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Adults' views and experiences of vaccines developed in response to the COVID-19 pandemic: a qualitative evidence synthesis (Protocol)

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[Qualitative Protocol]

Adults' views and experiences of vaccines developed in response to the COVID-19 pandemic: a qualitative evidence synthesis

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (qualitative). The objectives are as follows:

Objectives

The objective of this review is to identify, appraise and synthesise qualitative studies that explored adults' views and experiences towards vaccination in the context of the COVID-19 pandemic. A secondary objective is to compare this evidence with qualitative evidence that explores people's perspectives of vaccines developed in response to Ebola, Hong Kong flu and Swine flu.

BACKGROUND

To a large extent the global strategy to reduce the health and socio-economic impact of a pandemic relies on preventive efforts. Thus, the efforts of the scientific community and pharmaceutical industry, backed by government support, were and are directed towards developing effective and safe vaccines for COVID-19 (Conte 2020; Dayrit 2020; Larson 2016). Once a vaccine is developed the population should be offered a vaccine to reach herd immunity, reduce the risk of serious illness and prevent wider spread in the community.

There are many factors that might reduce vaccine uptake (Hickler 2015). These include environmental factors such as inadequate availability of vaccines and poor access to services (Hickler 2015; WHO 2018), people's experiences, attitudes and beliefs, and disease and vaccine specific factors such as safety and efficacy. Vaccine hesitancy, according to the World Health Organization's (WHO) global working group on Measuring Behavioural and Social Drivers of Vaccination (BeSD) is a "motivational state of being conflicted about, or opposed to, getting vaccinated" (Shapiro 2021; WHO 2021), and was named as a global health threat in 2019 by the WHO (WHO 2019). However, it is important to note that not all those who are hesitant refuse to be vaccinated (Wellcome 2021).

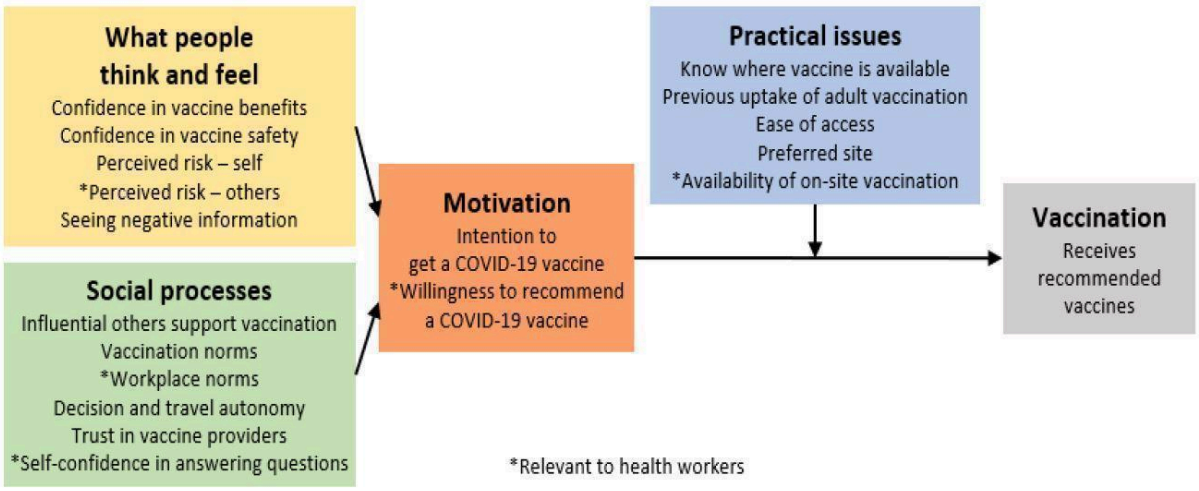
Evidence suggests that some factors known to contribute to hesitancy towards established vaccines are associated with COVID-19 vaccine hesitancy (Rutten 2020). For example, a Cochrane Review of communication with parents and informal caregivers found that a lack of information and uncertainty about sources of high-quality information could impact on parent's confidence to agree to a routine vaccination for their child; and that while parents viewed health workers as a potential source of information, communication problems could lower their confidence (Ames 2017). In the context of COVID-19, misleading information can undermine public health communication and particularly in settings where there is lower trust in government and science (Wellcome 2021). Structural and societal factors that limit access to vaccines can result in a lack of confidence, and concern about the risks associated with a vaccine (Domek 2018; MacDonald 2015; Shapiro 2018). Cooper 2021 reports that a complex interplay of factors influenced parent's views of routine childhood vaccinations, these included parent's views of health and illness and the role of vaccinations, social processes and relationships, and access to vaccine services and healthcare workers. In relation to COVID-19. there has been a rise in health inequalities (Marmot 2021), with systematic inequalities related to poverty and fragile health systems limiting access to vaccines (Wellcome 2021). How vaccines have been made available globally, with regions having differential access to vaccines of different efficacy, can undermine public health efforts by leading to a lower level of trust in the providers of vaccines. Another example is the UK digital COVID-19 test, track and trace and vaccine programme that has further disadvantaged older ethnic minority communities who are less likely to use online booking (Poole 2021).

