ETI Survey Findings

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Wednesday 12th December 2018
Innovations in Clinical Trial Design and Delivery for under-represented groups

**Workstream 1**
Aim: Find key areas of under-representation and related barriers within clinical trials.
Findings: No cohesive definition of under-representation. However, literature suggests under-representation is context-specific (e.g., group, indication, perceived barriers, etc.).

**Workstream 2**
Aim: Identify key areas of innovation.
Findings: Patient and trial-focused solutions – that address context-specific issues.

**Horizon Scanning Reports** (Spring 2018)

**Initiation Workshop** (Spring 2018)

**Project Initiation** (Autumn 2017)

**Dissemination Workshop** (Winter 2018)

**Practitioner & Patient Surveys** (Summer 2018)

**A need is identified**

Is there a sufficiently consistent definition of “under-represented groups” in clinical trials across stakeholders?

**Examples of Barriers**
- Trial sites – infrastructure, staffing, geography
- Logistical complications
- Restrictive eligibility criteria

**Our Stakeholders**
- Public and Patient Groups and Charities
- Practitioners and Health Professionals
- NIHR and CRN
- Lifesciences Industry
- Funders
- Regulatory Bodies

**VISION:** Better healthcare through more inclusive research
Aims of ETI Survey

• Understand what **under-representation** in clinical trials means to both the professionals working on trials, & those taking part in them

• Learn **what has been done & what could be done** to reduce under-representation & to make clinical trial research more inclusive & robust
Respondents & Representatives

101 Professionals
- Charity
- Clinical Trials Units
- CRN NIHR
- Industry
- NHS
- University

70 Participants
- Charity users
- PPIE representatives
- Research ambassadors
- Voice members

Emerging Technology and Innovation
Is under-representation hard to define?

Professional Survey

Themes of ‘inclusion’ & ‘epidemiology’ or provided commentary

Participant Survey

Themes of ‘access’, ‘barriers’, ‘epidemiology’ or ‘(lack of) subgroups’
Commonly identified under-represented groups

Current research suggests the following groups are under-represented in clinical trials:

- Children & young people < 18
- Older adults
- Frail
- Multiple health conditions
- Women
- Ethnic minorities
- Low paying jobs
- Learning disabilities

But are we missing anyone...?
The survey suggested ‘yes’…

Are there are **other** groups under-represented in clinical trials?

**Professional Survey**

- Yes: 50%
- No: 30%
- Don’t know: 20%

**Participant Survey**

- Yes: 40%
- No: 60%
- Don’t know: 0%

Missing groups common to both surveys reference:

- co-morbidities
- full-time employment
- carers
- remote location
- age extremes
- lacking capacity
- visually/hearing impaired
- language/communication barriers
- alternative-residential circumstances
- socio-economically disadvantaged
- educationally disadvantaged
- LGBTQ/sexual orientation
- learning disabilities
- physical disabilities
- mental illness
- pregnant women

Emerging Technology and Innovation
Are there groups listed who shouldn’t be considered under-represented?

Professional Survey

- Yes: 40%
- No: 60%
- Don’t know: 0%

Participant Survey

- Yes: 40%
- No: 60%
- Don’t know: 0%

“The trials need to be put in context. **Children** are not under-represented in paediatric terms. **Women** are not under-represented in trials of heart failure with a reduced ejection fraction because this is a male phenotype. A distinction should be drawn between a lack of trials in a particular field and enrolment of an epidemiologically representative population with the disease of interest.” **
Barriers to inclusion in clinical trials

**List of barriers** to inclusion in clinical trials provided to responders:

- **Not understanding** what a clinical trial is.
- **Not liking the idea** of being in a research study.
- Not wanting to **deal with health problems** (e.g. not getting help for their illness until too late to enter trial).
- **Communication barriers** e.g. English not first language; illiteracy; sight/hearing problems.
- Difficulty **getting to clinics or hospitals** (e.g. live a long way away; cannot drive).
- **Lack of time** to take part (e.g. work; caring for others; trial appointments taking too long).
- **Not being told** about trials or asked to take part by healthcare staff.
- Not fitting into the **criteria** that a trial is looking to include (e.g. due to age; other illnesses).

