MESSAGE
Medical Science Sex and Gender Equity

Policy Lab Briefing Pack

Co-designing sex and gender policy for UK biomedical research

Monday 22nd May 2023

MESSAGE

The George Institute for Global Health UK

wellcome trust

Imperial College London

MESSAGE project

MESSAGE (Medical Science Sex and Gender Equity) is a policy initiative to improve the **integration of sex and gender considerations in data collection, analysis and reporting in UK biomedical research**.

We will co-design a policy framework with stakeholders over the course of four Policy Labs:

Policy Lab 1
May 2023
Starting the conversation

Policy Lab 2
September 2023
Reviewing and refining a preliminary policy framework

Policy Lab 3
January 2024
Reviewing the final framework, thinking about implementation

Policy Lab 4
April 2024
Reflecting on implementation so far

What is a Policy Lab?

A policy lab is a focused, collaborative workshop bringing a range of stakeholders together around a particular challenge to:

Develop new ideas and practical approaches to address a real-world problem

Understand barriers and facilitators for bringing about that change

Improve outcomes for users and patients

What can you do to prepare?

Read and reflect on this briefing pack

What are your immediate responses?
What is missing? What is striking?
Did you learn anything new?

Think about why sex and gender policies haven't been widely developed and adopted in the UK*

What are the challenges for your organisation and in your own work?

Speak to your colleagues to hear their thoughts

What do they think about MESSAGE's goals?
What barriers do they foresee?
What capacities and ideas do they have?

Be prepared to share and articulate your thoughts on the day

Except MRC's policy,* **Sex in experimental design, *published in 2022*

Policy Lab 1: Aims and Scope

The Policy Lab series

The aim of the Policy Lab series is:

To co-design and implement a policy framework for funders which will ensure that biomedical researchers account for sex and gender in their funding applications and their research projects.

- By "**biomedical research**" we mean basic (cell/animal), clinical and population research.
- By "**sex and gender policies**" or **"policies that account for sex and gender",** we mean policies focused on improving integration of sex and gender considerations in data collection, analysis and reporting of biomedical research.
- These policies will have the greatest impact for women and gender minorities (who are under-represented in research currently), but **ultimately will benefit all sexes and genders**.
- The output of this Policy Lab series might be a policy framework, best practice recommendations, guidelines or principles, depending on and tailored to an organisation's size and/or focus.

The context in the UK

Biomedical research in the UK does not currently account for all sexes and genders in its design

- Evidence demonstrates that there is an **over-representation of male participants** in biomedical research and that **study data is rarely disaggregated on the basis of sex and gender** in reported results.
- Research which doesn't take account of sex and gender leads to **less targeted care and worse outcomes**, particularly for cis women and trans people.
- Research that accounts for sex and gender also highlights the health conditions which have **worse effects in men**.

The UK does not have any sex and gender policies for biomedical research on humans

- **Other countries already have policies in place** to encourage researchers to account for sex and gender in their research design when applying for funding.
- Reviews of existing policies in other countries have shown that **policies are effective** in improving how sex and gender are accounted for in research.

UK policymakers (eg Department of Health and Social Care's Women's Health Strategy) recognise the need to improve representation of women in research and report results separately for women and men.

The challenge in the UK

Challenges for considering sex and gender in research include:

- **Lack of awareness** about the relevance of sex and/or gender for almost all biomedical research questions.
- **Lack of training and confidence** in conducting sex- and gender-disaggregated analysis.
- Cost and feasibility of **recruiting participants** of all sexes and/or genders.
- Cost and complexity of **recruiting sample sizes** which will provide **statistically significant results**.
- A **volatile and inflammatory public and political context** around conversations on sex and gender in the UK.

Challenges for implementing a sex and gender policy in funding organisations include:

- **Lack of training for reviewers** funding applications, including **absence of criteria** to assess adequate or excellent integration of sex and gender in applications.
- **Lack of consensus** among UK biomedical research funders on what such policies should look like and contain, compounded by **heterogeneity of funders** in terms of size and resources.
- Factors that would **facilitate effective implementation** of sex and gender policies have not yet been explored.
- **Difficulties in implementing change** within large funding (and other) organisations.

Aim of Policy Lab 1

The central question of the event will be:

What is needed for UK policies to ensure biomedical researchers account for sex and gender to maximise the value of results and benefits for all patients?

