MESSAGE
Medical Science Sex and Gender Equity

Policy Lab Briefing Pack

Implementing sex and gender policies for UK biomedical, health and care research

Wednesday 31st January 2024

MESSAGE

The George Institute for Global Health UK

wellcome trust

Imperial College London

The 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, health and care research**.

The aim of the project is:

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

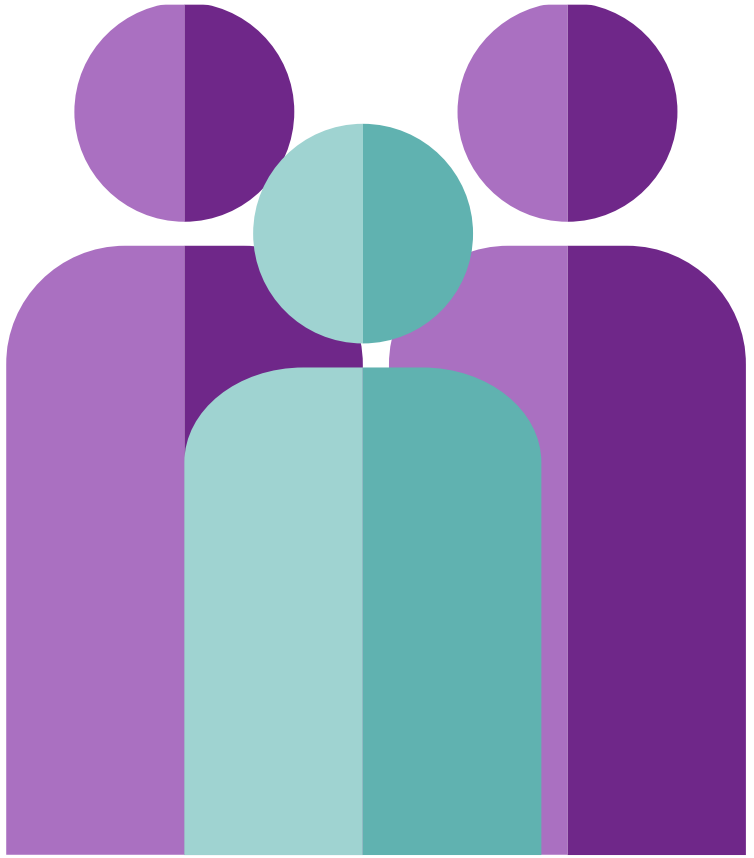
We are supporting co-design of a policy framework with stakeholders over the course of four Policy Labs. A policy lab is a collaborative workshop bringing together a range of stakeholders around a particular challenge to:

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

Contents of this briefing pack



Aim and scope of Policy Lab 3

Policy Lab 3 focuses on implementing the framework co-designed during Policy Labs 1 & 2

In Policy Lab 1 (May 2023) you identified two principal priorities for sex and gender policy implementation in the UK.

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

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

In Policy Lab 2 (Sept 2023) you have co-designed a gold standard sex and gender policy framework for UK biomedical, health and care research funders.

In Policy Lab 3 (Jan 2024) our focus will now turn to the **implementation of sex and gender policies** based on the co-designed framework, both by individual funders and the wider UK research sector.

There is momentum behind and keen support for roll-out of sex and gender policies in the UK

During Policy Lab 1, the group identified that **statements of support** for integrating sex and gender in research would pave the way for effective policy roll-out by signalling to the research community that this change is coming.

In December 2023, **31 members of the UK research sector showed their support for this change**. This hugely encouraging moment demonstrated the sector's unity around and prioritisation of this change, and was met with many positive responses.

- Academy of Medical Sciences
- Alzheimer's Research UK
- Alzheimer's Society
- Association of Medical Research Charities (AMRC)
- Asthma + Lung UK
- The BMJ
- BMJ Medicine
- BMJ Open
- Breast Cancer Now
- British Heart Foundation
- Chest, Heart & Stroke Scotland
- Diabetes UK
- The Dunhill Medical Trust
- Elsevier, including The Lancet Group and Cell Press
- Epilepsy Action
- Fight for Sight/Vision Foundation
- Health Research Authority (HRA)
- Heart Research UK
- JDRF
- Mankind Initiative
- Medical Research Council (MRC)
- Medical Research Foundation
- MHRA
- Medical Women's Federation
- Men & Boys Coalition
- Men's Health Forum
- NICE
- NIHR
- Stroke Association
- Trans Learning Partnership
- Wellcome Sanger Institute

Looking now to policy implementation, there is a need for both individual and collective action

Policy implementation plans must cover:

Individual steps (Funders)

- With their position at the start of the research pipeline, **funders have the power** to leverage change in how researchers account for sex and gender.
- It is important that funders **support and incentivise** change, rather than penalising researchers. Over time, as the research community becomes more familiar with new approaches, policy stipulations can **move from expectations to requirements**.

Collective steps (Whole sector)

- Previous policy initiatives have seen improvements to how sex and gender are accounted for, but **impact has not always been as widespread as expected**.
- Adoption of sex and gender policies/expectations **across the wider research sector** will compound the impact of funder policies and ensure change is more **sustainable and wide-reaching**.
- Similar policy expectations across the sector will also **maximise buy-in** and **ease the transition** for researchers.

Policy Lab 3 will focus on implementation of sex and gender policies in the UK

The central question of the event will be:

What are the practical steps the UK research sector, working individually and together, can take to implement sex and gender policies?

