# Protocol

# Understanding and reducing COVID-19 vaccine hesitancy among ethnic minorities in the UK

# Review #2: strategies addressing vaccine hesitancy among ethnic minority groups

## *1 Background [for Review #1 and #2]*

Since December 8th, 2020 the COVID-19 vaccination programme has been rolled out with more than 62 million doses given in the UK as of May 2021 (https://coronavirus.data.gov.uk/details/vaccinations). Achieving vaccination of the whole UK population is recognized as a key strategy for preventing disease and death from COVID-19. However, empirical studies and surveys have shown that there is a higher hesitancy for the vaccine among some ethnic minority groups than in the general population.{Robinson et al. 2021; Robertson et al. 2020; Royal Society for Public Health 2020}

Indeed, a retrospective cohort study using data from 23.4 million adults in England reported that uptake of COVID-19 vaccines is significantly lower among Black, Mixed, South Asian and Other ethnic groups compared with White groups.{MacKenna et al. 2021} By 17th March 2021, 96.7% of White British over-80s who were not living in care homes had been vaccinated compared with 89.9% of over-80s of Indian/British Indian heritage, 81.3% of those of Bangladeshi/British Bangladeshi heritage, 76.9% of those of Pakistani/British Pakistani heritage, 71.3% of those of Caribbean/Black British Caribbean heritage and 59.8% of those of African/Black British African heritage.{MacKenna et al. 2021} ONS (Office for National Statistics) data to 25 April 2021 on coronavirus and vaccine hesitancy in Great Britain show that 65% of the White population received the vaccine (one or two doses), compared with 45% of respondents from Ethnic Minority Groups overall (41% Mixed, 45% Asian or Asian British, 45% Black or Black British and 50% Other ethnic groups).{ONS 2021}

The World Health Organization (WHO) SAGE Working Group on Vaccine Hesitancy defines vaccine hesitancy as '*delay in acceptance or refusal of vaccination despite*

*availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence*'.{MacDonald et al. 2015} Vaccine hesitancy is specified as one of the 10 health threats to global health by the WHO in 2019 (https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019).

The UK Government in their 11th Jan COVID-19 vaccine delivery plan acknowledges the need to ensure that the vaccination programme is inclusive by addressing particular concerns of individuals who are more hesitant among ethnic minority communities. {Department of Health & Social Care 2021} It is, therefore, vital to understand the reasons behind hesitancy and identify effective vaccination strategies for ethnic minority groups. As part of a larger project entitled 'Working with community groups to understand and reduce COVID-19 vaccine hesitancy among ethnic minority groups in the UK', we aim to conduct two rapid systematic reviews to address the following research questions:

- What are the factors related to COVID-19 vaccine hesitancy in ethnic minority groups? (Review #1)
- What strategies have been advanced to address vaccine hesitancy in ethnic minority groups? (Review #2)

The remainder of this document focuses on Review #2.

## *2 Objectives*

The objective of this review (Review #2) is:

- To identify and assess the potential effectiveness of strategies that have been proposed or developed to address vaccine hesitancy in ethnic minority groups

## *3 Methods of the review*

We will follow recommendations from the Cochrane Rapid Reviews Methods Group {Garritty et al. 2021} and Healthcare Improvement Scotland for rapid evidence synthesis.{Health Care Improvement Scotland 2019}

### 3.1 Criteria for considering studies for this review

The key eligibility criteria for this rapid review are summarised using the PICO framework in Table 1. Details of each criterion are provided below.

**Table 1 Summary of eligibility criteria for Review #2 based on the PICO framework**

| Population | Intervention | Comparison | Outcome | Study design |
|---|---|---|---|---|
| Adults from ethnic minority population | Any intervention addressing vaccine hesitancy related to COVID-19 or other respiratory viral infections | Another intervention or no intervention | Vaccine uptake | 'Experimental design' with a control group |

*Types of population*

We define the eligible population as adults from ethnic minority groups or communities. We will also consider for inclusion general adult population with attention given to how factors affecting vaccine uptake may differ between different ethnic groups. The review primarily focuses on adults' decision about their own vaccination. Studies solely focusing on children and adolescents will be excluded as well as studies on parental refusal or delay of childhood vaccines. Studies done outside the UK, but which involve ethnic groups that are minorities in the UK will be excluded unless the study specifically highlighted minority groups within that jurisdiction. For example, a study conducted in India among the general Indian population would be excluded unless the study focused on minority groups within the Indian context.

*Types of intervention*

We will include all interventions designed to tackle vaccine hesitancy or enhance vaccine uptake in relation to:

- COVID-19 vaccine or

- Vaccines for other respiratory viral infections such as influenza/flu vaccine.

The Tdap (tetanus, diphtheria, and pertussis [whooping cough]) and flu vaccination programmes on pregnant women will be included. Vaccination programmes for non-respiratory infections and travel vaccines will not be considered suitable for inclusion.

