

Developing a roadmap to improve trial delivery for underserved groups: results from a UK multi-stakeholder process

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Research

Keywords: Trials, roadmap, underserved, recruitment, stakeholder

Posted Date: January 20th, 2020

DOI: <https://doi.org/10.21203/rs.2.21325/v1>

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Version of Record: A version of this preprint was published on August 1st, 2020. See the published version at <https://doi.org/10.1186/s13063-020-04613-7>.

Abstract

Background Participants in clinical research studies often do not reflect the populations for which healthcare interventions are needed or will be used. Enhancing representation of underserved groups in clinical research is important to ensure that research findings are widely applicable. We describe a multicomponent workstream project to improve representation of underserved groups in clinical trials.

Methods The project comprised three main strands: 1) a targeted scoping review of literature to identify previous work characterising underserved groups and barriers to inclusion; 2) surveys of professional stakeholders and participant representative groups involved in research delivery to refine these initial findings and identify examples of innovation and good practice; 3) a series of workshops bringing together key stakeholders from funding, design, delivery and participant groups to reach consensus on definitions, barriers and a strategic roadmap for future work. The work was commissioned by the UK National Institute for Health Research Clinical Research Network. Output from these strands was integrated by a steering committee to generate a series of goals, workstream plans, and a strategic roadmap for future development work in this area.

Results ‘Underserved groups’ was identified and agreed by the stakeholder group as the preferred term. Three-quarters of stakeholders felt that a clear definition of underserved groups did not currently exist; definition was challenging and context-specific but exemplar groups were identified as underserved. Barriers to successful inclusion of underserved groups could be clustered into: communication between research teams and participant groups; how trials are designed and delivered, differing agendas of research teams and participant groups; and lack of trust in the research process. Four key goals for future work were identified: building long-term relationships with underserved groups; developing training resources to improve design and delivery of trials for underserved groups; developing infrastructure and systems to support this work, and working with funders, regulators and other stakeholders to remove barriers to inclusion.

Conclusions The work of the INCLUDE group over the next 12 months will build on these findings by generating resources customised for different underserved groups to improve the representativeness of trial populations.

Introduction

Evidence from randomised controlled trials constitutes the most rigorous test of efficacy, effectiveness and safety for healthcare interventions. Such evidence is essential to identify both what works, and what does not work, and underpins the highest grade of recommendations in guidelines that shape clinical practice [1]. However, populations recruited into trials are often not representative of the target population who require evidence about interventions. For example, participants in heart failure trials are typically 20 years younger than those seen in clinical practice; patients in cancer trials lack the comorbidity typically seen in clinical practice; and, patients in diabetes trials are not the ethnically diverse populations typically seen in clinical practice [2–4]. The consequence of this disconnect between trial populations and the real world are manifold – treatment benefits and harms seen in trials may not translate to those seen in clinical practice [5], important findings specific to different populations may be missed, and

clinicians and patients may lack confidence in the applicability of some trial results. In addition, this lack of representation could be interpreted as discriminatory against some groups.

Some reasons for this disconnect between research and practice have been previously described. Trials often seek a narrowly defined, homogenous population to reduce variance and hence sample size, and the imposition of stringent inclusion and exclusion criteria leads to unrepresentative trial populations [2, 6, 7]. Recruitment strategies and trial logistics may also act as barriers to entry and retention. Examples include recruiting via tertiary care centres, or in urban environments far from rural populations, failing to provide taxi transportation for people who have poor mobility, or failing to provide translated study information for those who cannot read a given language [8]. Pressure from funders to recruit rapidly may also favour approaching groups who are easy to recruit, rather than recruiting a more representative, but harder to recruit, range of participants.

At present, a systematic approach to understanding and overcoming the lack of representativeness of trial populations has not been attempted. In the UK, the National Institute for Health Research (NIHR), a major funder of clinical trials designed to underpin guidelines and clinical practice, identified the need for a workstream to address this issue, latterly named the 'Innovations in Clinical Trial Design and Delivery for the Underserved' (INCLUDE) project. This paper reports the results of the first phase of this work which had the following key objectives: to create a framework to allow the identification of groups who are historically underrepresented in trials; to identify barriers and drivers to inclusion; and, to facilitate innovations in trial design and delivery to improve inclusion of underrepresented groups.