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

- Funding organisations *(Government and charitable)*
- Regulators
- Publishers
- Patient representatives
- Researchers

After this lab, **you will have the tools** to begin implementation of a sex and gender policy framework in your organisation.

Going forwards, **we will support you** through this process. In **Policy Lab 4**, we will **troubleshoot any implementation challenges** you encounter and plan for **long-term sustainability** of the Policy Lab group and its work.

Agenda

Time	Session
10:00*	Welcome and progress since Policy Lab 2
	What is successful policy implementation?
	Panel discussion: Experiences of implementing sex and gender policies at the NIH, MRC and CRUK
	Reviewing the proposed roadmap for implementation
13:00	Lunch
13:45	Developing implementation tools
14:45	Next steps and thanks
15:00	Close

*There will be a break during the morning session

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?

Speak to your colleagues to hear their thoughts

- What do they think needs to be in place to ease implementation? What barriers do they foresee?
- What ideas do they have about how you can prepare for this change as an organisation?

Think about what you would need for a sex and gender policy to be implemented in your organisation

- What and who would the process involve?
- Which expertise and sign-off would be needed?
- What hurdles do you foresee?

Be prepared to share your thoughts on the day

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 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.

Learning from the practical steps of other funders

Funders should seek to address known implementation gaps from the outset

Reviews of sex and gender policy implementation by NIH, CIHR and Horizon 2020 highlight **strengths and weaknesses** of their processes and offer **recommendations for improving policy uptake and impact**.

It will be helpful to **make plans to mitigate against the gaps** that other funders encountered before beginning UK policy implementation.

These gaps include:

- There were improvements to inclusion of females in research, but policy **impact on uptake of sex- and gender-based analysis was more limited**.
- There was **better policy uptake among clinical than pre-clinical** researchers (Arnegard et al., 2020).
- There was **limited uptake of training** on sex and gender, sometimes resulting in individuals who had done the training being brought into investigator teams in a **tokenistic** way.
- **Reviewers' feedback** on the sex and gender question was often **absent** and its content was **inconsistent** across different reviewers.
- Policies' impact on the integration of sex and gender in research outputs is unclear, but a review of NIH-funded research found **no significant increases in sex/gender reporting** (Geller et al., 2018).

Less than 30% of NIH-funded RCTs analysed data by sex or justified their reasons for not doing so (Geller et al., 2018)

Poor understanding persisted of the difference between sex and gender (Haverfield & Tannenbaum 2021) and of the gender dimension (de Cheveigné et al., 2017)

Learnings from other funders' experiences

1. Engaging hearts and minds

Practical steps to foster behaviour change across researchers and funders

It was helpful to **offer supplementary funding for existing awards** to encourage researchers to specifically assess sex as a biological variable. (NIH)

It is important to clearly integrate sex/gender **across the whole research cycle**, from the wording of the funding call to the application and evaluation process, as well as the granting, project monitoring and reporting phase. (Horizon)

Gave **clear reassurance that well-designed studies would not be excluded** just because they needed more money in order to account for sex and gender. (CIHR)

CIHR made it **clear they support and prioritise sex and gender**. Their actions to support researchers made their commitment to this change visible. (CIHR)

It was valuable to create a **scientific interest group on Sex and Gender in Health and Disease**, and disease-agnostic specialised centres of **Research Excellence on Sex Differences** to expand cross-disciplinary discussion and collaboration. (NIH)

Involvement of **social scientists and/or gender experts** by the research team led to better integration of the gender dimension in applications. Applicants should be **encouraged to include these experts** in their proposals. (Horizon)

Patient awareness-raising activities have encouraged funders to integrate sex/gender into funding calls and can provide valuable insights. (Horizon)

Identifying and supporting **role models and pioneers** is essential for helping to demonstrate the benefits of policy change. CIHR created the **Sex and Gender Champions programme** to support individuals with expertise in this area. (CIHR)

A pioneering step was to make financial investments to establish a **data resource and tissue bank** to build knowledge about different groups of people, including different sexes. (NIH)

de Cheveigné et al. (2017); Arnegard et al. (2020); Haverfield & Tannenbaum (2021)

Learnings from other funders' experiences (contd.)

2. Designing the application process

Practical steps to adapt existing application processes to reflect new policy expectations around s&g

Application forms must include **a question specifically asking about the integration of sex/gender**. (Horizon)

It was important to set up a **working group focused on delivering the policy** and to establish an **organisational strategy** to prioritise this work. (NIH)

Forms for reporting on project progress must include a section to describe aspects relating to integration of sex/gender. (Horizon)

There was an uptick in the integration of sex/gender in applications once applicants were asked to **justify their decisions, rather than just a yes/no tickbox** to say if sex/gender had been accounted for. (CIHR)

Engagement with the sex/gender question would be improved if applicants had to give a **justification** for why the gender dimension is **not relevant**. (Horizon)

Awareness-raising and training about the importance of this change **among funder staff** is key and must be **ongoing**. Staff who write funding calls and moderate evaluator panels should particularly be trained. (Horizon)

de Cheveigné et al. (2017); Arnegard et al. (2020); Haverfield & Tannenbaum (2021)

Learnings from other funders' experiences (contd.)

