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Current tools available for investigating vaccine hesitancy: a scoping review protocol

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ABSTRACT

Introduction

Vaccine hesitancy, defined as the delay in acceptance or refusal of vaccination despite availability of vaccination services is responsible in part for suboptimal levels of vaccination coverage worldwide. The WHO recommends that countries incorporate plans to measure and address vaccine hesitancy into their immunization programmes. This requires that governments and health institutions be able to detect concerns about vaccination in the population and monitor changes in vaccination behaviours. To do this effectively, tools to detect and measure vaccine hesitancy are required. The purpose of this scoping review is to give a broad overview of currently available vaccine hesitancy measuring tools and present a summary of their nature, similarities and differences.

Methods and analysis

The review will be conducted using the framework for scoping review proffered by Arksey and O'Malley. It will comply with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews' guidelines. The broader research question of this review is: what vaccine hesitancy measuring tools are currently available?

Search strategies will be developed using controlled vocabulary and selected keywords. PubMed, Web of Science, Scopus, and reference lists of relevant publications will be searched. Titles and abstracts will be independently screened by two authors and data from full-text articles meeting the inclusion criteria will be extracted independently by two authors using a pre-tested data charting form. Discrepancies will be resolved by discussion and consensus. Results will be presented using descriptive statistics such as percentages, tables, charts and flow diagrams as appropriate. Narrative analysis will be used to summarize the findings of the review.

Ethics and dissemination

Ethics approval is not required for the review. It will be submitted as part of a doctoral thesis, presented at conferences and published in a peer-reviewed journal.

Registration: https://osf.io/x8fjk/

ARTICLE SUMMARY

Strengths and limitations of this study

- The review will bring to the fore gaps that exists in the area of contextual development and validation of vaccine hesitancy measuring tools.
- The prescriptive study selection criteria will broaden the scope of included literature.
- Compliance with the PRISMA-ScR will enable the review to be one of its earliest use and test of impact.
- No meta-analysis is planned for this scoping review.

Key words: vaccine hesitancy, immunization, vaccination, tools, scoping review

INTRODUCTION

The significant contributions of vaccination to the health and general wellbeing of the human race cannot be overemphasised. The drastic reduction in the mortality, morbidity, and disability rates due to Vaccine Preventable Diseases (VPDs) worldwide since its introduction are great testimonials to the efficacy of vaccination. It has been estimated that over 3 million deaths and 75 thousand disabilities are prevented annually by vaccination.[1] This makes it one of the most successful public health interventions of modern times.[2] The progress made in vaccination coverage over the years was further accentuated and accelerated by the introduction of the World Health Organisation's (WHO) Expanded Programme on Immunization (EPI) in 1974.[3] EPI is a resounding success in most parts of the world. The global immunization coverage (indicated by the percentage of children who has received the third dose of diphtheria, tetanus and pertussis vaccine (DTP3)[4, 5] is estimated at 86% in 2015 according to WHO and UNICEF (United Nations International Children's Emergency Funds) data on global immunization. This coverage is said to have been sustained above 85% since the year 2010.[6] To continue to be a public health success, vaccines needs to be accepted and trusted by its target populace, and broadly and adequately used.[7]

The global challenge of vaccine hesitancy

The estimates reported above are calculated using the official national immunization coverage figures reported to WHO-UNICEF by member states.[4] They however, falls short of the Global Vaccine Action Plan's (GVAP's) target of 90% coverage at national level and 80% coverage at district levels for the Decade of Vaccines, that is, 2011-2020.[6, 8] Moreover, national coverage levels have been known to 'mask' variations within countries, concealing clusters of sub-national geographical or sociological areas where coverage is much lower.[5, 6] These areas with low or suboptimal vaccination coverage have provided fertile breeding grounds for intermittent outbreaks of vaccine preventable diseases in various parts of the world, including developed and developing countries.[9–11] These outbreaks have been attributed, in part, to the delay or outright refusal of some members of the population to vaccinate themselves or their children even when such services are available.

This phenomenon, that is, the delay in acceptance or refusal of vaccination despite availability of vaccination services, is defined as vaccine hesitancy.[12] Vaccine hesitancy is complex and context specific, and varies across time, place and vaccines.[12, 13] It can be described on a

continuum ranging from those who accept all vaccines without any doubt to those who reject all without any doubt. The large, heterogeneous group of individuals between these two extremes exhibits varying degrees of 'hesitancy'.[12] Vaccine hesitancy thus reflects the client's disposition towards vaccination as opposed to health system factors which impede vaccine uptake. Consequently, vaccine hesitancy shifts focus from the well-researched "supply" side of vaccination to the relatively under-studied "demand" side of vaccination, exploring people's willingness to accept vaccination for themselves or their children when supply and access are available. The extreme expression of vaccine hesitancy; vaccine refusal, is as old as the advent of vaccination itself.[9, 14, 15] Evidence suggests that it has become more pronounced on the global vaccination landscape in recent years, aided amongst other things by the increasing advancement in Information and Communication Technologies (ICTs).[3, 14]

Many of the countries in the world contend with vaccine hesitancy, with well over 90% of the 194 member states of the WHO reporting it over three years as against less than the 10% that reported "no hesitancy".[16] The three year (2015-2017) analysis of WHO/UNICEF member state Joint Reporting Form (JRF) by Sarah Lane and her team also revealed that vaccine hesitancy is present in all the six WHO regions, and it cuts across all the four categories of country income levels as classified by the WHO. These are: low, lower middle, upper middle and high income category.[16] On country level, vaccine hesitancy has been identified in urban and rural dwellers,[17] as well as amongst people of low literacy and those of high literacy[18, 19] howbeit for different reasons which are beyond the scope of this review protocol to elucidate. There are documented evidence that shows that vaccine hesitancy is present amongst adherents of the two major religions of the world[20] and is not limited to either gender.[21, 22]

