral contraceptives or long-term hormonal treatment, more generally, can have an impact on the metabolism of a drug, something that may not be noticed if no statistical analysis is dedicated to this type of patient.

Other questions particularly concern women, given their life expectancy: the exclusion of elderly people from clinical trials, or the absence of a comparative analysis between findings in young subjects and subjects over 65 years of age, the effects of interventions on polymedicated subjects.

All these reasons, in addition to the evaluation of health interventions, and in particular health products, justify consideration of sex and gender, both before and after their dissemination.

While it appears to be essential to study a health intervention in a diverse population of patients, in the context of appropriate clinical trials, before approving it, it is also important to have independent mechanisms for monitoring validated interventions (309) in order to assess their effects in real-life conditions, and to be able to make comparisons based on sex (and, less commonly, gender), especially if it was not considered appropriate or possible to do so at the time of the clinical trials.

This follow-up of “real-life” results is a crucial clinical research tool. It makes it possible to compare the efficacy observed in selective protocol-controlled studies with real efficacy (observed in the population actually treated, in all its diversity) (309, 310).

HAS participates in this follow-up since its assessment committees can request “post-registration” studies (studies conducted in real-life conditions, without a clinical trial protocol). These studies, which must recruit patients without selecting them, can provide access to results relating to the target population, in particular in sex proportions that correspond to the epidemiological reality (target population).

The representation of sex or gender minorities in clinical research

Alongside the continuing asymmetry in gender representation, minorities benefit from dedicated studies, but are not represented - or are invisible - in clinical research that does not exclusively concern them. From this perspective, intersex and trans people can be considered to share the same issues.

The problem considered in this chapter is posed more from a perspective of ensuring inclusiveness and non-discrimination of intersex and trans people in clinical research, rather than with a view to ensuring their representation in studies to achieve the statistical power necessary for a dedicated analysis of the results (except in special cases that may justify it).

However, it is worth noting that current research on intersex and trans health issues that are not specific to them (cancer risk and treatment, cardiovascular disease, efficacy and side effects of treatments, etc.) is limited: quasi-absence of prospective studies specific to these populations in most health fields, lack of details relative to gender identity, sex, and sexual preferences in registries and trials, and, finally, LGBTI groups lumped together as a homogeneous group in various existing studies, despite the fact that there is a very substantial amount of variability.

Research on the cancer risk among trans people

The trans population theoretically presents risk factors leading to a predisposition towards certain types of cancers. Smoking, alcohol or drug use, HIV-positive status or the presence of HPV (all factors associated with an increased incidence of certain cancers), are statistically more common risk factors among trans people than in the general population.

Furthermore, masculinising or feminising hormone therapy may predispose trans people to hormone-dependent cancers, although there is currently insufficient evidence to reach a conclusion in this respect.

However, current research on cancer risk and treatment in transgender people is limited, and the urgency of conducting research in this area is strongly debated (36, 37).

In practice, clinical research protocols schedule the systematic collection of information on the reported sex of study participants in the form of a binary choice (male or female), the only one proposed in trial forms. This methodological point has several consequences.

Firstly, it does not enable every individual's identity to be comprehended. Secondly, it automatically excludes individuals who do not fit into this binary framework, either from a biological sex or gender perspective, or includes them unknowingly with the risk of misinterpretation of the study results.

Variations in sex characteristics, sometimes very small populations

Altogether, around 1.7% of the population is concerned by a variation in sex characteristics, but these variations are very diverse: in terms of hormones, hormone production, hormone receptors, karyotype, internal/external genitalia, primary and secondary sex characteristics.

In total, the term covers around forty families of variations, with ramifications that depend on the genetic mutations and are, therefore, almost infinite, with, as a result, very small numbers of subjects per variation.

However, these difficulties need to be addressed, because the solution does not reside in exclusion. The individuals concerned do not simply represent the minorities they belong to as a result of their difference, but should also be considered in terms of everything they have in common with the population as a whole.

Unfortunately, the cumulative effects of traumatic experiences in many aspects of society, including health, often lead to mistrust and even fear among intersex people, with a direct impact on their participation in health research.

It is important that research players know and understand intersex and trans people in order to avoid further negative experiences, not to perpetuate discrimination and to acknowledge the existence of these individuals as they are.

The trans community, which is more active and more visible than the intersex community, has worked to make clinical research findings applicable to trans people. Many of the elements resulting from this reflection process are also applicable to intersex people. In reality, since associations have been more recently formed for the intersex community than for other minorities, it is the subject of few dedicated publications in the field of clinical research. However, intersex people are sometimes included in articles concerning the LGBTI community.

Avenues for improvement to promote the consideration of sex and gender in clinical trials, and in medical research more broadly

Identified by an analysis of the available national and international literature, various levers for action can be mobilised to improve the inclusion of women and sex and gender minorities in medical research. The tools identified as potentially useful for stakeholders for implementation are indicated in annexes 2.4. and 2.5.

These levers are outlined here for information purposes. The proposals that HAS chooses to formulate on this subject will be presented at the end of the report.

Improving knowledge among research players

In the years following the report submitted to the French Senate by Annick Billon and Françoise Laborde (112) recommending greater awareness among research players to encourage "biological and medical studies and research taking into consideration the differences between women and men", the INSERM ethics Committee's "Gender and health research" working group implemented awareness-raising actions (symposium, information campaign, training, etc.) targeting doctors, researchers, patients and members of civil society engaged for public health (188, 208).

First and foremost, the study of differences related to sex, and sometimes gender, should also be seen as an opportunity to increase knowledge, to develop drugs and medical devices that are more effective and better tolerated by patients, and to consider new possibilities (311, 312). To this end, the Canadian Institutes of Health Research published a strategic plan for the years 2018 – 2023, entitled "Science is better with sex and gender" (313).

Hence, for example, over the past 5 to 10 years, research has been looking at the progression of osteoporosis in women and men, assessing the risk using sex-specific reference models, whereas diagnostic models were traditionally developed for women. This paves the way for better diagnosis and treatment of the condition in men (314).

Similar considerations may lead to the development of medical devices that are better tailored to women and men. This is the case, for example, with certain joint replacements, which need to be adapted according to body size or bone strength, two factors that are related to sex. Other medical devices need to be gender-sensitive in their development, especially in the field of disability, since their use may differ to a degree depending on whether they are destined for a woman or a man.

Subsequently, the desired improvements require that research players be trained in sex and gender issues.

This training should teach players about the tools available for integrating sex and gender issues into research, particularly in order to determine the relevance of this issue to a given research project, but also to enhance the potential value of such studies.

In addition, there appears to be a need to train clinical research players in intersex and trans issues, the importance of including these individuals in studies and, more generally, how to behave towards the people concerned.

In addition, all those involved in research could usefully be made aware of the issues of equity in the field of clinical research, and the balance to be struck between protection, selection and access of patients to trials (258).

The awareness-raising and training tools identified in the context of this analysis are provided for information purposes in the annexes to this report (annexes 2.1 and 2.4).

In France, the *Comités de protection des personnes* (CPP - ethics committees), which are responsible for monitoring the effects of biomedical research on individuals, are also well placed to support the need to consider the importance of sex and gender, where warranted. More generally, vigilance with regard to this need can be achieved by raising awareness of such issues among these committees.

Creating tools to help scientists incorporate sex and gender considerations in research projects

Sex and, where relevant, gender should be considered at every stage in the construction of a research project: from the definition of research priorities and project objectives to the analysis of results, funding decisions and policy-making (see annex 2.4).

Various methods (297, 315) and several guides are available (316-320).

Reinforcing the requirements of research funders with respect to the representativeness of populations enrolled in studies

A growing number of funding bodies around the globe now require applicants to take sex and gender into account in their research projects. One example is the Canadian Institutes of Health Research, which, since 2010 has issued rules to this effect in the context of the grants it awards (321). Similarly, in 2014, the National Institutes of Health (NIH) in the USA announced its ambition to take measures to promote the inclusion of female cells and animals in preclinical research. Following this announcement, guidelines were issued during a consensus conference in order to support the NIH in its actions (322).

Secondly, raw sex-disaggregated trial data, even when there has not been any published analysis, could be mobilised by public research funders, in particular for health products covered by health systems, in order to enable meta-analyses to be carried out, and partial adjustment for biases related to under-representation, as well as a combined analysis with post-marketing data.

In order to improve the quality and public availability of demographic subgroup data, the FDA has funded a project to combine clinical trial data submitted to it in the context of marketing authorisation applications with post-marketing data. The objective was to analyse the sex-related differences in outcomes observed with medical devices, by performing a specific retrospective analysis (310).

Reinforcing the requirements of scientific journal publishers

Research findings should comply with principles of rigour, reproducibility and transparency, including, in particular, the description of the study population.

Each stage in the drafting of scientific articles must be considered and presented on the basis of sex or gender, and possible biases should be mentioned at the outset when necessary (294).

In 2016, guidelines were issued aimed at improving information relating to sex and gender in scientific publications, irrespective of the research discipline or stage: these are the SAGER guidelines (The Sex and Gender Equity in Research guidelines) (294) (see annex 2.1).

In the same year, a tool for assessing the quality of sex and gender integration in health research proposals was published for use by researchers and peer-reviewers (323).

Promoting gender-diverse representation in the research professions and in public health organisations

Gender imbalance in ethics committees, research funding bodies and advisory bodies, as well as the differentiated treatment of women scientists, have been recognised as factors contributing to gender bias in research (226). As a result, numerous organisations, including the WHO, are seeking to promote gender equality in research careers, as well as within their own institutions.

This may also be achieved by a more balanced representation of women and men in decision-making positions in the field of research. The European Institute for Gender Equality has recommended this solution in order to achieve less biased results (201).

The French Senate has already come out in favour of such a move, also recommending the continued encouragement of young girls to consider scientific careers and the promotion of the careers of women scientists (112) (see annex 2.3).

Facilitating the inclusion of women in clinical trials

A In the United States, a number of guides aimed at researchers detail actions to be implemented in order to successfully recruit more women in clinical trials: provision of transport, decentralisation of the trial, provision of childcare to relieve participants of a burden that they still often have to assume, feedback at the end of the trial, etc. (317-320) (see annex 2.5).

More specifically, in order to facilitate the inclusion of women of childbearing potential in clinical trials (who are often under-represented in order to avoid the risk of foetal exposure), various recommendations for sponsors have been drawn up: check that women have access to contraception, check before inclusion that women are not pregnant and set up a follow-up procedure, draw up an informed consent document that clearly specifies the risks incurred by the foetus in the event of pregnancy, etc. (324).

Evolving the documentation associated with studies

Subject to participants being able to provide it, the issue of free and informed consent does not differ according to sex or gender. Every individual has the right to say what risks they can, will or will not take for their own health and that of the community.

For intersex and trans minorities, forms are not suitable, as these minorities do not recognise themselves in the response choices offered.

An evolution of these forms and, more broadly, of the documentation associated with studies, may be a first step towards improving the consideration of sex and gender in medical research.

To tackle these problems, the AIDS Division of the National Institute of Allergy and Infectious Diseases (NIAID) in the USA created the Cross-Network Transgender Working Group (CNTWG) in 2015. The purpose of this group is to promote coordination, collaboration and information exchange on issues concerning trans people between HIV vaccine clinical trial networks, and to facilitate their participation (274).

This working group recommended the use of the so-called “two-step method” in which people participating in a study describe themselves by their gender identity and by their biological sex (274). This method therefore offers more response choices (see annex 2.5).

Reaching out to populations affected by under-representation

Furthermore, in a report produced in 2016, the European Parliament called on member states and the European Commission to invest in awareness-raising campaigns in order to encourage women to take part in clinical trials (325) (see annex 5.5).

Similarly, studies having analysed the reasons for the under-representation of trans people in HIV prevention trials have highlighted the need to develop recruitment strategies that specifically target the trans community (274).

However, this is not a substitute for effective community engagement.

Supplementing clinical trials with real-life follow-up studies

BAAlthough real-life studies cannot, and should not, replace clinical trials, non-protocolised data collection should not be overlooked as a means of having access to sex-differentiated information that can benefit the health of all.

Proper use of these studies can provide valuable data (309), and in turn lead to the conduct of protocol-controlled clinical studies where they identify sex or gender differences that need to be further explored.

Hence, in 2006, the Bureau of Women's Health and Gender Analysis at Health Canada recommended that (309):

- "independent post-market studies of new therapeutic drugs be made mandatory for all new drugs and be funded by industry. These follow-ups should be appropriate to the approval status of the drug involved, with those approved conditionally required to show they actually produce a clinical benefit; and those approved under a priority approval followed for determination of their safety in populations other than those initially studied by whatever methods are most appropriate (including registries and observational studies as well as randomised trials);
- conditional licensing (i.e., the use of Notice of Compliance with conditions) approvals for new products that have only limited pre-market testing be greatly improved to ensure it is a transparent process with close monitoring of what companies are doing to comply";
- "standards for gender-based analyses be established (...) in the clinical trials of drugs, including post-market surveillance and adverse drug reporting."

Professional and public health guidelines: making up for France's relative lag in taking sex and gender into account

Taking into account new knowledge about male/female differences in terms of pathophysiology, diagnosis and treatment would make it possible to improve the personalisation of care. Differentiating guidelines based on sex would mean that the sex of the person concerned would need to be systematically taken into account when analysing the clinical profile and defining the diagnostic work-up or management.

Almost no consideration of sex and gender in French guidelines

A Canadian team (326), from the Institute of Gender and Health in Montreal, performed a systematic search for the terms sex or gender in Canadian clinical practice guidelines, published between January 2013 and June 2015. It is specified whether the mention related to guidelines issued specifically as a function of sex or gender, or if it only related to data. The authors focused on around forty conditions deemed to be priorities for policy-makers or practitioners.

The clinical practice guidelines (CPGs) were analysed conducting an electronic search for key words related to sex and gender ("sex," "gender," "male," "female," "men," "women," "man," "woman," "boy," "girl" and "pregnant*"). Of the 118 CPGs meeting the inclusion criteria, 79 (67%) included a key word, including 25 (35%) in specifically gendered guidelines (excluding pregnancy); 5 (7%) mentioned sex-specific laboratory reference values, and 29 (41%) referred to differences in epidemiologic features or risk factors. Only 12 (17%) contained non-relevant mentions of one of the search keywords⁴⁰.