This question will be answered by representatives from across the biomedical research sector, including:

- Funding organisations (government and charitable)
- Regulators
- Publishers
- Researchers and clinicians
- Patient representatives

Agenda

Time	Session
09:30	Breakfast reception
10:00	Welcome and introductions Reviewing the briefing pack Creating a vision for including sex and gender in research Designing the elements for implementing sex and gender policies in the UK
13:00	Lunch
13:45	Developing proposals on practical next steps
15:45	Review and thanks
16:00	Close

Who is joining us?

Michael Brady & Tash Oakes-Monger – NHS England
Erin Shearman – Department of Health & Social Care
Lilian Hunt – Equality, Diversity and Inclusion in Science and Health (EDIS)
Jennifer Harris – Association of the British Pharmaceutical Industry

Funders

Esther Mukuka* & Emma Hadfield-Hudson – NIHR
Cheryl Hewer – UKRI
Ivan Pavlov – MRC
Louise Campbell* – Chief Scientist Office, Scotland
Michael Bowdery – Health & Care Research Wales
Janet Diffin* – Health & Social Care, Northern Ireland
Catriona Manville & Simon Turpin – Association of Medical Research Charities
Sophie Roberts – Alzheimer's Society
Suzanne Rix – Blood Cancer UK
Eleanor Garratt-Smith – Breast Cancer Now
Maeva May – British Heart Foundation
Karolin Kroese & Kieran Prior – Cancer Research UK
Elaine Davies* – Kidney Research UK
Beth Grimsey – MS Society
Marianna D'Arco – The Royal Society
Harri Weeks & Teresa Cisneros – Wellcome Trust

Regulators

Kathryn Ord & Larissa Jones – Medicines & Healthcare products Regulatory Agency (MHRA)
Naho Yamazaki – Health Research Authority (HRA)
Jean Masanyero-Bennie – National Institute for Health and Care Excellence (NICE)

Researchers & Clinicians

Lesley Regan – Women's Health Ambassador
Alan White – Men's Health Forum
Allyah Abbas-Hanif – Imperial College London
Anna Louise Pouncey* – Imperial College London
Claire Meek* – University of Cambridge
Joanna Martin – University of Cardiff
Maria Teresa Ferretti* – Women's Brain Project
Sally Hines* – University of Sheffield
Sanne Peters – Imperial College London & The George Institute for Global Health (TGI)
Zowie Davy – De Montfort University

Patient representatives

Sophie Strachan – SOPHIA Forum
Laur Evans – Mental Health
Kirstie English* – PhD student in Gender Studies
Kirsty Clarke – Kidney Research UK
Wendy Davis – Heart Voices

Publishers

Agniezska Freda & Isabel Goldman* – Elsevier
Heather van Epps – The Lancet
Navjoyt Ladher – The BMJ

Project team

Ross Pow – Policy lab facilitator (The Policy Institute at King's College London)
Robyn Norton* – Co-PI of MESSAGE (Imperial College London)
Kate Womersley – Co-PI of MESSAGE (Imperial College London)
Alice Witt – Research & Policy Fellow, MESSAGE (TGI)
Louise Cooper – Programme Manager, MESSAGE (TGI)
Ana-Catarina Pinho-Gomes* – Research Associate (TGI)
Anastasia Alden – Communications Manager (TGI)
Carinna Hockham – Research Associate (TGI)
Chloe Orkin – Professor of Infection and Inequities (Queen Mary University of London)
Katherine Ripullone – Research Associate (TGI)
Marina Politis – Medical student (Glasgow Medical School)

** Participants joining online*

House rules

Policy labs rely on all participants feeling comfortable to engage in open discussion, to share their honest perspectives, and to suggest ideas on issues which can be sensitive and prompt strong opinions.

We expect all participants to follow our code of conduct:

1. This is an **inclusive space** where people of all sex and gender identities are welcome and valued. Please respect people's chosen pronouns and opinions.
2. To ensure we hear a range of opinions and ideas, we ask that after you have spoken, you **allow at least three other people to speak before speaking again**, unless you are called on to respond.
3. Avoid academic or practitioner **jargon** where possible.
4. All discussions will follow Chatham House Rules, meaning that **anything said will not be linked back to individuals in any publications or reports** of the event. We ask that you adhere to the spirit of these rules in your actions during and after the day, including not live tweeting (or similar).
5. We will **record plenary sessions** for the purposes of creating an accurate record of the discussion. Only the research team will have access to this, and it will be destroyed after use according to data protection regulations.

