PROJECT LAUNCH





February 2023

A co-creation project developing best practice recommendations and a policy framework for funders and regulators, alongside educational materials for researchers to improve sex and gender equity in biomedical research in the UK.



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 prespecified 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.



Key funding stakeholders in the UK

BBSRC

MRC

ESRC NIHR WELLCOME

Health and Care Research Wales

> **UK Clinical** Research Collaboration

UK Research

Health and Social Care Research and Development

Association of Medical Research Charities



- 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.



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 cocreation 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.

Key regulatory stakeholders in the UK

Medicines and Healthcare
Products Regulatory Agency

GMC

National Research
Ethics Advisory Panel

UK Health Research
Authority

The Investigator group





Who is involved?

Professor Robyn

Norton Principal Founding Director, The George Institute Chair of Global Health, Faculty of Medicine, Imperial College London

Dr Kate

Womersley
Principal
Investigator

Research Associate, The George Institute UK Doctor in Psychiatry, NHS Lothian and The University of Edinburgh

Alice Witt

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Research and Policy Fellow, MESSAGE

Louise Cooper

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Anastasia Alden

The George Institute UK

Communications Manager

Professor Chloe

Orkin

Barts NHS Trust & Queen Mary University of London

Women's Federation

Professor Mark

Woodward

The George Institute

Chair of Statistics, Epidemiology and Women's

Professor of HIV Medicine, President, Medical

Health

Emma Feeny

Claudia Batz

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Dr Carinna Hockham

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Postdoctoral Research Associate in the Global

Women's Health Program

Dr Kat Ripullone

Research Associate The George Institute

Academic Clinical Fellow and ST1 Obstetrics &

Gynaecology NHS Thames Valley and University

of Oxford



Medical Science Sex and Gender Equity

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



The Advisory Group

PROJECT TIMELINE



Planning Meetings Stakeholder engagement Publication of commentary

Stakeholder Forum 2 Review and outline of materials Stakeholder
Forum 4
Early
implementati
on check-in

Monitoring and evaluation:

Survey of funders & regulators

Jan-Feb 2023

May 2023 Sep 2023 Jan Mar 2024 2024 July-Sep 2024 Oct-Dec 2024

Stakeholder
Forum 1
agreement on
project plan &
process

Stakeholder
Forum 3
Final review of
materials &
implementation

Finalise and launch educational materials





Introductory commentary



Educational materials



Website



Gold standard policy framework and toolkit



Academic journal articles & media pieces

