



# MESSAGE

Medical Science Sex and Gender Equity

Improved integration of sex and gender in research

## **A vision for the UK biomedical, health and care research sector**

*Policy Lab 1 – 31<sup>st</sup> May 2023*

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# 1. Executive summary

On 22nd May 2023, the MESSAGE (Medical Science Sex and Gender Equity) project held a Policy Lab to answer the question:

**“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?”<sup>1</sup>**

The Policy Lab was attended by government and charitable research funders, regulators, publishers, patient representatives and researchers, in addition to representatives from NHS England, the Department of Health and Social Care and the Association of Medical Research Charities. The event comprised discussions on participants' vision for a sex and gender policy framework in the UK, solutions for overcoming existing barriers to policy rollout, and development of proposals for next steps.

Overall, the group identified two principal priorities for future action:

## **1. Sex and gender policies should be designed and delivered through a whole system approach**

Successful implementation of sex and gender policies will require joined-up thinking from stakeholders across the biomedical, health and care research sector in the UK, which will be supported by adoption of a shared timeframe and roadmap for change. Funding organisations must be the first actors to implement policies, and should ensure they invest additional funds in supporting researchers through a transition to meet the new standard.

Consideration of appropriate framing of the issue and development of shared definitions of sex and gender, as well as guidance for collecting data on these variables, will enable smooth collaboration between multiple and diverse actors.

## **2. Technical capacity-building and culture change across the research sector is needed to support policy implementation**

For a policy to translate into practice, it will be important to raise awareness among the public and across the research sector about the importance of integrating sex and gender considerations into research. Considerable investment will be needed in training researchers to conduct high-quality research that accounts for sex and gender, and examples of best practice in this area must be showcased and rewarded. It will also be essential to create an enabling environment for this change within institutional structures, including increasing the diversity of the workforce, and developing effective evaluation processes to monitor policy effectiveness.

Going forwards, the MESSAGE project team will develop a draft policy framework for funders to be shared at a second Policy Lab planned for 27th September 2023. The team will also work on producing a vision statement to be endorsed by key stakeholders, training materials for researchers and potential metrics for evaluating policy implementation, and will work on building political buy-in for the initiative.

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<sup>1</sup> This is the question that was articulated to Policy Lab participants before and during the event. On the recommendation of the Lab, we have expanded the term “biomedical” research to “biomedical, health and care” research and use this latter term throughout the rest of this report.

## 2. Introduction

### 2.1 Not accounting for all sexes and genders in biomedical, health and care research design leads to less effective care and poorer health outcomes

Biomedical, health and care research produces knowledge that is used to inform clinical and public health guidelines. The UK has an extensive system for funding, regulating and publishing this research and is an important contributor to knowledge production worldwide.

Most UK-funded research, however, does not integrate sex and gender considerations into research design for data collection, analysis and the reporting of findings. Research which does not take account of sex and gender is less accurate, reproducible and equitable. This leads to inadequate knowledge production and translates into less targeted care and worse health outcomes, affecting all people but particularly women, trans and intersex people, and people with variations in sex characteristics (VSCs).

The Medical Research Council (MRC) published the first UK-based guidance on [integrating sex considerations in cell and animal studies](#) in 2022. However, at the start of 2023, the UK still had no sex and gender policies for human research<sup>2</sup> and currently has no standard, unified guidance for the sector as a whole. This contrasts with funding organisations in other countries (most notably [Canada](#), [the United States](#) and European nations under [Horizon Europe](#)) which have longstanding policies in place to ensure researchers applying for funding account for sex and gender in their study design. Evaluation of these policies shows their effectiveness in improving the frequency and quality of how sex and gender are accounted for in research (e.g., [Haverfield & Tannenbaum, 2021](#)).

### 2.2 The current policy climate is favourable to improving the integration of sex and gender dimensions in biomedical, health and care research

There are undoubtedly challenges to be overcome in integrating sex and gender considerations into research.

For the research sector, these include:

- A **lack of awareness** about the relevance of sex and/or gender for almost all biomedical, health and care research questions, particularly among basic scientists, and about the distinction between sex and gender.
- **Uncertainty around best practice** for collecting data on sex and/or gender as research variables.
- The **cost and complexity** of recruiting research subjects of all sexes and/or genders, linked to concerns about having sufficiently large sample sizes for results to be statistically significant for all sexes and or genders.
- A **lack of skills and confidence** to undertake sex- and gender-based analysis (SGBA), exacerbated by limited examples and role models of high-quality practice and statistical innovation for this type of analysis.

