The INCLUDE Ethnicity and other Frameworks to improve trial diversity & Pfizer’s commitment to achieve diversity in clinical trials
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Polls
Today’s presenters

Professor Shaun Treweek, University of Aberdeen

Makeida Stubbs
Clinical Trial Diversity Lead for Internal Medicine, Pfizer
The INCLUDE Ethnicity and other Frameworks to improve trial diversity

Shaun Treweek
University of Aberdeen
Design and inequality

• Research design is about making choices.
• Once made, there may be no way back from a bad choice.

• For trials, a common place to make bad choices is around who is involved in the trial. This can bake-in inequality.
Trials and ethnicity: examples

• Largest groups of smokers in UK are those of ‘Mixed’ and ‘Other’ ethnicity. NIHR smoking trial published in 2022 recruited entirely from an English stop smoking service where users are <6% ethnic minorities.

• Work on language criteria (unpublished): for 32 NIHR recent trials (24 depression and 8 diabetes), 18/32 had explicit language restrictions, including trials of talking-based therapies for depression.

• Of the 24 NIHR depression studies, the average proportion of white participants was 92%.
There are plenty of other under-served groups

• People experiencing socioeconomic disadvantage.

• People at age extremes.

• People with impaired capacity to consent.

• See example list at https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435
Researchers have traditionally thought more about how many rather than *who* needs to be in our trials.
The INCLUDE Ethnicity Framework – what is it?

A 2-part tool to help trialists to identify the ethnic groups needed in a trial. The two parts are:

1. Four Key Questions.
2. Worksheets to help you complete the questions.

https://www.trialforge.org/trial-forge-centre/include/
Part 1– Key Questions

1. Who should be in the trial?

2. Will the people identified respond to the treatment differently?

3. Will the intervention itself make it hard for some people to be involved?

4. Will the trial design make it hard for some people to be involved?
Part 2– Worksheets

Worksheets for thinking through factors that might affect ethnic group involvement in a trial

These worksheets are intended to be used by trial teams in partnership with patient and public partners to ensure that ethnic group involvement is considered at the trial design stage. Before completing the worksheets, the trial team should have answered Question 1 of the INCLUDE Key Questions with regard to ethnic group involvement.

The worksheet may cover issues that some trial teams already think about. The intention is that the worksheet will help to highlight issues consistently across trials for all trial teams, as well as raising some questions that may not be routinely considered at present.

Finally, while the worksheet asks trial teams to think about possible differences between ethnic groups, it is important to remember that there are also differences within ethnic groups, especially between generations and between men and women. No ethnic group is homogenous.

Worksheet 1

This worksheet provides some questions to guide your thinking about ethnic group involvement when answering Question 2 of the INCLUDE Key Questions.

Disease and cultural factors that might influence the effect of treatment for some ethnic groups

<table>
<thead>
<tr>
<th>Disease</th>
<th>How might the prevalence of the disease vary between each ethnic group in the target population?</th>
<th>Response:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How might the severity of the disease vary between each ethnic group?</td>
<td>Response:</td>
</tr>
</tbody>
</table>

Worksheet 2

This worksheet provides some questions to guide your thinking about ethnic group involvement when answering Question 3 of the INCLUDE Key Questions.

Intervention and comparator factors that might affect how some groups engage with the intervention and/or comparator:

<table>
<thead>
<tr>
<th>What</th>
<th>How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population?</th>
<th>Response:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator?</td>
<td>Response:</td>
</tr>
<tr>
<td>Other factors to consider:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Who | How might the person delivering the intervention/comparator limit participation of people from each ethnic group in the target population? | Response: |
| Other factors to consider: | | |

| How | How might the mode of delivery (e.g., telephone, video call, face-to-face, in groups) limit participation of people from each ethnic group in the target population? | Response: |
| Other factors to consider: | | |

| Where | How might where the intervention/comparator is delivered (e.g., hospital, general practice, local library) limit the participation of people from each ethnic group in the target population? | Response: |
| Other factors to consider: | | |
PROSPER

(a breast cancer trial)

Questions on the disease itself

How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)?