The authors concluded that these guidelines still mentioned sex and gender too inconsistently.

HAS drew inspiration from this study to analyse the consideration of sex and gender in French guidelines.

⁴⁰ In other words, the great majority of the guidelines containing these terms used them for a specific purpose and not in a trivial or anecdotal manner.

Inventory of French guidelines in the field of health

A search of “gendered” or “sex-differentiated” guidelines was conducted by HAS in the A.F. Lemanissier medical library. This library, which can be accessed online (www.bmlweb.org) lists consensus, recommendations, methodological guides, and guidelines developed for the evaluation of professional practices or continuing professional development. It provides an overview of French-language, institutional (including HAS documents) and learned societies' productions.

A search by keyword (“sex”, “gender”, “men”, “women”, “man”, “woman”, “boy”, “girl” or the equivalent in French if applicable) was conducted in the clinical practice guidelines in the library in four fields: addictology (alcohol, smoking), mental health (depression, suicide), cardiology (stroke, infarction) and oncology (bowel cancer).

These conditions or clinical situations were arbitrarily chosen, as they were assumed to be potentially the subject of “gendered/sex-related” guidelines although they affect both sexes.

The guidelines identified by this search are indicated in the annexes (annex 3.3).

Gendered guidelines for cardiovascular diseases

Cardiology is probably the most advanced speciality when it comes to understanding clinically significant biological differences between the sexes.

Risk factors for cardiovascular disease and stroke are variable depending on sex. The clinical profiles of acute coronary syndromes also differ: men present with the disease sooner, and women more frequently present with acute coronary syndrome (ACS) with ST elevation (ST+), which corresponds to the former acute myocardial infarction in old definitions. There are differences between the sexes in terms of both clinical manifestations and consequences, whether for heart failure, atrial fibrillation, aneurysm formation or aortic valve decompensation. Troponin levels - a biomarker of acute myocardial damage - are known to be sex-specific. In the same way, reference values differ for men and women for ECG, heart cavity volumes and arterial vessel size. Consequently, diagnostic methods do not necessarily all present the same efficacy for everyone. Even the effects of certain cardiovascular drugs vary depending on sex, in terms of both their efficacy and their toxicity. There are also diagnostic methods that are not equally effective in both sexes.

In fact, the Canadian Cardiovascular Society recently demonstrated that implementing a systematic process for critically appraising sex-specific evidence in the formulation of CPGs relating to the management of acute myocardial infarction (in particular with calculation of the participation/prevalence ratio, or PPR, which reflects the participation of women in the study analysed relative to the prevalence of this condition in women) was straightforward and feasible (333).

This keyword search did not identify any guidelines in the areas considered that explicitly relate to intersex or trans people. And when sex is mentioned without further precision, it implicitly refers to only women and men. Gender is never mentioned.

French guidelines specifically considering sex were identified in two of the four areas selected: relating to alcoholism (327, 328), and cardiology (85, 329-332). These guidelines differentiate between women and men in terms of values, diagnostic scores, interpretation of patient information, treatment objectives, and choice of medicinal products according to risk level. A number of them were produced by HAS (327, 329-332).

In the field of mental health, whether in terms of depression or suicide, data are reported based on sex in the guidelines (signs of depression in adolescence, major depression in adulthood), but this has not led to the formulation of specific guidelines (334, 335).

In 2014 and again in 2016, the Observatoire national du suicide (ONS - French Suicide Observatory) stated that gender should be a cross-cutting issue in research on suicide (98, 336). This is consistent with the findings of a study presented at the Guidelines International Network (GIN) conference in 2010, which compared four European CPGs for depression (Austria, Sweden, Finland and the UK) (337).

Gender under-considered in four European good clinical practice guidelines on depression (Austria, Sweden, Finland and the UK) (337)

It is demonstrated, firstly, that women are more often affected by depression than men, but that more men than women commit suicide. Secondly, depressed women have different symptoms and behaviours than men. The authors assessed and compared how these gender differences were taken into account in the guidelines of four European countries (Austria, Finland, Sweden and the United Kingdom). An analysis of the literature conducted in parallel confirmed significant differences between the sexes, particularly for certain behaviours (denial of the situation or increased alcohol drinking for men, compared to a propensity to talk about their feelings or cry for women) (338).

Ultimately, only the British and Finnish guidelines reported that depression was more common in women. The Swedish guidelines considered that male sex was a risk factor for suicide. The British guidelines also highlighted that women made greater use of the healthcare system and relied more on their social links.

Methodologically, the authors observe that the research strategy and the exclusion criteria are too restrictive and that the level of evidence of “gendered” studies is often low. Despite the availability of data demonstrating differences between the genders, these were not taken into consideration in these four guidelines. The authors even consider that the lack of gender-specific information in these guidelines could result in incorrect diagnosis or inappropriate treatment. Beyond the development of additional research on depression and gender, they conclude that it is necessary to get gender experts involved in the formulation of guidelines and to develop tools that can assess the incorporation of gender-related aspects in guidelines.

Similarly, in the field of tobacco addiction, epidemiological data are reported according to gender, without, however, resulting in the formulation of specific guidelines that may be justified in the implementation of prevention (339).

Finally, in oncology, the French guidelines are not specific, although the models used to calculate risk scores incorporate different variables, including sex (340).

Inventory of French guidelines in the social and medico-social field

There is no equivalent to the Lemanissier library to search for guidelines in the social and medico-social field. Consequently, for the purposes of this report, a search for “gendered” or “sex-differentiated” guidelines was conducted among the documents produced by the Agence nationale de l'évaluation et de la qualité des établissements et services sociaux et médico-sociaux (ANESM - French national agency for the assessment and quality of social and socio-medical facilities and services) and those of the HAS, with which the agency was merged in 2018.

As for the study conducted in the health field, a keyword search (“sex”, “gender”, “man”, “woman”, “boy”, “girl”) was conducted in the good practice guidelines published since 2016.

Guidelines that specifically consider sex-related differences were identified in three areas: child protection, social inclusion and disability.

In the area of child protection, guidelines on the “the prevention of violence between adolescent minors in care facilities” include several mentions aimed at making professionals aware of the issue of gender and the difference between the sexes (specific actions for mixed facilities, gender-related representations, etc.) (341).

Those on the “support for unaccompanied minors known as ‘unaccompanied foreign minors’ include indications on the usefulness of using reception interview techniques adapted on the basis of the sex and reported age of the person, of having a translator/interpreter if necessary and of taking into account the sex of this professional (342).

On the other hand, in the guidelines relating to “support for children with psychological difficulties that seriously disrupt the socialisation process” (343), no specific recommendation is made, even though data show that girls have twice as many disorders as boys.

In the guidelines on “identifying and supporting victims and perpetrators of domestic violence in accommodation and social reintegration centres (CHRS)”, it is recommended that preventive actions be developed focusing on the reduction of gender inequalities (344).

In those on “risk and harm reduction in French support centres for the reduction of drug-related harms (CAARUD)”, it is recommended that sex should be taken into account in the methods of intervention, including in the profile of peer helpers, and that care should be adapted to specific vulnerabilities or needs, particularly of women (345).

It should be noted that specific guidelines have been formulated by other bodies, such as the French Addiction Federation, relating to the support offered in addiction prevention and support and treatment centres (CSAPA) and support centres for the reduction of drug-related harms (CAARUD), for women with addictions (2016) (346).

Guidelines relating to “Quality of life: disability, somatic problems and painful phenomena” (347) and “problem behaviours within facilities and services catering for disabled children and adults”(348) specify that sex should be taken into consideration (with no further detail), both in terms of prevention and response.

What is the situation for consideration of sex/gender in the methodological guidance documents of French institutions?

No HAS methodological guide recommends specific consideration of sex and gender in the formulation of good practice guidelines (whether this concerns the method for the formulation of “clinical practice guidelines”, “formalised consensus-based guidelines” or “methods for the formulation of memos and relevance sheets”, or even the guide for “the assessment of ethical aspects at HAS”).

However, the guide published by France’s national health accreditation and assessment agency (ANAES) in 2004, entitled “*Comment évaluer a priori un programme de dépistage ?*” (How to perform prior evaluation of a screening policy?) (349), which remains a reference for public health guidelines, requires, in the list of questions to be considered before any evaluation, that the different characteristics of the individuals benefiting from the programme, including sex, be described and quantified. Similarly, epidemiology must be documented in terms of mortality, morbidity and disease burden by age and by sex.

In addition, HAS had drawn up an initial draft reading grid for consideration of differences between women and men following a seminar it organised in November 2013 on the theme of “Women and Health”, (350), to coincide with the International Day for the Elimination of Violence against Women. It could usefully be taken as a basis for reflection (see annex 2.6).

A search of the websites of the French National Agency for Medicines and Health Products Safety (ANSM) and INCa (French National Cancer Institute) does not indicate consideration of sex or gender in guideline and recommendation development guidance.

No methodological guidance is found on the website of the French National Council for Public Health (HCSP), and no reference is made to a guide of this type in its reports. The bibliographic search performed is included in the publications; we did not find any keywords that would suggest that sex and gender are subjects of interest to the HCSP.

Some countries already include sex and gender in their methodological guidance documents for the drawing up of guidelines

Taking sex and gender into account starts with the inclusion of sex and gender in working methods. Therefore for this report, HAS investigated whether similar organisations in other countries have incorporated this subject into their methodological guides, and how they have done so. In fact, consideration of sex and gender starts from the guidance preparation phase.

Various foreign or international organisations encourage consideration of sex in recommendations and guidelines via an appropriate method (351-353). The terms employed in these guides were identified; they are indicated in the table below.

Table 8. Sex or gender-related terms used in the methodology guides analysed

| Methodology guide | Words used |
|---|---|
| Scottish Intercollegiate Guidelines Network, 2019 (351) | Sex/Gender reassignment/Sexual orientation/Minority groups |
| National Institute for Health and Care Excellence, 2014 (352) | Sex/Gender/Gender reassignment/Sexual orientation |
| World Health Organisation, 2014 (353) | Sex/Gender/Sex parity/Gender-balanced/Sexual orientation |
| World Health Organisation, 2012 (354) | Sex/social identity/Behavioural characteristics/Gender-balanced |

Details of these guides are provided in the annexes (annex 2.6).

It should be noted that only the WHO guide (353) genuinely takes into account the question of gender, in addition to that of sex, and its importance in terms of health equality. A chapter is specifically dedicated to the importance of incorporating equity, human rights, gender and social determinants into guideline development. Hence, according to the WHO it is now necessary to incorporate sex- and gender-related questions from the very start of a project and throughout its development (through to the publishing and updating phase).

However, the effectiveness of these methodological guides is questionable. For example, although the WHO guidelines suggest respecting a male-female balance in the contributors to the development of guidelines, a study (355) demonstrated that out of 230 guidelines produced by the WHO itself between 2008 and 2018, men were more often represented in the groups (53.1%) than women (45.5%), with a male chair in 59.7% of cases⁴¹.

⁴¹ This study also demonstrated the influence of the chair’s sex on guideline development.

However, this situation was tending to improve: whereas a quarter of the groups were made up of less than 40% women between 2016 and 2017, this proportion was only 9.1% in 2018.

Moreover, some organisations, such as NICE, are committed to ensuring their guideline development process fully meets the conditions stipulated by the UK laws on equality (Equality Act, 2010). The aim is to eliminate discrimination and to advance equal opportunities in relation to people who share protected characteristics (sex, gender reassignment, sexual orientation, age, disability, religion, ethnic origin, marriage, pregnancy or maternity). **If one of these criteria is specified in a study protocol, it must be indicated in the evidence tables.** However, gender is not explicitly differentiated from sex.

NICE has extended this approach by publishing **an annual equality report** (356) since 2015. This report documents the composition and appointment of members to NICE committees (analysed particularly in terms of sex (male/female), disability and ethnicity), as well as for the NICE workforce itself. The different types of publications are also listed, indicating, for each of them, mention of the number of considerations related to the abovementioned protected characteristics and their impact in terms of guidelines. Hence, for example, five clinical practice guidelines (including two updates), two public health guidelines and one diagnostics guidance document took sex into account as an equality issue. Over the course of 2018 and 2019, the incorporation of sex impacted 8% of publications.

Avenues for improvement to incorporate sex and gender in guidelines

Raising awareness among guideline developers

Various examples support the fact that taking into account sex-related differences, whether in the field of prevention, screening, diagnosis or treatment strategies, has made it possible to develop gendered guidelines, but the question still needs to be raised. A pilot study (357) examined the characteristics of groups discussing data identified as being sex-related and demonstrated that a training programme including contact with “gender experts” improved contributors’ awareness of the need to give greater consideration to these differences. The dominant role of chairs was demonstrated: the discussions they initiated on this topic were more frequently included in the guidelines (355) (see annex 2.1).

Developing clinical practice guidelines following a structured approach to ensure the systematic consideration of sex

In 2017, MacGregor *et al.* (358) were already calling on healthcare professionals **to move away from standard, non-personalised care to the routine consideration of gendered guidelines where relevant.**

The first step involved identifying the patient’s biological sex, which can differ from their gender identity.

The second involves considering whether there is a potential variation in pathophysiology and symptoms depending on sex and taking into account potential gender bias in diagnostic methods, or biomarker thresholds for example, to make an initial assessment of the patient.

It is then necessary to adapt the treatment strategy accordingly (choice of doses, for example). Although decision-making may remain unchanged in many cases, thinking along these lines prepares healthcare professionals to implement sex-specific guidelines in their practice if necessary, as an opportunity to improve patient care, which becomes more personalised as a result.

In the development of CPGs, definition of the target population, intrinsic to the clinical question, is a crucial step. Hence CPGs can absolutely be developed for a particular sex or group, even if the disease affects the population as a whole. But usually, the target population is primarily defined by the disease or condition itself.

Consideration of sex and gender in guideline development requires a structured approach.