Methods

A series of tasks and events together addressed the objectives of the programme, which we describe below (summarised in Figure 1).

Steering group and stakeholder group meetings

Three stakeholder group meetings were held – in March 2018 as a project initiation workshop, December 2018 as a prioritisation and definition consensus meeting, and June 2019 as a goals and future work consensus meeting. Stakeholders invited to these meetings included NIHR national speciality leads and members from the NIHR Clinical Research Network, public and patient groups and charities, practitioners and health care professionals, the life sciences industry, funders and regulatory bodies. Additional meetings of a smaller steering group, comprising NIHR project and research network staff, clinical academics, trialists and leaders of public engagement activities, were held between these meetings to interpret and refine findings, provide strategic direction to the project, and to plan the content of the stakeholder group meetings.

Literature review

A targeted scoping review of published literature was undertaken by the NIHR Innovation Observatory relating to the concept of underrepresentation as it appears within clinical trial design and/or delivery. Keywords identified by the study team included: under-represented groups, hard to reach groups, outside of the standard medical settings, barriers to participation, and patient participation. A combination keyword method for the identification and inclusion of relevant studies was employed, including searches undertaken in MEDLINE, Embase, Cochrane Database of Systematic Reviews, Database of Promoting Health Effectiveness Reviews (DoPHER), Trial Register of Promoting Health Interventions (TRoPHI), Scopus, CINAHL (Cumulative Index to Nursing and Allied Health Literature) and PsycINFO. Searches were conducted in April and May 2018, and were limited to a five-year timeframe, starting 1st March 2013. Results not in English were excluded, as were results describing underrepresentation of an intervention as opposed to a group of participants. Letters, commentaries, editorials and animal studies were also excluded. A sample search strategy is shown in Additional File 1. Retrieved references were deduplicated in EndNote before scrutiny by the research team for relevance. All titles were scrutinised; clearly irrelevant titles were removed, and the remaining candidate studies proceeded to abstract review, where irrelevant abstracts were further removed. Much of the available literature focussed on patients with cancer, thus studies were divided into those focussing on cancer and non-cancer populations. Key findings were extracted by a research team member (SP) before further grouping into themes by the Steering Group. Final results were then fed into the work of the stakeholder meetings.

Surveys

Two surveys were designed, asking very similar questions to two distinct target groups. The first group constituted stakeholders identified from potentially underrepresented groups. The survey was sent to charity users, public and patient group representatives, NIHR Clinical Research Network research ambassadors and Newcastle University VOICE (Valuing Our Intellectual Capital and Experience; a public engagement organisation) members. The second group constituted professional stakeholders, drawn from a range of clinical research leaders within the NIHR Clinical Research Networks, charities, clinical trials units, other parts of the NIHR organisation, industry, NHS and universities. Surveys were hosted on SurveyMonkey and links sent via targeted emails. Results from the surveys were analysed via tabulation of descriptive statistics, and by thematic analysis of free-text responses. The survey questionnaires are presented in Additional File 2.

Results

Initial stakeholder meeting

At the initial stakeholder meeting, held in March 2018, 17/23 (74%) of participants answered 'no' to the statement: "Do you feel that there is a sufficiently consistent definition of what is meant by

‘underrepresented groups’ in clinical trials across stakeholders?”. No stakeholder at the meeting agreed with the statement, and 6/23 (26%) held no opinion. Stakeholders provided examples of under-represented groups, innovative practice aimed at successfully engaging with and recruiting such groups and suggested that a single definition may not capture all groups likely to be under-represented.

Targeted scoping review of definitions for underserved groups

A total of 58 full-text papers were eligible for review; a description of all considered full-text papers is given in Additional File 3. The majority of literature (39/58) selected was published in the United States of America, with datasets often reflective of North American demographics. Of 58 selected texts: 14 were published in journals based in the United Kingdom, 2 in the wider European Union, 2 in Switzerland, and 1 from New Zealand. Types of underrepresented groups were similar in both cancer and non-cancer literature, including broad groupings such as: children, older people, patients with multimorbidity, pregnant women, ethnic minorities, the socioeconomically disadvantaged, people outwith usual primary and secondary healthcare settings, and those with cognitive impairment. The majority of the literature (31/58 studies) engaged with a specific subgroup or population. Common thematic barriers identified in the literature that may lead to underrepresentation include: the presence of comorbidities, logistical barriers (including lack of transport, remoteness of study sites from usual abode), information not available in a language or form to allow easy comprehension, low trust or low engagement with healthcare services, and low awareness of clinical trial opportunities.