There are also challenges for funding organisations in adopting and implementing sex and gender policies. These include:

- **Limited joined-up thinking** across the research sector about effective roll-out of a new paradigm for considerations of sex and gender within biomedical, health and care research.
- A **lack of consensus** among UK research funders on what such policies should look like and contain, compounded by the heterogeneity of UK funders in terms of size, funding capacity and resources.
- The need to identify **criteria to determine inadequate, adequate or excellent integration** of sex and gender considerations in funding applications and ensure that reviewers and committees know how to evaluate the quality of plans to integrate sex and gender components.
- Difficulties in **changing standard thinking and practice** within and across large organisations.

<sup>2</sup> In June 2023, after the Policy Lab took place, the MRC published its policy, [Embedding diversity in research design](#), which addresses the inclusion of sex, gender and diversity considerations in clinical research with human participants.

- The volatile and inflammatory public and political discourse around sex and gender in the UK, including at the level of government and in health and medical settings.

Nonetheless, the policy context in 2023 is favourable to pursuing improvements in the study of sex and gender differences. The Department of Health and Social Care's [Women's Health Strategy for England \(2022\)](#) recognises the need to improve representation of women in research and to report sex-disaggregated research findings. The Scottish Government's [Women's Health Plan \(2021\)](#) likewise highlights how improving data collection practices and disaggregation on the basis of protected characteristics is critical for promoting women's health and experiences. Moreover, NHS England's 2016 report, [Improving Outcomes through Personalised Medicine](#), also emphasised the importance of moving away from a 'one-size-fits-all' approach to treatment of patients.

### 2.3 The MESSAGE project ran a Policy Lab in May 2023 to identify how policies can improve integration of sex and gender dimensions in biomedical, health and care research

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, health and care research.

This workshop brought together representatives from across the biomedical, health and care research sector, including government and charitable funding organisations, regulators, patient representatives, researchers, and publishers. Representatives from the Department of Health and Social Care, NHS England, and the Association of Medical Research Charities were also present.

The aim was to think as broadly as possible about what an ideal sex and gender policy framework for UK biomedical, health and care research might contain and what resources it will need to be accompanied by. Discussions also explored potential solutions to the challenges of implementing such a policy framework, building on opportunities and resources that already exist and considering further steps that might be taken.





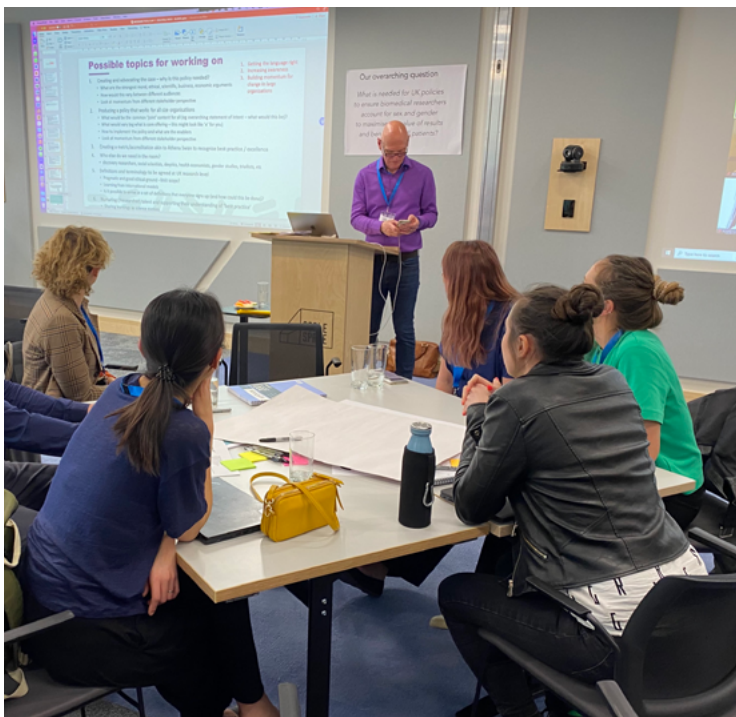
In summary, the recommendations from the Policy Lab were as follows:

### 1. Sex and gender policies should be designed and delivered through a whole system approach

- It is desirable to take a whole system approach to realising and delivering a shared vision for the integration of sex and gender considerations
- A robust policy implementation plan with a shared timescale for change will support effective collaboration across the sector
- It is important to make the case for integrating sex and gender in research in ways that will resonate with the priorities of each stakeholder
- Funders should co-design and implement sex and gender policies and allocate appropriate additional funding to support policy delivery
- Establishing clear and consistent definitions of sex and gender will enable effective collaboration across the research sector
- Guidance on how to collect data about sex and gender in biomedical, health and care will improve consistency across the sector

### 2. Technical capacity-building and culture change across the research sector is needed to support policy implementation

- Wider awareness and endorsement from the public will support effective policy uptake
- Researchers and reviewers must be trained to account for sex and gender in research
- Role models of good practice should be showcased and rewarded
- It is essential to create an enabling environment for this change within institutional structures
- Effective evaluation will be required to assess policy effectiveness and support accountability



The remainder of this document explores the outputs from the Policy Lab in more detail:

- **Section 3** focuses on the need for a whole system approach to the design and delivery of sex and gender policies.
- **Section 4** describes how technical capacity-building and culture change can be delivered to support policy implementation.
- **Section 5** summarises the key takeaways from the Policy Lab discussions.
- **Section 6** briefly summarises the next steps to be taken by the MESSAGE project.