Determinants of vaccine hesitancy

Determinants of vaccine hesitancy can also be referred to as factors, reasons or causes of vaccine hesitancy. According to the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) Working Group (WG) on vaccine hesitancy report of 2014,[23] there are myriads of factors that influences the vaccine decision-making process. This is not surprising given its complex and context specific nature. They proffered two models of vaccine hesitancy determinants; the 3C model which is a succinct, easy-to-grasp model

comprising of three determinants of vaccine hesitancy all starting with the letter 'C', and the more detailed, Working Group Determinants of Vaccine Hesitancy Matrix.[12, 23, 24]

In the 3C model, the determinants of vaccine hesitancy are identified as: **Confidence**, which covers issues of trust, not only in safety and effectiveness of vaccines, but also in the competence of the health care professionals that administer them and the health care systems that delivers them, as well as in the motives of the policy makers who proposes them. **Convenience** involves the ease or otherwise at which the vaccines and related services are accessed, their affordability and the willingness of the individuals to pay. And **Complacency**, which occurs when the need to vaccinate is low because the perceived risk of vaccine preventable diseases are deemed to be low. Complacency is particularly heightened in situations where other competing health or life responsibilities are present. These tend to dwarf the need for vaccination which is seen as a preventive measure against diseases, many of which are no longer common or seen as life-threatening, ironically, due to the successes of previous vaccination endeavours.[12, 23]

In recent years, additional two 'Cs' has been proposed to expand the '3C' model to a '5C' model. These are rational **Calculation** in which individuals with no strongly defined vaccination attitude embark on an intensive search for information, and depending on their findings, asses the risk of vaccination and makes a decision (usually a subjective one) either to vaccinate or not to vaccinate. **Collective** responsibility, on the other hand is implied when individuals or sub-groups makes vaccine decisions based on their sense of social responsibility. Such may decide to vaccinate themselves to protect others. For example, pregnant women deciding to take pertussis vaccines based on their understanding that the protection it offers is not for themselves but for their unborn babies.[13, 25, 26]

The second model, the Working Group Determinants of Vaccine Hesitancy Matrix is more complex and detailed than the 3C model as earlier mentioned, it broadly groups the determinants under three categories. The first is **Contextual influences**, the second, **Individual and group influences** and the third, **Vaccine and vaccination-specific issues**. Each of these categories has a number of factors listed under them that gives more details about the determinant and its scope.[24] Knowing the determinants of vaccine hesitancy in a particular context and setting allows for targeted interventions to be developed purposely to combat its effect in that particular context and setting; as not all intervention works in all

settings at all times and for all vaccines. Most of the interventions to mitigate against vaccine hesitancy and its effects have been designed and tested in High Income Countries (HICs), with precious little documented in Low and Middle Income Countries (LMICs), especially in Sub-Saharan Africa.

Effects of vaccine hesitancy

The effects of vaccine hesitancy, that is, the delay or refusal of vaccination for one's self or ones' dependant(s) despite the availability and offer of such services can be grave and far-reaching. Vaccine hesitancy is known to have a negative effect on vaccine demand, which in turn affects vaccine uptake and consequently the level of coverage needed to contain outbreaks and maintain control of vaccine preventable diseases. Ultimately, this undermines the effectiveness and successes of immunization programs.[9]

Vaccine hesitancy does not only pose a danger to the hesitant or vaccine-refusing individuals and / or their dependants, but also to the larger society. Vaccine hesitancy reduces 'herd immunity', that is, the level at which immunization coverage is to be maintained if protection is to be offered to those too young (for example, neonates) or too sick (the immunocompromised) to be immunized.[27] These sub-group of people depend on the immunization of other people in their community to protect them from contacting some vaccine preventable diseases. The level of coverage required for heard immunity in a community to prevent an outbreak of measles is estimated at 95%. If there is a reduction in this level for a sustained period of time in a community, an outbreak measles is imminent in such a community.

Controversies based on quasi 'scientific' claims such as the one ignited by the infamous Wakefield study conducted in the UK, which suggested a direct link between the Measles, Mumps and Rubella (MMR) vaccine and Autism, resulted in wide spread vaccine hesitancy and consequent negative effects. One of such effects is the erosion of confidence in the safety of vaccines, particularly the MMR vaccine, leading to marked decrease in vaccination levels and outbreaks of measles in the UK,[28] some parts of Europe such as Austria, Germany and France,[13] and the United States.[29] Another unfortunate example of the effect of vaccine hesitancy is demonstrated in the fivefold increase in the incidence of polio cases in Nigeria between 2002 -2006. This was caused by the boycott of the Oral Polio Vaccine (OPV), due to controversies emanating from unfounded rumours and distrust in the government.[25]

A lot of countries battle with the effects of vaccine hesitancy, the global influence of which prompted the WHO to recommend that it or its proxies should be constantly monitored. This necessitates the development of tools to detect and measure vaccine hesitancy.[12]