Response: As mentioned above, age at diagnosis is younger in ethnic minority women and the cancer stage at presentation is higher. Uptake of breast screening by ethnic minority women seems unclear with some reports saying uptake is lower, others higher.

Black women have a higher frequency of grade 3 tumours than White and Asian women, and higher proportions of oestrogen negative/progesterone negative/ HER2-negative tumours than other ethnic groups.

It is uncertain whether ethnic minority women experience shoulder pain after breast cancer treatment more or less often, or have more or less severe pain etc than ethnic majority women. A 2014 systematic review on post-treatment shoulder pain made no mention of ethnicity or race in its finding.

There are lots of examples at www.trialforge.org
There are other Frameworks

- INCLUDE Socioeconomic Disadvantage Framework
- INCLUDE Impaired Capacity to Consent Framework.
The 3 Ps from the UK Govt Child Poverty Strategy:

1. **Pockets** – Indicators closely linked with income and economic resource availability
2. **Prospects** – Indicators closely linked with wellbeing and life chances
3. **Place** – Indicators closely linked with housing and local environment
Impaired capacity to consent

Vicky Shepherd, Cardiff

https://www.capacityconsentresearch.com/
A systematic approach to making trials more efficient

The evidence base for how to make the trials process efficient is remarkably thin. Trial Forge aims to change this.

Lots of diversity support at [www.trialforge.org](http://www.trialforge.org)
These frameworks don’t fix everything

The first part of a Framework is tricky: who should be in your trial?

In addition, they often highlight problems but not the solutions.

STRIDE
Supporting Recruitment & retention Improvements for Diverse Ethnicities
STRIDE – sneak preview of some results

Where the trial team cannot reach a conclusion:

a. The minimum target is that **ethnic groups are included at the same proportion as is found among the population of people with the condition targeted by the trial.**
STRIDE – sneak preview of some results

Where disease data by ethnicity do not exist, or cannot be obtained:

b. The minimum target is that ethnic groups are included at the same proportion as is found in the most recent census data.
Summary and priorities

1. Researchers need to think explicitly about *who* needs to be in their study. This is more than thinking about the number of participants.

2. Researchers need to involve people who are like the people the trial needs in trial design. Trial teams themselves need to be more diverse.

3. The INCLUDE Frameworks can help (we think) because they ask questions and prompt discussion. Evaluation should be part of their use.

4. Trial teams need more help to do better.
Clinical Trial Diversity Center of Excellence

Makeida Stubbs
Clinical Trial Diversity Lead
Pfizer is committed to achieving racially and ethnically diverse participation at or above US census or disease prevalence levels (as appropriate) **in all of our trials**.

We are also working to include, educate, and support other underrepresented populations including older adults, women, the LGBTQ+ community, and persons with disabilities.
Equitable Representation in Clinical Trials

Understanding Health Needs and the Impact of Medicines and Vaccines

Ensuring diversity of volunteers in clinical trials is a matter of equity and reducing disparities in healthcare.

Race, ethnicity, age, and sex can all impact how different people respond to the same medicine or vaccine.

We recognize that to better understand health needs and the impact of our medicines, it is imperative that we recruit clinical trial participants who represent the communities of the countries in which we conduct our trials or are disproportionately impacted by the diseases we aim to address.
## Taking Action to Achieve Diversity & Equity in Clinical Research

| **Embedding the importance of diversity** | in clinical trials within our organization |
| **Expanding access** | by partnering with clinical trial PIs and sites who engage and serve diverse, multicultural communities |
| **Building trust and awareness** | in communities by partnering with patient advocacy organizations and local community groups |
| **Addressing practical barriers** | to trial participation by making clinical information easier to understand and access (including digital modalities) |
| **Sharing our knowledge** | on diversity in clinical trials |
Meeting Our Commitments

Embedding the importance of diversity within our organization

- We trained colleagues who manage clinical trial operations to understand the importance of representation.
- We created an interactive dashboard to enable real time enrollment analytics on trial diversity.
- We developed an epidemiology library to gain insights on the impact of a disease stratified across diverse populations, allowing us to define diversity goals.
- Our Multicultural Health Equity Collective is focused on improving health equity as well as multicultural competency and engagement across Pfizer.
Meeting Our Commitments

Expanding access/Evolving site partnerships

✔ We are taking a data-driven approach to choosing clinical trial sites in geographically and multiculturally diverse locations; easier to access trials
✔ We are closely partnering with sites and providing tools, information and strategies to build awareness, enhance recruitment efforts and address local community needs.
My Practice
Clinical Trial discussions with patients

My Institution
Engaging with peers and network for referrals

My Community
Outreach – foster diversity and equitable trial access
Meeting Our Commitments

Building trust and awareness in communities

✓ We partner with patient advocacy organizations and raise awareness through various media about the importance of diverse participation in clinical trials.