3. Guidance for researchers

Practical steps to support researchers to understand and meet new policy expectations

Checklists supported researchers (and reviewers) to understand the steps involved in accounting for sex/gender. (CIHR)

Uptake **among pre-clinical researchers has been more limited** than among clinical researchers, indicating that efforts are needed to **illustrate the relevance of the policy for pre-clinical research** more clearly. (NIH)

Guidance has to be regularly updated to reflect new evidence. (CIHR)

Making **training mandatory** and having **senior staff** encourage attendance would make it better-used. (Horizon)

Guidance included both an illustrative **webpage with key examples** and comprehensive **e-learning**. (NIH)

One effective means of training was to **give examples of wording/justifications that had been used in applications** and to ask respondents to assess if it was appropriate or not. (CIHR)

Training on sex and gender must be an **eligible cost for grant funding** and this should be **explicitly mentioned** in funding calls. (Horizon)

Researchers wanted guidance that was **discipline-specific**. (CIHR)

"Training" might be off-putting terminology, **"workshops"** may be more engaging. (Horizon)

Requiring training modules to have been **completed by at least one of the named applicants** appeared impactful. However, people who had completed the training were **often asked to join teams at the last minute (to tick this box)**. (CIHR)

de Cheveigné et al. (2017); Arnegard et al. (2020); Haverfield & Tannenbaum (2021)

Learnings from other funders' experiences (contd.)

4. Support for reviewers

Practical steps to ensure reviewers give regular, useful, consistent feedback regarding integration of s&g

There was an uptick in the number of applications that integrated sex and gender **once evaluators were required to factor s&g integration into their assessment** of proposals. In other words, the **researchers were aware of how seriously the funder took this aspect of the application form**. (CIHR)

It is essential to include a **specific box to comment on the sex/gender component** in the evaluation form. (Horizon)

Researchers more likely to engage with the question on sex and gender if they expected to receive **robust feedback**. (CIHR)

The frequency and quality of feedback on the gender dimension from evaluators **varied greatly depending on whether the evaluator was a gender expert or not**. Evaluation panels should consist of 5 people including **at least one expert with gender expertise**. (Horizon)

Disease-specific guidance on sex- and gender-based analysis enhanced evaluators' feedback. (CIHR)

There was **inconsistency in if/how reviewers evaluated** the integration of sex and gender, which would be improved by a **framework against which integration of s&g could be assessed**. (NIH)

de Cheveigné et al. (2017); Arnegard et al. (2020); Haverfield & Tannenbaum (2021)

Learnings from other funders' experiences (contd.)

5. Evaluating policy implementation

Practical steps for measuring policy uptake and impact, and identifying priority areas for further work

Regular assessments of funder performance are important to prompt **reflection on the effectiveness of different interventions**. (CIHR)

It is important to analyse policy implementation **across the whole funding portfolio** and ensure that the policy is being applied across **all disease areas**. (NIH)

Could be helpful to **ask applicants to self-evaluate** how they have integrated sex/gender. (Horizon)

Beneficiaries should be requested to report on **how much money is spent for gender training or for sub-contracting external gender expertise**. (Horizon)

de Cheveigné et al. (2017); Arnegard et al. (2020); Haverfield & Tannenbaum (2021)

Funders must consider how the integration of s&g will be factored into the application's overall score

One reason why the impact of other sex and gender policy initiatives has been more limited than hoped is that **it is not clear how the quality of the integration of s&g affects an application's overall score** and likelihood of it being funded. To mitigate against this, funders should consider **how the evaluation of s&g integration will feed into existing processes for scoring applications**.

Policy Lab 1 & 2 discussions clarified that, in the long term, applications which do not account for sex and gender in a high-quality way should not be accepted, but that a phased approach is needed to get to this point. A **proposed phased approach** is set out in the roadmap on slide 25.

In practice:

"The quality of the gender dimension **does not influence the overall scores that applications receive**"

"The integration of the gender dimension in the proposals is **evaluated as a plus**, but its absence not considered in a negative way or punished."

de Cheveigné et al. (2017)

CIHR found a positive correlation between the quality of integration of s&g and funding success, but **did not establish that there was a causative relationship** between the two.

Three reviewers scored integration of sex and gender as either a strength, a weakness or not applicable. Reviewers were **not compelled to reject applications where the integration of s&g was considered a weakness,** or otherwise factor the quality of sex and gender integration into their overall score for applications.

Haverfield & Tannenbaum (2021)

Little more than half (**55% and 61%**, in 2016 and 2017 respectively) of reviewers (panel members) thought that the score given to the integration of sex as a biological variable **impacted overall score given to applications.**

Arnegard et al. (2020)

NIH **does not have a system** to ensure that the quality of the integration of sex as a biological variable is factored into applications' overall score.

NIH (2019)

A roadmap for individual and collective policy implementation

A clear and achievable roadmap for policy implementation will enable meaningful change

The following roadmap draws on previous Policy Lab discussions to set out **practical steps** to be taken by the UK research sector, **individually and together**, to ensure **impactful and sustainable implementation** of sex and gender policies.