Pandemic specific factors that contribute to COVID-19 vaccine hesitancy have been reported, for example there is a perception that there is more uncertainty about the safety and efficacy profile of a vaccine that has been developed and tested in a relatively-short time frame during a pandemic (Carlsen 2016; WHO 2021; Nature News & Comment). A survey of a national sample of 1971 US adults reveals that a COVID-19 vaccine approved under an Emergency Use Authorization by the US Food and Drug Administration (FDA) was associated with a decrease in the probability of acceptance relative to full approval by the FDA (Kreps 2020). Variable rates of acceptance of COVID-19 vaccines are reported across countries. Context-specific issues, such as cultural and religious, reactions to government policy and legislation, attitudes and beliefs (such as beliefs about safety and the impact on the immune system), a lack of information, contradictory messaging, access and cost have been put forward to explain the differences between populations considering a COVID-19 vaccine (Hornsey 2018; Matos 2021; Murphy 2021; Wellcome 2021; WHO 1 April 2021). A survey of the public, stratified by 33 countries, (29/47, 62%) report variable rates of acceptance of COVID-19 vaccination with an average rate of ≥70%. Acceptance rates of >90% were reported for Ecuador, Malaysia, Indonesia and China, and rates of < 50% in Kuwait, Jordan, Italy, Russia, Poland, the USA and France (Sallam 2021). Solís Arce 2021 reported that willingness to accept a COVID-19 vaccine was relatively higher in Low-income and Middle-Income Countries (LMICs) (10 sampled) compared with Russia and the USA, with concern about side effects being the main reason for vaccine hesitancy. However, the situation is dynamic, and it might be that over time people's views alter and structural changes lead to increasing levels of acceptance.

Examples of interventions employed by different countries to increase the uptake of COVID-19 vaccines vary and have included government mandates, such as COVID vaccine passports for travel or to gain access to large events; mass media campaigns; walk-in vaccine clinics that are placed in strategic locations to ensure easy access; and, community champions to support populations most at risk from COVID-19 and improve vaccine uptake (gov.uk; The Guardian). Understanding how COVID-19 vaccines are perceived by different populations, compared with vaccines developed in response to other recent pandemics, and their relative importance might guide the implementation of public health strategies to improve the uptake of community vaccines and support informed choice.

A qualitative evidence synthesis of people's views, the social processes and practical issues that impact on a person's motivation and decision to accept or decline (Figure 1, Brewer 2017) a COVID-19 vaccine will determine the relative importance of these different factors,and help to shape strategies to support the uptake of COVID-19 vaccines and other vaccines developed and tested during a pandemic (Cobey 2021).

Figure 1. Figure 1: The BeSD of COVID-19 vaccination framework (adapted from Brewer et al 2017)



OBJECTIVES

Objectives

The objective of this review is to identify, appraise and synthesise qualitative studies that explored adults' views and experiences towards vaccination in the context of the COVID-19 pandemic. A secondary objective is to compare this evidence with qualitative evidence that explores people's perspectives of vaccines developed in response to Ebola, Hong Kong flu and Swine flu.

METHODS

When preparing this protocol, we used the EPOC protocol template for qualitative evidence synthesis (Glenton 2021).