Some authors propose a systematic approach aimed at analysing the quality of the evidence in the literature, and assessment of whether specific guidelines need to be formulated on the basis of sex (289).

As has already been indicated, various foreign or international organisations have defined a method to do this (351-353).

Finally, some authors (359) also propose using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group method (www.gradeworkinggroup.org). According to the authors, this approach makes it possible to address a number of methodological challenges concerning the consideration of issues related to sex and gender, and minorities: the heterogeneity and complexity of public health interventions, the scarcity of clinical studies, the use of indirect evidence, the integration of the values and preferences of the target population, the removal of social and legal barriers, the formulation of recommendations, etc.

These tools are briefly presented in the annexes (annex 2.6).

Future research needs to be encouraged to improve access to any sex- and gender-specific information, especially in relation to adequate representation in clinical trials. Where there is insufficient data to make gendered recommendations, a transparent synopsis of knowledge is required to guide the design of future studies.

Health and social sector professionals: encouraging consideration of sex and gender

A professional environment strongly marked by gender stereotypes

A highly gendered distribution of jobs and responsibilities

In France, women make up a majority of workers in the health, medico-social and social fields (360-363). Even the names of some professions are gender-specific. In French, the feminine versions “*infirmière*” (nurse) and “*assistante sociale*” (social worker) are often used, despite a masculine equivalent also existing. Conversely, the terms “*chirurgien*” (surgeon) or “*brancardier*” (stretcher-bearer) are used in the masculine form, while the term “*homme-sage-femme*” (male midwife) is readily used instead of the specifically masculine term “*maïeuticien*”.

Often, it is the history of a profession and the social perceptions associated with it that explain the masculine or feminine terms used for jobs in everyday language.

In the health field, the percentage of women among health professionals is estimated to be 76% and the figure is increasing (71% in 1983) (364). Women accounted for three quarters of hospital personnel in France in 2008 (360).

Sabine Bessière (361) suggests a categorisation of health professions in France on the basis of three main groups:

- professions that are very strongly and historically feminised, with more than 70% women: midwives, speech therapists, orthoptists, healthcare assistants, psychomotor therapists, occupational therapists,
- pharmacists and chiropodists/podiatrists: two professions in which the number of women is increasing significantly (women in the majority). In 2015, the majority of pharmacists were women (67%).
- professions in which men are still in the majority: opticians, physiotherapists, audiologists, physicians and dental surgeons.

This trend of feminisation will continue due to the fact that more and more women are graduating from initial training or are newly qualified (hence 75% of working pharmacists under the age of 30 are women, compared to 58% of those aged 60 to 69 years (364-366).

The nursing profession, historically very female-dominated (95% women in 1970), is an exception, however, with a trend towards more male nurses, although the majority of nurses are still women (83% in 2014).

As a result of this distribution, the DREES (French Directorate for Research, Surveys, Assessment and Statistics) portrait of health professionals(364), and a study by HAS and the *Agence nationale pour l'amélioration des conditions de travail* [French National agency for the improvement of working conditions (ANACT)] published in 2016 on occupational health in healthcare facilities (360), show that caregivers - in practice mostly women - have particularly difficult working conditions (night work and alternating shifts, in particular), and feel a strong lack of recognition. The analysis of the literature conducted for this work highlighted a relatively negative assessment of the evolution of working conditions as a result of new organisations, management and successive reforms of the health system. In particular, time pressures have increased in hospitals since the 2000s, with a negative impact, especially on care assistants, hospital service agents and nurses, although a 2013 survey revealed an improvement (360). The gendering of occupations therefore has differentiated consequences, with female-dominated jobs being more affected by this deterioration.

At the same time, women are still in the minority in positions of responsibility, in representative bodies and in the academic world.

For example, the French National Medical Association includes only 14 women out of 56 elected national advisors, and its board is composed of 17 members, of whom only 1 is a woman, despite the fact that the profession has become more feminised and that women now represent half of all doctors (367). From June 2019, the National Council was to be renewed by half every three years on a male-female parity basis.

As regards the world of academia, it is observed that out of 36 medical schools in France in 2020, only four had female deans.

In order to increase the presence of women in academia, a 40% quota for women in university selection committees has been required in France since 2015. An analysis of the impact of this reform shows that the increase in the proportion of women in the committees seems to have been paradoxically accompanied by a decrease in the chances of recruitment of women candidates. Addressing this inequality in the representation of women is therefore more complex than a matter of quotas. It is also necessary to focus on the issues of career guidance, work experience, career path and development norms, mobility, over-investment, hostile environment, etc. (368).

Citation practices in research work

A study analysed the way men and women present their results, and how this is subsequently associated with article citation rates (369).

This retrospective analysis was conducted on more than 100,000 clinical research articles and around 6.2 million general life sciences articles listed in PubMed and published between 2002 and 2017.

It emerged that clinical articles involving a male first or last author were more likely to present research findings positively in titles and abstracts compared with articles in which both the first and last author were women, particularly in the highest impact journals. And this positive presentation of research findings by men was associated with higher downstream citations.

Several reasons need to be considered to understand why women, especially female caregivers, find it more difficult to reach the highest positions, even with the same characteristics. Bosquet et al. sought to understand these differences in career progression in the academic environment in France (370). This difference is largely explained by the fact that women publish less than men on average, but these promotion gaps between men and women with similar characteristics (same age, level and educational background) are also possibly linked to discrimination against women, or at least to differences in candidates' preferences and/or attitudes when applying for positions of responsibility, and to their possible poorer performance in promotion processes (370).

In social work professions, women are even more present than in the health professions.

They account for 80% of workers in the social sector (362, 363), all jobs combined. The figures are 93% for social service assistants, 70% for specialised educators and 65% for leader/coordinator jobs. Homecare assistants and home helps are very predominantly women. The early childhood sector is also highly feminised.

The distribution of women and men therefore differs between occupations. It also depends on the type of facility or structure and the public catered for (362). Men are more present in fields related to integration, while women are still in the majority in jobs related to care, and those targeting people with disabilities.

The proportion of women undertaking initial and continuous training in these areas confirms this trend (371).

With the exception of technical educators⁴² (transmission of professional knowledge to people in difficulty or with disabilities), who are 86% male, men are clearly under-represented (372).

As is the case in the field of health care, this significant presence of women in the social sector is not necessarily reflected in the most senior positions (362, 363). **Two thirds of management positions are occupied by men**, except in early-years childcare facilities, where 97% of managers are women.

35% of management positions are held by women in the elderly care sector, 24% in the disabled children's sector, and 22% in the child welfare sector.

Similarly, there are also imbalances in professional social work organisations in terms of representation (373).

The Women in Global Health (WGH) movement, founded in 2015, works with other global health organisations to encourage public and private stakeholders, governments, civil society, foundations, universities and professional associations to achieve gender equality in global health leadership.

The WGH and the WHO have created a Gender equity Hub (374), which identifies data (including some in France), and proposes various resources in order to address gender inequities and biases in the global health and social workforce (375).

The most recent report, entitled "Delivered by women, led by men", produced in 2019 (376), is based on a review of the literature on the issue of gender and equity among the global health and social workforce. A summary of this report is available in French (374). The report indicates the following findings:

- on a global scale, women account for 70% of the health and social workforce. Their role is clearly critical. Despite everything, this predominance of women in health systems does not generally lead States to make gender equity in the sector a priority, despite it being important to consider the issue of the roles given to the two sexes.

⁴² A distinction should be made between technical educators and the role of specialised educators, who help people with disabilities or difficulties living independently. The majority of the latter are now women, whereas previously the occupation was relatively mixed.

- women face barriers at work not faced by their male colleagues. These barriers undermine their well-being and livelihoods, as well as gender equality and negatively impact health systems and the delivery of quality care.

Four themes emerge from this international analysis:

- the vertical and horizontal segregation of jobs: male/female discrimination that prevents women from occupying senior roles, existence of gender norms and stereotypes: "men's work" (surgeons), and "women's work" (nurses), lower status or lower paid jobs for women;
- bias and discrimination or harassment, including sexual harassment, suffered by women. This adversely affects their health. Many countries lack legislation;
- the gender pay gap of 26% (higher than in other sectors);
- absence of gender parity in leadership roles. Women occupy 25% of senior roles. The drivers are stereotypes, discrimination and power imbalances.

According to this report, **increasing the consideration of women as pillars of the health system, and thus combating these inequalities, should naturally constitute progress in terms of care provision and health coverage** (376).

The specific data indicated in this report place France among the best performing countries, based, in particular, on a pay gap of only 10% in 2017 between men and women working in the health sector (the European average is around 18%), and the amount of unpaid work by women per day (among the lowest in OECD countries), which nevertheless needs to be balanced against a paid work time that is also amongst the lowest (376).

In parallel, in 2017, the WHO had adopted a human resources for health strategy and a five-year action plan (2017-2021) (377). Considering that nurses and midwives contribute to the improvement of health for all, i.e. universal health coverage, the WHO even designated 2020 as the international year of these two professions (378). According to the Organisation, the training, reinforcement and professional development of these occupations are essential in order to offer high-quality care. All too often, these staff are undervalued and are unable to develop their full potential. They need to be given due recognition and offered leadership roles in order to guide policy and investment.

In France, the social relationship between doctors and nurses has undergone changes: the increase in the number of women in medicine, the more recent professionalisation of care professions, a relative increase in the number of men in nursing, and successive transformations in hospitals, a division between formulation and execution that has become less clear (379).

Stereotypical representations within the professional environment and on the part of users

A few examples help to illustrate the problem of gender stereotypes within and vis-à-vis the health and social work professions.

The profession of doctor is surrounded by perceptions linked to its predominantly male history (367): constant availability to the patient, the need for physical strength to practice. Female doctors are still subject to stereotypical representations, both on the part of their colleagues and users of the health system, even though they account for 50% of the profession.

They suffer from prejudices about their physical abilities and their full commitment to the job.

The feminisation of the profession has also been cited as a possible cause of the unequal distribution of doctors across the country. Women are more likely to be criticised for wanting to reconcile work and family life, whereas, in fact, more and more young male doctors are also seeking to improve their work-life balance (382). At the same time, women indicate that they force themselves to be warm or caring, conforming to traditional perceptions of femininity (364).

A large-scale survey (more than 3,000 respondents), carried out by hospital doctors' unions and published in 2019, shows that despite the feminisation of the profession, gender discrimination still appears to be as prevalent among young female hospital practitioners as it is among older women doctors over the age of 45 (380). According to this study, the high level of education and professional investment required for these positions does not change the distribution of household tasks at home, leading to chronic exhaustion among women (58%). In addition, women feel more discriminated against on the basis of their sex than men, and are more likely than their male colleagues to give up continuing training (49% for women and 33% for men).

Women, who accounted for 44% of general practitioners in 2015 (381) worked shorter hours on average than their male counterparts, accepted fewer on-call duties, and made fewer home visits. For these reasons, they are regularly accused of being less committed to their patients, or even of being less good doctors⁴³. Yet their consultations last longer (382).

Gender stereotyping in the choice of speciality

The choice of specialities in medicine also differs for men and women. Women are more likely to go into paediatrics (67% female), medical gynaecology (72%), dermatology (69%), occupational medicine (just over 70%) and public health (60%). Conversely, they account for 22% of surgeons.

Generally speaking, preventive medicine is also less valued than curative or emergency medicine; women are more represented in this field (387).

In addition, some studies have investigated the impact of the gender of the professional, on the one hand, and that of the patient, on the other, in medical practices. These suggest differences between men and women and effects on the quality of care.

For example, differences in outcomes were found depending on the sex of the practitioner in terms of elderly patient readmission and mortality rates, (383), and the percentage of deaths after surgery (384). Further studies, particularly in France, would be needed to confirm any potential influence of sex on medical practice and outcomes.

In parallel, studies have examined differences in practices according to the sex of the patient. For example, in a study conducted in Canada in 2011, differences in the choice of treatment for total hip or knee arthroplasty were revealed, based on the patient's sex. The rates of use of this procedure were lower in women than in men (among candidates willing to have the surgery and meeting the recommendations). The patient's sex plays a major role in the decision-making process, and female sex affects numerous steps in this process, which, according to the authors, suggests that barriers unique to women exist within the context of the patient-physician interaction. They recommend the use of shared decision-making tools in this field (385). A broader study, also examining arthroplasty practices in various countries, including France, confirms that women are less likely to be offered this procedure, and highlights other factors such as ethnicity, the patient's level of education, or their insurance cover (386).

⁴³ On 26 September, 2020, the French newspaper Le Monde published a collective statement by 330 female health professionals.
www.lemonde.fr/idees/article/2020/09/26/sexisme-dans-le-milieu-medical-les-discriminations-et-vexations-doivent-cesser-aussi-bien-pour-les-femmes-medecins-que-pour-l-avenir-de-l-hopital_6053685_3232.html

Violence during medical studies

Female students are still subject to violence during their medical studies. This type of stereotype-related violence has been assessed in various countries (374). In addition to having an impact on the physical and mental health of victims, it also affects their training and their career (avoidance of certain courses, dropping out), and probably the way they practice medicine. The impact is exacerbated by the fact that the system is based on peer-to-peer transmission of knowledge.

A number of studies have highlighted the extent of the issue in France, and an underestimation of its seriousness.

A survey conducted in 2018 among third to sixth-year medical students in the seven medical faculties in the Île-de-France region, revealed that 29.8% of respondents reported having experienced sexual violence during their studies (sexual assault 25.2%, and harassment 11.6%). The prevalence was higher among women and, in their sixth year, almost two in three female students (61.9%) had experienced at least one situation of sexual violence (compared to 14.8% of men). On average, 78% of respondents recognised the situations presented in the survey in the form of drawings as unacceptable, but only 52% considered them illegal. The study presents a potential bias since it is possible that the people who felt most concerned by this issue (particularly the victims) may be over-represented among the respondents. However, these results suggest that there is a high prevalence of sexual violence, especially among women, and that the illegality of such violence is largely underestimated by medical students (388).

The "Messiaen (The Medical Students Suffering from their professional environment)" study conducted in Marseille presents recent findings relative to sexual harassment experienced by young doctors: 20% of young female doctors report having already experienced sexual violence, compared to 5% of men (sexual innuendo (39.7%), sexist nicknames (36.1%) and wolf-whistles or inappropriate looks (20.6 %)).

