THE CHALLENGE

Over the last decade, funding organisations and governmental agencies in the EU (Horizon Europe, the European Commission, DFG), Canada (Canadian National Institutes of Health), and the USA (National Institutes of Health), have introduced diversity policies that require researchers to consider the relevance of sex and gender in their projects. By comparison, funding bodies and regulators in the UK still do not adequately stipulate requirements around sex and gender at any stage of the biomedical research pipeline.

The contribution of UK research to the growing body of evidence defining sex-specific disease presentation and epidemiology is limited because the diversity of sex, gender and interactions with other characteristics such as race, ethnicity, age and socio-economic status are not systematically investigated.

Sex is often controlled for within statistical models, or where stratification for sex and gender is conducted it is often as an afterthought rather than pre-specified as a key component of study design. The consequence is an impoverished understanding of sex and gender differences in disease and suboptimal diagnosis and treatment.

From our preliminary research conducted in 2020/21, we found that none of the 17 largest UK medical research funders, or any of the UK’s major regulators, including the Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Health Research Authority (UKHRA), have policies in place to ensure that sex and gender are considered and addressed in funded research projects.

Our engagement with these funders and organisations revealed their enthusiasm and support for engaging with the process of developing guidance and best-practice recommendations for the UK context. Since then, the MRC has announced that from September 2022 they “require both sexes are used in the experimental design of grant applications involving animals and human and animal tissues and cells, unless there is a strong justification for not doing so”. The initiation of the MESSAGE project in January 2023 therefore comes at a time when the momentum for change is growing, and the clinical need is more urgent than ever.
**PROJECT AIMS**

- To co-create and facilitate the implementation of a **policy framework, best practice recommendations and educational materials** to facilitate integration of sex and gender in UK health and medical research funding and regulation.
- To **unite medical research funders and regulators** around a core set of sex and gender principles and priorities for individual organisations to apply flexibly to suit their institutional context.
- To collaborate with **NHS England** on their project to **develop and implement data standards** for collecting sex and gender data.
- To share the methods, learning and insight of the co-creation process to **provide a framework that can be applied to address further diversity gaps** in research in a sensitive and intersectional way.

**METHODS**

Through policy framework co-creation with stakeholders, we will collaborate with **funders, government bodies and patient & public groups** to produce and implement recommendations to integrate sex and gender into the UK biomedical research landscape. By **analysing other international policies, educational outputs, and research review findings**, in the context of our discussions with stakeholder groups we will arrive at a UK-oriented framework of best practice which can be used by funding bodies of all sizes.

By **including experts and community champions** focused on different aspects of diversity in the co-creation process, we aspire to produce a robust framework that considers **intersectional aspects of diversity through the lens of sex and gender**. Central to this process is listening to the expertise of charitable and regulatory bodies and the public that funds them. We will invite contributions from funders, patient & public groups and regulators, **including those who are sceptical about EDI work and those who feel underserved by it**. The final products will reflect the **consensus of values and priorities** which can be applied across the UK research landscape. We will utilise Knowledge to Action (KTA) and i-Parihs models for turning evidence into research practice, which emphasise the role of facilitators to **ensure that a range of views are heard and included**.

Finally, we will **assist organisations to implement the recommendations and to monitor the effect of these changes** on the research community and their project outputs. A particular strength of the KTA model is the **regular reassessment of core knowledge** to evaluate how it is being utilised, leading to frequent adjustments in practice.

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**Key regulatory stakeholders in the UK**

- Medicines and Healthcare Products Regulatory Agency
- GMC
- National Research Ethics Advisory Panel
- Scottish Public Benefit and Privacy Panel
- NICE
- UK Health Research Authority
## Who is involved?