What happens after Policy Lab 1?

- Discussion from this policy lab will be summarised in a **short briefing note** which will be shared with participants.

- Between policy labs 1 and 2, the MESSAGE project team will work with the information and ideas you share to develop a **draft sex and gender policy framework**. Policy lab 2 will be focused on reviewing and improving this to fit the needs of UK funders.

- The first policy lab marks the start of an **ongoing conversation** and co-design process. Between policy labs, we may seek further information or clarification from you to inform the design of the framework.

- At the end of the MESSAGE project, we will publish our learnings about this co-creative process in a **methodology-focused research paper**.

Evidence for Discussion

Contents of this section

1. **Understanding how sex and gender are accounted for in research**
   - Sex and gender affect health differently and in complex ways
   - Evidence points to a clear predominance of male representation in research
   - Minimal representation of trans people in research leads to poorer health outcomes
   - Intersectionality compounds the impact of sex and gender
2. **Why it's important to account for sex and gender in research**
   - Five arguments for improved accounting of sex and gender considerations
   - Five case studies: Heart attack; Breast cancer; Autism; Diabetes; Adverse drug reactions
3. **Developing and implementing sex and gender policies for research**
   - A strong policy precedent set by other countries
   - The UK policy context in 2023 is favourable to the study of sex and gender differences
   - But there is no unified guidance in the UK
4. **Why have policies not been developed and implemented in the UK before?**
   - Challenges for researchers, funders and the research sector
   - Seven key barriers to overcome

1. Understanding how sex and gender are accounted for in research

Sex and gender affect health differently and in complex ways

Sex and gender affect our experience of illness, the conditions and/or symptoms we develop, how we are treated within a healthcare system, how we respond to treatment (including side effects), and ultimately our overall health outcomes.

It is important to understand these differences in order to conduct accurate and safe research, and improve health outcomes for everyone.

Though sex and gender are often conflated, they are not the same thing. Sex and gender may impact a person's health differently and may intersect in ways that we do not yet understand.

Sex

Cells, animals and people have a sex.

Sex can be determined at different levels, including:

- Chromosomes
- Gene expression
- Hormone levels and function
- Reproductive/sexual anatomy

Sex is not always binary (male/female). Sex may manifest differently at these different levels, including, but not only, in people with variations of sex characteristics (VSCs).

Gender

People have a gender; cells and animals do not.

Gender is a socially constructed phenomenon that is determined in relation to a person's roles, behaviours, expressions and identity.

Gender is not binary or static. It exists on a continuum and can change over time. Examples of gender identities/modalities are cis man, cis woman, trans or non-binary.

Knowledge around sex and gender is changing all the time and **definitions may change as thinking progresses**.

Canadian Institutes of Health Research

Evidence points to a clear predominance of male representation in research

BENCH RESEARCH

5.5 times
more males than females are used in cell and animal research

Why?

- Convention for decades
- Underappreciation of the potential magnitude of effect of sex on outcomes
- Erroneous assumption that females are intrinsically more variable than males due to the oestrous cycle

CLINICAL RESEARCH

In Phase I trials,
around 20% of participants are women

- Men are consistently over-represented in later stage trials even after accounting for sex distribution in disease populations.
- Pregnant and breastfeeding women are excluded by default due to concerns about the safety of the baby.

Ravindran et al. 2020

Minimal representation of trans people and people with VSCs in research leads to poorer health outcomes

Medical research and care is often built around the assumption that 'male' and 'female' are uniform categories based on distinct sets of sex characteristics. This assumption can mean researchers **fail to study or accurately account for trans people and people with variations of sex characteristics (VSCs)**.

Limited representation of these groups in clinical research means there is **limited knowledge about illness and how appropriate or safe treatments are for these groups**. This is compounded by stigma and discrimination from healthcare providers, which ultimately lead to **poorer health outcomes**.