*Types of comparison*

We plan to investigate the following comparisons:

- One intervention compared with another intervention
- One intervention compared with no intervention

*Types of outcomes*

Relevant studies or reports need to present data for the primary and/or secondary outcomes of interest.

The primary outcome of this review relates to a demonstrated change in vaccine behaviour, namely:

- an increase in vaccination uptake

The secondary outcomes relate to proxies that suggest a likely change in behaviour, for example:

- an increase in willingness, or intention, to vaccinate
- an increase in knowledge and awareness and/or a change in attitude in relation to vaccination intention and uptake
- an improvement in the access to vaccination

As we will use the findings of the review to produce recommendations using a GRADE Evidence-to-Decision Framework {Alonso-Coello et al. 2016} we will collect other outcomes related to the Evidence-to-Decision Framework including:

- Any undesirable effects
- Any indication of cost and resource use

*Types of study design*

We will include studies that use an experimental design such as:

- Randomised controlled trial (RCT)
- Non-randomised controlled trials
- Controlled before-after studies
- Interrupted time series (at least 3 data points pre- and post-intervention)

We will exclude studies with no control or comparison group (e.g. uncontrolled before-after studies).

## 3.2 Search strategy for identification of studies

### *3.2.1 Electronic searches*

An Information Specialist will develop a sensitive literature search strategy to identify published, peer-reviewed studies. The search strategy will include database index terms and free text to encompass the facets of COVID-19 and other respiratory viruses, ethnic minorities, and strategies to increase uptake of vaccines. Search strategies will be agreed with community organisations to ensure we are not missing relevant search terms. We will search the major clinical and social science databases, including Medline, Embase, CINAHL, ASSIA, and the Social Science Citation Index. The extracted results will be limited to articles published in English in the last five years (2016-21) but the search itself will not restrict language or study type. The results from Review 1 will also be examined for relevant strategies. All references will be exported to Endnote for recording and deduplication. An outline search for Ovid Medline is in Annex*.

We plan to re-run literature searches within 2 months (?) from the anticipated publication/submission of the reviews (end of July 2021?).

### *3.2.2 Searching for other sources*

The reference lists of all studies selected for full-text appraisal will be screened for additional studies. The websites of major international government departments, public health organisations, community and minority organisations, and curated collections of COVID-19 literature will be searched for relevant publications. Community organization representatives of the research team will also be contacted to locate additional studies or reports including publications in languages other than English.

## 3.3 Data collection and analysis

### *3.3.1 Study selection*

Two independent reviewers will screen the titles and abstracts of at least 20% of the results identified by the search to validate the process. These will then go through moderation and consensus, with all remaining abstracts screened by one reviewer. Full-text versions of potentially relevant articles will be retrieved and assessed for eligibility by the same two reviewers. Should we identify a very large number of eligible studies, we will use purposive sampling to ensure the inclusion of studies with rich data. {Cochrane Effective Practice and Organisation of Care 2017}

### *3.3.2 Data extraction*

Data extraction will be performed by one reviewer using a bespoke form and checked by a second reviewer for accuracy and completeness.

For studies that fulfilled our inclusion criteria, we will abstract the following information:

- Study design
- Study dates or participant recruitment date
- Study setting (country/minority community)
- Vaccines being targeted
- Participant inclusion and exclusion criteria
- Participant baseline characteristics
- Number of participants by study and study arms
- Details of intervention (including intervention purpose and categorisation of intervention according to the SAGE WG Model of determinants of Vaccine Hesitancy [see below])
- Definition of outcomes measured (primary or secondary), and method and timing of outcome measurement, as well as any relevant subgroups
- Study funding sources, and/or possible conflicts of interest

### *3.3.3 Quality assessment of included studies*

For Review #2, included studies will be assessed using the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies, developed

by the Effective Public Health Practice Project, Canada. {https://merst.ca/ephpp/}{Thomas 2004} Criteria for the assessment are:

- selection bias,
- design,
- confounders,
- blinding,
- data collection methods
- withdrawals and drop-outs
- Intervention integrity
- Analyses

Each criterion is scored as ‘strong’, ‘moderate’ or ‘weak’. The full criteria of the EPHPP tool are presented in Appendix 1. The quality assessment will be performed by one reviewer and checked by a second reviewer for accuracy and completeness.

### *3.3.4 Synthesis of the extracted evidence*

Review #2 will summarise proposed strategies together with their effect sizes (and uncertainty) where available and match them to factors affecting vaccine uptake. We will categorise proposed strategies using the same framework used for the analysis of factors in Review #1. One framework that may potentially be useful is the WHO SAGE working group (WG) model of determinants of vaccine hesitancy.{Larson et al. 2014}{WHO SAGE working group dealing with vaccine hesitancy 2014} We will calculate relative and absolute risk from available data to generate a Summary of Findings table to be used in the Evidence to Decision Framework later in the project.{Alonso-Coello et al 2016} We will tabulate the results and provide a narrative summary.