Surveys

Seventy people completed the participant stakeholder on-line survey. Respondents were not asked directly for details regarding which underserved group they were a member of but reported the route by which they had received the invitation to participate. Participants received the invitation via VOICE in 11 (16%) of cases, via their role as Patient Research Ambassadors in 8 (11%) of cases, from other sources within the NIHR Clinical Research Network in 11 (16%) cases, via medical charities in 6 (9%) of cases, and from other sources in 19 (27%) of cases. The remaining 15 (21%) did not respond to this question. Forty-one respondents (59%) agreed that it was difficult to be clear about what underrepresentation means.

One hundred and one professionals completed the survey. Thirteen (13%) were research nurses and 13 (13%) were academic researchers. Fourteen (14%) were staff from clinical trials units, including unit directors. Twelve (12%) were research managers, nine (9%) were CRN Specialty leads, and a further 11 (11%) held other CRN roles. Smaller numbers of contributors represented industry (6 [6%]), the NHS (6 [6%]), PPI engagement professionals (5 [5%]) and charities (2 [2%]), with 10 (10%) not responding to this question. Fifty-six respondents agreed that a universal definition of under-representation could not be given, 14 disagreed with the statement and 17 stated that they did not know. Table 1 shows the

additional underrepresented groups that were identified by the professional respondents, and Table 2 shows groups that professionals thought should not be counted as underrepresented.

Table 1: Under-represented groups.

Group	Frequency - professional groups (n=101) (%)	Frequency - participant groups (n=70) (%)
Age extremes (<18 and 'oldest old')	3 (3)	2 (3)
Carers	2 (2)	1 (1)
Rare disease	2 (2)	0 (0)
Educational disadvantage	5 (5)	1 (1)
Language barriers	8 (8)	2 (3)
Learning disability	8 (8)	1 (1)
LGBTQ / Sexual orientation	10 (10)	3 (4)
Looked after children	1 (1)	0 (0)
Male sex	0 (0)	2 (3)
Mental illness	8 (8)	7 (10)
Military veterans	0 (0)	1 (1)
People who don't attend regular medical appointments	1 (1)	1 (1)
People in full time employment	2 (2)	1 (1)
People in multiple excluded categories	1 (1)	0 (0)
People who lack capacity to consent for themselves	3 (3)	1 (1)
People in alternative residential circumstances*	11 (11)	5 (7)
People in cancer trials with brain metastases	2 (2)	0 (0)
People with addictions	0 (0)	1 (1)
Co-morbidities	1 (1)	2 (3)
Genetic disease sub-types	1 (1)	0 (0)
Physical disabilities	7 (7)	4 (6)
Pregnant women	4 (4)	2 (3)
People living in remote areas	3 (3)	2 (3)
Refugees/asylum seekers	0 (0)	2 (3)
Smokers	1 (1)	0 (0)
Socially marginalised people	2 (2)	0 (0)
Socio-economically disadvantaged / unemployed	1 (1)	4 (6)
Religious minorities	1 (1)	0 (0)
Stigmatised populations	2 (2)	0 (0)
Too severely ill	1 (1)	0 (0)
Visually / hearing impaired	3 (3)	3 (4)
Women of childbearing age	1 (1)	0 (0)

**This category includes migrants, asylum seekers, prison populations, care homes, traveller communities and homeless. Multiple categories may be chosen; categories may sum to greater than 100%*

Table 2. Groups not considered as under-represented by respondents.