Some specialities are more at risk than others (rare in paediatrics, but more common in surgery (78.5%) and anaesthesia (29.3%). One hypothesis is that in these specialities people change clothes for work, and that wearing a mask and a uniform can give the feeling of not being in one's ordinary environment. It is also suggested that the surgical culture observed in some departments is based on a "somewhat patriarchal hegemony" (389).

However, the issue of violence is not exclusive to medical studies. The Virage study, conducted in 2017, highlighted that studies are the second most common space where women report sexual violence of any kind, after the public space (390).

Nursing is still perceived as a woman's job, although more and more men are becoming nurses and the profession is gaining decision-making skills. It is also a profession that lacks recognition. It is perceived as secondary to medicine in the eyes of the general public, and seen as having a supporting or assisting role to practitioners.

As regards access to greater responsibilities, a report on nurse leadership (Investing in the power of nurse leadership, what will it take?) (391) particularly highlights the barriers nurses face in gaining access to decision-making roles. The following are mentioned: stereotypes devaluing women firstly, and nurses, secondly, the perception of a glass ceiling by those concerned, whereas their male colleagues advanced more rapidly to leadership roles, the need to juggle paid and unpaid work (family, relatives, etc.), self-censorship and lack of confidence in their ability to hold leadership roles. According to the authors, it is necessary to change the perception of the profession and elevate its status, eliminate employers' gender-based stereotypes (particularly the role of mother) and, conversely, promote opportunities for leadership training, restore confidence within the profession and foster increased access to professional networks.

Historically, the social work professions were aimed at women and could only be carried out by dedicated, single, childless women. Consequently, being a member of the female sex was the passport required to enter the profession (372). For Marc Bessin, “this feminisation relates to the construction of a gender considered to be naturally predisposed to nurture, support or help... (362).

This exclusive practice of certain fields of social work by women, depending on the target audience, may also have some justifications. In particular, this is the case in the social sector that provides assistance to victims of domestic violence, sexual assault, or support for women in prostitution.

This single-sex approach to social interventions was based on four principles: establishing equal relationships, raising awareness of women's realities, engaging with women and believing in their strength and potential.

However, needs have changed, and men also require support. Isabelle Astier studied the assessment and follow-up of applications for the French “Minimum Integration Income” (RMI) (392). She found that (in 1996) men did not perceive themselves as a target of social policies, since the RMI was the first aid available to able-bodied people without dependent children, and that - less familiar with social services - they were reluctant to talk about their private lives in their files. Hence, fewer men came forward than women, including when their benefits were stopped. She also noted that for a recipient who was not known to the services, they were treated differently depending on their sex: more elements were found to support the integration of women applying for the benefit than men, thus justifying the payment of a minimum income.

More recently, the cahier Stratégie et prospective “Genre et renouvellement du travail social” (“Gender and renewal of social work” booklet) published by the French Directorate General for Social Cohesion (DGCS) in 2014, (363), examined social intervention from a gender perspective and concluded that “The field of social intervention appears to be a space of reproduction that amplifies the gendered division of professional roles”.

At a time when the feminisation of the health professions is increasing, it may be pertinent to raise the question of the potential benefits of recruiting men to childcare and social work roles in order to help combat the stereotypes associated with traditional gender roles. Ultimately, this could have a positive impact on professional practices for the benefit of the person being assisted or cared for.

Does gender diversity bring about change, does it break down stereotypes? Not necessarily (372).

In particular, male social work professionals may be specifically called upon to deal with an aggressive or violent person, or to lift heavy loads, which some men perceive as being asked to do “the dirty work”. These men thus feel that their colleagues are relying primarily on their gendered identity and their associated expectations (male authority, strength) rather than on their professional skills. To an extent, therefore, each person remains a prisoner of perceptions and expected behaviours based on a male/female divide, a naturalization of skills in short (363, 373, 393).

Questioning the benefit of gender diversity to better manage or reduce the gender inequalities of users, Marc Bessin suggests that it is necessary to look more broadly at the gender of social interventions. He proposes to first reflect on the values mobilised in social work and the stereotypes at play, rather than automatically choosing gender diversity as the solution (393).

For example, social actions aimed at young people are hinged around protection and sanction, with care being delegated to female social workers and authority to male social workers. Gender diversity is often seen as a means of achieving complementarity, but what is essential are the social work values of availability to others and building a relationship over the long term. These values should be given priority over diversity.

Greater awareness of the influence of gender and stereotypes at work in professional and training practices will make it possible to reframe analyses and improve the care and support offered to people.

Training that does not adequately take into consideration sex and gender

Knowledge is an essential lever for change, with the objectives of raising awareness of sex- and gender-related differences and their influence on professional practices, disseminating a common culture and supporting changes in practices and behaviours. Initial and continuous training (as well as recommendations and experience) are essential pillars for this construction of professional knowledge. Ensuring that professionals are sufficiently aware of these differences is therefore crucially important.

Limited consideration of sex and gender in health studies

According to Prof. Mathieu Nendaz, vice-dean responsible for undergraduate training at Geneva University's Faculty of Medicine (UNIGE): “The influence of sex on disease prevention, detection and management is addressed during the curriculum for some conditions, but not systematically”. The faculty should generally strive to do a better job of making sure that learning materials differentiate between the variability of situations and symptoms related to sex or gender, that women are adequately represented in the case studies presented, and that teaching materials do not convey stereotypes. This requires input from teaching staff, but also from students (394). Students should feel able to discuss with their teachers - including during internships - any attitudes that they think are sexist.

This observation, as well as the underestimation of its consequences, seem to be equally applicable in France.

Differences in contraceptive practices explained by training and supervision of practices

Contraceptive use in France and England differs significantly when it comes to male methods, in particular: vasectomy and condoms are the methods utilised by half of users in the UK, but by only 15% of men in France (395).

Cecile Ventola's thesis proposes that the public regulation of training and practice in England results in a professional approach that more routinely takes into consideration user preferences with respect to contraceptive choice, including, in particular, male contraception.

In France, however, the principles of freedom in the field of medical training allow for a paternalistic approach to contraceptive choice and the expression of gendered professional reluctance with respect to male contraceptive methods. The 2-click recommendation “*Méthodes contraceptives : focus sur les méthodes les plus efficaces disponibles*” (“Contraceptive methods: focus on the most effective methods available”) is a tool designed to encourage professionals to offer a broader choice of options to couples or individuals seeking contraception (396).

Similarly, it is only recently that publications have made women aware that taking breaks during oral combined hormonal contraceptive use offers no medical benefits. This was highlighted by the Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists in a paper in 2019. This again indicates that individuals should be allowed to choose whether or not they want to maintain a monthly withdrawal bleed, without deciding, in advance, about any potential psychological impact of having no periods (397). In France, although this continuous administration (without monthly withdrawal bleeding) is included in the guidelines issued by the French National College of gynaecologists and obstetricians (398), the message has not yet been widely disseminated.

This example shows the importance of training and guidelines in order to evolve professional practices, particularly when they are characterised by gendered perceptions.

A short survey of students was conducted for this report. HAS wanted to collect the opinions of future doctors with respect to the consideration of sex and gender in their training, whether during academic teaching or practical training.

They were asked three simple questions via Google forms. The responses were in binary form only (yes/no), with the option to add a free comment.

The survey was conducted from 16 to 22 June 2020 via social media (Facebook and LinkedIn).

HAS received 1,122 responses and 873 from both medical residents (interns) and medical students (externs) were selected. The survey cannot therefore claim to be either representative or exhaustive⁴⁴.

This survey nevertheless provides an initial approach to the consideration of gender identity in medical studies in France today, from the point of view of future doctors, in the absence of any literature on this subject.

The results observed for the 873 responses from medical residents and medical students raise a few points worth examining:

- where differences are well established through research and communication of results, as is the case for stroke risk factors in women, gender differences are taught in medicine;
- however, when the differences have been the subject of fewer publications, or when stereotypes are very firmly entrenched, teaching still appears to be influenced by social role issues (this is the case for signs of depression, for example);
- awareness of the importance of considering sex and gender in medical practice is still limited in medical teaching.

These points are worthy of further, more in-depth exploration.

The majority of medical students and medical residents consider that their academic or practical training did not teach them how to adapt their care to the sex and gender of the patient (64%). They are divided on whether they have been taught that the signs of depression can be different in women and men (52% think they have not been taught this). However, the vast majority (93%) felt that they had been taught about women's specific risk factors for stroke related to pregnancy, menopause or oral contraceptive use.

The results seem to be consistent between women and men. They are identical for questions relating to depression and stroke, but differ significantly for the question relative to the adaptation of practices depending on an individual's sex or gender. Women appear to be less satisfied with their learning in this area (69% compared to 55%).

Medical students and medical residents completed their responses with a free comment in 59 cases (41 for women – 17 for men). They report stereotypical or even sexist attitudes on the part of teachers or professionals (the use of terms such as “hysterical” or “madwoman” with regard to female patients), but also by certain patients with regard to female doctors, the hierarchisation by caregivers of patients' accounts according to various criteria, including gender identity, particularly with regard to pain. And they reveal the need for training on sex-related differences, how to adapt their practice and attitude depending on a patient's sex and gender, how to care for LGBTI people, non-reproductive sexual health, and how to respond to sexist attitudes.

These results observed with the responses of medical students and residents point to avenues for progress in this area, in line with the other findings presented in this report. They also reveal a demand for the updating of teaching, which is in line with a more global trend among young doctors mentioned in the documents consulted for the report (18). It also emerges that female students, who are more critical of the teaching of sex- and gender-sensitive care than male students, are more desirous of change than male students.

⁴⁴ This difference can be explained by a desire to obtain a coherent set in order to limit analysis bias. The responses of first-year students were excluded since they were deemed to be unusable. Details concerning the survey methods and its limitations will be presented in annex 3.2.

Treatise on women's complaints

Preface extract:

"Hippocrates regards Women's complaints in two ways; firstly, in a very broad sense, for all sorts of ailments may befall women, who are nevertheless considered in a very specific way, with cures of their own.

Epilepsy, Apoplexy, Syncope and the like may be given as examples; for though they are disorders common to both sexes, in Women they derive a certain sympathy from the womb, & take on a malignancy from her excretions; for which reason Hippocrates, in regard to them, has generally said that the cures for Men's and Women's ailments are quite different.

Hence a Physician who must take care of humankind across the species will not think solely of delivering man, in particular, from the insult of diseases, but of dividing the species into two sexes. He considers the ailments that may befall both of them & destroy the nature of each, in particular, or finally prevent reproduction. For my part, wanting to explain the most difficult part, but also the most useful, namely Women's complaints, I will adopt this method and follow this order. Firstly I shall give ample consideration to the nature of Women as individuals, who form a part of the species of Man, distinguished from males and subject to their own diseases: Secondly, I will consider them as necessary for the propagation of the species. While they labour to this end, they are prone to a hundred symptoms, which cause them and their offspring much discomfort."

<https://gallica.bnf.fr/ark:/12148/bpt6k64741881/f582.textelimage>



No teaching on variations in sex characteristics or trans identity, except in specialised courses

All healthcare professionals should be properly trained in the nuances of sex and gender. Regular training on appropriate interactions with patients, and the provision of simple, practical tools to help medical personnel absorb such training and information would be the most effective approach (274).

The liberation of the voice of intersex people, following the Chicago Consensus of 2005, and the creation of activist interest groups, has brought to light major shortcomings on the part of caregivers. Reference has already been made to the tactlessness of some caregivers, and the fact that it is sometimes up to patients to educate their doctors about the health problems arising from their variation or resulting surgical procedures.

This lack of knowledge is both a source of rejection for intersex people and a source of unease for health professionals. Moreover, it is also likely to have a negative influence on the solutions offered in response to patients' problems, (239), with associated long-term consequences for intersex children and, later, adults, their parents, and the intersex community as a whole (10).

According to a survey of intersex people in the UK, the proportion of people reporting having encountered an unsympathetic healthcare professional was three times higher than for non-intersex people (356). Another study conducted in the Netherlands reported that intersex people felt that they had been treated with a particular lack of sensitivity by healthcare professionals (399).

Two major obstacles to the current training of healthcare personnel are, firstly, the limited time devoted to variations in sex characteristics and, more generally, to the care of people from sex or gender minorities, outside of specific courses, and, secondly, the highly medicalised nature of the teaching delivered.

Training is needed to ensure all healthcare professionals have a basic understanding of intersex and trans identities and their impact on health, as well as the behaviours they should adopt to build a care relationship built on trust.

More and more young doctors are becoming actively engaged. For example, the November 2019 issue of a French newsletter aimed at young general practitioners published an article on trans patients, explaining the differences between biological, gonadal and social sex, intersex and trans people (18).

A more holistic approach that needs to be more sex and gender-sensitive

At a time when we are hearing more and more about “personalised medicine”, it is becoming essential to integrate these sex- and gender-related differences into professional practices and attitudes.

The holistic approach (also known as integrative medicine) primarily takes two forms in the field of medicine. Patient-centred care means focusing on all the specifics of the patient, to achieve better care and improve the patient’s perception of their own health (400). In addition, patient education refers to programmes designed to support patients with a chronic illness or condition throughout their care pathway and life course (401).

Several areas of medicine are more specifically sensitive to these approaches: school health (402), occupational health (403), mental health (403), and they can be combined with community health strategies (404). The holistic approach has been shown to be effective in patient education (405) and in HIV/AIDS prevention (406). This approach is also recommended for the health and autonomy of elderly people by the French Ministry of Solidarity and Health (407).

Considering the individual as a whole implies, among other things, taking into account their sex as well as behaviours associated with their gender, in addition to any other determinant. A lack of attention to these factors results in poorer interactions with patients, and a risk of alienation for those whose relationship with the health system is already strained.

For example, a US study of women aged 30 to 55 admitted to hospital due to myocardial infarction found that this population may be reluctant to report worrying cardiac signs for fear that health professionals will see them as hypochondriacs based primarily on their gender (408). A review of the literature also highlights a lack of knowledge about the influence of the patient’s gender on the assessment of pain by health professionals, encouraging the perpetuation of gender stereotypes rather than a real consideration of the associated differences, as would be recommended by a holistic approach (409).