## 3. Sex and gender policies should be designed and delivered through a whole system approach

### 3.1 It is desirable to take a whole system approach to realising and delivering a shared vision for the integration of sex and gender considerations

A whole system approach brings together diverse stakeholders within a system to address a particular challenge. A whole system approach in the biomedical, health and care research sector and beyond, involving funders, regulators, research institutions and publishers, will have many advantages in supporting the delivery of a new paradigm for integrating sex and gender in research and in ensuring adherence to new stipulations. Effecting change in this area will involve the stakeholders using a combination of 'carrots' (e.g., incentives for improved practice) and 'sticks' (e.g., new minimum requirements).

Funders, whose role comes first in the research pipeline, must set out updated funding requirements stipulating the need for researchers to consider sex and gender from the study design phase. All funders acting simultaneously will increase the likelihood of achieving a meaningful shift in research practice and will prevent the integration of sex and gender considerations becoming a point of contention or competition between funders.

Regulators, publishers and research institutions should then introduce their own policies to mirror or build on funder stipulations. For this reason, it is desirable for stakeholders from across the research sector to be involved in the design of funders' policies from the outset. Again, having a common approach will prevent variation in stipulations around sex and gender considerations and competition between organisations, and support consistency in messaging for researchers trying to meet these criteria in their funding applications.

In addition to these stakeholders, the pharmaceutical industry and biotechnology companies are key players in the biomedical, health and care research system. To engage industry in this change, the Medicines and Healthcare products Regulatory Agency (MHRA) must implement policy guidelines that ensure the research conducted

in the private sector adequately accounts for sex and gender. Regulator action in this space could be modelled on the US Food and Drug Administration's recent diversity framework and be linked to the guidance on medical devices expected in autumn 2023.

To demonstrate their joined-up thinking, stakeholder organisations could create and commit to a vision statement (or 'statement of intent') that sets out their commitment to the integration of sex and gender in research. A vision statement or statement of intent will be preferable to a shared position statement as it will be adaptable to the needs and perspectives of different sizes and types of organisations. This could take a values-based approach, setting out how integration of sex and gender considerations is tied to the wider vision and mission of an organisation.

The planned series of MESSAGE Policy Labs will be an effective and efficient place for diverse stakeholders to think about these system changes. It will be critical for individual stakeholders to take ownership of this work and gradually assume growing responsibility for policy implementation.

### 3.2 A robust policy implementation plan with a shared timescale for change will support effective collaboration across the sector

A roadmap for how change will be delivered will support effective collaboration across the research sector. A shared timescale for how the sector will move towards this new goal is essential and should stipulate when sex and gender requirements will transition from recommendations to mandatory stipulations. The timescale could take the form of a 10-year plan to align with the [Women's Health Strategy for England \(2022\)](#), involving an initial pilot phase (perhaps 2-3 years) followed by more widespread policy implementation and evaluation, before a final period of ensuring universal delivery of 'gold standard' practice.

Other stakeholders suggested the plan could be considerably shorter – perhaps less than five years. It will be important to avoid this transition period being seen as punitive in nature but rather fostering a safe ‘work in progress’ environment for researchers to acquire new skills and techniques. It will be useful to draw on organisational, culture and behaviour change expertise to develop a framework for system change (such as a theory of change or maturity model). Similarly, system mapping to identify the potential roles and levers for change in the sector will be helpful. There are likely to be useful learnings from where policy change in research has been effective in the past, such as in relation to patient and public involvement (PPI) or ethics in animal research.

Given that sex and gender can be contentious and inflammatory topics, organisations will benefit from seeking human rights and inequalities experts advice on navigating the current UK political context. While there is always scope for error or misinterpretation in rolling out a new policy, organisations should seek out and draw upon external advice when needed, for example from human rights and inequalities. Against this backdrop, it will be easier for stakeholders to progress in this space if multiple organisations are simultaneously making similar cases for the importance of sex and gender.

It is important to ensure that this policy change doesn’t increase inequities between organisations of different sizes. Consideration should be given to how larger and better-resourced funders can show leadership through the process and support smaller funders, for example by sharing or subsidising training and best practice guidance.