Measures of vaccine hesitancy

The menace of vaccine hesitancy and its attendant undesirable effects are a threat to public health globally. Its complex and context specific nature, and variability across time, place and vaccines makes its detection and measure somewhat challenging. There had been several efforts in recent past to develop tools for the detection and measures of vaccine hesitancy, such as Parent Attitudes about Childhood Vaccines Survey (PACV),[30] Vaccine Confidence Scale (VCS),[31, 32] Global Vaccine Confidence Index (GVCI)[19] and Vaccine Hesitancy Scale (VHS).[33] Most were developed for used in High Income Countries (HIC), and some, like the VHS has been validated and used in such context and settings.[33] Whilst acknowledging the work of Wallace *et al*,[34] who recently developed and validated a tool; the Caregiver Vaccine Acceptance Scale (CVAS) in Ghana, a Low and Middle Income County (LMIC) in sub-Saharan Africa, there is, nevertheless a dearth of such context specific tools to measure vaccine hesitancy in many other sub-Saharan LMIC context and settings. Hence there is a need for deliberate and concerted effort to fill this existing knowledge gap. As imperative this need is; care must be taken in executing this mandate to ensure that such generated tools are not just context-specific and valid, but can also provide a basis for data comparison with, and possible integration with those generated in other parts of the world. This can only be possible if similar templates are adapted and used in the development of such tools. This seems to be an implicit rationale behind the SAGE working group on vaccine hesitancy's' recommendation #1 in their full report of 2014 to WHO member states. The recommendation states that member states should "incorporate a plan to measure and address vaccine hesitancy into their country's immunization program as part of good program practices; the compendium of vaccine hesitancy survey questions may help; use of questions from the compendium facilitates inter-country comparisons, though the survey questions still remain to be validated throughout different settings".[23] This is exemplified in the effort of Wallace and his team,[34] and is the main thrust of the research project which the scoping review subsequent to this protocol aims to address. The crux of the project is to develop a context-specific validated tool in a sub-Saharan LMIC setting based on the compendium of vaccine hesitancy survey questions developed by Larson and her team in 2015[35]

commissioned by the WHO. The use of the compendium questions is expected to facilitate inter-country comparisons when validated in different settings as stated in the recommendation.

METHODS AND ANALYSIS

The use of scoping reviews, especially in health and related fields, has steadily been on the rise since 2012.[36, 37] Scoping reviews are used to identify research gaps, map key concepts and identify main sources of evidence available in a particular area of research.[38, 39] A Scoping review is particularly useful when the area of research is a complex and heterogeneous one,[39] such as vaccine hesitancy. The complex and contextual nature of vaccine hesitancy, and its variation across time, place and vaccines makes scoping review an ideal tool for its investigation. Also, the usability of scoping reviews to capture the breadth of evidence available on a particular area of research is in alignment with the aim of this scoping review. The aim of the scoping review subsequent to this protocol is to give a broad overview of currently available vaccine hesitancy measuring tools, and present a summary of their nature, similarities and differences.

The scoping review will utilise the Askey and O'Malley framework for conducting scoping reviews.[38] It will incorporate suggested improvements and recommendations by other authors such as Levac,[40] Pham[36] and the Joanna Briggs Institute's (JBI) manual for review authors[41] where appropriate. The JBI's manual for review authors stipulates the use of an a-priori protocol for scoping reviews, it also recommends that the inclusion and exclusion criteria for such reviews should clearly relate to the objectives and research questions of such reviews. This protocol is in compliance with this stipulation, and the scoping review will adopt the recommendations in the process of its conduct. The mandatory five stages of the six stage steps of the Askey and O'Malley framework will be utilised in the conduct of this scoping review, with the optional sixth stage not included. The six stages are:

1. Identifying a research question;
2. Identifying relevant studies
3. Study selection
4. Charting the data

5. Collating, summarizing and reporting the result
6. Consultation exercise (optional step)

The sixth stage, the consultation stage, is an optional stage, though Askey and O'Malley alluded to its inclusion enhancing their scoping review.[38] The objective of this particular scoping review does not require a consultation stage.

Stage 1: Identifying a research question

The research question for the scoping review is an off-shoot of the broader research question for the project of which the scoping review forms part of the evidence synthesis phase. The research question is clearly articulated and focused as recommended by Levac and the JBI's manual for review authors,[40,41] and the scope of the review is indicated in the question. The review question is: **What vaccine hesitancy measuring tools are currently available?** The phrase "currently available" for the purpose of this scoping review refers to tools published in peer-reviewed journals available in the public domain from the year 2010 to date. This period includes the first nine years of the decade of vaccines which spans 2011-20.[8] Most of the tools in use were developed within this time frame, the few that might be before this period would have had their essence captured in their successors, as using an existing tool as the template for the development of a new one is a consistent method of tool development. This further clarification of the research question will also help in the development of an effective search strategy, and aid in the selection of the inclusion and exclusion criteria of retrieved records.

Stage 2: Identifying relevant studies

Several bibliographic databases of peer reviewed journals will be searched, these will include, but will not be limited to; MEDLINE (PubMed), Web of Science and Scopus. The three-step search strategy recommended by the Joanna Briggs Institute's (JBI) manual for review authors[41] will be carried out in this stage. The first step includes the use of broad search terms to interrogate at least two electronic databases to retrieve relevant articles. Table 1 lists the proposed search strategy to be used to search MEDLINE. This strategy will be tailored for the other databases. The title and abstract of selected articles from this initial broad search will be scanned for key words and index terms used to describe the articles. In the second step, the key words and index terms identified in the first step will be used to develop

comprehensive search strategies (search strings) using controlled vocabulary and text words. The focused search strategy, reflective of the research question, will include the use of major key words such as tools, surveys, scales, interviews and questionnaires in conjunction with the main search term 'vaccine hesitancy' and its variants. The search strategy will be tailored to the specifications of each of databases searched. The third and final step will include the "hand-searching" of selected relevant records to ensure comprehensive coverage of relevant and available literature. Two or more authors including a seasoned evidence synthesis researcher will be involved in this three-step search for relevant records, this process ensures the optimization of the search strategy, and will lay a solid foundation for the determination of the inclusion and exclusion criteria as well as the subsequent stages.