Slides 24 and 25 set out steps for **funders** to take over the next **1-2 years** to begin successful implementation of sex and gender policies. These steps cover the **five priority areas** identified in Policy Labs 1 & 2:

Engaging hearts and minds

Designing the application process

Guidance for researchers

Support for reviewers

Evaluation mechanisms

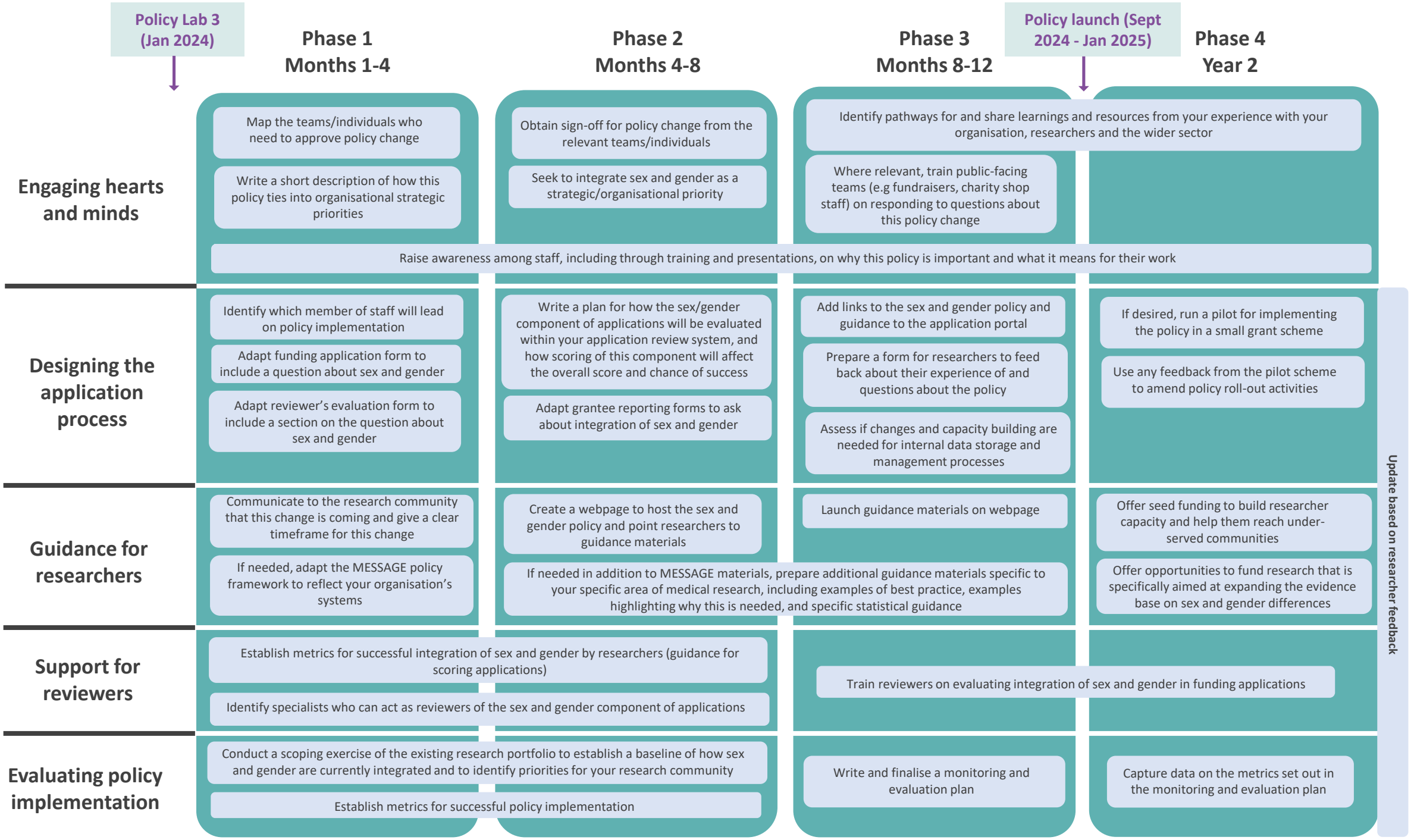
Simultaneously, publishers, regulators and research institutes can take steps to **mirror these expectations** and ensure there are **incentives and accountability for research outputs** to reflect the stipulations set out in funding applications.