In terms of scope, the MESSAGE remit should be expanded from biomedical research to ‘health and social care’ research more broadly. Looking further ahead, it will also be helpful to consider the work needed to set an international standard for inclusion of sex and gender in research. Working with the [Ensuring Value in Research \(EViR\)](#) forum, an international funders’ forum, is one opportunity for doing this.

### 3.3 It is important to make the case for integrating sex and gender in research in ways that will resonate with the priorities of each stakeholder

Successful policy implementation will rely on senior staff being convinced of the merits of this agenda for their organisation and championing the cause of sex and gender equity within their individual organisation’s work. There are a range of motivations for bringing about this paradigm shift and different motivations will be more appropriate or compelling to different stakeholder audiences. Framing the issue correctly for different audiences will be essential to get buy-in and navigate the challenging political discourse around sex and gender.

Above all, it is important to emphasise how research that accounts for sex and gender is part of what makes ‘good science’. Many stakeholders are likely to respond positively to the fact that this shift in research practice would improve reproducibility and generalisability of science, maximise patient safety, minimise adverse drug reactions and lead to improved health outcomes for all people. It will also reduce research waste, increase research impact and further the agenda of personalised medicine. The evidence generated by other nations which have implemented sex and gender policies should be drawn upon to underscore how a policy can translate into these positive outcomes.

It will also be beneficial to emphasise the positive economic impacts of sex and gender policies. These justifications – a “business case” – will be of particular interest to industry and government stakeholders.

These positive impacts include:

- A new gold standard of practice will make the UK **attractive as a site for clinical trials** which prioritise rigorous science.
- Better understanding of sex and gender differences in medical conditions and responses to treatment will lead to **improved and more cost-effective care**, which could save the NHS money. Better tailored treatments according to sex and gender will also reduce pressure on the NHS by preventing illness in the first place.



- Better understanding of adverse drug reactions in different sexes and genders will make **medicines safer, and also more cost-effective** if fewer drugs need to be withdrawn from the market. More robust understanding of, and therefore potential elimination of, drug side effects will have economic benefits.

For many actors in the research sector, maintaining a positive reputation and a competitive edge is a key motivation for enacting change. Framing how the integration of sex and gender considerations meets a new gold standard for research is therefore a way to mobilise buy-in from these stakeholders. Likewise, publicly funded organisations are likely to be motivated to act based on their accountability to the public and desire to win and maintain public trust. Government bodies are likely to be motivated by calls for transparency around public funds and legal obligations, including adherence to the Equality Act 2010, and charitable funders by accountability to their donors and the remit of the Charity Commission.



### 3.4 Funders should co-design and implement sex and gender policies and allocate appropriate additional funding to support policy delivery

Each funding organisation must integrate sex and gender considerations as a core part of their approach towards biomedical, health and care research – it should not be seen simply as a “bolt-on” – and the way they measure organisational impact and successful research.

In developing their own sex and gender policy and accompanying guidance, each funder should consider:

- **The timeline for policy roll-out**, including the move from recommended guidance to mandatory requirements. In line with this timeline, funders must decide when and how the quality of sex and gender inclusion in study design will affect funding outcomes, including renewals of existing awards.
- **Minimum requirements and ambitious standards for integration of sex and gender into research, and how these designations might change over time.** Guidance will be needed for reviewers to rate the standard of the incorporation of sex and gender considerations in funding applications as inadequate, adequate and excellent. One recommendation is that sex- or gender-disaggregated data be included in paper supplements as a minimum standard to enable effective secondary research and meta-analyses.
- **Technical guidance for researchers**, including: how requirements differ between basic and clinical research; circumstances in which it is acceptable for study designs not to account for sex and gender differences (e.g., sex-specific diseases); whether sample sizes should be proportional to the disease population, the whole population or not at all; how the policy applies to the study of rare diseases; and how to integrate intersectional components into analysis.
- **Extending timelines for funding calls in the short term**, to allow researchers sufficient time to familiarise themselves with new information and skills.

- **Allocating funds to cover extra costs associated with adhering to the policy.** These could include absolute costs (larger sample sizes) and associated costs (such as for increased animal housing and handlers), additional recruitment costs, and extra costs for PPI engagement and compensation (including for childcare). Pump priming funding might also be offered in the early years of a sex and gender policy to enable researchers to undertake training, incorporate new techniques into their research designs or to identify cell lines that are appropriate for a given research area.
- **Encouraging integration of sex and gender in research that is already underway.** For example, this could involve encouraging researchers to flag the non-inclusion of sex and gender as a limitation in published papers or providing top-ups of funding to existing grants.
- **The best format for the policy:** whether a policy, guidance or best practice recommendations would be most effective. It was suggested that funders should produce a simple 1-2 page document to set out the key points of the policy in an accessible way.

