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Improving inclusion of underserved groups in clinical research: Summary of findings from the National Institute for Health Research 'INCLUDE' programme

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Background of INCLUDE

In 2017, the NIHR Clinical Research Network executive team commissioned a project to examine how to improve inclusion of underrepresented groups into clinical research with a particular focus on the role of the NIHR Clinical Research Network. During 2018 and 2019, a series of scoping reviews, surveys, stakeholder events were held, with a steering group drawing together the strands of work into a roadmap to steer development of guidance and initiatives to improve inclusion of underserved groups.

INCLUDE provides a suggested framework of questions to guide the deliberations of funders, researchers and delivery teams as the design and assess clinical research proposals, and gives examples of good practice and other resources to guide teams seeking to engage with, and improve inclusion of underserved groups in clinical research.

Below is a summary of what an underserved group is; examples of underserved groups and example barriers to inclusion; key themes for patient based solutions; priorities identified to achieve better healthcare through more inclusive research; and a framework including a roadmap suggesting intervention points to improve inclusion, and objectives and work streams; also a note on engagement and impact.

What is an underserved group and who are they?

The INCLUDE project work settled on the term 'underserved group' as the term preferred by stakeholders – most particularly by those from underserved groups. The term reflects the perspective that the research community needs to provide a better service for people in these groups – the lack of inclusion is not due to any fault of the members of these groups. The term 'underserved' reminds us of this perspective in a way that alternative terms such as 'underrepresented' do not.

The work of the INCLUDE project shows that there is no single definition for an underserved group. Some key characteristics that are common to several underserved groups are:

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

The key idea here is that the definition of 'underserved' is highly context-specific; it will depend on the population, the condition under study, the question being asked by research teams, the context in which they live (care homes, prison etc.), and the intervention being tested. No single, simple definition can encompass all underserved groups.

Examples of underserved groups

A key finding from the work is that the definition of underserved is often very context and study specific. An underserved group for one disease are or type of study may be the opposite to that of another. The following are presented as examples which were derived from surveys, stakeholder group discussion and the literature review used in the INCLUDE project. This list should not be viewed as exhaustive, but serves to provide examples of group that may be underserved either in specific contexts or more generally across the research landscape.

Groups by Demographic Factors (Age, Sex, Ethnicity, Education)
Age extremes (under 18 and over 75)
Women of childbearing age
Black, Asian and Ethnic Minorities (BAME)
Male/female sex (depending on the context of the trial)
LGBTQ/ sexual orientation
Educational disadvantage
Groups by Social and Economic Factors
People in full time employment
Socio-economically disadvantaged/ unemployed
Military veterans
People in alternative residential circumstances (e.g. residential care homes, prisons, the homeless and those of no fixed abode)
People living in remote areas
Refugees/asylum seekers
Religious minorities
Carers
Language barriers
Digital exclusion/disadvantage
People who do not attend regular medical appointments
People in multiple excluded categories
Socially marginalised people
Stigmatised populations
Carers
Groups by Health Status
People with mental health issues
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
Too severely ill
Smokers
Obesity
Groups by Disease Specific Factors
Rare disease
People in cancer trials with brain metastases
Genetic disease sub-types

Example barriers to inclusion of underserved groups

The following are examples derived from surveys, stakeholder group discussion and the literature review used in the INCLUDE project. Again, this list is not exhaustive, but serves to give a general idea of the categories of barriers encountered. Individual projects, communities and disease areas will have specific barriers, which it is important to identify in tailoring solutions for inclusion of underserved groups in a context-specific way.

Barrier
Barriers relating to physical disability
Difficulties in consenting for another person
Feeling unqualified to take part (e.g. due to lack of education)
Lack of available trials / poor trial promotion
Lack of effective incentives for participation
Lack of interest in research
Lack of trust in trials
Negative attitudes to the concept of research
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
Specific cultural barriers
Specific health fears (e.g. hospitals, needles)
Treatment centres not set up for research
Trials asking too much for participation
Unwilling to receive placebo

**Key themes for patient based solutions**

- Improved Communication:

    - Clearer explanation from the clinician about the trial prior to enrolment.
    - Better patient support from trial investigators and clinicians while the trial is taking place.
    - Clinician awareness of ongoing trials in which their patients could participate.
    - Trial information available in appropriate language and in a variety of media (e.g. leaflets, internet sites, video presentations).
    - Mobile technologies (e.g. social networks or online advertisements for recruiting, web/phone contact during trial).

- Educating patients and communities about the benefits of clinical trials to science and the wider Community Partnered Participatory Research (CPPR) – an approach that equitably involves partnership between communities and academics in all phases of the research process.
- Staff (e.g. involve staff that work with the underserved population, include staff from the minority population in the research team).
- Patient concierge service or trial navigators.