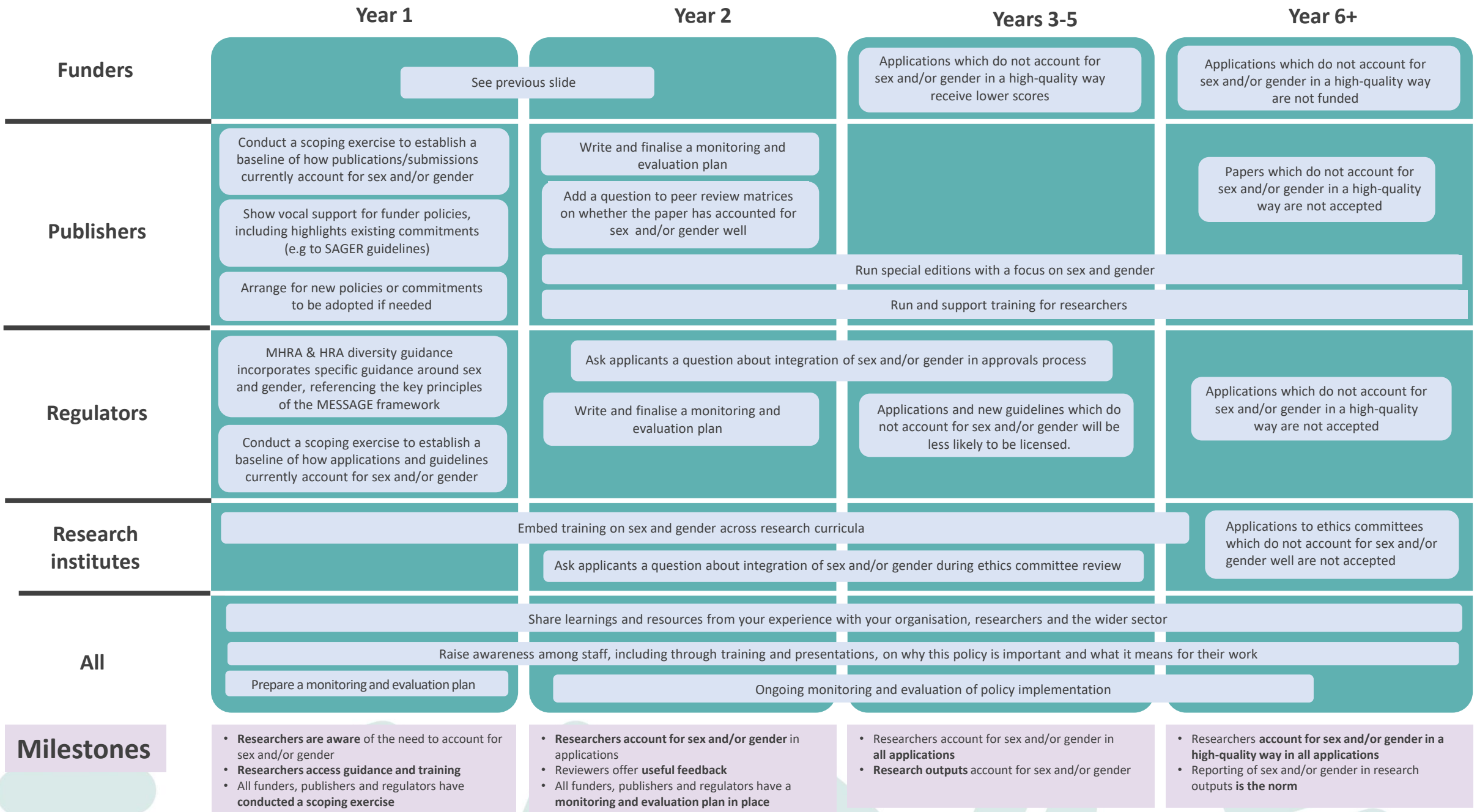
Researchers will play a key role in **pioneering new approaches to research, helping to prepare guidance materials, and sharing feedback** to optimise policy implementation. Patients are likewise essential to help **spread the word** about this change (and the need for it) and **holding funders to account**.

The roadmap steps will be made into a **checklist** and **tracker** to help you measure your **progress**.

Consider the roadmap and reflect on the following questions:

- Do the **five priority areas** encompass all the steps that need to be taken? If not, what else should be added?
- Which practical steps look **manageable**? Which ones feel more **challenging**?
- Does the **planned timeframe** seem feasible? Would you make any changes?
- What would you add to or change about the **milestones** on slide 25?
- **For non-funders:** Are these **reasonable and practical expectations** for your organisations to reflect funders' policies? What would you change or add?


Policy Lab 3 (Jan 2024)
Phase 1 Months 1-4
Phase 2 Months 4-8
Phase 3 Months 8-12
Policy launch (Sept 2024 - Jan 2025)
Phase 4 Year 2
Engaging hearts and minds
Map the teams/individuals who need to approve policy change
Write a short description of how this policy ties into organisational strategic priorities
Obtain sign-off for policy change from the relevant teams/individuals
Seek to integrate sex and gender as a strategic/organisational priority
Identify pathways for and share learnings and resources from your experience with your organisation, researchers and the wider sector
Where relevant, train public-facing teams (e.g fundraisers, charity shop staff) on responding to questions about this policy change
Raise awareness among staff, including through training and presentations, on why this policy is important and what it means for their work
Designing the application process
Identify which member of staff will lead on policy implementation
Adapt funding application form to include a question about sex and gender
Adapt reviewer's evaluation form to include a section on the question about sex and gender
Write a plan for how the sex/gender component of applications will be evaluated within your application review system, and how scoring of this component will affect the overall score and chance of success
Adapt grantee reporting forms to ask about integration of sex and gender
Add links to the sex and gender policy and guidance to the application portal
Prepare a form for researchers to feed back about their experience of and questions about the policy
Assess if changes and capacity building are needed for internal data storage and management processes
If desired, run a pilot for implementing the policy in a small grant scheme
Use any feedback from the pilot scheme to amend policy roll-out activities
Guidance for researchers
Communicate to the research community that this change is coming and give a clear timeframe for this change
If needed, adapt the MESSAGE policy framework to reflect your organisation's systems
Create a webpage to host the sex and gender policy and point researchers to guidance materials
If needed in addition to MESSAGE materials, prepare additional guidance materials specific to your specific area of medical research, including examples of best practice, examples highlighting why this is needed, and specific statistical guidance
Launch guidance materials on webpage
Offer seed funding to build researcher capacity and help them reach under-served communities
Offer opportunities to fund research that is specifically aimed at expanding the evidence base on sex and gender differences
Support for reviewers
Establish metrics for successful integration of sex and gender by researchers (guidance for scoring applications)
Identify specialists who can act as reviewers of the sex and gender component of applications
Train reviewers on evaluating integration of sex and gender in funding applications
Evaluating policy implementation
Conduct a scoping exercise of the existing research portfolio to establish a baseline of how sex and gender are currently integrated and to identify priorities for your research community
Establish metrics for successful policy implementation
Write and finalise a monitoring and evaluation plan
Capture data on the metrics set out in the monitoring and evaluation plan
Update based on researcher feedback