Types of studies

We will include studies that use both qualitative methods for data collection (e.g. focus group discussions, individual interviews, observation, diaries, document analysis, open-ended survey questions) and qualitative methods for data analysis (e.g. thematic analysis, framework analysis, grounded theory), and mixed-method studies if it is possible to extract data that were collected and analysed using qualitative research methods. We will include studies regardless of whether they were conducted alongside studies of the effectiveness of interventions to support the uptake of vaccination. We will exclude studies that collect data using qualitative methods but do not analyse these data using qualitative analysis methods (e.g. open-ended survey questions where the response data are analysed using descriptive statistics only). We will use our assessment of methodological limitations to inform our confidence in the review findings.

Topic of interest

We will include studies from any setting that focused on the views and experiences of adults aged 18 years and older of a COVID-19 vaccine or a vaccine developed in response to Ebola, Hong Kong flu and Swine flu. This includes, but is not limited to, people's background experiences, vaccine and disease related factors, and environmental factors. We will not exclude studies based on language, if we can not access a translation we will list these studies as awaiting assessment.

We will exclude studies that seek the views of adults on vaccines for children, studies of routine vaccines, studies of recruitment to vaccine trials and hypothetical scenarios.

Search methods

We will search Epistemonikos for related reviews. We will search the following sources for primary studies.

- MEDLINE (Ovid)
- Scopus (Elsevier)
- CINAHL (EBSCO)
- PsycINFO (Ovid)
- Global Index Medicus (World Health Organization; pesquisa.bvsalud.org/gim/)
- Dissertations and Theses Global (ProQuest)
- Education Database (ProQuest)
- ERIC (ProQuest)
- International Bibliography of the Social Sciences (IBSS) (ProQuest)
- Social Science Database (ProQuest)
- Applied Social Sciences Index & Abstracts (ASSIA) (ProQuest)
- Social Services Abstracts (ProQuest)
- Sociological Abstracts (ProQuest)
- Sociology Database (ProQuest)
- Cochrane COVID-19 study register (covid-19.cochrane.org/)
- COVID-19 L.OVE (Epistemonikos Foundation; app.iloveevidence.com/loves)

We will consider updating the search in relation to findings based on low or very low confidence, in order to identify additional recent evidence. The Cochrane EPOC Information Specialist will develop

search strategies for each database, using guidelines developed by the Cochrane Qualitative Research Methods Group for searching for qualitative evidence. The draft MEDLINE search is in Appendix 1. We will review the reference lists of all the included studies and conduct a cited reference search in Web of Science Core Collection Citation Indexes (Clarivate).

One review author will conduct the initial screen of the titles and abstracts to exclude studies with irrelevant content or that did not report using qualitative methods, two review authors will independently review the full text of studies included from this first screen for eligibility. We will resolve disagreement by discussion, or when required by involving a third review author.

Assessing the methodological limitations of included studies

Two or more review authors will assess methodological limitations using criteria derived from the Critical Skills Appraisal Programme (CASP) tool for qualitative studies (CASP 2019) and that have been used in previous Cochrane QES: adequate description of the setting and context, sampling strategy described and appropriate, data collection strategy described and justified, data analysis described and appropriate, findings supported by the evidence generated, evidence of reflexivity, sensitivity to ethical concerns, and other concerns (Ames 2017). We will resolve disagreements by discussion among the authors. We will report our assessments in a table of methodological limitations of included studies.

Data extraction and analysis

Two review authors will independently extract data, using an adapted pro forma from a vaccine-related Cochrane EPOC QES (Cooper 2021) and the WHO guidance on COVID (WHO 1 April 2021). We will extract the following data from each included study: study characteristics to include date and setting of the study, stage of the pandemic (defined by the prevalent COVID-19 variant or wave of the pandemic at the time the study was conducted), vaccine coverage in the study setting, study population characteristics (age, gender, socio-economic factors, ethnicity, co-morbidities or underlying conditions, type of employment, healthcare worker or the public), previous diagnosis of COVID-19, general vaccination status (for example, seasonal influenza), type of COVID-19 vaccine, sampling method, study design, the analytical approach used and main findings. We will use the conceptual model of behavioural and social drivers and practical issues described in the BesD to structure data extraction (Brewer 2017), as these map to the broad categories of people's experience, disease and vaccine factors, and environmental factors that we will use to organise the findings from each included study (see Table 1 below).