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Institution</th>
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<tr>
<td><strong>Professor Robyn Norton</strong></td>
<td>Founding Director, Principal Investigator</td>
<td>The George Institute</td>
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<td><strong>Dr Kate Womersley</strong></td>
<td>Research Associate, Principal Investigator</td>
<td>The George Institute UK</td>
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<td><strong>Alice Witt</strong></td>
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<td><strong>Louise Cooper</strong></td>
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<td><strong>Anastasia Alden</strong></td>
<td>Communications Manager, Research and Policy Fellow, MESSAGE</td>
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<tr>
<td><strong>Professor Chloe Orkin</strong></td>
<td>Professor of HIV Medicine, President, Medical Women's Federation</td>
<td>Barts NHS Trust &amp; Queen Mary University of London</td>
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<tr>
<td><strong>Professor Mark Woodward</strong></td>
<td>Chair of Statistics, Epidemiology and Women's Health</td>
<td>The George Institute</td>
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<tr>
<td><strong>Emma Feeny</strong></td>
<td>Director of Global Advocacy and Policy Engagement</td>
<td>The George Institute</td>
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<tr>
<td><strong>Claudia Batz</strong></td>
<td>Policy and Advocacy Advisor UK</td>
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<tr>
<td><strong>Dr Carinna Hockham</strong></td>
<td>Postdoctoral Research Associate in the Global Women’s Health Program</td>
<td>The George Institute UK</td>
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<tr>
<td><strong>Dr Kat Ripullone</strong></td>
<td>Academic Clinical Fellow and ST1 Obstetrics &amp; Gynaecology NHS Thames Valley and University of Oxford</td>
<td>The George Institute</td>
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The Advisory Group

**Professor Kathryn Abel** Professor of Psychological Medicine and Honorary Consultant Psychiatrist and Director of the Centre for Women’s Mental Health, University of Manchester

**Dr Michael Brady** National advisor for LGBT Health at NHS England; HIV and Sexual Health consultant at Kings Cross Hospital, London; Medical director of the Terrence Higgins Trust

**Prof Kent Buse** Director, Healthier Societies Programme, The George Institute for Global Health; Co-founder and Co-director, Global Health 5050

**Dr Rageshri Dhairyawan** Consultant physician in Sexual Health and HIV, Barts Health Honorary Senior Lecturer, Queen Mary University of London

**Prof Sally Hines** Chair of Sociology, Director of Equality, Diversity and Inclusion, University of Sheffield, Principal Investigator, ESRC-funded project, “Trans Pregnancy”

**Dr Lilian Hunt** Equality, Diversity and Inclusion in Science and Health (EDIS) Lead, Wellcome Trust

**Dr Ian Kidd** Assistant Professor, Dept. Philosophy University of Nottingham

**Dr Catriona Manville** Director of Policy and Public Affairs, Association of Medical Research Charities (AMRC)

**Prof Neena Modi** Professor of Neonatal Medicine, Imperial College, London and Consultant in Neonatal Medicine at Chelsea and Westminster Foundation Trust, member of the UK Research Ethics Advisory Panel; Former President of the Medical Federation; President of the British Medical Association

**Dr Esther Mukuka** Head of Equality, Diversity and Inclusion (EDI) at NIHR

**Dr Sanne Peters** Associate professor, The George Institute for Global Health; Senior Lecturer, Faculty of Medicine, Imperial College London and Associate Professor at the University Medical Center Utrecht.

**Marina Politis** Medical student, University of Glasgow

**Prof Londa Schiebinger** John L. Hinds Professor of History of Science in the History Department, Stanford University; Director of the EU/US Gendered Innovations in Science, Health & Medicine, Engineering, and Environment Project

**Dr Amy Vassallo** Honorary Research Fellow, Global Women’s Health Program, The George Institute for Global Health, Australia

**Dr Ben Vincent** Research Coordinator at the Trans Learning Partnership
PROJECT TIMELINE

Planning Meetings
Stakeholder engagement
Publication of commentary

Jan-Feb 2023

Stakeholder Forum 2
Review and outline of materials

May 2023

Stakeholder Forum 4
Early implementation check-in

Sep 2023

Monitoring and evaluation:
Survey of funders & regulators

Jan 2024

Stakeholder Forum 1
Agreement on project plan & process

Mar 2024

Stakeholder Forum 3
Final review of materials & implementation

Jul-Sep 2024

Finalise and launch educational materials

Oct-Dec 2024

PROJECT OUTPUTS

Introductory commentary

Educational materials

Website

Gold standard policy framework and toolkit

Academic journal articles & media pieces

Email: MESSAGE@georgeinstitute.org.uk