Some areas where lack of knowledge and/or inclusive practices could lead to poorer health outcomes for these groups are:

- Lack of clinical understanding of **how hormone treatments interact** with medical conditions or other drugs
- Patients not being contacted for **relevant screenings tests**
- **Hesitancy** among medical professionals for treating patients
- **"Broken arm syndrome"**, where any health problem is attributed to a person's trans status or hormone profile, which can be used as justification for withdrawing hormone therapy.

41% of trans people said healthcare staff lacked understanding of trans health needs

16% of LGBTQIA+ Individuals have had negative experiences due to their sexual orientation when accessing health services, 38% due to their gender identity.

Stonewall, 2018

Intersectionality compounds the impact of sex and gender

https://www.netunzel.com/interviews/comments/k/Intersectionality-2023

- **Sex and gender interact with other variables** such as age, race/ethnicity, disability and socioeconomic status to shape someone's risk of disease, experience of illness and response to treatment.
- The impact of intersectional discrimination can be **masked if looking at individual demographic categories**. e.g. Black women have worse health outcomes than their race or sex/gender alone would predict.
- The MESSAGE policy framework needs to **complement and work alongside existing frameworks** (e.g. INCLUDE Ethnicity Framework) to encourage researchers to take an intersectional view of disease and treatment.

> **A prism for seeing the way in which various forms of inequality often operate together and exacerbate each other**

Kimberlé Crenshaw , American race scholar and civil rights advocate

2. Why is it important to account for sex and gender in research?

Five arguments for improved accounting of sex and gender considerations

1 **Scientific rigour**
Understanding sex and gender differences increases the accuracy, translatability and reproducibility of research

2 **Human rights and ethics**
A moral imperative to ensure that biomedical research benefits all people in society and fulfils everyone's right to health

3 **Legal justification**
Research that is not inclusive of all sexes and genders can be seen as discrimination under the Equality Act 2010

4 **Poorer health outcomes and adverse drug reactions**
Clinical practice may be ineffective or actively harmful to patients if not enough is known about sex and gender differences in diseases and treatment responses

5 **Economic impacts**
Negative economic impacts due to poorer health outcomes and adverse drug reactions that result from a lack of information and understanding about sex and gender differences.

Case study: Heart attack

- Women are more likely to have symptoms that are not identified as serious, to be misdiagnosed, have delayed management, and **experience worse outcomes after a heart attack (myocardial infarction) than men**. *Wilkinson et al. 2018*
- Evidence that troponin levels (a blood test detecting a heart attack) are lower in women, yet patients are reviewed against **non-sex-specific thresholds**. *Chapman et al. 2018*
- When patients were reviewed against **sex-specific thresholds**, diagnosis increased by 42% in women and 6% in men. *Lee et al. 2019*
- **Gendered narratives of women's pain** mean that chest pain is more likely to be dismissed as psychological, delaying necessary treatment for women.

https://www.bhf.org.uk/what-we-do/news-from-the-bhf/news-archive/2019/september/heart-attack-gender-gap-is-costing-womens-lives

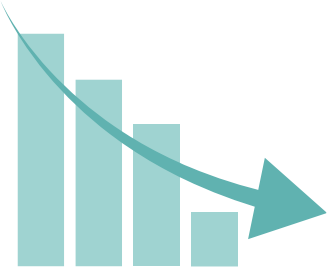
https://www.templehealth.org/about/blog/heart-attack-symptoms-men-women-differences

Case study: Breast cancer

- Breast cancer is conventionally thought of as a female-specific illness, yet **around 400 men a year in the UK are diagnosed with breast cancer**. Lack of knowledge and awareness about male breast cancer can lead to poorer health outcomes. *Breast Cancer UK*
- The **genetic risk of breast cancer is greater in men than in woman**: inherited mutations in BRCA1 and BRCA2 genes account for 4-6% of cases in women compared to 11-12% of cases in men. *Breast Cancer UK*
- Research has found that **men with breast cancer receive more invasive surgery** than women. Compared to women, men are more likely to have an entire breast removed as opposed to removal of cancerous cells or tissues. *Estrada et al. 2023*

67% men
with breast cancer received unilateral mastectomies compared with 24% women with breast cancer

42% reduction in **male mortality** if men receive partial mastectomy compared to unilateral mastectomy