Group	Frequency – professional groups (n=101) (%)	Frequency – participant groups (n=70) (%)
Children	1 (1)	1 (1)
Frail	1 (1)	0 (0)
Multiple health conditions	1 (1)	0 (0)
Older people	2 (2)	0 (0)
Socioeconomically disadvantaged	1 (1)	1 (1)
Women	6 (6)	7 (10)

Multiple categories may be chosen; categories may sum to greater than 100%

Twenty respondents went on to provide their own definition of under-representation. These definitions were broadly grouped into three areas: (1) Inclusion; (2) Epidemiology and (3) Miscellaneous. Inclusion includes all submissions that considered under-representation to be defined by poor access to trials in certain population groups. Epidemiology is those that consider under-representation to be defined in epidemiological terms, i.e. the trial participant population demographics failing to mirror the demographics of the target population in the ‘real world’. Miscellaneous includes those submissions that could not be grouped (n=7). Some of these submissions did attempt to provide definitions of under-representation, for example ‘People who do not usually feature in the demographics of those recruited to clinical trials’ (participant ID 10210064831). However, many were commentary on the issue rather than definition, for example ‘I have found - for example - none of the studies I have been involved with have been gender specific, however, nearly always I screen and recruit more males than females...’ (participant ID 10210238642). Table 3 summarises the barriers to trial inclusion identified by the participant and professional surveys.

Table 3. Barriers to inclusion

Barrier	Frequency - professional groups (n=101) (%)	Frequency - participant groups (n=70) (%)
Barriers relating to physical disability	1 (1)	0 (0)
Difficulties in consenting for another person	1 (1)	0 (0)
Feeling unqualified to take part (e.g. due to lack of education)	0 (0)	2 (3)
Lack of available trials / poor trial promotion	2 (2)	0 (0)
Lack of effective incentives for participation	2 (2)	0 (0)
Lack of interest in research	0 (0)	4 (6)
Lack of trust in trials	4 (4)	4 (6)
Negative attitudes to the concept of research	0 (0)	2 (3)
Negative financial impact	0 (0)	3 (4)
Potential participants refusing to accept their health condition	1 (1)	0 (0)
Poor consent procedures	1 (1)	0 (0)
Requirement for additional carer time to aid participant	1 (1)	0 (0)
Participant risk perception	1 (1)	0 (0)
Specific cultural barriers	1 (1)	3 (4)
Specific health fears (e.g. hospitals, needles)	0 (0)	2 (3)
Treatment centres not set up for research	1 (1)	0 (0)
Trials asking too much for participation	2 (2)	2 (3)
Unwilling to receive placebo	0 (0)	1 (1)

Multiple categories may be chosen; categories may sum to greater than 100%

Output from second stakeholder meeting

The consensus meetings considered the information from the literature review and surveys, adding to and refining the list of examples of innovative practice that had emerged from the survey. A consensus emerged that “underserved groups” be used as the preferred term for describing the target for the group as this was felt to avoid any attachment of blame for low levels of participation. It also ensured that the onus was firmly on the research infrastructure and process to find ways to provide an appropriate solution or service to prospective research participants. Consensus was also reached that a single

universal definition for what constitutes an underserved group was unlikely to be possible. There was consensus that the definition is context-specific, but that important elements include a mismatch between a population affected by a condition and those enrolled in studies, a lack of opportunity to participate due to study design, logistical or cultural barriers, and a lack of suitability of the intervention under study for a particular group due to physiological, logistical or cultural factors. Stakeholders listed their priorities for the work of the group over the coming year to achieve the vision of “better healthcare through more inclusive research”; the top six priorities were:

1. Embed research within healthcare to improve access
2. Need for a set of information resources and training to support research teams, community representatives and clinical/support staff /other key stakeholders (including funders) in building capacity and sustainable engagement to enable development and delivery of research to the underserved
3. Funders to engage with and enable provision for underserved groups, making trials appropriate to the real world group(s) targeted by the intervention.
4. More patient-centredness throughout the research process (for example information & consent, dissemination); Community Partnered Participatory Research (CPPR)
5. Nationwide publicity drive on what clinical trials are and why they matter - TV series, features, etc
6. Baseline measurement to assess current situation and to help document improvement

Following the second consensus meeting, the steering group reviewed all the project outputs and proposed a set of overarching goals together with an initial list of potential solutions and actions to achieve these goals. The project was branded as “Innovations in Clinical Trial Design and Delivery for the underserved” (INCLUDE) at this point.