Funders should be aware that the policy and associated guidance will need to be updated regularly and funders should implement procedures to ensure this occurs. This will be especially important to reflect significant technological developments that affect the understanding and communication of sex and gender issues, such as the expansion of artificial intelligence and use of digital biomarkers.

### 3.5 Establishing clear and consistent definitions of sex and gender will enable effective collaboration across the research sector

It is important that all stakeholders work to a shared understanding of what sex and gender mean and the difference between the terms from the outset. Ideally, definitions should emphasise 'sex contextualisation' over 'sex essentialism', breaking sex into its component parts (chromosomal,

hormonal, anatomical etc.) rather than positioning it as a single biological variable. Policy guidance should offer a toolkit to help researchers think about which sex characteristics are relevant or not for their research question(s), and therefore who they need to recruit and how they should analyse their data. Beyond sex and gender, it is also key to think about intersectionality and to view integration of sex and gender as one strand of a wider picture of equality, diversity and inclusion (EDI) efforts.

Sex and gender must be defined and measured beyond the binaries of male/female or man/woman. Definitions should capture the needs and experiences of sex-diverse people, not just gender-diverse people, and to capture these individuals outside of binary categories. Intersex people and people with VSCs, who are often excluded from the conversation on defining and collecting data on sex and gender, should also be brought into these discussions.

Definitions of sex and gender will change over time and differ by socio-cultural contexts. To avoid reinventing the wheel, it will be important to build on the work of other groups with expertise in sex and gender in biomedical, health and care research, including [Gendered Innovations](#), the [Canadian Institutes for Health Research](#), the [SOGI \(sexual orientation and gender identity\) monitoring group](#) at the United States' National Institutes of Health and, in the UK, the [LGBT Foundation](#) and the [NHS LGBT team](#). Involving statisticians in the design of definitions will also help to ensure that they can be pragmatically adopted for data collection tools.

Initial suggestions for definitions of sex and gender generated at the Policy Lab were:

- **Sex:** A set of biological variables including reproductive organs, external genitalia, hormones, and chromosomes that create a socially understood biological system.
- **Gender:** The internal and external personal experience of and connection to a gendered category, which is socially constructed in each society and impacts on the social elements of an individual's life.

### 3.6 Guidance on how to collect data about sex and gender in biomedical, health and care will improve consistency across the sector

There is currently huge variation in the extent to which sex and gender data is captured, the questions that are asked of participants about their sex and gender, and how the data is gathered. Guidance on how to collect sex and gender data effectively should be provided to ensure consistency across the sector and improve inclusivity. The [DAISY guidelines](#) are already a key resource in this area.

Where appropriate, guidance on data collection should be accompanied by changes to NHS and other administrative systems (e.g., the community health index numbers in Scotland). It was suggested that there is currently limited political will to produce a single sex and gender 'information standard' in the UK so achieving this will need to be part of the overall roadmap for change.

At the research design level, the Policy Lab pointed to several best practice recommendations which could be included in future guidance:

- Questions about sex and gender should **only be asked when needed**, and patients should be told why those questions are being asked. There should be recognition that it is not always relevant to ask about sex assigned at birth.
- Questions on **gender should be asked first**, before those on sex/sex characteristics.
- There should be **multiple options on sex** (i.e., more than male/female) as well as the option to 'Prefer not to say'.
- The thinking behind this guidance must recognise that **sex assigned at birth is a historical state** that may not be relevant in the present.
- It is valuable to offer **free text boxes**, to enable respondents to **tick more than one box**, and to ask a **gender modality question** (about trans status) separately from a gender identity question.



## 4. Technical capacity-building and culture change across the research sector is needed to support policy implementation

### 4.1 Wider awareness and endorsement from the public will support effective policy uptake

Efforts should be made to improve public awareness about the need for sex and gender inclusivity in biomedical, health and care research and the fallout of it not being done. Ensuring that this messaging targets everyone, including men and boys, is also important.

Examples of areas it is critical to improve public awareness of are:

- Understanding sex and gender differences benefits **everyone's health**, including men's.
- How sex and gender affect women's health **beyond their reproductive system**, with conditions such as cardiovascular disease and Alzheimer's.
- **The relevance of gender**, not only sex, for shaping a person's health.
- How current gaps in knowledge, including poor understanding of how a person's chromosomes, anatomy, hormones and social experiences interact, lead to **health disparities and poor health outcomes**.