Partial mastectomy: removal of cells or tissue

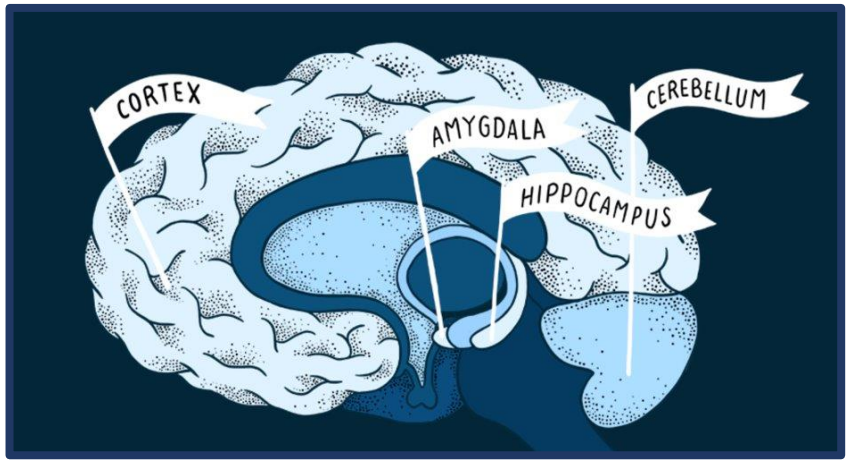
Unilateral mastectomy: removal of an entire breast

Case study: Autism

- It was traditionally **assumed that autism overwhelmingly affected men and boys**, and much more rarely women and girls. But more recent epidemiological studies **revised the prevalence in males compared to females to 3:1** *Looms et al. 2017*

- Research shows that **women and girls are more likely to 'mask' or 'camouflage' their autistic traits** (the stress of which can cause anxiety). This results in women and girls being more likely to be described as anxious instead, and an autism diagnosis not identified. *Wood-Downie et al. 2021*

- Studies highlight the importance of using **sex- and/or gender-specific targeted assessment tools** in research and diagnostic processes. *Mandy & Lai, 2017*



https://www.spectrumnews.org/news/brain-structure-changes-in-autism-explained/

Camouflaging Autistic Traits Questionnaire (CAT-Q)

Instructions:

Please read each statement below and choose the answer that best fits your experiences during social interactions.

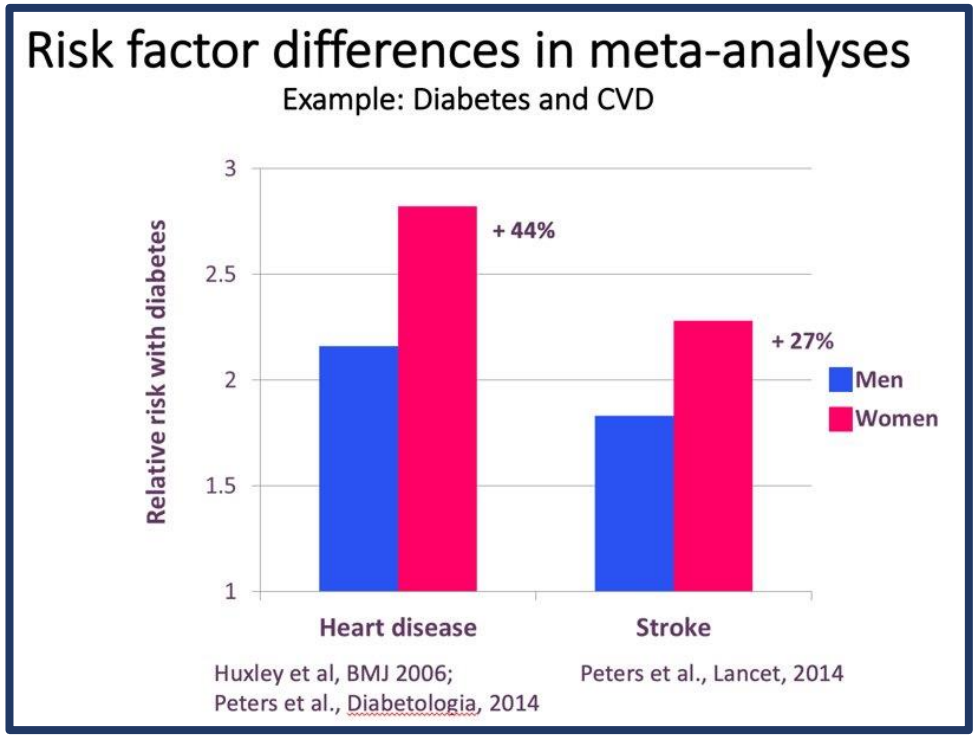
		Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
1	When I am interacting with someone, I deliberately copy their body language or facial expressions.	1	2	3	4	5	6	7
2	I monitor my body language or facial expressions so that I appear relaxed.	1	2	3	4	5	6	7
3	I rarely feel the need to put on an act in order to get through a social situation.	7	6	5	4	3	2	1
4	I have developed a script to follow in social situations.	1	2	3	4	5	6	7
5	I will repeat phrases that I have heard others say in the exact same way that I first heard them.	1	2	3	4	5	6	7
6	I adjust my body language or facial expressions so that I appear interested by the person I am interacting with.	1	2	3	4	5	6	7