Patient-centred care is a recognised approach in the field of medicine today, as is the need to adapt care to the patient’s sex. Similarly, the effectiveness of listening skills is well established (410-414), yet they are not sufficiently valued, particularly in selection processes during studies or professional careers. This is an obstacle to their dissemination, as well as to awareness of the need to avoid gender stereotypes in relation to the patient.

Pain: an individual approach

Could sex hormones perhaps affect sensitivity to pain? Could it be that the mechanisms underpinning pain differ between the sexes? Could social norms lead men to downplay their pain? Is pain affected by sex or gender and the way an individual is brought up? It is hard to determine the various influences (416).

Until more detailed scientific evidence is available, it is essential that all healthcare professionals and relatives listen without bias to the description of each person’s pain, as every individual’s pain experience is unique. It is now accepted that pain needs to be measured using an individual scale in order to be able to treat it.

Training in how to give greater consideration to sex and gender in practices could be improved. The survey conducted among medical students prior to the present report shows results along these lines, with the great majority of respondents reporting that they had not received adequate training.

The holistic approach also plays a central role in the social professions, where disregarding social circumstances and taking action without listening would be unthinkable (415)⁴⁵. Beyond the holistic approach, the social professions also use the terms systemic or ecological approach: “this conceptual and pragmatic approach, which considers individuals in relation to their history, environment and family, is fundamental in the field of child protection”.

Initial and continuing training courses for social professionals develop the holistic and ecosystemic approach, and the role of active listening is central to the assessment of a social situation and the actions to be taken. However, the importance of sex and gender could be further highlighted.

Trans people: treating the individual

When it comes to health inequalities affecting trans people, healthcare providers often refer to the idea of “treating all patients the same” (417).

In reality, this approach is problematic because it ignores the uniqueness of each person, overlooks the importance of individual factors and characteristics on outcomes, and contradicts the vision of patient-centred care. Clinically, it affects the patient-caregiver relationship, with repercussions on patients’ compliance with their treatment, and can lead to deficient screening uptake for certain diseases, such as cancer (418).

Under these circumstances, it is not surprising that fewer than 40% of trans people report that their doctor is aware of their gender identity.

How much consideration is given to gender in social work training?

While knowledge related to listening skills and the holistic approach is widely disseminated through social work training, sex and gender questions are still not adequately included in teaching.

For some, the question of gender in social work appears to be a blind spot, and there is even a denial of the issue (362, 363, 419).

This blind spot is reflected in the relative absence of published social science research on the issue, although this is changing, and the issue of gender in social work is the focus of increasing attention (164, 373, 420).

Yet in September 2013, the French Directorate General for Social Cohesion (DGCS) had launched a forward-looking reflection process on the theme of “Gender and renewal of social work” (363). This study revealed the value of incorporating gender questions into social work and, therefore, of training professionals in order to improve their understanding of the issue. It should be noted that this document considered “genders” in the plural and focused on the intersection between different reasons for discrimination, represented by disability, age... and gender(s).

It advocated the creation and dissemination of knowledge and proposed that an overhaul of social work training and job standards planned for the following year should incorporate gender-related issues.

⁴⁵ See the standard for the occupation of social work assistant: www.unaforis.eu/sites/default/files/public/fichiers/telechargements/referentiel_deass_maquette_vt_2018-02-06.pdf

Did the *États généraux du travail social* (EGTS social world round-table talks) in 2015 result in any changes? Six major cross-cutting themes were analysed through the lens of social policies, including gender equality. The job and training standards, which define the professions, training and areas of competence of the 14 social work qualifications, were reviewed (421). In 2018 training in France was reorganised via two decrees and six orders⁴⁶ for State diplomas for social service assistants, family social economy counsellors, young child educators, specialised educators, and specialised technical educators.

The common training core includes skills such as analysing demand and needs, assessing a situation, welcoming people, encouraging expression and autonomy, and cross-cutting knowledge such as ethics and values in social work, introduction to the research process, history of social work and its professions. No mention is made of gender or equality between sexes.

At best, today, a few hours about women are included in training centres, but there is still little focus on gender.

Various initiatives do exist, however: some social work training centres are introducing the issue of gender and gender equality into their training programmes, but these initiatives remain sporadic and limited. In fact, there is still no clear incentive in the content of social work qualifications to address issues related to gender or gender equality in social work (see annex 2.1).

An avenue for improvement: taking action by leveraging knowledge

It is the responsibility of universities and training centres to provide students and professionals with the tools they need to ensure they get into the habit of considering sex- and gender-related differences among the people they care for or support, and how gender impacts their actions and organisations.

Medical and nursing research, as well as real-life data collection and analysis need to be mobilised in order to inform the content of training for caregivers on sex-related biological differences, and the importance of considering gender in practice.

Social sciences also need to work on the issue of gender in social work from an operational perspective in order to help raise awareness of the influence of gender and provide tools to help take it into account (422). Academic research needs to be conducted and action research also needs to be mobilised, with the results recorded in order to share good practices, overcoming existing cultural obstacles (linked to professional confidentiality, protection of individuals, the specific characteristics of the person being assisted, etc.).

The aim of the training should be to update perceptions, provide objective and impartial information enabling the removal of bias and a professional rather than personal approach to the debate. Professionals hosting students on work placements must be vigilant about their attitudes towards users, and towards their student colleagues, so as not to perpetuate stereotypes.

⁴⁶ Decree No. 2018-733 of 22 August 2018 relative to social work training and qualifications; Decree No. 2018-734 of 22 August 2018 relative to social work training and qualifications; Order of 22 August 2018 relative to the common core of skills and knowledge in level II social work training; Order of 22 August 2018 relative to the State diploma for specialised educators; Order of 22 August 2018 relative to the State diploma for young child educators; Order of 22 August 2018 relative to the State diploma for social service assistants; Order of 22 August 2018 relative to the State diploma for specialised technical educators; Order of 22 August 2018 relative to the State diploma for family social economy counsellors; Decree No. 2016-74 of 29 January 2016 creating the State diploma in educational and social support (DEAES) qualification.

Finally, training courses should include a common core of knowledge on sex and gender, and educate professionals to talk to and care for intersex and trans people, in order to best respond to their health needs.

Following the information report submitted to the French Senate in 2017, “one of the main challenges for improving our society's awareness of intersex people lies in the training of all the educational and social players who are actually in contact with children and adolescents” (177).

Various awareness-raising and training tools identified during this analysis are provided for information purposes in the annexes to this report (annex 2.1).

Proposals for developing more inclusive public health policy instruments

(proposals aimed at operators)

Broader collection and analysis of sex data in the field of health with the aim of understanding the influence of sex and gender on health

Proposal 5

Mobilise public statistics

Public statistics should make it possible to detect sex or gender-related differences in order to inform public policy and enable their sex-based differentiation. In order to promote the use of these already sex-differentiated data as determinants of health, it would be useful to:

- make data more accessible via open data;
- more systematically show sex-based differentiation in research work, define priorities and a work programme;
- establish coordination of this cross-disciplinary topic, a role that could be taken on by one of the French National Council for Statistical Information's theme-based committees.

Proposal 6

Explicitly consider sex in clinical trials on health products and medical procedures

In order for potential sex-related differences to be better documented, HAS recommends that these differences be considered at every stage in the construction of a research project (in the definition of the project's objectives, in the analysis of the results, and in their presentation). This implies taking into account sex:

- in the prior literature search strategy, which should make it possible to identify the expected differences related to sex and possibly gender;
- in the definition of research questions and hypotheses in order to be able to collect sex-disaggregated data, where relevant;
- in the study population, which should reflect the patients who will be treated, including in paediatric studies.

HAS particularly recommends that ethics committees be especially vigilant in this area. This also requires that all those involved in the research ensure compliance with the rules relating to equal representation of women and men in decision-making structures and research teams.

Finally, HAS recommends that an assessment of the representation of men and women in clinical trials conducted on the national territory be carried out.

Proposal 7

Analyse data

Public statistics data and real-life data should be disaggregated on the basis of sex. Their analysis should go beyond a straightforward presentation in two columns (men/women). If significant differences appear, or if a difference does not appear when it was expected, explanations need to be sought, if necessary through additional studies. In all cases, the result of the analysis should be indicated.

Proposal 8

Evolve initial and continuous training

Be it in the social, medico-social or health fields, initial and continuous training needs to be supplemented in order to integrate sex or gender-related differences, and to tend towards a more global approach to individuals incorporating a gender perspective.

The battle against stereotyping in professional practice needs to begin from the initial training stage.

Proposal 9

Adapt the methodology for drawing up guidelines

Consideration of the sex and gender of individuals in professional practices in the health, social and medico-social sectors should be encouraged by a methodology for the drawing up of guidelines that itself takes these factors into account.

The various issuers of guidelines (institutions, professionals) should define methods for systematically asking whether it is possible that the clinical or social profile, the diagnostic assessment, the care or support might have been different for each user of the healthcare system if they had been of the opposite sex.

Proposal 10

A specific concern for intersex and trans people

A reflection process should be initiated with the communities concerned in order to define one or more set(s) of values for sex and gender that can be used in health-related administrative procedures, in order to be more inclusive, and at the same time preventing the risk of re-identification when using data.

The PMSI database rules which check the compliance of a procedure or a stay against the sex of a user (in order to avoid input errors) should no longer be blocking when the coding actually corresponds to the patient's circumstances.

Intersex and trans people should not be automatically excluded from clinical trials.

Conclusion

Sex- and gender-related issues cut across all fields of health: medical, social and medico-social. All health-care players - and, more broadly, society as a whole - need to be aware of these issues. It is for this reason that HAS focuses on this in its first proposal: improving overall health requires a greater awareness that women's health is not limited to reproductive issues; that men's excess mortality up to the age of 65 should not be seen as inevitable; that the health of intersex people is not limited to sex reassignment operations; and that the health of trans people is not limited to sex transitioning issues. This awareness is a prerequisite for all the other changes recommended by HAS in this report.

Analysis through the prism of sex and gender reveals a complex overlapping of determinants of health, between biological differences and the influence of social roles on the health of individuals. Without advocating that the consideration of sex and gender should take precedence over other determinants or that it should be systematic, this report proposes ways of improving public policies and tools in order to make them more inclusive with regard to all the dimensions of sex and gender, and to improve knowledge and consideration of these issues by all players, in particular politicians, professionals and associations.

Through the observations and proposals made in its prospective analysis report, HAS envisages possible and desirable changes to our healthcare system. It identifies a variety of actions that may serve as inspiration for all stakeholders. Beyond the specific theme of this report, the question of sex and gender in health inevitably raises the broader question of the extent to which differences between individuals are taken into consideration in the field of health. Age, ethnic origin, a life course involving precariousness in its various forms and many other biological and social determinants could usefully be more effectively taken into account in order to improve our health system. These parameters cannot be overlooked when it comes to health. Consequently, the associated data need to be analysed and then mobilised more extensively. In this sense, these proposals concerning sex and gender may constitute a relevant starting point for a broader reflection process on the recognition and consideration of differences by the French health system.

As a public authority, HAS makes a commitment

From today

- HAS will bring to the table the concerns arising from this report in the national, European and international bodies in which it participates.

In the short term

- Make sex- and gender-related issues in the field of health one of the priorities in the training programme for HAS officers.
- Encourage manufacturers to take on board the issue of women/men representation, by raising awareness during the early dialogue process and requesting these data in the post-registration studies. HAS will make this a systematic consideration in its assessments.
- In the context of requirements relating to the representativeness of training and test bases for artificial intelligence that HAS has already formulated, the relevance of the sex ratio needs to be documented.
- HAS will continue to seek balanced women/men representation in its committees and working groups.

In the medium term

- Integrate sex- and gender-related issues into HAS's methodological guidance documents and working methods (literature search, sex and gender analysis of the studies used in its work, reporting in publications, evidence reports or opinions), without systematically producing differentiated conclusions.
- HAS will monitor the impact of its commitments on its work and will review progress in its activity report.

In the long term

- Take into account sex and gender differences in its next strategic project in the broader context of the fight against inequalities.