It will be important, however, to bear in mind that the public may expect sex and gender to be included as standard considerations of existing research, so may be surprised to learn that it is currently not. The sector must therefore be mindful that raising public awareness of these gaps may provoke medical and scientific scepticism and fears around health misinformation.

It is possible that improving public awareness of the need to account for sex and gender in research will translate into improved recognition of this within

the scientific community. Over the longer term, sex and gender should be integrated into the science curricula from primary school all the way through to postgraduate studies, and higher education institutions should offer placements focused specifically on sex and gender in biomedical, health and care research (as is now done for PPI). Literature reviews to highlight the gaps in existing research regarding sex and gender will also support awareness-raising among the scientific community. Furthermore, two-way knowledge exchange programmes between researchers and research users about research processes and findings will help build public awareness and ultimately improve research quality. Likewise, it is important to involve patients and community groups at every stage of research.

More broadly, securing positive media coverage of the proposed changes will be key to realising meaningful culture change. Celebrity endorsement will help increase the visibility of and commitment to this agenda, such as in the activism of Caroline Criado Perez, Davina McCall and Barbara Streisand, though seeking out more diverse ambassadors, including non-white and non-cisgender individuals, is also important. Likewise, championing of this policy change by England's Women's Health Ambassador, Professor Lesley Regan, and Chief Scientific Advisor, Professor Lucy Chappell, should be sought alongside support from the Academy of Medical Sciences, Medical Schools Council and General Medical Council. Political buy-in should also be sought from the outset, including through all-party parliamentary groups such as the group on Medical Research.



#### 4.2 Researchers and reviewers must be trained to account for sex and gender in research

Researchers need to be trained both in why accounting for sex and gender is important and how to do this well in their own research. Areas they will require general training on include:

- **Definitions of sex and gender**, the difference between them and why it is important to use them as variables in research.
- **Target sample sizes for each sex/gender.** This training should clarify that even if a study is not powered to produce statistically significant results for each sex/gender, it is still important to collect, disaggregate and report sex and gender data to facilitate high-quality secondary research and meta-analyses.
- **Statistical skills** for SGBA.
- **Strategies for improving diverse recruitment**, including thinking about recruitment via international collaborations. This training should cover and address historic marginalisation and exploitation of certain communities by science and should emphasise improving accessibility and intersectionality within recruitment. For basic research, consideration should also be given to logistical considerations of procuring and maintaining cell lines and animals of both sexes.
- **Conducting PPI activities effectively** to understand sex and gender differences, including involving carers and people of different ages (especially older people) in those conversations.

Specific technical areas which will require attention include:

- **Using secondary data** which has not accounted for sex and gender.
- Using data which contains gaps (**estimands**).
- Accounting for sex and gender in relation to **rare diseases**.

Ideally, training should encourage and enable researchers to engage in autonomous thinking about the best way to incorporate a fuller knowledge of sex and gender into their study design, rather than seeing this as a tokenistic or tick-box exercise. One way to do this will be to emphasise how the identification of sex and gender differences opens exciting avenues for discovery research.

While consideration will need to be given to how to fund training, it was noted that there is goodwill in the pharmaceutical industry to do this. Development of training materials should build on existing training materials, including existing training offered to Dutch PhD students, the Erasmus sex and gender summer school and Elsevier research academy training. An extensive directory and/or set of guidance of how sex and gender is relevant in each area of biomedical, health and care research will be a useful resource to help researchers understand why and how to account for these factors in their work.

Within research institutions, specific and targeted guidance and training for Research Ethics Committees and researchers who act as peer reviewers is critical to support effective policy roll-out across the sector. There is currently a limited number of people with the expertise to review sex and gender components of funding applications, particularly when combined with statistical considerations. The time pressures on potential reviewers mean that funders are, in general, encountering challenges with finding reviewers and having them undertake additional training, including on EDI topics. It may therefore be preferable to train reviewers through their research institutions rather than separately via funders.

Offering funding calls and PhDs that focus specifically on understanding sex and gender differences will expand the number of researchers able to design, undertake or review research that fully accounts for sex and gender.



Though directed funding calls are not universally popular, setting out expected sample size splits and appropriate statistical methods in grant stipulations could, at least during the initial phase of policy rollout, be helpful to researchers in understanding how to integrate sex and gender considerations into their work.

#### 4.3 Role models of good practice should be showcased and rewarded

Researchers conducting high-quality SGBA in each biomedical, health and care research area should be showcased as role models and their work presented as case studies of best practice. Publishers can support this through calls for papers and special issues which focus specifically on sex and gender differences. This could be accompanied by an award scheme across all disciplines to reward best practice in study of sex and gender differences, and could be built on the model of Nature's recent award for [Inclusive Health Research](#).