Table 1: Proposed search strategy to search MEDLINE (PubMed)

	Search terms
#1	(Vaccination Refusal) OR (Vaccine refusal) OR (Anti Vaccination Movement) OR (Vaccine hesitant) OR (vaccination hesitant) OR (Vaccine hesitancy) OR (vaccination hesitancy) OR (immunization hesitancy) OR (immunization hesitant) OR (immunization refusal) OR (immunisation hesitancy) OR (immunisation hesitant) OR (immunisation refusal)
#2	"Pro-vaccination" OR "Vaccination acceptance" OR "vaccine acceptance" OR "Immunization acceptance" OR "Pro-vaccine" OR "Vaccine confidence" OR "Vaccination confidence"
#3	#1 OR #2
#4	"measurement tools" OR Surveys OR Questionnaire OR Questionnaires OR Interviews OR tool OR tools OR measure OR measures OR measurements OR survey OR interview
#5	#3 AND #4

Inclusion and exclusion criteria: All relevant studies recovered from the comprehensive search irrespective of the language, study design, country of origin, purpose, target populace and vaccines covered will be included. Though the search strategy will be filtered to focus on studies available from the year 2010 as earlier indicated, it will also be expanded to include

relevant studies that may be available before that time period, and any retrieved record will be reported. Efforts will be made to contact authors of relevant articles whose titles and abstracts meet the inclusion criterial, but whose full-text is not available in the public domain, via e-mail.

Studies that are irrelevant, do not include any form of measurement tools, or with tools not measuring vaccine hesitancy will be excluded.

Stage 3: Study selection

The three-step search strategy will inform the selection of studies to be included in the scoping review. All studies that meet the inclusion criteria will be imported into a reference management package (EndNote). The total number of relevant studies retrieved from the first step of the search will be recorded, as will the total number of studies retrieved from each source of information in the second step. The records will be de-duplicated and the number of duplicates removed recorded. The number of studies excluded after screening of titles, abstracts and full texts will be recorded, as will the reasons for exclusion. All this information will be presented in a PRISMA-ScR extension[42] flow diagram.

Stage 4: Charting the data

A data charting form that will provide a logical summary of information extracted from each full text article included in the study will be developed prior to the commencement of the scoping review and will be updated as necessary as the study progresses.[41] The data charting form will be designed to extract information relevant to the review question and objectives and will include, but may not be limited to: title, authors, year of publication, WHO region, country where study was conducted, type of tool, target population, vaccines investigated, domain investigated, number of constructs and total number of items. Data charting will be carried out independently in duplicate by two authors including an evidence synthesis researcher, and as with the preceding stages, other authors will be consulted to resolve differing opinions and to provide supervisory oversight.

Stage 5: Collating, summarizing and reporting the results

Information from data extracted from included studies will be collated, and quantitative results presented using descriptive statistics such as percentages, tables, charts and flow diagrams as appropriate, while the qualitative results will be reported thematically. This will be followed

by an informed discussion based on careful consideration of the results in keeping with the purpose and objective of the review. No meta-analysis is planned for the review, neither will the quality of evidence of included studies be assessed as the purpose of the scoping review is to give a descriptive overview of currently available vaccine hesitancy measuring tools in the literature, and present a summary of their nature, similarities and differences.

Stage 6: Consultation exercise (optional step)

A consultation exercise is not intended for this review as its relevance to the review question and objectives is negligible. However, if in the course of the review the need for it should arise, relevant stakeholders will be consulted and the outcomes of such consultations will be reported and used to further understand and interpret the results and implications of the review.

Conclusion

The scoping review will, in line with its objectives, provide a broad overview of currently available vaccine hesitancy measuring tools, their similarities and differences, and highlight gaps in existing knowledge related to contextual development and validation of such tools, as well as identify areas where more research is required.

This is aimed at providing useful and relevant information for current and future users of such tools and helpful insights for those intending to validate such tools in any context or setting.

ETHICS AND DISSEMINATION

Ethics approval is not a requirement for the review. All data will be obtained from publicly available documents, and no primary data will be generated. The scoping review forms part of the evidence synthesis phase of a doctoral research project that has obtained ethics approval from the host institution. The Project identity number is: 8945 and the Human Research Ethics Committee (HREC) reference is # S19/01/014 (PhD).

The review will be presented at conferences and other relevant and appropriate platforms. It will also be published in a peer-reviewed journal.

DATA STATEMENT

Data generated will be published in the review, and will be publicly accessible.

Author Contributions

EO led the conceptualization, design, and drafted the protocol. EDP and CSW developed the search strategy and conducted the preliminary searches; HM and CSW provided supervisory overview and feedback on the methodology and the manuscript. This team of four authors give their approval to the publishing of this protocol manuscript.

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Competing interests

None declared.

Patient consent

Not required.

Ethics approval

Research ethics approval is not required for a scoping review.