Output from third stakeholder meeting

At the final meeting, the set of goals identified from the work to date was presented to the stakeholder group. The group generated further potential solutions and high-level actions, and the steering group then generated four key objectives for future work:

1. Develop Community Partnered Participatory Research (CPPR) building long-term relationships with underserved groups and opportunities for participation
2. Develop training resources to design and deliver trials for underserved for all stakeholders involved, and tailor resources to the needs of specific groups
3. Develop infrastructure and systems to reach, engage, recruit and retain underserved groups

4. Work with funders, regulators and other stakeholders to ensure barriers in funding, regulations and policies are removed to enable inclusion of underserved groups

To address these objectives, the steering group identified four overlapping workstreams to take forward; each workstream addresses multiple objectives. These are shown in Figure 2.

Final strategic roadmap

The steering group combined all the outputs from the project surveys, scoping review and stakeholder meetings to produce a strategic roadmap for initiatives to improve access to clinical research for underserved groups. The roadmap is intended to guide groups wishing to focus on the needs of specific underserved groups, and to help researchers work with underrepresented groups; it does not aim to provide solutions (which will be specific to each underserved group) but provides a structure for both future research and for initiatives to address barriers to participation that have been identified during the project. The final roadmap is shown in Figure 3.

Discussion And Future Directions

The INCLUDE project has identified a preferred label ('underserved groups') to support conversations around this issue, has identified a range of example underserved groups, has identified common barriers to participation and has produced a strategic roadmap and plan to inform future work in this field. The recognition that clinical research often fails to engage with groups that it needs to is not new, but attempts to address the problem in a systemic way have been lacking to date. Most studies on barriers to recruitment originate from the USA, and many are specific to cancer research [9,10]. Examples exist of research exploring barriers and solutions to participation in other areas, for instance older people, those from ethnic minorities, and those in acute or critical care [11-15]. Different areas of research have different barriers in engagement to overcome, hence a tailored approach is required. Nevertheless, there are likely to be common, generic issues (such as funding and regulatory disincentives) that could be tackled by generic action, and a framework for future action such as we propose here is also likely to reduce duplication of effort, redundancy and hence research waste in identifying good practice and approaches to the problem.

The barriers identified by our surveys accorded well with those identified in our literature search and encompassed those initially suggested by our stakeholder group. Previous work has identified themes of trial awareness, opportunity, acceptance of enrolment, perceptions of the research process, logistical barriers, and whether trial processes were able to fit into participants' existing lives [16, 17]. These issues group in a similar way to the barriers we identified. Although we did not find initiatives with exactly the same aim and scope as our work, there are others that either overlap or are complementary. Of particular note are initiatives to improve recruitment to and retention in trials [18], and ways to improve trial design methods [19]. Our work is well placed to complement and enhance these and other initiatives.

Strengths

The work we describe was successful in obtaining consensus on strategic guidance for future work in this area and had the strength of involving a wide range of stakeholders including those from underserved groups. The use of a range of methods, drawing on expert opinion, published literature and focussed surveys, provided the ability to triangulate data from multiple sources, strengthening the final set of objectives and the final roadmap.

Limitations

The work we describe was conducted as a focussed, time-limited project. It was not conceived or executed as a pure scientific investigation, and thus some compromises were necessary in terms of depth and extent of enquiry. We did not attempt to apply a full systematic review methodology to our literature review, but instead used a focussed scoping review method which better fitted the needs of the project. Although we were successful in obtaining a wide range of stakeholder views, we acknowledge that in terms of numbers, representation was stronger from the academic and research delivery communities than from other areas such as commercial or charity representatives.

Future directions

Several key strands of activity within the UK research community will flow from the work reported here, using the roadmap as a strategic guide to address the needs of underserved groups in research. Through its next phase, the INCLUDE project will focus on the four workstreams shown above. The project will engage with funders and regulators to ensure that the issue of representation of underserved groups is taken into account in funding decisions, regulatory approvals, policies, and making sufficient resources available. In addition, the project will partner with others already working in this field, signposting research and delivery teams to existing resources [14], collaborating with others to develop infrastructure and training solutions tailored to the needs of distinct underserved groups, and developing the tools that research teams require to engage with underserved groups and design clinical studies that effectively recruit and retain people (which current studies fail to achieve). Although our focus remains on improving UK research delivery, the generic nature of the barriers we identified means that our roadmap is equally applicable to international initiatives to improve research delivery, including initiatives in lower and middle income countries.