They were then asked if they thought there were any **additional barriers** that should be listed...
Agreement that there are **additional barriers** that *should* be listed

**Professional Survey**
- Yes: 75%
- No: 25%
- Don't know: 0%

**Participant Survey**
- Yes: 75%
- No: 25%
- Don't know: 0%

**Other barriers included:**
- Feeling ‘unqualified’ to take part
- Lack of interest, trust or safety
- Negative attitudes (self/family/staff)
- Negative financial impact
- Health fears (e.g. hospitals; needles)
- Cultural

Additional barriers cited were **already included within the original list** e.g. ‘lack of trust in trials’ & ‘participant risk perception’ can both be considered as part of the category ‘participant attitude to research’.

- General agreement that **no barriers** should be removed from the list.
Successful Innovations in Trial Design (Professional Survey)

• Consent procedures
• Effective PPIE
• Promoting importance of under-representation within clinical trial staff
• Recruitment methods
• Trial procedures
• Trial promotion

“more time to talk through studies with participants. Reading information sheets together & checking understanding. Putting the information in words they can understand.”

“ways of working that value people from BAME communities as partners in the design & application process - before project starts.”

“images & audio instead of paper copy information sheet, - address illiteracy rates in Gypsy & Irish Traveller communities.”

“adapted times to avoid conflict with work & home”

“different settings & community groups to encourage ethnic minorities e.g. charities & churches”
Unsuccessful Innovations in Trial Design (Professional Survey) 1

- Impact assessment
- Unsuitable patients
- PPIE issues
- Staff issues
- Problems with promotion/recruitment

“Patients don't find it easy to access information about trials. We have worked to improve information, but we don't get good feedback from patients.”

“tried to include PPI feedback but patients often atypical of target population.”
Unsuccessful Innovations in Trial Design (Professional Survey) 2

“… A recent trial aimed to have a particular % of participants from more socially deprived parts of the community. It was only partially successful. There are a range of reasons, but one was the *willingness of clinical sites to engage* with the process and follow the protocol agreed. The centres that did this were fine, others far less so.”

“In General Practices, there is one problem that the most disadvantaged areas may have the highest challenged General Practices. Therefore their participation in research is lower. Whilst there is a gatekeeper approach or lack of expertise in professionals supporting research, that is likely to persist. There is a risk that Clinical Research Network *incentivisation of research (funding) is not sufficient* to drive uptake in all practices, leaving whole populations *under-served* and in effect with no *opportunity to participate in research*.”
Limitations to Innovations (Professional Survey)

- Funding
- Infrastructure
- Participant acceptance
- Ethical concerns

"Home visits for studies more convenient for participants but staff time & funding often means these aren't possible.”

“I did want to help set up a system to search patient records at CCG level to identify populations to take part but difficult as insufficient IT capacity/support in primary care. In principle it seemed it might be a runner, but there was a lack of senior push to make it happen.”

“The use of risk-adjusted patient information sheets i.e. using simple & short PIS for low-risk/observational studies for frail older patients. Mostly blocked by University Sponsors, who insist on ridiculously long & complex forms.”
Personal Experiences in Trials (Participant Survey) 1

• Reasons for **declining**:
  - Did not fit trial criteria
  - Difficulty getting to clinics/hospitals
  - Embarrassment to take part
  - Fears surrounding data protection/confidentiality
  - Fears surrounding proposed treatment
  - Lack of support to make decision
  - Lack of time to take part
  - Specific cultural barrier
  - Too unwell at time of being asked
  - Trial difficult to participate in (equipment based)
  - Unwilling to take proposed treatment/procedure

• Reasons for **dropping out**:
  - Adverse reaction to trial medication
  - Death before study completed
  - Difficulty getting to clinics/hospitals
  - Fears during study
  - Loss of interest
  - Trial not as expected
  - Trial stopped
  - Trial too complicated
  - Worsening health
Personal Experiences in Trials (Participant Survey) 2

- **Reasons difficult to take part**
  - Adverse reaction/side effects
  - Communication/language barrier
  - Interference with current treatments
  - Lack of staff support during trial
  - Negative financial impact
  - Physical disability
  - Trial taking up too much time
  - Trial too complicated

- **Reasons easy to take part**
  - Clear explanations
  - Continuity of care
  - Convenient visit timings/location
  - No side effects to medication taken
  - Online/postal aspect to trial
  - Quicker access to healthcare
  - Transport help (practical/financial)
  - Supportive research team
Conclusions

- Surveys support findings of literature review
- Also expand further on them – better granularity
- Common understanding of issues in general across both surveys
- Professional respondents less forthcoming in defining ‘under-representation’ than participant respondents
- Good platform to build from for future research avenues
- Under-representation should be embedded in the research process at every stage
Thank you

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