If the number of eligible studies are considered too large to analyse adequately we will select a sample of studies (EPOC 2019), using an appropriate purposeful sampling strategy (Suri 2011). One option might be to deploy a maximum variation (heterogeneity) sampling approach by identifying potential areas of variation (e.g. geographic setting, type of health settings, country income level, study method), create a sampling frame based on these dimensions and map all eligible studies onto the frame. We will then assess the number of studies relating to each dimension and decide how many of these studies we will include in the review.

We will use a 'Best-fit' framework synthesis method as our overarching analytical approach (Carroll 2013). Our first step will be to group the findings from the individual studies by theme, and fit these to an established framework of three broad categories: people's background experiences, disease and vaccine-related factors, and environmental factors (see Table 1 below) to accommodate the behavioural, social and practical drivers of vaccination described by BeSD (Brewer 2017; WHO 2021). People's background views and experiences are dependent on knowledge, previous experience, education and income levels (Kumar D 2016; Olson 2020; Simas 2021). Vaccine and disease factors involve the perception of vaccine safety and effectiveness, besides the perceived susceptibility to the disease (Dube 2015; Larson 2011; Salmon 2015). Environmental factors include public health policies, social factors, practical constraints (such as access) and supply problems, and the messages spread by the media (Arede 2019; Daley 2018). We will adopt a flexible approach, and add additional themes as they emerge from the data.

Each theme included in the framework will be coded and a list of codes generated to facilitate the management of the findings and aid comparison among studies. Codes will be applied to the findings of each study by two review authors working independently, findings that might require a new code will be discussed by three of the review team (AM; SC; SS plus consultation with the review team) to determine if this is required. At the outset, the application of the codes to the first five studies will be reviewed by the review authors to assess consistency across studies.

We will conduct a thematic analysis of the sub-themes within the people, agent and environmental categories and any additional themes, using a constant comparison strategy to merge themes with similar content and identify separate standalone themes (Thomas 2008; Tong 2012). If possible we will group and synthesise the findings that relate to decisions around the uptake of a vaccine, those that facilitate uptake and those that support informed choice by writing a summary of how the findings relate to each area. We will also actively seek and consider disconfirming cases or data as part of this analysis. If sufficient findings are available, we will group studies by regions that have similar characteristics, for example minority populations, low-income populations and low-income settings. We will discuss the findings of this synthesis with the review team for revision and interpretation, and refine until we reach agreement. We will use QSR NVIVO V12 to help manage the analysis, and will report the findings in tabular format with a narrative synthesis.

We will compare our findings with the findings reported by qualitative studies and systematic reviews of qualitative evidence that focus on a previous pandemic (Ebola, Hong Kong flu, Swine flu) by creating a table of comparisons that highlights the similarities and differences across the studies.

To develop implications for practice, we will examine each finding to identify issues that may influence vaccine delivery for adults. Based on these, we will develop prompts for implementers to consider when designing strategies to support vaccination roll-out and uptake during a pandemic(Glenton 2022). We will share these prompts with a small number of stakeholders (see below) to obtain feedback on their relevance and whether the prompts are easy to understand.

We will establish a small group of stakeholders with experience of vaccination in different contexts and use an adapted TRANSFER approach to identify how the findings might be applied to different settings by inviting topic experts and patient and public involvement representatives who represent a range of contexts to comment on the objectives and the perspective taken for the plan of analysis (Munthe-Kaas 2020). Throughout the review process we will consult with the Oxford Population Health public advisory panel for feedback on the selection of studies, the analytical approach, interpretation of the findings and plain language summary.

Assessing our confidence in the review findings

Two or more review authors will use the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach to assess our confidence in each finding (Lewin 2015, Lewin 2018). GRADE-CERQual assesses confidence in the evidence, based on the following four key components.

1. Methodological limitations of included studies: the extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to an individual review finding.
2. Coherence of the review finding: an assessment of how clear and cogent the fit is between the data from the primary studies and a review finding that synthesises those data. By cogent, we mean well-supported or compelling.
3. Adequacy of the data contributing to a review finding: an overall determination of the degree of richness and quantity of data supporting a review finding.
4. Relevance of the included studies to the review question: the extent to which the body of evidence from the primary studies supporting a review finding is applicable to the context (perspective or population, phenomenon of interest, setting) specified in the review question.