https://link.springer.com/referenceworkentry/10.1007/978-1-4614-6435-8_102327-1

Case study: Diabetes

- While diabetes is more prevalent in men than in women, **women are at greater risk of diabetes-related mortality than men**.
- Women are at **greater risk of complications** from diabetes such as stroke and coronary heart disease.
- Women from high income countries are less likely than men to **receive the care recommended by guidelines or to meet treatment targets** for glycaemia and lipids.
- Women have **different adverse events** to diabetes drugs and sex specific treatment guidelines are rare.

Sex disparities in diabetes: bridging the gap, 2017



https://link.springer.com/article/10.1007/s00125-014-3260-6

44% higher excess risk of coronary heart disease among women than men

27% higher excess risk of stroke among women than men

Case study: Adverse drug reactions (ADRs)

- A growing body of evidence shows **ADRs tend to be more common and more severe in women**.
- This evidence highlights how the lack of sex- and gender-disaggregated analysis can severely impact **patient safety**.
- For example, **current treatment guidelines for patients with schizophrenia do not take sex differences into account**.

https://pubmed.ncbi.nlm.nih.gov/34408155/

Research (*Hoekstra et al, 2021*) has found that:

- **Women do not receive the clinical benefit men do** from high doses of antipsychotic drugs, such as amisulpride and aripiprazole.
- But **women experience more side effects** from these high doses, such as weight gain and raised prolactin levels.
- This means that current prescribing practices are designed for men, and may in fact be **harming women unnecessarily**.

https://pubmed.ncbi.nlm.nih.gov/34408155/

3. Developing and implementing sex and gender policies for research

A strong policy precedent set by other countries

1993

In the U.S., the National Institutes of Health (NIH) Revitalization Act is enshrined in law. The act mandated that women be included in all NIH-funded clinical research and trials be designed to analyse if variables affect women differently.

2010

The Canadian Institutes of Health Research (CIHR) mandate that all funding applicants must explain how their planned research accounts for sex or gender or if not, why not.

2014

The European Commission, via Horizon 2020 funding, invites applicants to explore “the gender dimension” in their research. Applications are scored on this basis.

2016

The NIH Policy on Sex as a Biological Variable is published, stating that the NIH will expect all funding applications to factor “sex as a biological variable” into their research design, analysis and reporting for animal and human studies.

2016

European Association of Science Editors (EASE) publishes the Sex and Gender Equity in Research (SAGER) guidelines which provide guidance to publishers on ensuring adequate reporting of sex and gender differences.

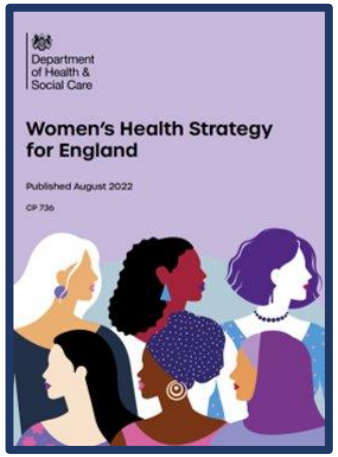
The policy context in 2023 is favourable to the study of sex and gender differences

NHS England (2016): Improving Outcomes through Personalised Medicine

"Personalised medicine: a move away from a 'one size fits all' approach to the treatment and care of patients with a particular condition, to one which uses new approaches to better manage patients' health and target therapies to achieve the best outcomes in the management of a patient's disease or predisposition to disease."