Provenance and peer review

Not commissioned; externally peer reviewed.

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Current tools available for investigating vaccine hesitancy: a scoping review protocol

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ABSTRACT

Introduction

Vaccine hesitancy, defined as the delay in acceptance or refusal of vaccination despite availability of vaccination services is responsible in part for suboptimal levels of vaccination coverage worldwide. The WHO recommends that countries incorporate plans to measure and address vaccine hesitancy into their immunization programmes. This requires that governments and health institutions be able to detect concerns about vaccination in the population and monitor changes in vaccination behaviours. To do this effectively, tools to detect and measure vaccine hesitancy are required. The purpose of this scoping review is to give a broad overview of currently available vaccine hesitancy measuring tools and present a summary of their nature, similarities and differences.

Methods and analysis

The review will be conducted using the framework for scoping review proffered by Arksey and O'Malley. It will comply with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews' guidelines. The broader research question of this review is: what vaccine hesitancy measuring tools are currently available?

Search strategies will be developed using controlled vocabulary and selected keywords. PubMed, Web of Science, Scopus, and reference lists of relevant publications will be searched. Titles and abstracts will be independently screened by two authors and data from full-text articles meeting the inclusion criteria will be extracted independently by two authors using a pre-tested data charting form. Discrepancies will be resolved by discussion and consensus. Results will be presented using descriptive statistics such as percentages, tables, charts and flow diagrams as appropriate. Narrative analysis will be used to summarize the findings of the review.

Ethics and dissemination

Ethics approval is not required for the review. It will be submitted as part of a doctoral thesis, presented at conferences and published in a peer-reviewed journal.

Registration: https://osf.io/x8fjk/

ARTICLE SUMMARY

Strengths and limitations of this study

- The review will bring to the fore gaps that exist in the area of contextual development and validation of vaccine hesitancy measuring tools.
- The non-prescriptive study selection criteria will broaden the scope of included literature.
- Compliance with the PRISMA-ScR will enable the review to be one of its earliest use and test of impact.
- No meta-analysis is planned for this scoping review.

Key words: vaccine hesitancy, immunization, vaccination, tools, scoping review

INTRODUCTION

The significant contributions of vaccination to the health and general wellbeing of the human race cannot be overemphasised. The drastic reduction in the mortality, morbidity, and disability rates due to Vaccine Preventable Diseases (VPDs) worldwide since its introduction are great testimonials to the efficacy of vaccination. It has been estimated that over 3 million deaths and 75 thousand disabilities are prevented annually by vaccination.[1] This makes it one of the most successful public health interventions of modern times.[2] The progress made in vaccination coverage over the years was further accentuated and accelerated by the introduction of the World Health Organisation's (WHO) Expanded Programme on Immunization (EPI) in 1974.[3] EPI is a resounding success in most parts of the world. The global immunization coverage (indicated by the percentage of children who has received the third dose of diphtheria, tetanus and pertussis vaccine (DTP3)[4, 5] is estimated at 86% in 2015 according to WHO and UNICEF (United Nations International Children's Emergency Funds) data on global immunization. This coverage is said to have been sustained above 85% since the year 2010.[6] To continue to be a public health success, vaccines needs to be accepted and trusted by its target populace, and broadly and adequately used.[7]

The global challenge of vaccine hesitancy

The estimates reported above are calculated using the official national immunization coverage figures reported to WHO-UNICEF by member states.[4] They however, falls short of the Global Vaccine Action Plan's (GVAP's) target of 90% coverage at national level and 80% coverage at district levels for the Decade of Vaccines, that is, 2011-2020.[6, 8] Moreover, national coverage levels have been known to 'mask' variations within countries, concealing clusters of sub-national geographical or sociological areas where coverage is much lower.[5, 6] These areas with low or suboptimal vaccination coverage have provided fertile breeding grounds for intermittent outbreaks of vaccine preventable diseases in various parts of the world, including developed and developing countries.[9–11] These outbreaks have been attributed, in part, to the delay or outright refusal of some members of the population to vaccinate themselves or their children even when such services are available.

This phenomenon, that is, the delay in acceptance or refusal of vaccination despite availability of vaccination services, is defined as vaccine hesitancy.[12] Vaccine hesitancy is complex and context specific, and varies across time, place and vaccines.[12, 13] It can be described on a

continuum ranging from those who accept all vaccines without any doubt to those who reject all without any doubt. The large, heterogeneous group of individuals between these two extremes exhibits varying degrees of 'hesitancy'.[12] Vaccine hesitancy thus reflects the client's disposition towards vaccination as opposed to health system factors which impede vaccine uptake. Consequently, vaccine hesitancy shifts focus from the well-researched "supply" side of vaccination to the relatively under-studied "demand" side of vaccination, exploring people's willingness to accept vaccination for themselves or their children when supply and access are available. The extreme expression of vaccine hesitancy; vaccine refusal, is as old as the advent of vaccination itself.[9, 14, 15] Evidence suggests that it has become more pronounced on the global vaccination landscape in recent years, aided amongst other things by the increasing advancement in Information and Communication Technologies (ICTs).[3, 14]