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Annex 1. Summary of epidemiological findings – Situation of women and men in France

| Indicators | Women | Men | Difference or ratio W/M | Year of reference | Source, year of publication (reference) |
|--|---|---|-------------------------|-------------------|---|
| DEMOGRAPHY | | | | | |
| Total Population | 33 450 613 | 31 361 439 | 2 089 174 | 2018 | INSEE, 2019 (1); INED, 2018 (7) |
| under 20 | 7 543 914 | 7 901 395 | - 357 481 | | |
| from 20 to 64 years old | 18 436 179 | 17 797 310 | 638 869 | | |
| 65 years or older | 7 470 520 | 5 662 734 | 1 807 786 | | |
| Life expectancy at birth | 85.3 years (+ 1 year/2008) | 79.4 years (+ 1 year et 10 months/2008) | 5.9 years | 2018 | INSEE, 2019 (1) |
| Disability-free life expectancy | 64.5 years (stable/2008 -0.5 months/2017) | 63.4 years (+ 8 months /2008 +10 months/2017) | 1.1 years | 2018 | INSEE, 2019 (1) |
| Share of years lived without a disability | 75% | 79% | - 4 pts | 2018 | DREES, 2019 (2) |
| MORTALITY | | | | | |
| Number of deaths of which are premature deaths | 290 304 32 918 | 288 926 65 273 | 1.004 2 | 2016 | Boulat <i>et al.</i> , 2019 (75) |
| Deaths from non-communicable diseases | 445.4 | 743.5 | 1.7 | 2016 | Boulat <i>et al.</i> , 2019 (75) |
| Of which cardiovascular diseases | 156.2 | 252.7 | 1.6 | | |
| of which cancers | 128.8 | 347.4 | 2.7 | | |
| Death by violent death | 33.4 | 74.8 | 2.2 | 2016 | Boulat <i>et al.</i> , 2019 (75) |
| Deaths from communicable diseases | 11.7 | 18.4 | 1.6 | 2016 | Boulat <i>et al.</i> , 2019 (75) |

| Indicators | Women | Men | Difference or ratio W/M | Year of reference | Source, year of publication (reference) |
|--|--------|--------|-------------------------|-------------------|---|
| SOCIO-ECONOMIC DATA | | | | | |
| Schooling at the age of majority | 79% | 77% | + 2 pts | 2017 | Ministère de l'Éducation nationale, 2019 (41) |
| Average net monthly salary in the private sector (euros) | 1 986 | 2 238 | 18% | 2015 | INSEE - Berger <i>et al.</i> , 2017 (56) |
| Evolution of purchasing power linked to the average salary (1997-2015) | + 20% | +8% | 2.5 | 2019 2018 | CEREQ - Couppié <i>et al.</i> , 2018 (423) |
| Share of active part-time workers | 30.4% | 7.9% | 3.8 | 2015 | INSEE - Collet et Rioux, 2017 (424) |
| Homeless population | 38% | 62% | 1.6 | 2012 | INSEE - Yaouancq <i>et al.</i> , 2013 (149) |
| Of which are homeless | 5% | 95% | 19 | | |
| Of which have collective overnight accommodation | 9% | 91% | 10.1 | | |
| Of which have collective accommodation night & day | 36% | 64% | 1.8 | | |
| Including hotel | 63% | 37% | 1.7 | | |
| SMOKING | | | | | |
| Prevalence of daily smoking 18-75 years | 22.9% | 28.2% | 1.2 | 2017 | Andler <i>et al.</i> , 2019 (55) |
| ALCOHOL USE | | | | | |
| Frequency in the last 12 months 18-75 years | | | | 2017 | Richard <i>et al.</i> , 2019 (60) |
| Lifetime abstinence | 6.9% | 3.9% | 0.6 | | |
| Yearly abstinence | 9.4% | 6.7% | 0.7 | | |
| < once per month | 36.2% | 17.7% | 0.5 | | |
| Less than once/month and less than once/week | 19.5% | 19.1% | 1.0 | | |
| 1 to 2 times/week | 20.3% | 29.8% | 1.5 | | |
| 4 to 6 times/week | 2.6% | 7.6% | 2.9 | | |
| Everyday | 5.1% | 15.2% | 3.3 | | |
| Significant occasional alcoholism in the last month | 38% | 49% | 1.3 | 2017 | Richard <i>et al.</i> , 2019 (60) |
| Estimation of deaths attributable to alcohol | 11 000 | 30 000 | 2.7 | 2015 | Bonaldi et Hill, 2019 (63) |

| Indicators | Women | Men | Difference or ratio W/M | Year of reference | Source, year of publication (reference) |
|--|-------|-------|-------------------------|-------------------|--|
| ILLICIT PSYCHOACTIVE SUBSTANCES | | | | | |
| Cannabis Experimentation | 37.2% | 52% | 1.4 | 2017 | OFDT - SPF - Spilka <i>et al.</i> , 2018 (64) |
| Regular use | 1.8% | 5.4% | 3 | | |
| Cocaine (experimentation) | 3.2% | 8% | 2.5 | | |
| Heroine (experimentation) | 0.5% | 2.1% | 4.2 | | |
| NUTRITION DISORDERS | | | | | |
| Adults aged 18-74 % overweight or obese (BMI ≥25) | 44 | 54 | 10 pts | 2015 | SPF - Étude ESTEBAN, 2018 (68) |
| % of obesity (BMI ≥30) | 17 | 17 | 0 pts | | |
| SEXUALLY TRANSMITTED INFECTIONS | | | | | |
| Discovery of seropositivity | 2 131 | 4 024 | 1.9 | 2018 | SPF, 2019 (109) |
| % chlamydia trachomatis infections | 60 | 40 | 1.5 | 2017 | SPF, 2019 (109) |
| % gonococcal infections | 26 | 74 | 3 | 2017 | SPF, 2019 (109) |
| % syphilis infections | 5 | 95 | 19 | 2017 | SPF, 2019 (109) |
| MENTAL HEALTH | | | | | |
| Depression declared in the last 12 months in population aged 18-75 | 13% | 6.4% | X2 | 2017 | Baromètre Santé - Léon <i>et al.</i> , 2018 (91) |
| Major depression 14+ years | | | 2.3 | 2011 | Witthen <i>et al.</i> , 2011 (88) |
| Bipolar disorders 18-65 years | | | 1.2 | | |
| Anxiety disorders 14+ years | | | 2.5 | | |
| Anorexia 14-65 years | | | 4.5 | | |
| Bulimia 14-65 years | | | 8 | | |
| Psychotic disorders 18+ years | | | 0.8 | | |
| Alcohol dependence 15+ years | | | 0.3 | | |
| Dementia 60+ years | | | 1.6 | | |
| Self-reported suicide attempts (18-75 years old) | 9.9% | 4.4% | 0.4 | 2017 | Baromètre Santé publique France - Léon <i>et al.</i> , 2019 (86) |
| Number of suicide deaths | 2 014 | 6 566 | 3.2 | 2016 | SPF - CépiDc, 2019 (77) |

| Indicators | Women | Men | Difference or ratio W/M | Year of reference | Source, year of publication (reference) |
|--|-------|-------|-------------------------|-------------------|---|
| CARDIOVASCULAR DISEASES | | | | | |
| Impact of smoking on the occurrence of the first heart attack (in years in advance per non-smoker) | 13.7 | 6.2 | 2.2 | 2009 | Grundtvig et al., 2009 (83) |
| LIFE WITH CANCER | | | | | |
| Memory disorders declared 5 years after diagnosis | 70.5% | 61.1% | 1.2 | 2018 | INCa - VICAN 5, 2018 (120) |
| Employment retention 5 years after diagnosis | 82.8% | 74.3% | 1.1 | 2018 | INCa - VICAN 5, 2018 (120) |
| Use of social support | 17.7% | 8.7% | 2 | 2018 | INCa - VICAN 5, 2018 (120) |

Annex 2. Toolkit to help take into account sex and gender in health

This appendix describes tools to help integrate sex and gender both in public health policies (health and social welfare) and in the design of instruments necessary for their operational implementation. Not intended to be exhaustive, the toolkit does provide an overview of the type of resources available.

These tools have neither been tested nor validated by the HAS (which is not directly concerned by all fields of application). They are cited for information and supplement available scientific reports and publications.

2.1. Tools to improve the knowledge base on the importance of taking into account sex and gender

Awareness-raising and knowledge-sharing

INSERM conducted an awareness campaign among the general public and organized an international symposium on the theme “Sex and gender in health research: an innovative approach” which represent two examples of tools designed to improve the knowledge base of all audiences on sex and gender issues in health.

The knowledge base dissemination tools provided by the Émilie du Châtelet Institute (IEC) are more interdisciplinary and combine human sciences, social sciences and biomedical sciences.

The Hubertine Auclert Center⁴⁷ offers a series of videos which aims to explain in 3 minutes often complex notions such as gender or sexism, or victims with preconceived ideas.

Finally, the French Equality Lab provides information on gender equality and conducts awareness campaigns.

In 2016, the EASE Gender Policy Committee drawn the SAGER (Sex And Gender Equity in Research) Guidelines, a comprehensive procedure to improve information on sex and gender in scientific publications, whatever the discipline and stage of research. (294).

⁴⁷ The Hubertine Auclert Center is the Ile-de-France center for gender equality. It contributes, with all of its members, to the fight against inequalities and discrimination based on sex and gender and promotes equality between women and men.

According to these guidelines:

- authors should use the terms “sex” and “gender” with caution, without confusing the two terms;
- when the research topics relate to organisms capable of differentiating by sex, the research should be designed and conducted in a way that may reveal gender differences in the results, even if they were not initially expected;
- where subjects can also be differentiated by gender, research should be conducted in such a way as to consider this additional level of distinction.

To assess the quality of the integration of sex and gender in health research proposals, a tool was published in 2016 for researchers who prepare research protocols, but also for peer-reviewers who evaluate research (323).

Training

The Hubertine Auclert Center offers a range of training courses to develop local equality policies, end violence against women, educate about equality, and strengthen associative development in favour of gender equality.

These training courses are aimed at local elected officials, facility directors, associations, professionals and volunteers.

In Canada, the National Institute of Public Health of Quebec has set up free training “Sex, gender and sexual orientation: understanding diversity” (level 1) and “Adapting our interventions to the realities of people of sexual diversity, their couple and their family” (level 2), intended for staff and stakeholders in health and social services, education and public or community services.

Additionally, the Institute of Gender and Health (IGH) of Canada created online resources to foster excellence in research and its application with regards to the influence of gender and biological sex on health.

Training modules are available online, in French, on the Canadian Institutes of Health Research website:

- “Why integrate sex and gender in research?”;
- “Sex and gender in biomedical research”;
- “Sex and gender in the collection of primary data in humans”;
- “Sex and gender in the analysis of secondary data from human subjects”.

The Regional Center for Training in Social Trades (CRFMS - ERASME) located in Toulouse has been offering a required “Gender and social work” module for several years in training specialist educators (the module was optional up until 2007) (425).

We can also mention the document “Gender and social work: for the promotion of the gender approach in social work training” of the Saint Simon Institute (CFA professions in social work) (426), and the training of “Gender and sexual health” in supportive social work, especially for young people, organized by the Bouches-du-Rhône family planning.

In France, there are various university training courses intended for health professionals and / or those in social welfare:

- degree from the University of Paris-Diderot “Gender practices: education, medicine, psychoanalysis and society”.
- degree from the Sorbonne University School of Medicine, and the inter-university program between the universities of Paris-Diderot, Lyon-Claude Bernard, Aix-Marseille-Méditerranée, and Bordeaux-Segalen offer a degree in the management of trans-identity.

In medicine, variations in sexual development are most often taught in paediatric endocrinology curriculums (more or less focused on reproduction), such as the program offered by the University of Paris-Saclay, in collaboration with the French Society of Paediatric Endocrinology and Diabetology.

The Montreal Institute for the Health of Sexual Minorities has a wide range of training courses for professionals working with trans people, including several modules such as “Towards a comprehensive approach to the health and well-being of transgender, non-binary and creative people of the like” (online, paid).

The Interministerial Delegation for the Fight against Racism, Anti-Semitism and Anti-LGBT Hate (DILCRAH) provides a practical sheet on respecting the rights of trans people. It is particularly aimed at all administrations, including public service schools to optimize the welcoming of trans personnel and users (427).

The advice booklet “Variations in genital development” developed by an English team (adapted and translated for France by reference centres in Lyon and Paris) is intended for parents whose child was born with unusual genitalia (428).

The “Collectif Intersexes et Allié.e.s”, a French association by and for intersex people, provides numerous online educational resources and data on intersex and variations in sexual development on its website. It is part of the Organization Intersex International (OI).

Many other French associations offer brochures and training-awareness workshops around trans-identities for trans people, medical, paramedical, social professionals, companies, or associations (the associations OTrans and Chrysalide are examples among others).

There are also many documentary resources that allow one to deepen his/her knowledge base.

There is also training offered in specific fields, for example an e-learning (paid) called “Gender in the Age of Pandemics: Understanding Health Crises and Planning Gender Responses” from the Graduate Institute Geneva (in French or in English depending on the session).

Referenced tools

Centre Hubertine Auclert: www.centre-hubertine-auclert.fr

Centre régional de formation aux métiers du social - ERASME: www.erasme.fr
(see « éducateur spécialisé » page)

Chrysalide (association): www.chrysalide-asso.fr (see the « nos-documents » page)

Collectif Intersexes et Allié.e.s - OII France: cia-oii.france.org

Faculté de médecine - Sorbonne université: medecine.sorbonne-universite.fr

Graduate Institute Geneva: www.graduateinstitute.ch/genderp

Institut Émilie du Châtelet: www.institutemilieduchatelet.org

Institut national de la santé et de la recherche médicale:
www.inserm.fr/information-en-sante/dossiers-information/genre-et-sante
(dossier d’information « Genre et santé »)

Institut national de santé publique du Québec: www.inspq.qc.ca/formation

Institut pour la santé des minorités sexuelles de Montréal: fr.ismh-isms.com/ateliers/

Institut Saint Simon - CFA métiers du travail social: institutsaintsimon.com

Instituts de recherche en santé du Canada: cihr-irsc.gc.ca/f/8673.html

Laboratoire de l’égalité: www.laboratoiredelegalite.org

OTrans (association): outrans.org

Planning familial des Bouches-du-Rhône: www.leplanning13.org

Société française d’endocrinologie et diabétologie pédiatrique: www.sfedp.org

Société française d’études et de prise en charge de la transidentité: www.sofect.fr

Université Paris-Saclay: www.universite-paris-saclay.fr

Université Paris-Diderot: www.ep.univ-paris-diderot.fr (see « diplômes d’université »)

2.2. Tools to better integrate gender in the design of public policies

The Hubertine Auclert Center published a first guide on the merits of local policies in gender equality, for public agents and elected officials of local authorities to promote and disseminate a culture of equality (431). In 2014, the center published a second guide on planning, conducting and evaluating a local policy on gender equality (232). This guide provided a methodological approach and tools to implement a local gender equality policy: from initial diagnosis to monitoring and evaluation, including the definition of the action plan.

If such an approach is conceived within the framework of local policies, it can constitute an interesting inspiration at the regional and national levels. Likewise, the city policy sector must be able to inspire health policies in the mobilization of tools, such as self-diagnosis grids designed to assess the compliance of local actors with each field of the the European charter for equality of women and men in local life (232) (432).

Referenced tools

Centre Hubertine Auclert: www.centre-hubertine-auclert.fr
Haut conseil à l'égalité entre les femmes et les hommes: www.haut-conseil-egalite.gouv.fr

2.3. Tools to promote the representation of women in the scientific community

The creation of peer-to-peer networks for women in the research community

To promote women's access to research professions, several countries and organizations have tried to organize the structuring of learning and solidarity between peers in the sector. Two main tools can be used with such an aim:

- the creation of mentoring programs for young researchers by women with more experience in the field. A think tank from the French Ministry of Higher Education proposed in 2018 the establishment of a more in-depth mentoring at key career stages (ex. preparation for accreditation to supervise research) (433). Actions of this type are implemented by the Association Femmes et sciences;
- the constitution of regional or national networks of women engaged in research to coordinate large-scale work and encourage peer support through the network. These networks are widely acclaimed by the WHO, which finances, for example, their establishment by public research organizations in several African countries.