An accreditation process akin to Athena Swan could also be developed to highlight papers, researchers and/or institutions which demonstrate excellence in sex- and gender-informed research. Ideally, this should be a universal accreditation (rather than owned or issued by a particular organisation or funder), discipline agnostic, and relevant or adaptable to different types of research. Such an accreditation could be given or taken into consideration, for example, at the point of submitting papers to journals or applying for postdoctoral positions. An annual showcase of those who have met the gold standard will also help incentivise others.

Role modelling of best practice will be supported by facilitation of networking between experts and a website acting as a hub to showcase expertise in this area will be of benefit to this endeavour. A system for matching supervisors with students and schemes for mentoring early career researchers will also contribute to nurturing talent in this space, though care should be taken not to overburden the researchers who are doing this work well.

#### 4.4 It is essential to create an enabling environment for this change within institutional structures

Integration of sex and gender in research will be aided by improving the diversity, and particularly the sex and gender diversity, of the research workforce. This will require investment and institutional support, for example through meeting childcare costs. Improving the diversity of groups engaged throughout the research cycle, including expert and reviewer panels and other key decision-makers, should likewise be a priority.

Efforts may also be needed to address research culture and environment barriers, including work to address power dynamics that affect junior researchers, and broader EDI initiatives to effect culture change. Standards and training on EDI in research should be treated and incorporated in the same way as Good Clinical Practice standards and training have been.

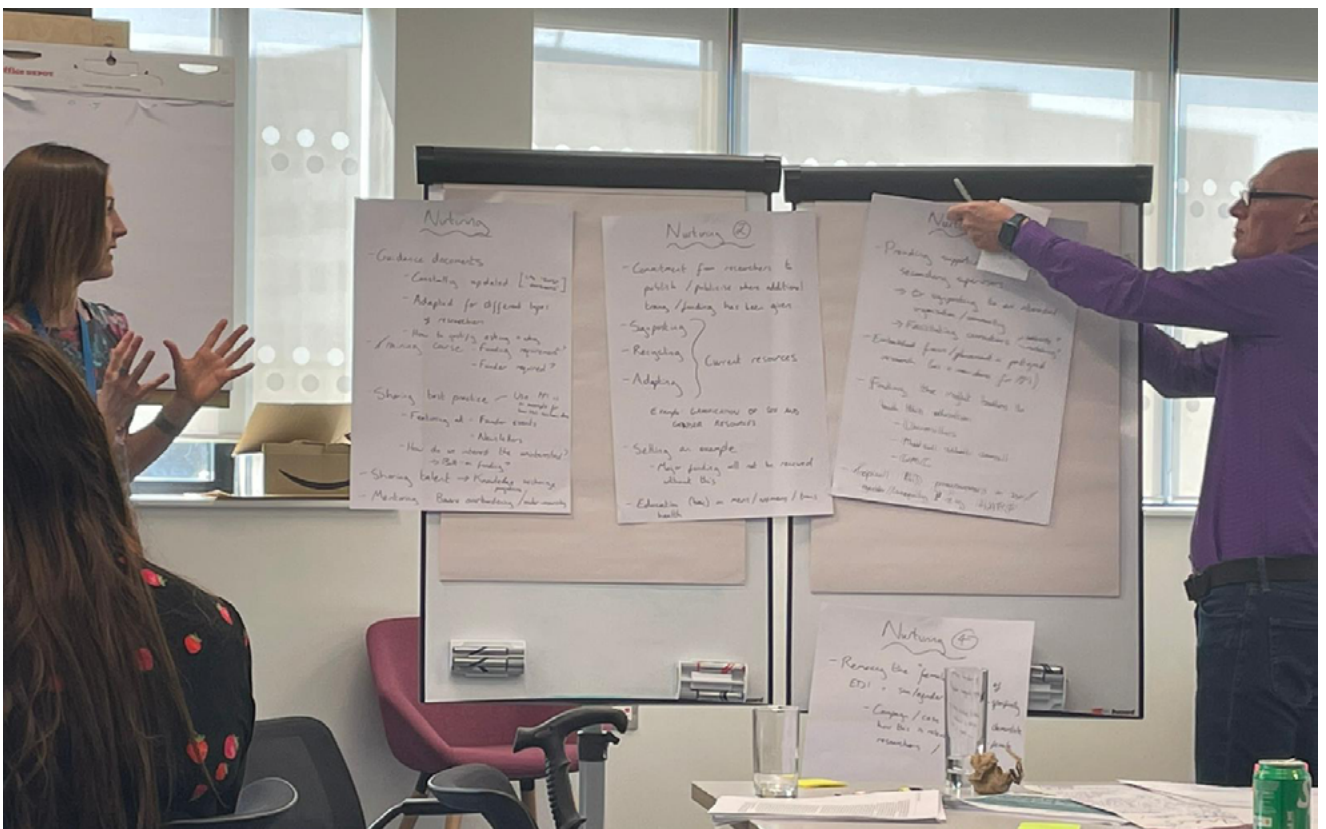
It is anticipated that there may be resistance to policy changes regarding accounting for sex and gender in research institutions, particularly among principal investigators or other senior staff. For this reason, it will be necessary for funders to eventually implement mandatory requirements for the inclusion of sex and gender and to signal that this is the direction of travel early on in the policy implementation process. Similarly, accountability mechanisms must be put in place for researchers to report feedback from funding application reviewers that is inadequate or harmful (e.g., misogynistic or transphobic). In funding, regulatory and publishing organisations, staff should be hired specifically to work on the implementation of sex and gender policies, rather than it being a 'passion project' or a non-remunerated add-on to the job description of existing staff. Efforts should also be made to move EDI work away from being primarily the responsibility of women and sex- and gender-diverse individuals. This will be supported by demonstrating how studying sex and gender differences is relevant to the work of all researchers and the experiences of all patients.

