

## Frequently Asked Questions

### What is the MESSAGE project?

The [MESSAGE](#) (Medical Science Sex and Gender Equity) project is a policy initiative to improve how UK biomedical, health and care researchers account for sex and gender in study design. The project is **leading co-design and supporting implementation of a sex and gender policy framework** for UK research funders. The overall goal of MESSAGE is to bring about **culture change** in UK research practice to bring sex and gender dimensions to the centre of medical research.

### Why does research need to account for sex and gender?

Sex and gender affect our **experience of health and illness**, the conditions and symptoms we develop, how we are cared for within a healthcare system, the ways we respond to treatment and our overall health outcomes. However, historically **most research has been conducted on male cells, animals and/or people**, which has led to gaps in the scientific evidence base about how health and disease manifest differently in non-males. For example, up to **5.5** times more males than females are used in cell and animal research (Beery & Zucker, 2011), and in phase I clinical trials just **22%** of participants are female (Labots et al., 2018). Likewise, analysis and reporting rarely disaggregate data on the basis of sex and gender (Sugimoto et al., 2019).

Poor accounting of sex and gender dimensions in research means that the results are **less accurate and reproducible** and bring benefit to a smaller proportion of society. Sex and gender inclusive research leads to **more targeted care** and **better outcomes** for all people, particularly for cis women, trans, non-binary and intersex people and people with variations of sex characteristics.

### What do you mean by a “sex and gender” policy?

The aim of a sex and gender policy is to **encourage researchers to think about the sex and/or gender dimensions** of the cells, animals and people they study at **all stages of the research cycle**, from data collection and analysis to reporting of findings.

A person’s experience of health and disease can be conditioned by their **biological attributes** (their **sex**) and by their **roles, behaviours and identity in society** (their **gender**). Under this policy, research involving cells and animals will be concerned only with sex. Research involving humans may be concerned with the sex of its participants or with their gender, or both. This will depend on the research question that is being asked.

The MESSAGE policy framework will be adopted by **UK research funders** and means that researchers will need to explain how they will account for sex and/or gender dimensions when they apply for research funding. More information about the project can be found here: [www.messageproject.co.uk](http://www.messageproject.co.uk). It should be noted that this policy is not about improving sex and gender diversity in the workplace.

### 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 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 key variable.

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

Many aspects of health and disease are determined by **society’s norms and expectations about how people of a certain gender are viewed and treated**. For example, the gendered expectation that women may be more anxious and emotional than men means that when women state they are in pain, this pain is too often dismissed as psychological rather than physical in nature. 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 that men should be tough may prevent men from seeking help for mental health problems, which contributes to elevated rates of suicide 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 their gender and account for this variable.

Though many people feel that their sex and gender are the same, and they don’t notice any differences between them, **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. Because of this, **it is not always relevant to just ask a person about their sex**.

### Can a person change sex?

The terminology around this can be confusing, but the key thing to remember is that **a person’s biological sex can be different to their documented sex (i.e. the sex on their birth certificate)**.

Sex is a protected characteristic under the Equality Act 2010. Under this legislation, sex is “a reference to a man or a woman” and **people can change their documented sex**. This definition is **not specific to biological sex and can encompass a person’s self-identity (their gender)**. A person who is transgender can change their sex in the eyes of the law by obtaining a gender recognition certificate (GRC). For example, if a person is born female but identifies as a man and has a GRC, they can change their documented sex to “man”.

The MESSAGE policy is not proscriptive on whether someone can change sex in a sense other than their documented sex. Instead, **the policy asks researchers to think precisely about which sex or gender characteristics they need to study to answer their research question**, and to justify this before proceeding with their research. Depending on the research question, it might be appropriate to study a person’s sex (their biological characteristics) and/or their gender (how they identify).

### 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 **all minoritised sexes and genders**, including cis

women, trans, non-binary and intersex people and people with 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. As many trans and intersex people take **long-term hormone replacement therapies**, it is important to build understanding of how those therapies may interact with medical conditions or other medications. Furthermore, including trans and non-binary people in research may help researchers to understand if an effect they are seeing in the study population is a result of a **sex- or a gender-specific trend**.

### **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 research includes **a more representative number of non-male participants** (who have historically been excluded) and that data on the sex and/or gender of participants (which may affect study findings) is **collected, analysed and reported**. The policy will encourage researchers to be more precise and proactive in considering who they need to include in research to make it applicable to the wider population. It will set out clear, comprehensive definitions of sex and gender that have been co-designed 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 greatly improve understanding of health and disease in all people, but particularly cis women and sex- and gender-diverse people who have historically been excluded from research. The policy also will improve knowledge about men's experiences in disease areas where this may have been under-studied, such as osteoporosis or 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 as these are a notable omission from the majority of biomedical, health and care research and impact a large proportion of the population. We recognise there is a real 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 their capacity to conduct meaningfully intersectional analysis in future. The MESSAGE team is working closely with members of the team who developed the [INCLUDE Ethnicity Framework](#) and would be delighted to see further initiatives to improve research inclusion more widely.

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

This policy change will require a fundamental shift in the way that research is conducted and it is our priority to support researchers through this process. The MESSAGE project will be publishing **comprehensive training materials** on how to integrate sex and/or gender at every stage of the research cycle in 2024. These will be available on the MESSAGE website in 2024: [www.messageproject.co.uk](http://www.messageproject.co.uk).

### There's already a high burden of work on researchers, isn't this 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 our ability to care for all patients safely, effectively, and cost-effectively.

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

This policy does not necessarily require researchers to double the number of participants. Amendments to study sample sizes will need to be considered on a case-by-case basis, but **in many instances a researcher will be able to comply with the policy requirements just by using different statistical methods**, such as multi-factorial analysis. This policy is **not requiring researchers to ensure that every study can produce statistically significant results** for all sexes and/or genders included in the sample. The MESSAGE team will launch comprehensive guidance for researchers on sample sizes and statistical methods in 2024.

### 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 have hormonal variability, and **female variability does not affect study outcomes any more than in males** (Prendergast, Onish & Zucker 2014; Beery 2018; Karp & Reavy 2018).

### When will the MESSAGE policy be launched?

The MESSAGE policy framework will be launched in 2024 and then adopted by research funders. The first changes to funding applications are likely to be in **autumn 2024**.

### How can I get involved?

**We encourage anyone interested to get involved in the MESSAGE project**, whether you are a funder, a patient, a researcher, a regulator, a publisher – or anyone else. You can email us at [MESSAGE@georgeinstitute.org.uk](mailto:MESSAGE@georgeinstitute.org.uk) or contact our Policy Fellow, Alice Witt: [awitt@georgeinstitute.org.uk](mailto:awitt@georgeinstitute.org.uk).

### Where can I learn more about improving research inclusion?

- Medical Science Sex and Gender Equity: [www.messageproject.co.uk](http://www.messageproject.co.uk)
- 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/nih.ac.uk/include/home?authuser=0>