Mobilization of training actors

Encouraging young women to pursue careers in research, and science in general, is an important step towards achieving greater diversity in the field as well as a more balanced consideration of sex and gender.

The "Femmes et sciences" association also works in this field by organizing conferences, actions in schools, actions towards institutions and decision-makers ...

The lever of training is highlighted by the pact for egalitarian artificial intelligence between women and men (on the "Laboratoire de l'égalité" website).

Financial mechanisms to remove obstacles to the involvement of women in research

The think tank of the Ministry of Higher Education and Research proposed the idea of a game on the financing of certain costs to remove obstacles that prevent women participation (433). For example, in view of the weight of family life, which is even more important for women than for men on average, it is proposed to set up support systems for childcare costs, on the example of a mechanism in place at INSERM.

Referenced tools

Femmes et sciences (association): www.femmesetsciences.fr
Laboratoire de l'égalité: www.laboratoiredeegalite.org
Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation: www.enseignementsup-recherche.gouv.fr/pid38153/egalite-et-lutte-contre-les-discriminations.html
Organisation mondiale de la santé: www.who.int/tdr/capacity/gender/en/
(liste des projets financés)

2.4. Tools to improve the consideration of sex and gender in clinical research

A methodology to guide each stage of a research project

Stanford University makes available on its website "Gendered innovations in Science, Health and Medicine, Engineering and Environment", a list of methods allowing the analysis of gender and sex at each stage of research and provides some examples to apply these methods in the medical field.

Other tools are also available: we can cite the checklist established by the university to carry out a step-by-step follow-up of research projects in terms of taking sex and gender into account:

- determining the importance of sex and gender in the project;
- literature review;
- formulation of questions and hypotheses;
- preparation of the research method and data analysis;
- interpretation of data;
- writing of results;
- production of conclusions and recommendations.

This checklist contains both the principles of reflection for each phase of the project and their operational variation, and outlines what to do but also pitfalls to avoid.

In Canada, CIHR requires teams applying for funding to incorporate sex and gender into their research plan, where applicable. To facilitate this integration, they provide a large documentary base (videos, official reports, scientific articles, etc.) and propose a methodology for taking sex and gender into account at each stage of this plan.

Mechanisms for including sex and gender in literature research and analysis

An effective literature search strategy is essential to be able to integrate gender and sex into research. For example, the Texas Tech University Health Sciences Center developed and validated a PubMed literature search tool on sex and gender health. This is readily and freely available to clinical researchers and practitioners (316, 434).

Guides to strengthen the requirements of research evaluators

For those seeking an NIH grant, a guide intended for evaluators was published in 2015 by the NIH: it makes it possible to verify that sex has been correctly integrated as a biological variable in research relating to vertebrate animals and humans. The guide is presented as a series of questions to determine that sex and gender are considered. Failure to take sex into account is encouraged to be seen as a study weakness, particularly if not justified.

The CIHR College of Reviewers in Canada also established criteria to consider sex a strength of the research project:

- clear indication of the presence or absence of sex-related differences in the subject under investigation;
- recruitment of women and men in good proportion if the subject of the search concerns both sexes;
- documentation and analysis of the sex of cells used in the protocol;
- disaggregation of results by sex;
- review of pre-existing knowledge on gender differences in the field of study.

In addition, it is specified that the concepts of sex and gender should not be dissolved into each other, which would constitute a weak point in the study evaluated.

Referenced tools

Texas Tech University Health Sciences Center: www.sexandgenderhealth.org

Instituts de recherche en santé du Canada: cihr-irsc.gc.ca/f/50836.html

National Institutes of Health – Central resource for grants and funding information: grants.nih.gov/policy/peer/index.htm
(Reviewer Guidance to Evaluate Sex as a Biological Variable)

Université de Stanford - Gendered innovations in Science, Health and Medicine, Engineering and Environment: genderedinnovations.stanford.edu

2.5. Tools to improve the inclusion and representation of populations in clinical trials

Targeting specific populations

Several ways to target specific populations, for instance women or other smaller groups, have been implemented locally or nationally in the United States:

- in 2016, an awareness campaign to encourage women to participate in clinical trials was carried out in the United States by the FDA women's health office ("Women in clinical trials - Make a difference for yourself and for women like you") (207);
- another example is the use of the Illinois Women's Health Registry as a platform for connecting clinical trial sponsors with women (320). The Women's Health Research Institute (WHRI) also offers many other resources to educate stakeholders about the importance of including sex in all biomedical sciences, to promote research that explores the differences between sexes.

A study evaluated and compared the effectiveness of several styles of advertising on websites or social media as recruiting tools for studies. Participants' analysis of iconography, text, and style identified the need for visible representation, and the usefulness of personalized campaigns rather than a blanket campaign (274).

Forms more suited to the diversity of situations

The HIV vaccine trials network (HVTN) revised its forms according to the principles of the two-step method (biological sex on the one hand, gender identity on the other) (274). The answer choices are listed in alphabetical order, for sex on the one hand and gender on the other hand, with an "Other" box, as well as a possibility to not answer for those fearing repercussion. In this form, the sex is that declared at birth, with the possibility of intersex.

Within a toolbox set up by a center on clinical trials (Multi-regional clinical trials Center of Birgham and Women's hospital and Harvard) managed by Harvard University to achieve a sufficient degree of diversity and equity in clinical trials there is a series of elements to make clinical trials inclusive of different minorities. The idea of more comprehensive forms and two-step identification is included, alongside a recommendation to let the participant determine and indicate their gender identity themselves (436, 437).

Methods to promote the literacy of participants for clinical trials that take into account gender identity

To ensure better inclusion of under-represented people in trials and clinical studies, it is also necessary to develop tools to make health issues more understandable. The WHO European region, for example, established in 2019 an action network on health literacy for the prevention and control of NCDs. The challenges related to literacy go well beyond sex and gender, but these two factors show the complexity of its implementation and thus invite its strengthening.

Health literacy is identified as a clinical trial issue by the Harvard University Clinical Trials Center, to better integrate minorities including those related to sex and gender. The "Health Literacy in clinical research" platform offers many tools to make clinical research clearer and more accessible. It invites researchers to establish "two-way" exchanges with participants to let them develop their individual characteristics, in particular their gender identity, which allows professionals to adapt their discourse depending on what can be best understood.

In the same vein, NIH set up listening sessions in the United States for LGBTQI people, with the support of several research centers and local associations. These sessions, carried out with limited staff, can enable the people concerned to communicate their health priorities, to strengthen their proximity to the area of research and to improve the understanding of communities by research teams.

Referenced tools

Community compass: www.hvtn.org/en/community.html
(HIV Vaccine Trials Network, rubrique Community)

Food and Drug Administration:
www.fda.gov/consumers/womens-health-topics/women-clinical-trials

HIV vaccine trials network: www.hvtn.org/en/community/community-compass.html

Multi-regional clinical trials Center of Birgham and Women's hospital and Harvard:
mrctcenter.org/resources
(Projets Diversity, Inclusion, and Equity in Clinical Trials et Health literacy in clinical research)

National Institutes of Health (Sexual & Gender Minority Research Office):
dpcpsi.nih.gov/sgmro/listening-session

Organisation mondiale de la santé (regional office for Europe):
www.euro.who.int/en/health-topics/disease-prevention/health-literacy

Women's Health Research Institute (Northwestern University):
www.womenshealth.northwestern.edu

2.6. Tools to improve the consideration of sex and gender in guidelines

Methodological guides aiming to develop guidelines taking into account sex, or even gender

Various institutional methodological guides for developing guidelines were identified during the work related to this report. They are listed below.

The Scottish Intercollegiate Guidelines Network (SIGN) updated in 2019 its methodological guide called "A guideline developer's handbook" (351).

The Scottish Guide specifically includes gender and sexual preferences (sex, gender reassignment, sexual orientation), but not gender in the definition of the target population that the literature search should cover. The authors stress that when questions are of clinical importance, they should be answered, even though it is not believed that there will be good evidence. These possible gaps in the evidence base will make it possible to prioritize future research projects. They go even further with the notion of equity, demanding that any subgroup ("specific social and minority groups") with special needs in relation to the subject of the study (or for which any evidence of differences in the effectiveness of interventions is highlighted) is taken into account specifically within the patient population.

The National Institute for Health and Care Excellence (NICE) updated its manual (352), and its list of key principles for developing guidelines, in 2018 and 2020 respectively.

These principles especially include the ethical principles and values that guide the decisions of their advisory committees (227). One of them is to seek to reduce health inequalities through guidelines, including gender inequalities, or at least not to widen existing gaps. Another principle is to consider whether it is appropriate to make specific guidelines for different groups of people. NICE restricts this possibility to cases with sufficient evidence that the effectiveness or efficiency of an intervention is superior for a given subgroup, or where a legal obligation requires it, or where there are other reasons relating to equity for society as a whole.

The World Health Organisation (WHO) introduced in 2014, within the second edition of its guide to developing guidelines, a chapter specifically dedicated to the importance of considering equity, human rights, gender and social determinants of health in the formulation of guidelines ("Handbook for guideline development" (353)). Thus, from now on according to WHO, from the start of any project and throughout its development (including its publication and update), the following questions shall be asked:

- is there a possible impact of the guidelines on equity, human rights and gender inequalities?
- is it relevant to consider sub-groups in the key questions for developing guidelines?

One of the entry points proposed in the WHO guide concerns the analysis and the strategies to be put in place to address sex and gender issues. The guide stresses the importance of being mindful of gender identities that do not fit into binary patterns of feminine and masculine. Contributors can use some tools, such as a gender-specific analysis matrix and rating scale (439), to examine the extent to which the interventions evaluated address these issues.

In addition, good practice guides should promote gender equality both in procedures and in the organization of programs and services.

The WHO guide also addresses the subject of language to be used which should not be stigmatizing, as well as questions of adaptation, implementation and evaluation of guidelines which must take into account sex and gender.

Developing recommendations with particular attention to the targeted population

The "Grading of Recommendations Assessment, Development and Evaluation" working group (abbreviated GRADE) has developed a five-step approach to assess the quality of the available evidence and the strength of health recommendations (440).

This method makes it possible, especially through a precise definition of the population of interest (PICO questions), to properly take into account sex and gender (359, 441). The PICO framework requires attention to four elements:

- P: the patients or the population to whom the recommendations are supposed to apply;
- I: the therapeutic, diagnostic or other intervention under study (for example, the experimental intervention or, in observational studies, the exposure factor);
- C: comparison with the alternative intervention or with the control group;
- O: the outcome.

In the development of recommendations, defining the "P", the target population, is a crucial step. The PICO framework helps to ensure that recommendations usefully cover specific groups of patients.

This questioning could also usefully be associated with other methods of developing recommendations besides the GRADE method, in terms of integrating sex and gender issues.

Including the specificities of the study population through adapted systematic literature reviews

The Cochrane Library and the Campbell Collaboration produce and disseminate systematic reviews of the literature. Both are international, non-profit and independent organizations. The Campbell and Cochrane “Equity Methods” Group encourages authors of systematic reviews to explicitly describe the potential effect of health interventions, not only on society as a whole, but also according to sex and to the social gradient (including disadvantaged and marginalized subpopulations).

They issue tools for producers and users of systematic reviews.

They have specifically published recommendations and a checklist for authors of systematic reviews wishing to take an interest in health equity (442-444).

According to this group, health equity can be considered in the following ten steps of the systematic review process (444):

1. defining a conceptual approach to health equity;
2. developing a theoretical approach which can include an analytical framework that identifies health equity as an outcome;
3. formulating health equity questions;
4. including relevant study designs for assessing health equity issues;
5. identifying sources of information for health equity issues;
6. defining search terms for health equity issues;
7. developing data mining tools for health equity;
8. assessing the influence of context and process on health equity outcomes;
9. using synthetic approaches to assess the effects on health equity;
10. collecting data on applicability and fairness.

The checklist for authors itself contains about thirty points (443), some of which refer to the PICO framework described above.

Considering that improved knowledge about gender differences is shifting medical practice from a universal approach to a more individualized process, the team of Tannenbaum et al. (289) proposes a systematic approach aiming to analyze the quality of evidence in the literature, and to assess whether sex-specific recommendations are to be made.

The authors highlight various challenges to be met in order to implement such an approach:

- **terminology:** a confusion often exists between the terms sex and gender, which raises the concern of how the data was collected and which subgroups were formed in the analyses;
- **the documentary research** raises another problem: the guides and guidelines for good clinical practice do not include sex or gender specific terminology in the search strategy, which potentially leads to the omission of important sources of evidence for the different sub-groups. Song et al. (316) proposed a standardized strategy to cover all the publications addressing diagnosis or treatment specifically according to sex (female-male);
- **the representation of subgroups in the study population** can also be a barrier to the development of sex or gender based guidelines. It is indeed necessary to assess whether one of the groups is over-represented or under-represented (this criterion is used by the Food and Drug Administration for men and women). Efficacy results and adverse events, for example, should also be reported by sex, and by gender where possible;
- **statistical power**, which refers to the probability of detecting a statistically significant difference between two subgroups, implies to ask the question beforehand. Otherwise, multivariate analyses are necessary to take into account other variables such as age or comorbidities.

A reading grid for guidelines

Taking into account the differences between women and men in the guidelines: draft reading grid developed during the “Women and health” day, organized by the HAS in November 2013 (350).

Step 1: selection

- Q1.1: Is the gender balance respected in the choice of subjects?
- Q1.2: Does the choice of subject respond to priority public health concerns?

Step 2: framing

- Q2.1: Has the relevance of sex or gender-based differentiation criteria been established, particularly in terms of needs, preferences and impacts?
- Q2.2: Are the working groups balanced and representative?

