

INCLUDE

**Better healthcare through more
inclusive research**



Laurie Oliva
Head of Public Involvement
NIHR Clinical Research Network



Pa rai o'r termau hyn sy'n cael eu defnyddio'n rheolaidd yn eich amgylchedd gwaith?

- Grwpiau anodd i'w cyrraedd
- Grwpiau heb gynrychiolaeth ddigonol
- Grwpiau ar y cyrion
- Grwpiau nas clywir yn aml
- Grwpiau dan anfantais
- Grwpiau heb eu gwasanaethu'n ddigonol



About INCLUDE

Innovations in Clinical Trial Design and Delivery for the under-served

Phase I - We developed an understanding of who is under-served, the barriers to inclusion and innovations to enhance inclusion

- Researched the **under-served** in clinical trials; professionals working on trials; and those taking part in them
- Collated the **barriers** and **challenges** that contribute
- Identified **innovations** in trial design and delivery to **enhance inclusion**

Phase II – We developed a Framework to improve inclusion (including roadmap and objectives with work streams)

- Produced the Framework: **a roadmap** suggesting intervention points to improve inclusion and core objectives and work streams
- Identified the importance of working with **funders**, **regulators** and other **stakeholders** to implement INCLUDE
- Working with stakeholders to decide routes to **implementation** and ways to **evidence** impact

Where we are now:

Phase III – Implementation and Evidence

- Disseminating the **INCLUDE Guidance** (including **COVID-19 specific guidance**)
- Continuing **engagement** and seeking opportunities to **raise awareness**
- **Measuring success and impact**

Pa grwpiau, yn eich profiad chi, dydy ymchwil iechyd a gofal ddim yn eu gwasanaethu'n ddigonol?



Who are the under-served groups?

There is **no single definition of what it means to be under-served**. It is **highly context specific**. However, some key characteristics common to several under-served groups are:

- Lower inclusion in health research than one would expect from population estimates
- Higher healthcare burden not matched by the volume of research designed for the group
- Important differences in how a group responds or engages with healthcare interventions compared to other groups, with research neglecting to address these factors

Example underserved groups by geo-demographic factors

Age extremes (e.g. under 18 and over 75); Black and African-, Asian- and Caribbean-heritage individuals; male/female sex (depending on trial context); those living in remote areas; those experiencing poverty e.g. those on low income; individuals with low education levels; LGBTQ communities; religious minorities

Example underserved groups by social and economic factors

People in full time employment; people in alternative residential circumstances (e.g. migrants, asylum seekers, care homes, prison populations, traveller communities, the homeless and those of no fixed abode); carers; the digitally excluded; those who do not access health services; stigmatised populations; looked after children

Example underserved groups by health condition

Mental health conditions; people who lack capacity to consent for themselves; cognitive impairment; learning disability; people with addictions; pregnant women; people with multiple health conditions; physical disabilities; visually/ hearing impaired; obese individuals; those with rare diseases and genetic disease sub-types

Pam ei bod hi'n bwysig cynnwys grwpiau heb eu gwasanaethu'n ddigonol mewn ymchwil glinigol?

- Ni fydd ymchwil nad yw'n adlewyrchu'r boblogaeth y mae'n ceisio'i helpu yn arwain at well gofal iechyd
- Ni fydd ymchwil nad yw'n gynhwysol yn ennyn hyder cleifion neu glinigwyr
- Dyma'r peth sy'n foesol iawn i'w wneud

“I didn’t know this was a thing. I would have liked to take part in research to help myself or my baby or to just be part of helping learn stuff for other women, for my future daughters, you know. If the research is about women, then all women should be involved. From all walks of life and cultures. Otherwise, it is not about all of us. Just some.”

Black African participant in MBRRACE UK PPIE project

**Yn eich profiad chi, pa
rwystrau i ymchwil y mae
grwpiau heb eu
gwasanaethu'n ddigonol
yn dod ar eu traws?**



Mentimeter

Intrinsic Barriers

Feeling unqualified to take part (e.g. due to lack of education)
Specific cultural barriers
Specific health fears (e.g. hospitals, needles)
Lack of interest in research
Lack of trust in trials
Negative attitudes to the concept of research



Community engagement and development
communications strategies
Information sharing
Peer networks
Research visibility in community places and spaces
Community endorsement for research

Extrinsic Barriers

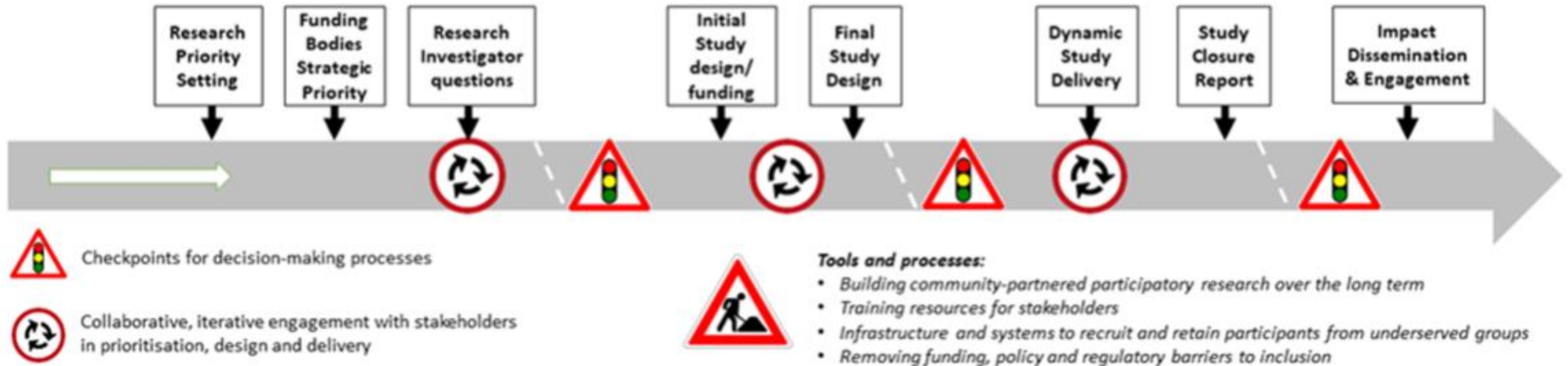
Barriers related to disability
Difficulties in consenting for another person
Lack of available trials / poor trial promotion
Lack of effective incentives for participation
Negative financial impact
Potential participants refusing to accept their health condition
Poor consent procedures
Requirement for additional carer time to aid participant
Participant risk perception
Treatment centres not set up for research
Trials asking too much for participation