Many of the countries in the world contend with vaccine hesitancy, with well over 90% of the 194 member states of the WHO reporting it over three years as against less than the 10% that reported "no hesitancy".[16] The three year (2015-2017) analysis of WHO/UNICEF member state Joint Reporting Form (JRF) by Sarah Lane and her team also revealed that vaccine hesitancy is present in all the six WHO regions, and it cuts across all the four categories of country income levels as classified by the WHO. These are: low, lower middle, upper middle and high income category.[16] On country level, vaccine hesitancy has been identified in urban and rural dwellers,[17] as well as amongst people of low literacy and those of high literacy[18, 19] howbeit for different reasons which are beyond the scope of this review protocol to elucidate. There are documented evidence that shows that vaccine hesitancy is present amongst adherents of the two major religions of the world[20] and is not limited to either gender.[21, 22] Also, notable is the fact that vaccine hesitancy may have an inverse relationship with **vaccine confidence**, the lack of which may be regarded as one of the main determinants of vaccine hesitancy; covering issues of trust. When confidence is low or lacking, there is the tendency to be hesitant, delay or out rightly refuse vaccination.[23]

Determinants of vaccine hesitancy

Determinants of vaccine hesitancy can also be referred to as factors, reasons or causes of vaccine hesitancy. According to the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) Working Group (WG) on vaccine hesitancy report of 2014,[24] there

are myriads of factors that influences the vaccine decision-making process. This is not surprising given its complex and context specific nature. They proffered two models of vaccine hesitancy determinants; the 3C model which is a succinct, easy-to-grasp model comprising of three determinants of vaccine hesitancy all starting with the letter 'C', and the more detailed, Working Group Determinants of Vaccine Hesitancy Matrix.[12, 24, 25]

In the 3C model, the determinants of vaccine hesitancy are identified as: **confidence**, which covers issues of trust, not only in safety and effectiveness of vaccines, but also in the competence of the health care professionals that administer them and the health care systems that delivers them, as well as in the motives of the policy makers who proposes them. **Convenience** involves the ease or otherwise at which the vaccines and related services are accessed, their affordability and the willingness of the individuals to pay. And **complacency**, which occurs when the need to vaccinate is low because the perceived risk of vaccine preventable diseases are deemed to be low. Complacency is particularly heightened in situations where other competing health or life responsibilities are present. These tend to dwarf the need for vaccination which is seen as a preventive measure against diseases, many of which are no longer common or seen as life-threatening, ironically, due to the successes of previous vaccination endeavours.[12, 24]

In recent years, additional two 'Cs' have been proposed to expand the '3C' model to a '5C' model. These are rational **calculation** in which individuals with no strongly defined vaccination attitude embark on an intensive search for information, and depending on their findings, asses the risk of vaccination and makes a decision (usually a subjective one) either to vaccinate or not to vaccinate. **Collective** responsibility, on the other hand is implied when individuals or sub-groups makes vaccine decisions based on their sense of social responsibility. Such may decide to vaccinate themselves to protect others. For example, pregnant women deciding to take pertussis vaccines based on their understanding that the protection it offers is not for themselves but for their unborn babies.[13, 26, 27]

The second model, the Working Group Determinants of Vaccine Hesitancy Matrix is more complex and detailed than the 3C model as earlier mentioned, it broadly groups the determinants under three categories. The first is **contextual influences**, the second, **individual and group influences** and the third, **vaccine and vaccination-specific issues**. Each of these categories has a number of factors listed under them that gives more details about the

determinant and its scope.[25] Knowing the determinants of vaccine hesitancy in a particular context and setting allows for targeted interventions to be developed purposely to combat its effect in that particular context and setting; as not all intervention works in all settings at all times and for all vaccines. Most of the interventions to mitigate against vaccine hesitancy and its effects have been designed and tested in high income countries (HICs), with precious little documented in low and middle income countries (LMICs), especially in sub-Saharan Africa.

Effects of vaccine hesitancy

The effects of vaccine hesitancy, that is, the delay or refusal of vaccination for one's self or ones' dependant(s) despite the availability and offer of such services can be grave and far-reaching. Vaccine hesitancy is known to have a negative effect on vaccine demand, which in turn affects vaccine uptake and consequently the level of coverage needed to contain outbreaks and maintain control of vaccine preventable diseases. Ultimately, this undermines the effectiveness and successes of immunization programs.[9]

Vaccine hesitancy does not only pose a danger to the hesitant or vaccine-refusing individuals and / or their dependants, but also to the larger society. Vaccine hesitancy reduces 'herd immunity', that is, the level at which immunization coverage is to be maintained if protection is to be offered to those too young (for example, neonates) or too sick (the immunocompromised) to be immunized.[28] These sub-group of people depend on the immunization of other people in their community to protect them from contacting some vaccine preventable diseases. The level of coverage required for heard immunity in a community to prevent an outbreak of measles is estimated at 95%. If there is a reduction in this level for a sustained period of time in a community, an outbreak measles is imminent in such a community.

Controversies based on quasi 'scientific' claims such as the one ignited by the infamous Wakefield study conducted in the UK, which suggested a direct link between the measles, mumps and rubella (MMR) vaccine and autism, resulted in wide spread vaccine hesitancy and consequent negative effects. One of such effects is the erosion of confidence in the safety of vaccines, particularly the MMR vaccine, leading to marked decrease in vaccination levels and outbreaks of measles in the UK,[29] some parts of Europe such as Austria, Germany and France,[13] and the United States.[30] Another unfortunate example of the effect of vaccine hesitancy is demonstrated in the fivefold increase in the incidence of polio cases in Nigeria

between 2002 -2006. This was caused by the boycott of the oral polio vaccine (OPV), due to controversies emanating from unfounded rumours and distrust in the government.[26]