Step 3: realization

- Q3.1: Do the collection of qualitative and quantitative data and the collection of bibliographic information make it possible to trace the differences between women and men?
- Q3.2: Do the conclusions of this work have differentiated consequences?
- Q3.3: will they modify therapeutic relationships, or even social relationships?

Step 4: diffusion

- Q4.1: Does the presentation of conclusions allow for differentiation or, on the contrary, to ensure neutrality between women and men?
- Q4.2: Does the dissemination strategy consider any possible differences between women and men? (to remind healthcare professionals to be vigilant)
- Q4.3: Are research perspectives on differences between women and men documented?

Referenced tools

Campbell and Cochrane Equity Methods Group: equity.cochrane.org

GRADE working group: www.gradeworkinggroup.org

Haute Autorité de santé (journée « Les femmes et la santé », in French):
www.has-sante.fr/jcms/c_1650986/fr/journee-has-les-femmes-et-la-sante-paris-14-novembre-2013

National Institute for Health and Care Excellence:
www.nice.org.uk/about/who-we-are/our-principles

Scottish Intercollegiate Guidelines Network: www.sign.ac.uk/our-guidelines

World Health Organization: www.who.int/gender-equity-rights/en

Annex 3. Specific works conducted by HAS for this report

3.1. Analysis of clinical trials submitted to HAS by pharmaceutical and medical device companies to request reimbursement by the community

Analysis of clinical trials submitted to HAS by pharmaceutical companies

A Descriptive analysis of the studies in the preparatory documents analyzed by HAS's Transparency Committee, which is competent to assess medicinal products for inclusion onto the list of reimbursable medicines.

Methods: retrospective analysis of the preparatory documents analyzed by the French Transparency Committee according to a complete procedure from January 8, 2020 to February 19, 2020, which corresponds to four meetings of the Transparency Committee.

During these four sessions, 25 cases were presented for the full investigation procedure, and 49 trials were analyzed.

Trials in which the percentage of males was greater than 65% corresponded to the following:

- DOVATO (dolutegravir/ lamivudine) (two trials: 90% vs 10% and 85% vs 15%): this percentage can be explained by the fact that approximately 70% of men are HIV positive;
- LIBTAYO (cemiplimab) (83.3% vs 16.6%): this percentage is explained by the fact that cutaneous squamous cell carcinoma affects about twice as many men as women;
- BAVENCIO (avelumab) (73.9% vs. 26.1%): this percentage is explained by the fact that Merkel cell carcinoma affects men more frequently than women, in the order of 60%;
- NASACORT (triamcinolone) (66% vs 34%): this percentage cannot be explained because women are normally more frequently affected by allergic rhinitis;
- TROGARZO (ibalizumab) (two studies: 85% vs. 15% and 86.8% vs. 23.2%): this percentage can be explained by the fact that men represent 70% of HIV-positive people in France.

Trials in which the percentage of women was greater than 65% corresponded to the following:

- VABOREM méropénème / vaborbactam) (66.2% vs. 33.8%): this percentage is explained by the fact that women are more affected than men by complicated urinary tract infections, including pyelonephritis;

- ZYNTEGLO (bétibéglogène autotemcel) (two trials: 70% vs. 30% and 70.6% vs. 29.4%): this percentage cannot really be explained because women are affected as much as men by beta thalassemia;
- CUFENCE (trientine dichlorhydrate) (67.3% vs. 32.7%): this percentage is not really explained because women are as affected as men by Wilson's disease;
- CALIVA (obeticholic acid) (92% vs 8%): this percentage can be explained by an M / F ratio of 1/10 for primary biliary cholangitis.

It is important to stress that the applications submitted could include several trials, some of which with a representation of women and men closer to the target population.

Analysis of clinical trials submitted to HAS by medical device companies

Descriptive analysis of the trials submitted by the applicants for evaluation to HAS's National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS).

Methods: study carried out prospectively between January 20 and February 20, 2020 on the files analyzed by the HAS service providing the scientific secretariat of the CNEDiMTS.

In total, 26 files (66 studies) were analyzed without prejudice to the subsequent mode of investigation of the file in committee (investigation in full procedure or in simplified procedure).

The studies in which the percentage of males was greater than 65% corresponded to the following records and pathologies:

- THORAFLEX HYBRID (a 71% vs 29% trial): management of aortic dissections;
- EDWARDS SAPIEN 3 (a 69.3% vs 30.7% trial): management of aortic valve stenosis;
- OPTIMIZER SMART (four trials: 76% vs 24%; 94% vs 6%; 79% vs 21%; 76% vs 24%): management of advanced chronic heart failure (NYHA class \geq III and $25\% \leq$ LVEF \leq 45%), insufficiently controlled by optimal medical treatment;
- IMPELLA CP & IMPELLA 5.0 (21 trials or non-comparative case series with sex ratios between 65 and 85%): management of cardiogenic shock refractory to optimal medical treatment occurring following cardiac surgery or a myocardial infarction (MI);
- ACTIVA RC (a 66.7% vs 33.3% trial): treatment of the symptoms of idiopathic Parkinson's disease, when a certain functional discomfort appears despite optimized drug treatment;
- ORSIRO & ORSIRO MISSION (five trials 76% vs 24%; 72% vs 28%; 77% vs 23%; 74.7% vs 25.3%; 71.6% vs 28.4%): acute coronary syndromes;
- TITAN OPTIMAX (four trials 75% vs 25%; 76% vs 24%; 76% vs 24%; 77.5% vs 22.5%): management of acute coronary syndromes;
- XPRESS (a 66% vs 34% trials): management of uncomplicated chronic rhino-sinusitis, after failure of optimal medical treatments;
- Trials in which the percentage of women was greater than 65% corresponded to the following:
- DERIVO & SILK (two trials 83% vs 17%; 79% vs 21%): management of unruptured intracranial aneurysms with risk of spontaneous rupture greater than the risk associated with the embolization procedure;
- VISMED GEL MULTI & HYLOVIS GEL MULTI (a 87.7% vs 12.3% trial): symptomatic treatment of dry eyes with keratitis or keratoconjunctivitis sicca in third line after failure of low viscosity tear substitutes and gels;
- SPYSCOPE DS & SPYSCOPE DS II (a 68% vs 32% trial): treatment of complex gallstones and pancreatic stones when other endoscopic treatments have failed.

3.2. Details of responses to the HAS survey of medical students and interns

As explained in this report (see chapter 3.5.2), HAS carried out a questionnaire survey of medical students in order to obtain their opinion on the consideration of sex and gender on three specific topics.

As a reminder, this survey is in no way intended to be exhaustive or representative as its methodology does not allow it. It was only used to fill a lack of data in the literature, to get a general idea of the consideration of sex and gender on certain specific points in medical studies.

Respondents had the option of adding a free comment in addition to the answers on the three topics of the questionnaire. The synthesis of these responses is presented here.

The students and interns supplemented their responses with a free comment in 59 cases (37 for non interns - 22 for interns; 41 for women - 17 for men - one from an intern who did not wish to disclose their gender):

- 9 question the survey methodology or question its principle (one question on depression should be reviewed according to six respondents in that it itself takes up a stereotypical view of the pathology in men and women);
- 13 highlight stereotypes on the part of teachers or seniors. The term "sexism" comes up several times, women would be called "hysterical", "crazy", they "would do too much" in the face of pain. Several comments emphasize that the words of certain patients, especially women, are hierarchized according to various criteria including sex and gender, and even delegitimized by certain doctors;
- 2 note the sexist attitudes of certain patients towards female doctors;
- 6 are rather in favor of the existing training, considering that the teaching of physiology is sufficient, or that future doctors are trained to adapt to each person on a case-by-case basis beyond the sole criteria of sex and gender;
- 6 appeared neutral from the point of view of the subject of the survey or questioning the notion of sex and gender in general, such as, for example, a remark on the importance of taking sex into account in consultation, not just gender (which ties in with the conclusions of this report);
- 1 could not be interpreted, on the interest of introducing teachings on "non-binary" people;
- 16 provide details on training needs or gaps in courses on sex and gender related issues:
 - teaching would be dated (sometimes even in cardiology, where biological differences are well-documented),
 - there are many who would convey stereotypes,
 - Both non interns and interns speaking on the issue would like to be provided with more or better training on:
 - the difference between sex and gender;
 - how to adapt patient management according to the sex of the patient and how to behave with the opposite sex, in particular for intimate examinations;
 - how to welcome LGBTI patients (especially trans and intersex);
 - how to respond to sexist attitudes;
 - sexual health (not reproductive health);
 - psychology, sociology, and demography related sex and gender topics.

Several respondents indicated that they were looking themselves for information or noted some optional courses.

3.3. Results of a study carried out on French guidelines

Analysis of French guidelines in the medical field

Research was carried out via the Lemanissier Library in four pathologies or situations.

The table below reproduces the list of guidelines identified explicitly mentioning sex or gender, depending on whether they lead to differentiated or undifferentiated indications.

| Pathologies or clinical situations | Organization and title of the guideline (year) |
|--|--|
| SEX OR GENDER DIFFERENTIATED INDICATIONS | |
| Alcohol | Mésusage de l'alcool : dépistage, diagnostic et traitement (2015) – SFA Outil d'aide au repérage précoce et intervention brève : alcool, cannabis, tabac chez l'adulte – Haute Autorité de santé (HAS) - December 2014 |
| Cardiology | Guide parcours de soins - Maladie coronarienne stable – Haute Autorité de santé (HAS) - July 2015 Prévention vasculaire après un infarctus cérébral ou un accident ischémique transitoire : synthèse des recommandations, recommandations, argumentaire – Haute Autorité de santé (HAS) - July 2014 Guide parcours de soins Fibrillation atriale et Synthèse – Haute Autorité de santé (HAS) - February 2014 Prévention cardio-vasculaire : le choix de la statine la mieux adaptée dépend de son efficacité et de son efficacité - Fiche de bon usage du médicament – Haute Autorité de santé (HAS) - v 2012 Consensus d'experts de la Société française d'hypertension artérielle sur les spécificités de la prise en charge de l'hypertension artérielle (HTA) de la femme. December 2018 |
| UNDIFFERENTIATED INDICATION WITH MENTION OF SEX OR GENDER | |
| Depression and suicidal risk | HAS - Manifestations dépressives à l'adolescence : repérage, diagnostic et prise en charge en soins de premier recours (2014) Suicide - État des lieux des connaissances et perspectives de recherche – 1 ^{er} rapport de l'Observatoire national du suicide (ONS) Suicide. Connaître pour prévenir : dimensions nationales, locales et associatives - 2 ^e rapport de l' Observatoire national du suicide – Ministère des Affaires sociales, de la Santé et des Droits des femmes - February 2016 Épisode dépressif caractérisé de l'adulte : prise en charge en premier recours (2017) |
| Tobacco | Arrêt de la consommation de tabac : du dépistage individuel au maintien de l'abstinence en premier recours : Reco2clics, Recommandations, Argumentaire scientifique - Recommandations pour la pratique clinique – Haute Autorité de santé (HAS) - actualisation October 2014 |
| Cancerology | Cancer colorectal : modalités de dépistage et de prévention chez les sujets à risque élevé et très élevé – Fiche memo – Haute Autorité de santé (HAS) – May 2017 |

Analysis of French guidelines in the social and medico-social fields

Search for any elements relating to sex or gender in the good practice guides of the National Agency for the Evaluation and Quality of Social and Medico-Social Establishments and Services (ANESM), then of HAS in the social and medico-social fields, published since 2016.

The table below reproduces the list of identified guidelines explicitly mentioning sex or gender, depending on whether they lead to differentiated or undifferentiated indications.

| Domaines | Titre de la recommandation de bonne pratique (année) |
|--|---|
| SEX OR GENDER DIFFERENTIATED INDICATIONS | |
| Child welfare | <u>La prévention de la violence entre les mineurs adolescents au sein des établissements d'accueil (2019)</u> <u>L'accompagnement des mineurs non accompagnés dits « Mineurs isolés étrangers » (2018)</u> |
| Social inclusion | Repérage et accompagnement en centre d'hébergement et de réinsertion sociale (CHRS) des victimes et des auteurs de violences au sein du couple (2018) La réduction des risques et des dommages dans les centres d'accueil et d'accompagnement à la réduction des risques pour usagers de drogues (CAARUD) (2017) |
| Disabled persons | <u>Qualité de vie : handicap, les problèmes somatiques et les phénomènes douloureux (2017)</u> <u>Les « comportements-problèmes » au sein des établissements et services accueillant des enfants et adultes handicapés : prévention et réponses (2016)</u> |
| UNDIFFERENTIATED INDICATION WITH MENTION OF SEX OR GENDER | |
| Child welfare | <u>L'accompagnement des enfants ayant des difficultés psychologiques perturbant gravement les processus de socialisation (2017)</u> |

Annex 4. Abbreviations

| | |
|--------|---|
| AIDS | Acquired ImmunoDeficiency Syndrome |
| CCAM | <i>Classification commune des actes médicaux</i> Joint classification of medical procedures |
| CPG's | Clinical practice guidelines |
| FDA | Food and Drug Administration |
| GRADE | Grading of Recommendations Assessment, Development and Evaluation |
| HAS | <i>Haute Autorité de santé</i> French National Authority for Health |
| HIV | Human immunodeficiency virus |
| HPV | Human papillomavirus |
| LGBTI | Lesbian, Gay, Bisexual, Trans, Intersex |
| INCa | <i>Institut national du cancer</i> French National Cancer Institute |
| INED | <i>Institut national des études démographiques</i> French National Institute of Demographic Studies |
| INS | <i>Identifiant national de santé</i> French national health identifier |
| INSEE | <i>Institut national de la statistique et des études économiques</i> French National Institute for Statistics and Economic Studies |
| INSERM | <i>Institut national de la santé et de la recherche médicale</i> French National Institute of Health and Medical Research |
| NCD's | Noncommunicable diseases |
| NICE | National Institute for Health and Care Excellence |
| NIH | National Institutes of Health |
| OECD | Organisation for Economic Co-operation and Development |
| PMSI | <i>Programme de médicalisation des systèmes d'information</i> French Medical IT Programme |
| STI's | Sexually transmitted infections |
| WHO | World Health Organisation |

Annex 5. Bibliography

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