After assessing each of the four components, we will make a judgement about the overall confidence in the evidence supporting the review finding. We will judge confidence as high, moderate, low, or very low. The final assessment will be based on consensus among the review authors. All findings start as high confidence and will then be graded down if there are important concerns regarding any of the GRADE-CERQual components.

We will present summaries of the findings and our assessments of confidence in these findings in the Summary of Qualitative Findings table(s). We will present detailed descriptions of our confidence assessment in an Evidence Profile(s).

Review author reflexivity

Our review team comprises authors with different disciplinary backgrounds. At the outset of the review protocol, we all held the view that individuals have a right to make their own healthcare decisions, including about vaccination. Moreover, we believed that it is important for people to have easy access to balanced and transparent information about vaccination, including about adverse effects and evidence gaps. We recognised that there are many potential tensions between public health, community obligation, and individual choice, particularly in the pandemic context.

Throughout the review process, authors involved with selecting studies for inclusion, data extraction, analysis and interpretation of the findings will be asked to reflect and articulate how their perspectives and experiences might influence the shape and conclusion of the review. We will consider how our individual and collective views, beliefs and experiences will influence the choices we will make in terms of the scope of the review and our review methods; our interpretation of the data and our interpretation of our own findings.

AM is a general practitioner and the only author providing patient care, including vaccine-related services to adults. This may allow us to understand issues raised by healthcare providers in these studies.

SC is a social scientist (medical sociologist) with experience in qualitative research methods. She has led a related Cochrane Review on childhood vaccination acceptance (Cooper 2021) and is currently leading a related Cochrane Review on acceptance of human papillomavirus (HPV) vaccination for adolescents (Cooper 2019). The findings from those reviews may influence how she interprets the data in this review.

CG: is a social scientist with a health professional background who works primarily in the field of health systems and policy research in a National Institute of Public Health. She has been involved in a range of work on vaccination for children, adolescents and older adults (for example: Glenton 2021b; Kaufman 2017), but is not involved in providing patient care. She supports the right of individuals to reach their own decisions about vaccination and other types of health care, guided by easily accessible evidence-informed information. She also takes a public health perspective and regards adherence to vaccination recommendation as a key public health measure, particularly in the pandemic context, and has personally received three does of a COVID-19 vaccine. CG acknowledges that there may be tensions between the individual and public health perspectives in this review, and the importance of reflecting on these issues.

SL is a social scientist with a health professional background who works primarily in the field of health systems and policy research in a National Institute of Public Health. He has been involved in a range of work on vaccination for children, adolescents and older adults (for example: Glenton 2021b; Kaufman 2017), but is not involved in providing patient care. He supports the right of individuals to reach their own decisions about vaccination and other types of health care, guided by easily accessible evidence-informed information. He also takes a public health perspective and regards adherence to vaccination recommendation as a key public health measure, particularly in the pandemic context. SL acknowledges that there may be tensions between the individual and public health perspectives in this review, and the importance of reflecting on these issues.

PM is a nurse and academic. She is leading a Cochrane qualitative evidence synthesis on recruitment to vaccine trials in a pandemic/epidemic (Meskell 2022). This experience may influence how she interprets the data in this review

MS is a medically trained bioethicist and public health researcher with experience of qualitative research methods. She led the Health Foundation's COVID-19 Impact Inquiry on the impact of the pandemic on health and health inequalities. She also has extensive experience working with minority ethnic communities and conducts research on barriers and inequalities in access to healthcare services.

SS is a health systems researcher, her experience is mainly in quantitative research methods with some qualitative research. She co-led the DISCERN project that provides users with a standardised method to assess the quality of information on treatment choices for a health problem http://www.discern.org.uk/ SS is collaborating with colleagues on a Cochrane qualitative evidence synthesis on recruitment to vaccine trials in a pandemic/epidemic (Meskell 2022). This experience may influence how she interprets the data in this review.

Table 1 Draft matrix to organise the findings

People's experience	Vaccine and disease factors	Environmental factors
Knowledge	Safety	Public health policies
Attitudes	Effectiveness	Equity: social and economic factors, high- or low-income setting,
Beliefs	Susceptibility to the disease	Practical constraints to access
Previous experience	Income	Supply problems, for example related to income and health system
Education		Information: source (healthcare workers, social media etc)
Income		Cost
Cultural factors		
Cognitive		
Psychological		
Confidence/uncertainty		
Risk assessment		

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The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR Systematic Reviews Programme, National Health Service (NHS), or the Department of Health.