It will be useful to harness internal institutional mechanisms to deliver training and spread the message of the importance of incorporating sex and gender, including institutional newsletters and Continuing Professional Development infrastructure. In addition, training on sex and gender could be included as a mandatory training module during staff onboarding.

#### 4.5 Effective evaluation will be required to assess policy effectiveness and support accountability

Metrics should be developed for evaluating the extent and effectiveness of the rollout of sex and gender policies within institutions. In particular, qualitative analysis of reviewers' comments is key to understanding how policies are being implemented. To do this, it will be important to develop criteria for reviewers to assess whether inclusion of sex and gender in research is inadequate, adequate or excellent.

Further metrics should also be developed and implemented to evaluate the impact of sex and gender policies on how research is conducted, analysed and reported, and how that translates into improved health outcomes. Funders should begin including these metrics in their annual reporting and publicising these figures on their website and in reports. They should also use interim reports from grantees to monitor the sex and gender split of study participants and, where this is inadequate, take action to address this with researchers.



## 5. Conclusion

### **“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?”**

The first MESSAGE Policy Lab brought together stakeholders from across the UK biomedical, health and care research sector to discuss a vision for incorporating sex and gender dimensions into research. The event generated a sense of shared momentum around this issue and gave stakeholders a shared forum to collaboratively discuss the design and longer-term implementation of a sex and gender policy framework.

Policy Lab participants articulated the need for a shared policy implementation plan and timescale for change for the sector. Funding organisations must implement sex and gender policies first to ensure new standards are integrated in research from the study design phase, followed by policy action from regulators, publishers and research institutions, in addition to the private sector.

Co-design of a policy framework for funders is essential to ensure cohesion across the sector in the requirements made of researchers in the UK. Likewise, a timescale must be agreed for the stages at which funder requirements will transition from being recommended to mandatory.

Participants emphasised that it will be essential to support researchers throughout this transition with effective training and guidance, additional financial support, and opportunities to showcase and reward best practice. They highlighted that this is a project of culture change which will require wide-scale efforts to centre the importance of sex and gender considerations in research in the minds of both researchers and the wider public, including through championing by senior figures. In addition, there is a need for institutional environments to enable this change, including through increased diversity of the workforce, and for organisations to implement robust systems for monitoring and evaluation of policy implementation.

#### **Two principal priorities emerged from discussions of what is needed for UK policies to ensure biomedical, health and care researchers account for sex and gender:**

1. Sex and gender policies should be designed and delivered through a whole system approach.
2. Technical capacity-building and culture change across the research sector is needed to support policy implementation.

## 6. Next steps

The MESSAGE project will continue into 2024 and plans to hold three further Policy Labs. A second Policy Lab is planned for Wednesday 27th September 2023, where the same group of stakeholders will come together to review and refine the preliminary policy framework and further consider the roadmap to sector-wide implementation.

On the recommendation of the first Policy Lab, the next steps for the MESSAGE project team to take will include:

1. Creating a statement of intent to be signed by funding organisations and other members of the research sector



2. Designing a preliminary policy framework for funders, including defining sex and gender in a way that is inclusive and can be used effectively by researchers



3. Preparing training materials for researchers, including guidance on how to collect data on sex and gender



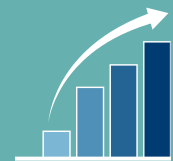
4. Developing a website to host policy guidance and training materials, showcase examples of best practice, and facilitate connections between researchers committed to the integration of sex and gender dimensions



5. Gaining buy-in from potential political champions



6. Exploring possible metrics for evaluating policy implementation and its impact



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