Abbreviations

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CPPR: Community Partnered Participatory Research

DoPHER: Cochrane Database of Systematic Reviews, Database of Promoting Health Effectiveness Reviews

NIHR: National Institute for Health Research

TroPHI: Trial Register of Promoting Health Interventions

VOICE: Valuing Our Intellectual Capital and Experience

Declarations

Ethical approval and consent to participate

No ethical approval was required for this work

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

This work was commissioned and funded by the UK National Institute for Health Research Clinical Research Network Coordinating Centre.

Authors contributions

MDW wrote the initial draft of the paper; GN and LR revised the initial draft. SP conducted the literature review. EA conducted the survey. All authors contributed to the conception, design and planning of the work, the conduct of the steering and stakeholder groups, the interpretation of the results, and critically revised the manuscript.

Acknowledgements

We thank the directors and staff of the NIHR Innovation Observatory for their support for this work.

References

- [1] Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64:401-6.
- [2] Cherubini A, Oristrell J, Pla X, Ruggiero C, Ferretti R, Diestre G, et al. The persistent exclusion of older patients from ongoing clinical trials regarding heart failure. *Arch Intern Med*. 2011;171:550-6.
- [3] Treweek S, Dryden R, McCowan C, Harrow A, Thompson A. Do participants in major breast cancer trials reflect the breast cancer patient population? *Eur J Cancer*. 2015;51:90714.
- [4] Khunti K, Bellary S, Karamat MA, Patel K, Patel V, Jones A, et al. Representation of people of South Asian origin in cardiovascular outcome trials of glucose-lowering therapies in Type 2 diabetes. *Diabet Med*. 2017;34:64-8.
- [5] Ferdinand KC, Elkayam U, Mancini D, Ofili E, Piña I, Anand I. Use of isosorbide dinitrate and hydralazine in African-Americans with heart failure 9 years after the African-American Heart Failure Trial. *Am J Cardiol*. 2014;114:151-9.
- [6] McMurdo ME, Witham MD, Gillespie ND. Including older people in clinical research. *BMJ*. 2005;331:1036-7.
- [7] Carroll CB, Zajicek JP. Designing clinical trials in older people. *Maturitas*. 2011;68:337-41.
- [8] Quay TAW, Frimer L, Janssen PA, Lamers Y. Barriers and facilitators to recruitment of South Asians to health research: a scoping review. *BMJ Open*. 2017;7:e014889.
- [9] Torres S, de la Riva EE, Tom LS, Clayman ML, Taylor C, Dong X, Simon MA. The Development of a Communication Tool to Facilitate the Cancer Trial Recruitment Process and Increase Research Literacy among Underrepresented Populations. *J Cancer Educ*. 2015;30:792–8.
- [10] Costa LJ, Hari PN, Kumar SK. Differences between unselected patients and participants in multiple myeloma clinical trials in US: a threat to external validity. *Leukem Lymphoma*. 2016;57:2827-32.
- [11] Crome P, Cherubini A, Oristrell J. The PREDICT (increasing the participation of the elderly in clinical trials) study: the charter and beyond. *Expert Rev Clin Pharmacol*. 2014;7:457-68.
- [12] McMurdo ME, Roberts H, Parker S, Wyatt N, May H, Goodman C et al. Improving recruitment of older people to research through good practice. *Age Ageing*. 2011;40:659-65.
- [13] Otado J, Kwagyan J, Edwards D, Ukaegbu A, Rockcliffe F, Osafa N. Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials. *Clin Translat Sci*. 2015;8:460-6.