### *3.3.5 ‘Summary of findings’ table*

We will present the overall certainty of the evidence for each outcome, according to the GRADE approach. {Guyatt 2008} Two review authors working together will rate the certainty of the evidence for each outcome as 'high', 'moderate', 'low', or 'very low' using the GRADEpro Guideline Development Tool (GRADEpro GDT). The GRADE assessment uses five criteria, not only related to internal validity (risk of bias, inconsistency, imprecision, and publication bias), but also external validity (directness

of results), for downgrading or upgrading the certainty of the evidence for a specific outcome. {Schünemann 2017} For each comparison, we will present a summary of the evidence for the main outcomes in the 'Summary of findings' table, which provides key information about the best estimate of the magnitude of effect in relative terms and absolute differences; numbers of participants and studies addressing each important outcome; and the rating of the overall certainty in effect estimates for each outcome. {Guyatt 2011; Schünemann 2017}

**References (for Review #1 and #2)**


Alonso-Coello P, Schunemann S, Moberg J,Brignardello-Petersen R, Akl E, Davoli M, Treweek S, Mustafa R, Rada G, Rosenbaum S, Morelli A, Guyatt G, Oxman AD: GRADE Working Group. GRADE Evidence to Decision (EtD) frameworks: A systematic and transparent approach to making well-informed healthcare choices. 1. Introduction. BMJ 2016;353:i2016

Booth, A., Carroll, C., 2015. How to build up the actionable knowledge base: the role of 'best fit' framework synthesis for studies of improvement in healthcare. BMJ Quality & Safety, 24: 700-708.

Carroll C, Booth A, Cooper K. A worked example of "best fit" framework synthesis: A systematic review of views concerning the taking of some potential chemopreventive agents. BMC Medical Research Methodology. 2011;11(29)

Cochrane Effective Practice and Organisation of Care (EPOC). EPOC Resources for review authors, 2017. https://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/qes_guidance_on_sampling.pdf

Department of Health & Social Care. UK COVID-19 vaccine delivery plan. Published January 11th 2021.

Effective Public Health Practice Project. Quality Assessment tool for Quantitative Studies. McMaster University, Canada. Available from: https://merst.ca/ephpp/ and https://merst.ca/wp-content/uploads/2018/02/quality-assessment-tool_2010.pdf

Garritty C, Gartlehner G, Nussbaumer-Streit B, King VJ, Hamel C, Kamel C, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol 2021;130:13–22. https://doi.org/10.1016/j.jclinepi.2020.10.007

Guyatt G, OxmanAD, AklEA, KunzR, VistG, BrozekJ, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. Journal of Clinical Epidemiology 2011;64(4):383-94.

Guyatt GH, OxmanAD, KunzR, VistGE, Falck-YtterY, SchunemannHJ. What is "quality of evidence" and why is it important to clinicians? BMJ (Clinical Research Ed.) 2008;336(7651):995-8.

Health Care Improvement Scotland. A guide to conducting rapid qualitative evidence synthesis for health technology assessment. October 2019. https://htai.org/wp-content/uploads/2019/11/Rapid-qualitative-evidence-synthesis-guide.pdf

Larson HJ, Caitlin Jarrett, Elisabeth Eckersberger, David M.D. Smith, Pauline Paterson, Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: A systematic review of published literature, 2007–2012, Vaccine, Volume 32, Issue 19, 2014, Pages 2150-2159. https://doi.org/10.1016/j.vaccine.2014.01.081

MacDonald et al. Vaccine hesitancy: Definition, scope and determinants, Vaccine, Volume 33, Issue 34, 2015, Pages 4161-4164, 2015. https://doi.org/10.1016/j.vaccine.2015.04.036

MacKenna B, Curtis HJ, Morton CE et al. Trends, regional variation, and clinical characteristics of COVID-19 vaccine recipients: a retrospective cohort study in 23.4 million patients using OpenSAFELY. medRxiv preprint 2021 Jan 26. doi: https://doi.org/10.1101/2021.01.25.21250356

Office for National Statistics. Coronavirus and vaccine hesitancy, Great Britain: 31 March to 25 April 2021 – Hesitancy towards the coronavirus (COVID-19) vaccine, based on the Opinions and Lifestyle Survey covering the period 31 March to 25 April 2021. Release date: 6 May 2021. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/bulletins/coronavirusandvaccinehesitancygreatbritain/31marchto25april

Relevant data set available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/datasets/coronavirusandvaccinehesitancygreatbritain

Royal Society for Public Health. New poll finds BAME groups less likely to want COVID vaccine. 2020. https://www.rsph.org.uk/about-us/news/new-poll-finds-bame-groups-less-likely-to-want-covid-vaccine.html