A lot of countries battle with the effects of vaccine hesitancy, the global influence of which prompted the WHO to recommend that it or its proxies should be constantly monitored. This necessitates the development of tools to detect and measure vaccine hesitancy.[12]

Measures of vaccine hesitancy

The menace of vaccine hesitancy and its attendant undesirable effects are a threat to public health globally. Its complex and context specific nature, and variability across time, place and vaccines makes its detection and measure somewhat challenging. There had been several efforts in recent past to develop tools for the detection and measures of vaccine hesitancy, such as Parent Attitudes about Childhood Vaccines Survey (PACV),[31] Vaccine Confidence Scale (VCS),[32, 33] Global Vaccine Confidence Index (GVCI)[19] and Vaccine Hesitancy Scale (VHS).[34] Most were developed for used in high income countries (HIC), and some, like the VHS has been validated and used in such context and settings.[34] Whilst acknowledging the work of Wallace *et al*,[35] who recently developed and validated a tool; the Caregiver Vaccine Acceptance Scale (CVAS) in Ghana, an LMIC in sub-Saharan Africa, there is, nevertheless a dearth of such context specific tools to measure vaccine hesitancy in many other sub-Saharan LMIC context and settings. Hence there is a need for deliberate and concerted effort to fill this existing knowledge gap. As imperative this need is; care must be taken in executing this mandate to ensure that such generated tools are not just context-specific and valid, but can also provide a basis for data comparison with, and possible integration with those generated in other parts of the world. This can only be possible if similar templates are adapted and used in the development of such tools. This seems to be an implicit rationale behind the SAGE working group on vaccine hesitancy's' recommendation #1 in their full report of 2014 to WHO member states. The recommendation states that member states should "incorporate a plan to measure and address vaccine hesitancy into their country's immunization program as part of good program practices; the compendium of vaccine hesitancy survey questions may help; use of questions from the compendium facilitates inter-country comparisons, though the survey questions still remain to be validated throughout different settings".[24] This is exemplified in the effort of Wallace and his team,[35] and is the main thrust of the research project which the scoping review subsequent to this protocol

aims to address. The crux of the project is to develop a context-specific validated tool in a sub-Saharan LMIC setting based on the compendium of vaccine hesitancy survey questions developed by Larson and her team in 2015[36] commissioned by the WHO. The use of the compendium questions is expected to facilitate inter-country comparisons when validated in different settings as stated in the recommendation.

METHODS AND ANALYSIS

The use of scoping reviews, especially in health and related fields, has steadily been on the rise since 2012.[37, 38] Scoping reviews are used to identify research gaps, map key concepts and identify main sources of evidence available in a particular area of research.[39, 40] A Scoping review is particularly useful when the area of research is a complex and heterogeneous one,[40] such as vaccine hesitancy. The complex and contextual nature of vaccine hesitancy, and its variation across time, place and vaccines makes scoping review an ideal tool for its investigation. Also, the usability of scoping reviews to capture the breadth of evidence available on a particular area of research is in alignment with the aim of this scoping review. The aim of the scoping review subsequent to this protocol is to give a broad overview of currently available vaccine hesitancy measuring tools, and present a summary of their nature, and similarities and differences. In keeping with this aim, no empirical evaluation of the tools will be conducted. However, variations in the target groups of the different tools and the types of scales used will be highlighted in the data extraction and discussion sections of the final review.

The scoping review will utilise the Askey and O'Malley framework for conducting scoping reviews.[39] It will incorporate suggested improvements and recommendations by other authors such as Levac,[41] Pham[37] and the Joanna Briggs Institute's (JBI) manual for review authors[42] where appropriate. The JBI's manual for review authors stipulates the use of an a-priori protocol for scoping reviews, it also recommends that the inclusion and exclusion criteria for such reviews should clearly relate to the objectives and research questions of such reviews. This protocol is in compliance with this stipulation, and the scoping review will adopt the recommendations in the process of its conduct. The mandatory five stages of the six stage steps of the Askey and O'Malley framework will be utilised in the conduct of this scoping review, with the optional sixth stage not included. The six stages are:

1. Identifying a research question;
2. Identifying relevant studies
3. Study selection
4. Charting the data
5. Collating, summarizing and reporting the result
6. Consultation exercise (optional step)

The sixth stage, the consultation stage, is an optional stage, though Askey and O'Malley alluded to its inclusion enhancing their scoping review.[39] The objective of this particular scoping review does not require a consultation stage.

Stage 1: Identifying a research question

The research question for the scoping review is an off-shoot of the broader research question for the project of which the scoping review forms part of the evidence synthesis phase. The research question is clearly articulated and focused as recommended by Levac and the JBI's manual for review authors,[40,41] and the scope of the review is indicated in the question. The review question is: **What vaccine hesitancy measuring tools are currently available?** The phrase "currently available" for the purpose of this scoping review refers to tools published in peer-reviewed journals available in the public domain from the year 2010 to date. This period includes the first nine years of the decade of vaccines which spans 2011-20.[8] Most of the tools in use were developed within this time frame, the few that might be before this period would have had their essence captured in their successors, as using an existing tool as the template for the development of a new one is a consistent method of tool development. This further clarification of the research question will also help in the development of an effective search strategy, and aid in the selection of the inclusion and exclusion criteria of retrieved records.