- [14] NIHR Collaboration for Leadership in Applied Health Research and Care East Midlands. Increasing participation of Black Asian and Minority Ethnic (BAME) groups in health and social care research. Downloaded from: <http://www.clahrc-em.nihr.ac.uk/clahracs-store/increasing-participation-black-asian-and-minority-ethnic-bame-groups-health-and-social> [Accessed 19th September 2019]
- [15] Pattison N, Arulkamaran N, Humphreys S, Walsh T. Exploring obstacles to critical care trials in the UK: A qualitative investigation. *J Intensive Care Soc.* 2017;19:36-46.
- [16] Heller C, Balls-Berry JE, Nery JD, Erwin PJ, Littleton D, Kim M, et al. Strategies addressing barriers to clinical trial enrollment of underrepresented populations: a systematic review. *Contemp Clin Trials.* 2014;39:169-82.
- [17] Skea ZC, Newlands R, Gillies K. Exploring non-retention in clinical trials: a meta-ethnographic synthesis of studies reporting participant reasons for drop out. *BMJ Open.* 2019;9:e021959.
- [18] Gillies K, Bower P, Elliott J, MacLennan G, Newlands RSN, Ogden M, et al. Systematic Techniques to Enhance rEtention in Randomised controlled trials: the STEER study protocol. *Trials.* 2018;19:197.
- [19] Treweek S, Altman DG, Bower P, Campbell M, Chalmers I, Cotton S, et al. Making randomised trials more efficient: report of the first meeting to discuss the Trial Forge platform. *Trials.* 2015;16:261.

Additional File Legends

Additional File 1 (Word.doc): Sample search strategy for targeted scoping review – Medline database search

Additional File 2 (Word.doc): Content of survey questions for stakeholder groups

Additional File 3 (Word.doc): Description of included studies from targeted scoping review