✓ We provide culturally sensitive/linguistically appropriate materials tailored to trial volunteers in languages they read and understand so they know what to expect when participating.
Meeting Our Commitments

Addressing practical barriers to trial participation

✓ We are leveraging digital tools to reduce the burden on volunteers and introducing flexibility in trial design and conduct.

✓ With decentralized clinical trial modalities, we can bring clinical trials to homes rather than asking volunteers to travel to a research site.

✓ We are providing direct support to participants by offering to cover transportation costs and other impediments.

✓ We launched Pfizerclinicaltrials.com and Pfizerestudiosclinicos.com website as a single destination that makes it easier to find information on trials and to learn how to participate.
Meeting Our Commitments

Sharing our knowledge on clinical trial diversity

- We published a manuscript to establish a baseline of diversity in our clinical trials.
- We continue to analyze our own clinical trial diversity data to quantify the impact of our efforts.
- By sharing our baseline data on clinical trial diversity, our methodology can serve as a standard for other companies and encourage other companies to make similar commitments.
Baseline Publication
Assessing Diversity in Our Clinical Trials

Previously, there had been no – or extremely limited – information reported by biopharmaceutical companies about clinical trial diversity.

Pfizer conducted a rigorous, in-depth analysis of demographics in our US clinical trials that took place between 2011 and 2020, which examined:

- 213 therapeutic, clinical pharmacology and vaccine trials with 103,103 participants in the United States
- Overall trial demographics of race, ethnicity, sex and age
- Percentage of trials that achieved racial and ethnic distribution levels at or above US census levels
- Clinical trials across six therapeutic areas:
  - Oncology
  - Inflammation & Immunology
  - Rare Disease
  - Vaccines
  - Internal Medicine
  - Neuroscience (legacy)

LINK TO PUBLICATION
Demographic diversity of participants in Pfizer sponsored clinical trials in the United States - ScienceDirect (openathens.net)
Our Findings

Our analysis of these clinical trials was published in a peer-reviewed journal. By publishing our methodology and data, we are taking steps towards better transparency and raising awareness to ensure equity in our clinical trials.

Percentage of trials with participant levels **above census:**

Representation in Pfizer Trials vs. US Census Level:*
Pfizer’s Baseline for Improvement

We identified differences in racial and ethnic participation across different trial types

**Vaccine trials** had a lower percentage of Black or African American and Hispanic or Latino participants, and a higher percentage of Asian, White, and Non-Hispanic White participants compared with clinical pharmacology or therapeutic trials.

**Clinical pharmacology trials** had higher percentages of Black or African American and Hispanic or Latino participants compared with therapeutic trials.

**Therapeutic trials** had a higher percentage of White participants compared with clinical pharmacology trials.

Over 60% of trials in **Cardiology, Hematology, Endocrinology and Nephrology** had representation above census levels of Black or African American and Hispanic or Latino populations.

**Oncology trials** had an underrepresentation of Black or African American and Hispanic or Latino populations.
Epidemiology Framework
Epidemiology Framework for Diversity Goal Setting

Guiding Principles

- Designed primarily to address underrepresentation of underserved groups
- When RWD indicates increased risk of disease, we use it
- When RWD indicates decreased or equal risk of disease, we increase proportions to Census levels
  - Except when the literature supports a decreased risk and there is no evidence of more severe disease
- Process considers access to care and severity of disease/outcome

External Communications

- We published our goal setting framework/methodology in June 2023
- A framework for setting enrollment goals to ensure participant diversity in sponsored clinical trials in the United States - ScienceDirect
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