Frequently Asked Questions on Sex and Gender in Research

What do you mean by a sex and gender policy?

A person's experience of health and disease can be influenced by their **biological attributes** (their **sex**) and by their **roles, behaviours and identity in society** (their **gender**). Historically, most research has been (and continues to be) conducted on male cells and animals, and with male participants, and data are rarely disaggregated by sex and/or gender (meaning they are separated by sex and/or gender groups and then compared) in published research. This has led to gaps in the scientific evidence base about how health and disease manifest differently in different sexes and/or genders. Sex is relevant to research on cells, animals and humans; gender is relevant to research only on humans.

The aim of a sex and gender policy is to encourage researchers to think about the sex and/or gender dimensions of their research to address gaps and improve the accuracy of scientific research. The MESSAGE project has designed a policy framework for research funders. Adoption of sex and gender policies by UK research funders will mean that applicants will need to set out in funding applications how they plan to account for sex and gender in their study design.

It should be noted that this policy framework is not focused on enhancing sex and gender diversity in the workplace, although that is also essential for improving research inclusion.

The MESSAGE policy framework is not prescriptive and asks researchers to critically consider sex and gender dimensions in the specific context of their research question. In particular, the framework asks researchers to think precisely about the specific sex and/or gender characteristic(s) they need to account for given their research question and to design data collection accordingly.

Why are you calling on researchers to collect data on sex?

It is critical to collect data about sex to address gaps in the scientific evidence base about how health and disease manifest differently (or similarly) in people of different sexes. Sex characteristics – including genes, reproductive anatomy and endogenous hormones – all contribute to an individual's risk of developing diseases and their responses to treatment. When sex is relevant to a research question about health or illness, it is important that researchers ask about and account for this.

Why are you calling on researchers to collect data on gender?

Many aspects of health and disease are shaped by **society's norms and expectations about how people of a certain gender are viewed and treated**. For example, a gendered expectation that women may be more anxious and emotional than men leads to women's pain being dismissed more often as having a psychological rather than a physical cause. When women present to hospital with symptoms of a heart attack, evidence shows they are more likely than men to be misdiagnosed as having a panic attack, and discharged without appropriate care. Similarly, gendered expectations about male resilience may prevent men from seeking help for mental health problems, which may contribute to the elevated rates of suicide seen in this group. If a scientist is studying an area of biomedical, health or care research

where a person's gender could affect their health or experience of illness, it is important to ask about participants' gender and account for this variable.

Though many people feel that their sex and gender are the same, **some people's gender (self-identity) is different to their sex (biological characteristics)**. People in this category may describe themselves with labels such as transgender, trans, gender fluid or non-binary. Collecting data on gender is therefore important to maximise the accuracy of study findings.

What does this policy say about including trans, non-binary and intersex people in research?

This policy is aimed at improving representation in research, and therefore clinical outcomes, for **all people**. The policy encourages researchers to include where possible **all minoritised sexes and genders**, including cisgender women, trans, non-binary and intersex people/people with VSCs (I/VSCs), wherever possible. Trans, non-binary and intersex people have historically been largely excluded from research, meaning the evidence base on medical conditions and appropriate treatments for these members of the population is limited.

How does this sit in the context of current divisions in society around gender (and sex)?

The aim of the MESSAGE policy is to improve **scientific rigour** by ensuring that researchers account for sex and gender in their projects, and that data on the sex and/or gender of participants (which may affect study findings) is **collected**, **analysed and reported**. The policy encourages researchers to be precise and proactive when considering who they need to include in research to make it applicable to the wider population. It sets out clear, comprehensive definitions of sex and gender that have been codesigned by experts across the research sector.

Who will benefit from these changes?

The MESSAGE policy framework will benefit all members of society. Addressing sex and gender gaps in the scientific evidence base will improve understanding of health and disease in all people, and particularly cisgender women and sex- and gender-diverse people who have historically been excluded from research. New policies will improve knowledge about men's experience of conditions where they may have been under-studied, such as osteoporosis, or where disease progression and outcomes may differ, such as Covid-19.

Why are you prioritising sex and gender over other characteristics such as race and ethnicity, disability, or socio-economic status?

The MESSAGE project is addressing sex and gender gaps specifically as the UK lags behind other countries regarding policy in this area. This is a notable omission that impacts a large proportion of the population. We recognise there is a need to understand how other characteristics affect health outcomes, and how they intersect with sex and gender characteristics. We envisage MESSAGE as a first step towards more inclusive research that will upskill researchers to begin thinking about these characteristics and build capacity to conduct meaningfully intersectional analysis in the future.

How are you going to support researchers to adapt to this new way of conducting research?

It is our priority to help researchers to upskill to account for sex and gender in a high-quality way. We will be sharing **educational resources** on the <u>MESSAGE project website</u>. Researchers can currently access our <u>resource library</u>, which includes **best practice sex and gender research** across a range of medical fields to provide some inspiration and initial guidance. Researchers are welcome to <u>submit their research</u> for inclusion in the library.

There's already a high burden of work on researchers. Isn't this framework just adding to that?

Accounting for sex and gender is not an optional add-on to research; it is essential for producing accurate, high-quality evidence, and therefore treatment for all patients that is safe, effective, and cost-effective.

Will this policy mean researchers need to increase the number of research participants?

This policy does not necessarily require researchers to increase the number of participants, and any amendments to study sample sizes will need to be considered on a case-by-case basis. Although powering studies to produce statistically significant findings for each sex/gender group is ideal, this is not necessary to meet the expectations of the MESSAGE policy framework. Instead, researchers must critically consider sex and/or gender at every stage of the research cycle and design studies in such a way that potential sex and/or gender differences may be identified. Publication of sex- and/or gender-disaggregated data in research papers will enable meta-analyses to be conducted which may generate significant findings regarding sex and/or gender differences.

I've heard females are difficult to study because of hormonal variations in the menstrual cycle.

This is a common misconception. Scientific studies have shown that both males and females display hormonal variability, and **female variability does not affect study outcomes any more than in males** (Prendergast, Onish & Zucker 2014; Beery 2018; Karp & Reavy 2018).

How can I get involved?

We encourage anyone interested in our work to get involved in the MESSAGE project, whether you are a funder, a patient, a researcher, a regulator, a publisher, a clinician or you want to learn more. You can email us at MESSAGE@georgeinstitute.org.uk or contact us on X: @MESSAGE_TGI.

Where can I learn more about improving research inclusion?

- Medical Science Sex and Gender Equity: <u>www.messageproject.co.uk</u>
- Equality, Diversity and Inclusion in Science and Health: https://edisgroup.org/
- Canadian Institutes of Health Research How to integrate sex and gender into research: https://cihr-irsc.gc.ca/e/50836.html
- National Institutes of Health Sex as a Biological Variable: https://orwh.od.nih.gov/e-learning/sex-as-biological-variable-primer
- Gendered Innovations: https://genderedinnovations.stanford.edu/

• Innovations in Clinical Trial Design and Delivery for the Under-served: https://sites.google.com/nihr.ac.uk/include/home?authuser=0