Year 1
Year 2
Years 3-5
Year 6+
Funders
See previous slide
Applications which do not account for sex and/or gender in a high-quality way receive lower scores
Applications which do not account for sex and/or gender in a high-quality way are not funded
Publishers
Conduct a scoping exercise to establish a baseline of how publications/submissions currently account for sex and/or gender
Show vocal support for funder policies, including highlights existing commitments (e.g to SAGER guidelines)
Arrange for new policies or commitments to be adopted if needed
Write and finalise a monitoring and evaluation plan
Add a question to peer review matrices on whether the paper has accounted for sex and/or gender well
Papers which do not account for sex and/or gender in a high-quality way are not accepted
Run special editions with a focus on sex and gender
Run and support training for researchers
Regulators
MHRA & HRA diversity guidance incorporates specific guidance around sex and gender, referencing the key principles of the MESSAGE framework
Conduct a scoping exercise to establish a baseline of how applications and guidelines currently account for sex and/or gender
Ask applicants a question about integration of sex and/or gender in approvals process
Write and finalise a monitoring and evaluation plan
Applications and new guidelines which do not account for sex and/or gender will be less likely to be licensed.
Applications which do not account for sex and/or gender in a high-quality way are not accepted
Research institutes
Embed training on sex and gender across research curricula
Ask applicants a question about integration of sex and/or gender during ethics committee review
Applications to ethics committees which do not account for sex and/or gender well are not accepted
All
Share learnings and resources from your experience with your organisation, researchers and the wider sector
Raise awareness among staff, including through training and presentations, on why this policy is important and what it means for their work
Prepare a monitoring and evaluation plan
Ongoing monitoring and evaluation of policy implementation
Milestones
• Researchers are aware of the need to account for sex and/or gender
• Researchers access guidance and training
• All funders, publishers and regulators have conducted a scoping exercise
• Researchers account for sex and/or gender in applications
• Reviewers offer useful feedback
• All funders, publishers and regulators have a monitoring and evaluation plan in place
• Researchers account for sex and/or gender in all applications
• Research outputs account for sex and/or gender
• Researchers account for sex and/or gender in a high-quality way in all applications
• Reporting of sex and/or gender in research outputs is the norm

Implementation tools

Development of supporting materials will support policy implementation

The following slides outline **implementation tools** to support change in the five priority areas. They are designed with funders in mind, but these tools will be useful for **all research stakeholders** taking steps to improve integration of sex and gender in their processes.

To prepare for Policy Lab 3 discussions, we recommend you **familiarise yourself with the information** in these slides and **consider the key questions** outlined in the blue box for each tool.

Theme	Tool
Engaging hearts and minds	Guidance for communicating about the policy (internally and externally)
Designing the application process	Drafting question wording for application forms
Guidance for researchers	Planned structure of guidance tools for researchers
Support for reviewers	Matrix for evaluating integration of s&g
Evaluating policy implementation	Designing metrics for monitoring and evaluating policy implementation

Engaging hearts and minds

The launch of sex and gender policies must be accompanied by behaviour change efforts targeted at both researchers and funders' (and other stakeholders') staff.

These steps will include raising awareness of existing gaps in the evidence base, the negative impacts of this, and the urgent need to address it.

The framing of this policy will shape how researchers respond to it

It is helpful to consider **the framing and language** we will use to communicate about the MESSAGE policy to audiences both **internal and external** to our organisations.

Consistency in communication around key questions to do with this work will demonstrate **confidence** in the authority of the policy and the degree to which the MESSAGE community has **thoroughly considered** each challenge.

MESSAGE Policy Lab 1 identified that it is preferable to frame this work in terms of:

- **Enhancing scientific rigour and reproducibility**
- **Ensuring patient safety**
- **Reducing research waste**
- **Establishing the UK as a world-class site for biomedical, health and care research**
- **Maximising research impact**
- **Improving health outcomes**
- **Addressing existing gaps in the evidence base**
- **Taking us closer to personalised medicine**
- **Minimising adverse drug reactions**
- **Reducing pressure on the NHS and making care more cost-effective**

It will be helpful to prepare answers to potentially challenging questions in advance

Questions that are often asked about this policy work include:

Why do we need to account for gender when only sex is relevant for health?	Why are you prioritising sex and gender over other protected characteristics like race and ethnicity?
Women live longer than men so why should this be a priority?	Isn't this just creating more work for already over-burdened researchers?

- How should MESSAGE stakeholders **respond** to these questions?
- What **other challenging questions** do you anticipate this policy could receive?
- What are they **key touchstones to come back to** when responding to challenging questions about the MESSAGE policy?

Designing the application process

How an application form asks about sex and gender determines if/how researchers engage with the question

To ensure that researchers account for sex and gender in their application, it is important to **include a question in your application form** that specifically asks about this.