Figures

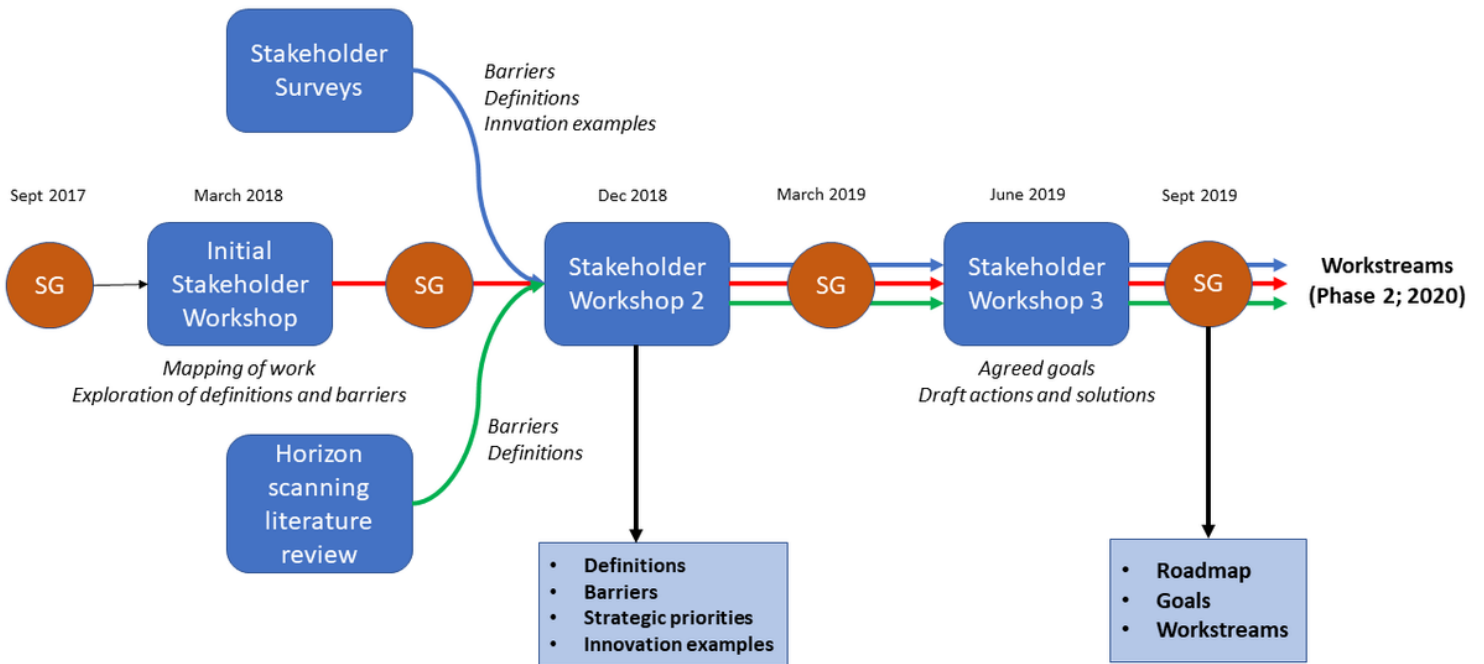


Figure 1

Components of the programme SG: Steering group

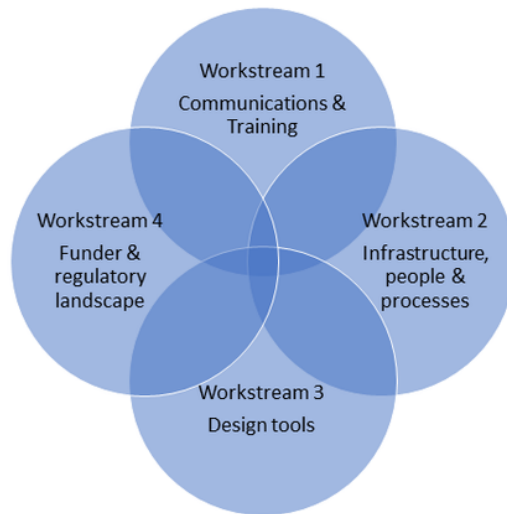


Figure 2

Workstreams to take forward in the programme

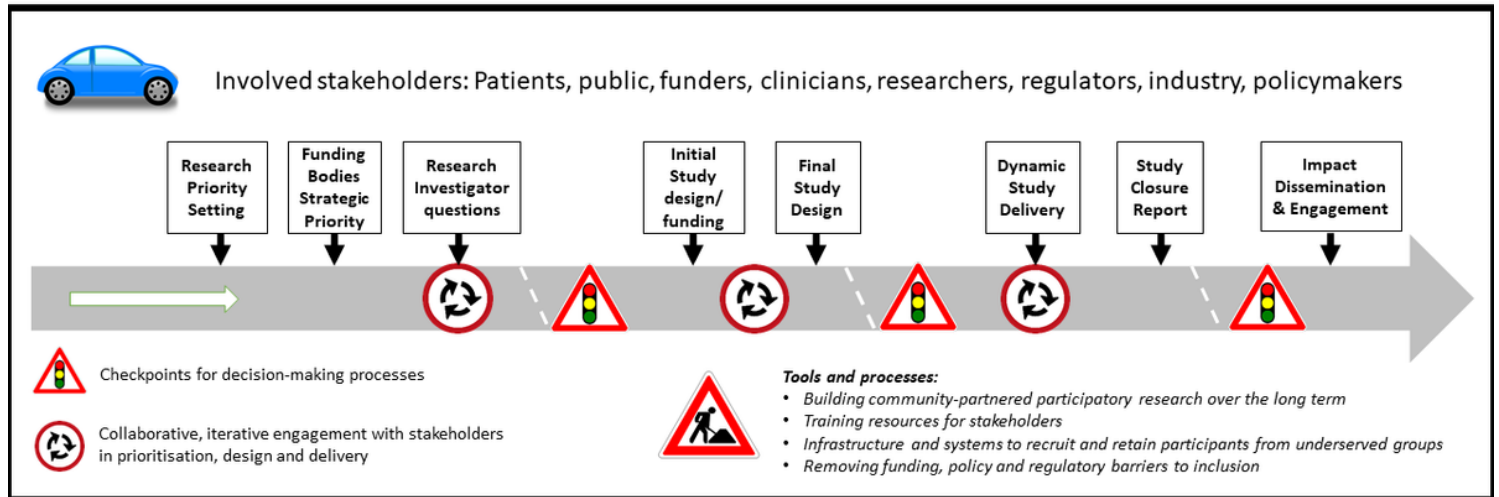


Figure 3

Roadmap to guide initiatives to improve inclusion of underserved groups into clinical research. 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 lifecourse of the study

Supplementary Files

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