Involvement of under-served groups in research design and delivery
Funder requirements and expectations
Workforce capacity and confidence
Research design
Research questions



Involved stakeholders: Patients, public, funders, clinicians, researchers, regulators, industry, policymakers



- 1) Develop training resources
- 2) Build infrastructure, tools and processes for research design and delivery
- 3) Remove barriers in funding, regulation and policy



Our partners



Examples of progress so far

NIHR Research Standard Application Form & Guidance

Updated Wellcome clinical trials policy

Resources

INCLUDE Guidance

INCLUDE COVID-19 Guidance

Published *Trials* article

Published BMJ article

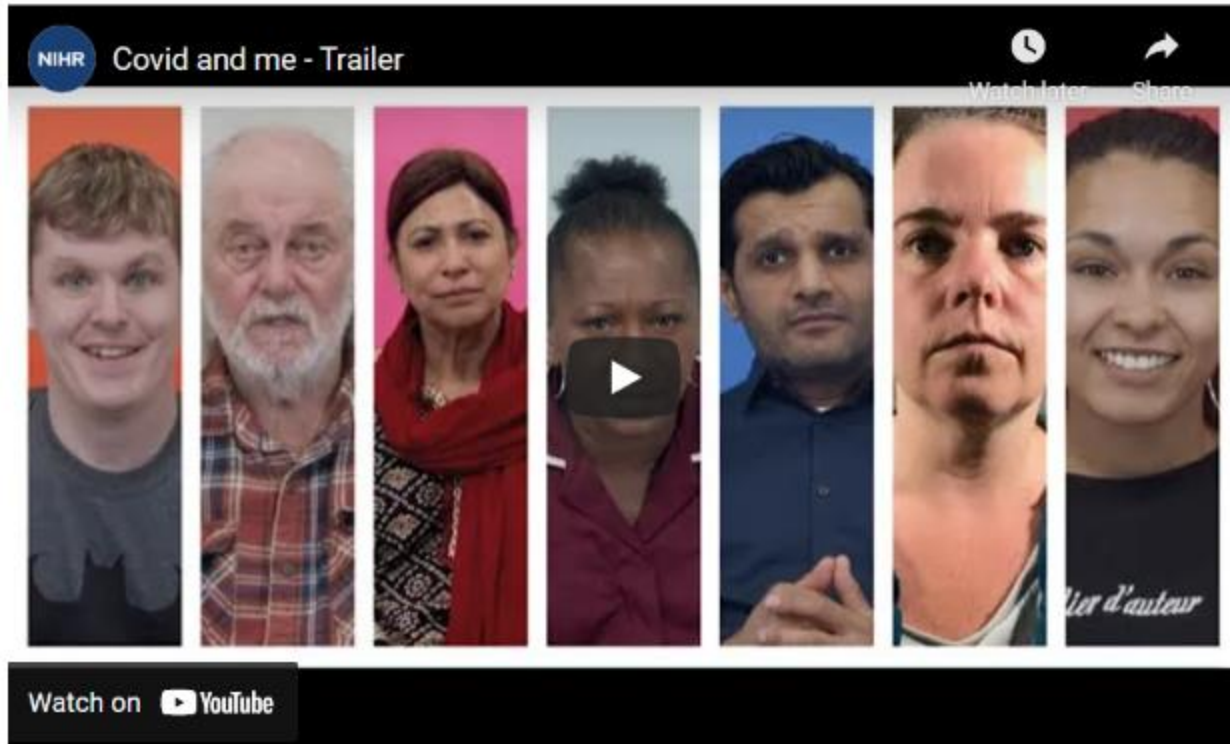
INCLUDE Ethnicity Framework

INCLUDE resource tracker

INCLUDE course on NIHR Learn

COVID and Me

Take part to help the NHS find the solution



Questions to guide research teams in designing inclusive research

1. What are the characteristics/demographics of the population which your research looks to serve?
2. How will your inclusion/exclusion criteria enable your trial population to match the population that you aim to serve?
3. Justify any difference between your projected trial population and the population you aim to serve
4. How will your recruitment and retention methods engage with under-served groups?
5. What evidence have you that your intervention is feasible and accessible to a broad range of patients in the populations that your research seeks to serve?
6. Are your outcomes validated and relevant to a broad range of patients in the populations that your research seeks to serve?

Questions to guide delivery teams in considering how to improve inclusion of under-served groups

1. Who are the under-served groups within our delivery area? (e.g. geographical or disease area that the delivery team operates in)
2. What are the barriers to including these groups in research in our area?
3. What actions can we take to overcome those local barriers?
4. What tools, training and resources do we need to implement these actions successfully?

Any questions?

THANK YOU

website

<https://sites.google.com/nih.ac.uk/include/home>