Though each organisation's application system is different, there are some **general principles for asking about sex and gender** to consider. You may find it helpful to see **how other funders have framed the question** on their application form (see slide 33) and consider what you like or don't like about each approach.

Reflect on the following questions:

- Should there be **two questions**, one for sex and one for gender?
- Should the question include a **Yes/No tickbox** for whether sex and/or gender have been accounted for? Should the question require a **descriptive answer**?
- Should there be one question box for **each policy expectation**, or just **one question box for all**?
- How would you **phrase the question**? (e.g Accounting for sex and/or gender? Integrating? Something else?)
- Would sex and/or gender be adequately covered in a question about **diversity characteristics in general** or should it be a **standalone question**?

Funders' application forms ask about sex and gender in different ways

"When relevant for your project, refer briefly to…**How the gender dimension (i.e. sex and/or gender analysis) is taken into account in the project's research and innovation content**.

Note: This section is mandatory except for topics which have been identified in the work programme as not requiring the integration of the gender dimension into R&I content."

af_he-ria-ia-stage-1_en.pdf (europa.eu)

- This form asks applicants to "**refer briefly**" to the gender dimension.
- It does not give details of what "the gender dimension" refers to but leaves this **broad and open**.
- This system **denotes funding calls where sex/gender should be integrated** in advance, rather than applying it to all.

"Is **sex as a biological variable taken into account** in the research design methods, analysis and interpretation, and/or dissemination of findings? Yes/No

Is **gender as a socio-cultural factor taken into account** in the research design, methods, analysis and interpretation, and/or dissemination of findings? Yes/No

If yes, please describe **how you will integrate sex and/or gender considerations** into your research proposal (limit of 2000 characters). If no, please **explain why sex and/or gender are not applicable** to your research proposal."

https://cihr-irsc.gc.ca/e/49560.html

- This form asks **Yes/No questions initially**, followed by **descriptive** questions.
- It asks about sex and gender **separately.**
- It designates a space for applicants who are **not accounting for sex and/or gender** to justify why not.
- It asks how sex/gender will be integrated but does **not explain what that refers to**.

"Address the following points:

- Describe the **planned distribution of subjects** by sex/gender, race, and ethnicity.
- Describe the **rationale for selection** of sex/gender, racial and ethnic group members in terms of the scientific objectives and proposed study design. The description may include but is not limited to information on the population characteristics of the disease or condition under study.
- Describe **proposed outreach programmes** for recruiting sex/gender, racial and ethnic group members.
- Inclusion and Excluded Groups: **Provide a reason for limiting inclusion** of any group by sex/gender and/or ethnicity."

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf#page=252

This form asks **one question on each** policy stipulation.

Guidance for researchers

Guidance will illustrate what policy expectations look like in practice

Detailed guidance and examples will be essential to help researchers understand policy expectations and put them into practice in their own work. Over 2024, the MESSAGE team will produce a **handbook and other guidance materials** for researchers.

Slides 36 and 37 share an outline for a **handbook** on translating the policy expectations into practice. Slide 38 offers some suggestions of **additional resources** that could be of use to researchers.

Read over the following slides and consider:

- Would you make any changes to the **structure** of the handbook?
- What **alterations** would you make to the handbook's content? What **other guidance** should be included?
- What other **guidance resources** would be helpful to researchers?

Guidance on how ‘sex' and ‘gender' are used in this policy will ensure consistency

Introduction:

Explain **why this policy is necessary** - to address **inaccuracies** and **inequities** - with case studies and examples to illustrate this

How to use this resource - signpost the parts of the handbook that cover pre-clinical, clinical, and population health research

Section 1: How are we using ‘sex’ and ‘gender’ in this policy?

Explain that ‘sex’ and ‘gender’ are labels that can refer to a **range of characteristics**, and that accounting for specific characteristics improves the **precision** of scientific research.

Explain that we are **not offering immutable definitions** of these terms but rather offering a way for the terms to be used that **maximises scientific rigour, reproducibility and benefit for all**.

Sex characteristics:

- Detailed **list of sex characteristics and examples** of how each can impact health
- Explain the **types of data** that can be collected for each sex characteristic

Gender characteristics:

- Explain what is meant by **gendered pressures** (covering both constraints & privileges), including **examples of how these impact health**
- List of different gender characteristics that data can be collected on (**gender identity, expression and modality**) and **explanation/examples to illustrate** when it would be appropriate to collect data on each characteristic

Guidance will provide direction for each stage of the research cycle

Section 2: How do I account for sex and gender at each stage of the research cycle?

Describe how sex and gender can be integrated **at each stage of the research cycle**, covering broad information on **which factors need to be taken into consideration**. The stages include:

- Study design
- Planning the target sex/gender distribution
- Patient and public involvement
- Recruiting/procuring participants, subjects or datasets
- Data collection practices
- Data analysis
- Reporting findings

Describe how to complete each stage in the context of **pre-clinical, clinical and population health research**. This section is organised into a separate section for each research type). Each section will contain **examples of best practice** and **key considerations** for each stage specific to that research type.

Description of key additional considerations for **quantitative studies**, **qualitative studies** and studies using **secondary data**.