Top priorities identified to achieve better healthcare through more inclusive research:

1. Embedding research within healthcare to improve access for underserved groups.
2. Providing resources and training to support research teams, community representatives, clinical & support staff and other key stakeholders to build capacity and encourage sustainable engagement with underserved groups.
3. For funders to understand and address the barriers to research for underserved groups.
4. Place patients at the centre of the research process (e.g. information, consent, dissemination) and link in with Community Partnered Participatory Research (CPPR).
5. Nationwide publicity drive on what clinical trials are and why they matter. Examples might include greater interaction with the media (e.g. TV) or social media.
6. Establish a baseline to help better understand how the current situation regarding underserved cohorts, and how this relates to undertaking research. From here, explore ways to measure change.

The INCLUDE Framework

The INCLUDE Framework includes the INCLUDE project roadmap as well as the core objectives and work streams. The roadmap gives a strategic level overview of potential points for intervention to improve inclusion of underserved groups across the life course of research. Some points are addressable at the level of individual communities or projects; others require action at national or supra-national level to provide appropriate regulatory, funding, governance and support environments. The objectives and work streams highlight what the project is aiming to do and how those objectives will be achieved.
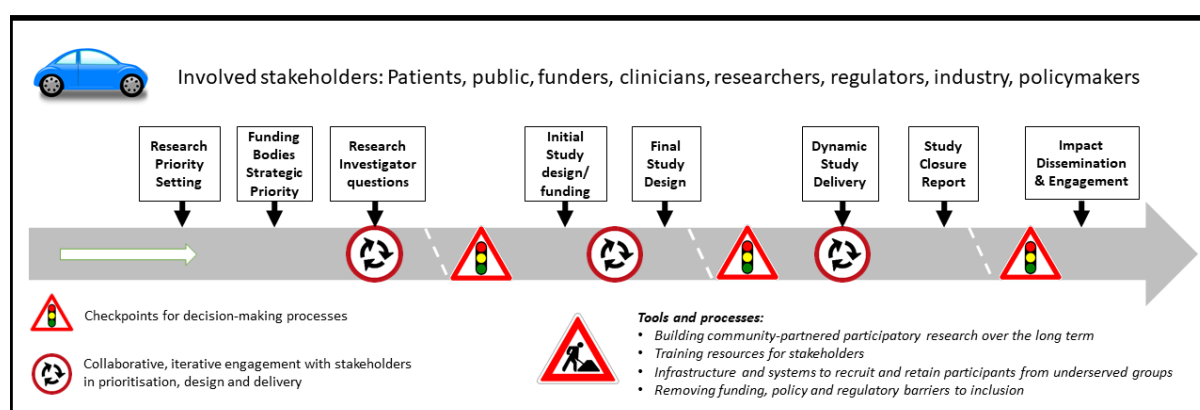
Processes are embedded in the context of ethics and regulatory requirements and evolving digital technology developments
Boxes represent key points for considering inclusion of underserved groups over the life course of the study
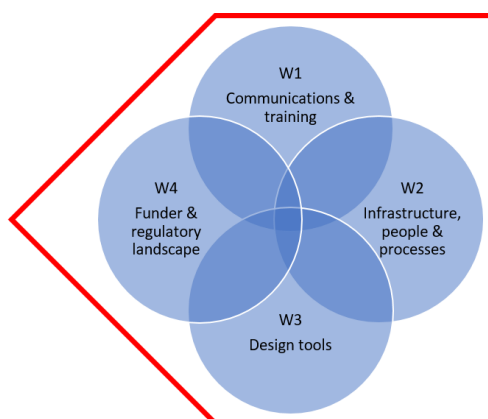
Core Objectives

Develop *Community Partnered Participatory Research* building long-term relationships and opportunities for participation for underserved groups.

Develop tailored training resources to design & deliver trials for underserved groups.

Develop infrastructure & systems to reach, engage, recruit & retain underserved groups.

Work with funders, regulators and other stakeholders to remove barriers to including underserved groups in clinical trials.

Workstreams

W1
Communications & training

W4
Funder & regulatory landscape

W2
Infrastructure, people & processes

W3
Design tools

Engagement and impact

We are working with our stakeholders, including charities, participants and their families and carers, practitioners and health professionals, funders, regulatory bodies, the life sciences industry and wider National Institute for Health Research (NIHR) to help us reach the audiences INCLUDE needs to influence and engage with. We want to share the message of INCLUDE, that healthcare is better when research is inclusive, and to ensure that we can measure the impact of that message.

INCLUDE Steering Group:

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