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APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (OVID)

MEDALL (1946 to present)

Search date: 3 Noveber 2022

No.	Search terms
1	exp vaccines/
2	exp vaccination/

(Continued)

3	exp immunization/
4	or/1-3
5	exp decision making/
6	exp attitude to health/
7	or/5-6
8	4 and 7
9	vaccination refusal/
10	anti-vaccination movement/
11	((barrier? or motivat* or decision? or decline? or refuse? or accept* or refusal or experience? or attitude? or perception? or willingness or view? or hesitan* or concern?) adj6 (vaccin* or immuni*)).ti,ab,kf.
12	(anti-vaccin* or anti-vax* or antivaccin* or antivax*).ti,ab,kf.
13	or/8-12
14	covid-19/ or exp covid-19 testing/ or sars-cov-2/
15	(coronavirus/ or betacoronavirus/ or coronavirus infections/) and (disease outbreaks/ or epidemics/ or pandemics/)
16	(ncov* or 2019ncov or 19ncov or covid19* or covid or sars-cov-2 or sarscov-2 or sars-cov2 or sarscov2 or sars coronavirus 2 or severe acute respiratory syndrome coronavirus 2 or severe acute respiratory syndrome corona virus 2).ti,ab,kf,nm,ot,ox,rx,px.
17	((new or novel or "19" or "2019" or wuhan or hubei or china or chinese) adj3 (coronavirus* or corona virus* or betacoronavirus* or cov or hcov)).ti,ab,kf,ot.
18	(longcovid* or postcovid* or postcoronavirus* or postsars*).ti,ab,kf,ot.
19	(long covid* or post covid* or post coronavirus* or post sars*).ti,ab,kf,ot.
20	((coronavirus* or corona virus* or betacoronavirus*) adj3 (pandemic* or epidemic* or outbreak* or crisis)).ti,ab,kf,ot.
21	((wuhan or hubei) adj5 pneumonia).ti,ab,kf,ot.
22	or/14-21
23	13 and 22
24	epidemics/
25	pandemics/
26	disease outbreaks/
27	(outbreak* or out break* or pandemic* or epidemic*).ti,ab,kf.

(Continued)

28	(avian flu or avian influenza or bird flu or bird influenza or h1n1 or "a/h1n1" or 1957 flu or 1958 flu or 1957 influenza or 1958 influenza or asian flu or asian influenza or h2n2 or "a/h2n2" or cholera or hong kong flu or hong kong influenza or h3n2 or "a/h3n2" or 1968 influenza or 1968 flu or severe acute respiratory syndrome or sars or sars-cov* or swine flu or swine influenza or 2009 flu or 2009 influenza or middle east respiratory syndrome or mers or mers-cov* or "emc/2012" or "hcov-emc/2012" or ebola*).ti,ab,kf.
29	Influenza A Virus, H1N1 Subtype/
30	Influenza A Virus, H2N2 Subtype/
31	cholera/
32	Influenza A Virus, H3N2 Subtype/
33	Severe Acute Respiratory Syndrome/
34	SARS virus/
35	Middle East Respiratory Syndrome Coronavirus/
36	Ebolavirus/
37	Ebola vaccines/
38	Hemorrhagic Fever, Ebola/
39	or/24-38
40	13 and 39
41	covid-19 vaccines/
42	((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide) adj3 (interview* or discussion* or questionnaire*)) or (focus group* or qualitative or ethnograph* or fieldwork or "field work" or "key informant")).ti,ab. or interviews as topic/ or focus groups/ or narration/ or qualitative research/
43	mixed method?.ti,ab,kf.
44	px.fs.
45	or/42-44
46	(23 or 41) and 45 [COVID-19 only]
47	40 and 45 [previous pandemics including named pandemics]
48	46 or 47

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All review authors conceived the idea for the review; AM, SC and SS led the writing of the protocol and all review authors provided critical comment.

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SS declares no conflict of interest. SS is the Joint Co-ordinating Editor for EPOC but was not involved in the editorial process for this review.

SL declares no financial conflicts of interest. SL is the Joint Co-ordinating Editor for EPOC but was not involved in the editorial process for this review.

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