Scottish Government (2021): Women's Health Plan 2021-24

"Improve collection and use of data, including qualitative evidence of women's lived experiences, ensuring disaggregation by protected characteristics. Robust intersectional analysis of this data should be used to inform service design and improve healthcare services and women's care and experiences."



Department of Health & Social Care (2022): Women's Health Strategy for England

"We, along with the NIHR, have a long term aim to explore how we can encourage researchers to disaggregate research findings by sex. This will also help us understand sex-based differences in health conditions. As part of this, we will work with research funders to explore how females are included across different types of research, including discovery science and early phase clinical work."

But there is no unified guidance in the UK

In 2021, MESSAGE asked **17** UK medical research **funders** (>£5M annual budget) and 4 UK medical regulators:

"Do you have a sex and gender policy in place for the research that you fund?"

None of the funders and regulators had a sex and gender policy at that time.

In 2022, the Medical Research Council was the first UK funder to publish guidance regarding sex and gender in animal and cell studies:

Yet there remains **no unifying guidance or set of principles for the UK research sector** regarding incorporation of sex and gender considerations, and **no guidance for clinical studies**.

4. Why have UK policies not been developed and implemented before?

Challenges for researchers

- **Lack of awareness** that sex and gender questions are relevant to the vast majority of biomedical questions
- Lack of knowledge about **differences between sex and gender**
- Lack of clarity on **how to measure** sex and/or gender in research
- Female hormones and the **oestrous cycle** are (incorrectly) thought to make female participants unreliable
- Fears of **exposing more participants to the risk of trials**, particularly if they are vulnerable or pregnant
- Cost and complexity of recruiting sample sizes which will provide **statistically significant results**
- Cost and feasibility of **recruiting a range of sexes and gender identities** for research
- **Cell lines** of both sexes not always available
- **Researchers lack training and confidence** for conducting sex- and gender-disaggregated analysis

Challenges for funders

- **Reviewers lack training and clear criteria** for assessing grant proposals on the basis of sex and gender
- Lack of guidance for reviewers on **how to respond** to applications that do not account for sex and gender
- Sex and gender considerations **differ between basic and clinical research**, meaning a one-size-fits-all policy may be ineffective
- **Heterogeneous funding landscape** in the UK (funders of different sizes and resources) means a one-size-fits-all policy may be ineffective
- Uncertainty about the **best way** to encourage researchers to account for sex and gender (e.g. policy vs best practice recommendations vs guidelines vs principles)
- Concerns about **effectiveness of policies** as a means of leveraging change

Challenges for the research sector

- **Lack of precedent, leaders in the field, and prestige** attributed to conducting research that accounts for sex and gender effectively
- **Sensitive public debate** around sex and gender leads to hesitation and fear of ‘getting it wrong'
- **Lack of consensus and incentives** across the research pipeline: from funders and regulators, via researchers, to publishers
- Perceived lack of incentive for the **pharmaceutical industry** to address sex and gender differences
- Lack of understanding of the **economic fallout** of not accounting for sex and gender
- Concerns about how UK policies interact with other **international standards** around sex and gender
- Competing **equality, diversity and inclusion needs** and lack of knowledge about how to integrate an **intersectional** lens into research

Seven key barriers to overcome

During the policy lab, we will brainstorm how to overcome the following challenges. Please have a think in advance about **opportunities and resources in your network** that could help to address them.

1. **Heterogeneous funding landscape:** Funders of different sizes, different subject areas and different funding capacities.
2. **No consensus on how to define (and therefore study) sex and gender** in biomedical research.
3. **Lack of guidance on what counts (or doesn't count) as adequate or excellent integration of sex and gender** in a funding application.
4. **Challenges recruiting sufficiently large sample sizes of each sex and/or gender identity** (across cell, animal and human studies), and the cost implications of this.
5. **Lack of clarity from a statistical perspective** on how to conduct sex and gender analysis effectively.
6. **Inadequate training for researchers** on why sex and gender analysis is important and how to conduct it well.
7. **Change across large and complex institutions requires momentum** from many departments and individuals.

MESSAGE Policy Lab 1

Monday 22nd May 2023

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Link to Google Maps

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MESSAGE website: Medical Science Sex and Gender Equity

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