Other guidance resources suggested in Policy Labs 1 & 2 include:

- Effective strategies for **recruiting and retaining under-represented groups**, particularly women/girls, trans people and people with VSCs.
- How to **collect data** from participants about their sex and/or gender characteristics.
- How data collection on s&g characteristics **aligns with NHS data collection** practices.
- A **"decision tree"** for identifying if a study should account for sex and/or gender.
- A list of **existing datasets** which account for sex and gender well.
- How to account for **exogenous hormones** (e.g. contraception, gender-affirming hormone therapy), the **oestrous cycle** and **different stages of the female lifecourse** (e.g. menopause, pregnancy).

Support for reviewers

Reviewers play a pivotal role in determining whether applicants account for sex and gender

Evidence has found that researchers are more likely to engage with the application question on sex and gender if they know that reviewers will **factor their response into the application's overall score** and will offer **robust, helpful feedback**.

Reviewers will need to be upskilled in assessing high-, mid- and poor-quality integration of sex and gender in applications. A **clear framework** for evaluating this component of applications will ensure there is **consistency** in how applications are judged **across organisations and funding streams** within organisations.

The following slide sets out an outline for a **matrix** for evaluating applications' integration of sex and gender.

- What would you **add, remove or edit** from the matrix's content?
- What do you think of this way of **structuring** the matrix?
- Should a **numerical scoring system** be attached to this matrix? How would you design it?
- Should the matrix focus on if s&g have been integrated **('yes/no' tickbox)** and/or if s&g have been **integrated *well***?

Evaluation matrix for reviewers

	Included? (Y/N)	Considerations	Applies to?
S/g characteristic(s) to be studied are listed and justified		Selected s/g characteristic(s) are appropriate to answer the research question	All
Choice to study sex and/or gender stated and justified		Applicant demonstrates understanding of the difference between sex and gender	Clinical and population health
If choosing not to account for sex and/or gender, a strong, evidence-based justification is given		Applicant's justification is appropriate (see section 3f of policy for further details)	All
Appropriate participants/subjects included to reflect the chosen s/g characteristic(s)		Study sample includes an appropriate number and proportion of: For **sex**: female, male & I?/VSC ppts/subjects For **gender**: women, men & non-binary and trans participants	All research collecting primary data

Evaluation matrix for reviewers (contd.)

	Included? (Y/N)	Considerations	Applies to?
Strategies for recruitment and retainment of participants		Strategies for overcoming barriers to recruitment and retention of particular groups (e.g. caring responsibilities) Strategies shared for reaching I/VSC, trans and/or non-binary participants	Clinical and population health using primary data
Actions for procuring, managing and housing/storing subjects		Appropriate actions for planned sample Appropriate feasibility and cost considerations	Pre-clinical research using primary data
Overview of the planned analyses		Does the researcher plan to conduct s/g-disaggregated analysis? **If yes:** Are the analyses robust? **If no:** Is a justification given? Is the justification adequate?	All

Evaluating policy implementation

It is important to establish metrics for successful policy implementation from the outset

Regular, **ongoing monitoring of policy implementation** is essential for understanding which actions are working or not, and which areas need to be prioritised.

Development of a **monitoring and evaluation plan** before policy implementation begins will support your organisation to measure impact effectively. It is also important to **establish a baseline** against which to evaluate future progress.

Use of similar metrics across the research sector will make it easier to **compare progress** across organisations, disease areas, and different stages of the research pipeline.

The following slides give examples of metrics that have been used and recommended by funders and experts.

- Which metrics would you **adopt**? Which do you **dislike**? **Why**?
- What **other indicators** of successful policy implementation would you measure?

Possible metrics for monitoring and evaluating policy implementation

Hunt et al. identify five metrics for monitoring and evaluating policy implementation:

1 Number and proportion of **proposals** that include sex- and gender-based analysis (SGBA).

- Number of applications which integrate sex and gender. (CIHR)
- Percentage of projects taking into account the gender dimension based on Y/N tickbox on application form. (Horizon)

2 Number and proportion of proposals that include **quality SGBA**.

3 The **quality** of evaluators' scoring and comments (qualitative analysis).

4 Number of applicants, evaluators and staff who engaged in **trainings** and in what type of training.

5 **Number and proportion of peer-reviewed publications** that result from funded proposals that incorporated SGBA (Tracking research outputs using grant numbers).

- Publications from CIHR-funded research containing the keyword sex or gender. (CIHR)

Other metrics used by funders with sex and gender policies cover:

Sex/gender of included participants:

- Percentage of women enrolled in clinical research. (NIH)
- Percentage of women participants. (Horizon)

Funds spent:

- Quantity of funding spent on research which accounts for sex and gender. (CIHR)
- Number of research projects funded within specialised centres on sex differences. (NIH)
- Total funding awarded to supplement work to examine sex as a biological variable and success rate of applications. (NIH)

Link between integration of s&g and funding success:

- Likelihood of receiving funding when integration of sex and gender has been scored as a strength in the application. (CIHR)

European Commission (2015), Hunt et al. (2022), OWRH (2022), CIHR (2023)

What can MESSAGE do for you?

What other resources could the MESSAGE team prepare that would be useful to you?

What other questions do you have?

What would you like us to cover during Policy Lab 4?

Please let us know by emailing Alice Witt on *awitt@georgeinstitute.org.uk*

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MESSAGE Policy Lab 3

Wednesday 31st January 2024

Joining details:

Zoom link: https://georgehub.zoom.us/j/89744096265?pwd=mDhoZDRelS0ARUterlt9ap4wxZ2UvY.1
Meeting ID: 897 4409 6265 **Password:** 612919

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