An example of implementation - Ensuring that COVID-19 Research is Inclusive: Guidance from the INCLUDE Project

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Background

- COVID-19 is not an equal opportunities disease
- It causes severe disease and death more often in certain groups:
  - Some BAME communities
  - Men
  - People living with obesity
  - People living with multimorbidity
  - Older people
- Research on COVID-19 therefore needs to include these groups but does not always do so
- COVID-19 is an exemplar of everything that the INCLUDE project is about
Using the INCLUDE framework for COVID-19 guidance

- The vision for INCLUDE is that it would provide a roadmap and framework for others to develop specific guidance for different intersections of research and underserved groups
- We used the INCLUDE framework to develop COVID-19 specific guidance
- Developed by the INCLUDE Steering group
- Group includes individuals with clinical and research experience of COVID-19
INCLUDE framework for COVID-19 guidance

• Developed recommendations and suggestions

Based on

• A) the roadmap and workstreams
• B) the draft INCLUDE generic guidance document
COVID-19 guidance content

• Identifies who is at heightened risk from COVID-19
• Identifies groups likely to be underserved in COVID-19 research (e.g. those self-isolating, care home residents, BAME groups, those without a car)
• Then works through the research journey
• Finishes with three checklists for promoting inclusion of underserved groups:
  • For researcher designing studies
  • For funders and reviewers evaluating proposals and analyses
  • For teams delivering research projects
### Implementing and disseminating INCLUDE COVID-19 guidance

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<tr>
<th>Area</th>
<th>Example</th>
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<tr>
<td>Priority setting</td>
<td>Include underserved groups in national priority setting exercises for COVID research</td>
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<td>Funding bodies</td>
<td>Ensure PPIE representatives from underserved groups sit on funding panels</td>
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<td>Research questions</td>
<td>Co-develop questions between target groups, government, researchers, funders</td>
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<td>Population</td>
<td>Minimise exclusion criteria – esp on age, ethnicity, obesity, multimorbidity. Recruit via wide range of settings</td>
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<td>Outcomes</td>
<td>Evaluable remotely, or in a range of settings whilst wearing PPE. Routine data-based if possible</td>
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<td>Ethics</td>
<td>Ethics committees have a key role in preventing unnecessary exclusion and facilitating novel recruitment and retention strategies</td>
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<td>Delivery</td>
<td>Local teams should ask reps from local underserved groups how best to engage. Be flexible in how and where study delivery takes place (e.g. in participants homes).</td>
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<td>Analysis and reporting</td>
<td>Include underserved group characteristics in baseline descriptors. Preplanned subgroup analyses of underserved groups</td>
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<td>Impact and dissemination</td>
<td>Plan with input from underserved groups; strategies to reach specific underserved groups</td>
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Where next?

• Feedback from this group to refine content
• Aim would be to disseminate this document to all components of the research pathway (e.g. funders, UPH committee, LCRNs, researchers)
• Document and separate paper in medical journal
• Social media
• Hosting and championing on outward facing websites (e.g. NIHR, NICE, charities, UKRI, HRA)
• Dissemination and championing within NIHR (NETSCC, CRN, BRCs, ARCs, NOCRI)
• Other ideas?
Questions?