Robinson E et al., International estimates of intended uptake and refusal of COVID-19 vaccines: A rapid systematic review and meta-analysis of large nationally representative samples, Vaccine, Volume 39, Issue 15, 2021, Pages 2024-2034. https://doi.org/10.1016/j.vaccine.2021.02.005

Robertson E et al. Predictors of COVID-19 vaccine hesitancy in the UK household longitudinal study, Brain, Behavior, and Immunity, Volume 94, 2021, Pages 41-50. https://doi.org/10.1016/j.bbi.2021.03.008

SchünemannHJ, HigginsJPT, VistGE, GlasziouP, AklEA, SkoetzN, GuyattGH. Chapter 14: Completing 'Summary of findings' tables and grading the certainty of the evidence. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.1 (updated September 2020).

Thomas, B., Ciliska, D., Dobbins, M. and Micucci, S. (2004) A Process for Systematically Reviewing the Literature: Providing the Research Evidence for Public Health Nursing Interventions. Worldviews on Evidence-Based Nursing, 1: 176-184. https://doi.org/10.1111/j.1524-475X.2004.04006.x

WHO SAGE working group dealing with vaccine hesitancy. Strategies for addressing vaccine hesitancy – a systematic review. October 2014. https://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf

**Appendix 1 Effective Public Health Practice Project (EPHPP) quality assessment tool (https://merst.ca/wp-content/uploads/2018/02/quality-assessment-tool_2010.pdf)**

## QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

### COMPONENT RATINGS

**A) SELECTION BIAS**

**(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?**

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

**(Q2) What percentage of selected individuals agreed to participate?**

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

**B) STUDY DESIGN**

**Indicate the study design**

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

**Was the study described as randomized? If NO, go to Component C.**

No Yes

**If Yes, was the method of randomization described? (See dictionary)**

No Yes

**If Yes, was the method appropriate? (See dictionary)**

No Yes

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| **See dictionary** | 1 | 2 | 3 |

## C) CONFOUNDERS

**(Q1) Were there important differences between groups prior to the intervention?**

1 Yes
2 No
3 Can't tell

**The following are examples of confounders:**

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

**(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?**

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## D) BLINDING

**(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?**

1 Yes
2 No
3 Can't tell

**(Q2) Were the study participants aware of the research question?**

1 Yes
2 No
3 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## E) DATA COLLECTION METHODS

**(Q1) Were data collection tools shown to be valid?**

1 Yes
2 No
3 Can't tell

**(Q2) Were data collection tools shown to be reliable?**

1 Yes
2 No
3 Can't tell

| RATE THIS SECTION | STRONG | MODERATE | WEAK |
|---|---|---|---|
| See dictionary | 1 | 2 | 3 |

## F) WITHDRAWALS AND DROP-OUTS

**(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?**

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

**(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).**

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

| RATE THIS SECTION | STRONG | MODERATE | WEAK | |
|---|---|---|---|---|
| See dictionary | 1 | 2 | 3 | Not Applicable |

## G) INTERVENTION INTEGRITY

**(Q1) What percentage of participants received the allocated intervention or exposure of interest?**

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

**(Q2) Was the consistency of the intervention measured?**

1 Yes
2 No
3 Can't tell

**(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?**

4 Yes
5 No
6 Can't tell

## H) ANALYSES

**(Q1) Indicate the unit of allocation (circle one)**

community organization/institution practice/office individual

**(Q2) Indicate the unit of analysis (circle one)**

community organization/institution practice/office individual

**(Q3) Are the statistical methods appropriate for the study design?**

1 Yes
2 No
3 Can't tell

**(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?**

1 Yes
2 No
3 Can't tell

**GLOBAL RATING**

**COMPONENT RATINGS**

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

| | | | | | |
|---|---|---|---|---|---|
| **A** | **SELECTION BIAS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **B** | **STUDY DESIGN** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **C** | **CONFOUNDERS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **D** | **BLINDING** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **E** | **DATA COLLECTION METHOD** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | |
| **F** | **WITHDRAWALS AND DROPOUTS** | **STRONG** | **MODERATE** | **WEAK** | |
| | | 1 | 2 | 3 | Not Applicable |

**GLOBAL RATING FOR THIS PAPER** (circle one):

| | | |
|---|---|---|
| 1 | STRONG | (no WEAK ratings) |
| 2 | MODERATE | (one WEAK rating) |
| 3 | WEAK | (two or more WEAK ratings) |

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

| | |
|---|---|
| 1 | Oversight |
| 2 | Differences in interpretation of criteria |
| 3 | Differences in interpretation of study |

**Final decision of both reviewers (circle one):**

| | |
|---|---|
| **1** | **STRONG** |
| **2** | **MODERATE** |
| **3** | **WEAK** |