Stage 2: Identifying relevant studies

Several bibliographic databases of peer reviewed journals will be searched, these will include, but will not be limited to; MEDLINE (PubMed), Web of Science and Scopus. The three-step search strategy recommended by the Joanna Briggs Institute's (JBI) manual for review

authors[42] will be carried out in this stage. The first step includes the use of broad search terms to interrogate at least two electronic databases to retrieve relevant articles. Table 1 shows the proposed search strategy to be used to search MEDLINE. This strategy will be tailored for the other databases. The title and abstract of selected articles from this initial broad search will be scanned for key words and index terms used to describe the articles. In the second step, the key words and index terms identified in the first step will be used to develop comprehensive search strategies (search strings) using controlled vocabulary and text words. The focused search strategy, reflective of the research question, will include the use of major key words such as tools, surveys, scales, interviews and questionnaires in conjunction with the main search term 'vaccine hesitancy' and its variants. The search strategy will be tailored to the specifications of each of databases searched. The third and final step will include the "hand-searching" of selected relevant records to ensure comprehensive coverage of relevant and available literature. Two or more authors including a seasoned evidence synthesis researcher will be involved in this three-step search for relevant records, this process ensures the optimization of the search strategy, and will lay a solid foundation for the determination of the inclusion and exclusion criteria as well as the subsequent stages.

A preliminary search in PubMed was conducted in July 2019, using an earlier version of the search strategy shown in Table 1. During the peer review process additional search terms were included, and the updated search strategy tested in PubMed in October 2019. The expanded search strategy (tailored to each electronic database) will be used to conduct a comprehensive search of the literature for the scoping review in January – February 2020.

Table 1: Proposed search strategy to search MEDLINE (PubMed)

	Search terms
#1	(Vaccination Refusal) OR (Vaccine refusal) OR (Anti Vaccination Movement) OR (Vaccine hesitant) OR (vaccination hesitant) OR (Vaccine hesitancy) OR (vaccination hesitancy) OR (immunization hesitancy) OR (immunization hesitant) OR (immunization refusal) OR (immunisation hesitancy) OR (immunisation hesitant) OR (immunisation refusal) OR (vaccine avoidance) OR (vaccination

	avoidance) OR (vaccine resistance) OR (vaccination resistance) OR (immunization avoidance) OR (immunization resistance) OR (vaccine waiver) OR (mandatory vaccination)
#2	"Pro-vaccination" OR "Vaccination acceptance" OR "vaccine acceptance" OR "Immunization acceptance" OR "Pro-vaccine" OR "Vaccine confidence" OR "Vaccination confidence"
#3	#1 OR #2
#4	"measurement tools" OR Surveys OR Questionnaire OR Questionnaires OR Interviews OR tool OR tools OR measure OR measures OR measurements OR survey OR interview OR scales OR scale OR index
#5	#3 AND #4

Inclusion and exclusion criteria: All relevant studies recovered from the comprehensive search irrespective of study design, country of origin, purpose, vaccines, and target populace (e.g. population sub-sets of all demographic strata) covered will be included. Though the search strategy will be filtered to focus on studies available from the year 2010 as earlier indicated, it will also be expanded to include relevant studies that may be available before that time period, and any retrieved record will be reported. Efforts will be made to contact authors of relevant articles whose titles and abstracts meet the inclusion criterial, but whose full-text is not available in the public domain, via e-mail.

Studies that are irrelevant, not published in English, do not include any form of measurement tools, or with tools not measuring vaccine hesitancy will be excluded.

Stage 3: Study selection

The three-step search strategy will inform the selection of studies to be included in the scoping review. All studies that meet the inclusion criteria will be imported into a reference management package (EndNote). The total number of relevant studies retrieved from the first step of the search will be recorded, as will the total number of studies retrieved from each source of information in the second step. The records will be de-duplicated and the number of duplicates removed recorded. The number of studies excluded after screening of titles, abstracts and full texts will be recorded, as will the reasons for exclusion. This information

will be presented in a PRISMA flow diagram, a schematic draft of which is presented as figure 1 as recommended in the PRISMA-ScR extension checklist.[43]

Stage 4: Charting the data

A data charting form that will provide a logical summary of information extracted from each full text article included in the study will be developed prior to the commencement of the scoping review and will be updated as necessary as the study progresses.[42] The data charting form will be designed to extract information relevant to the review question and objectives, and will include, but may not be limited to: title, authors, year of publication, WHO region, country where study was conducted, type of tool, target population, vaccines investigated, domain investigated, number of constructs and total number of items. Data charting will be carried out independently in duplicate by two authors including an evidence synthesis researcher, and as with the preceding stages, other authors will be consulted to resolve differing opinions and to provide supervisory oversight. Below is the tentative list of fields to be completed in the data charting form:

First author, Title, Journal name, Year of publication, Name of measure/tool, Study type, Country, WHO region, World Bank economic classification, Target population, Vaccine(s) investigated, Total number of items, Subscales, Construct/or domains investigated, Method of data collection, Validation tests, Item generation process, Study limitations, Other important information.

Stage 5: Collating, summarizing and reporting the results

Information from data extracted from included studies will be collated, and quantitative results presented using descriptive statistics such as percentages, tables, charts and flow diagrams as appropriate, while the qualitative results will be reported thematically. This will be followed by an informed discussion based on careful consideration of the results in keeping with the purpose and objective of the review. No meta-analysis is planned for the review, neither will the quality of evidence of included studies be assessed as the purpose of the scoping review is to give a descriptive overview of currently available vaccine hesitancy measuring tools in the literature, and present a summary of their nature, similarities and differences. Therefore,

the findings of the review will be reported as described above, and no empirical evaluation of the tools will be conducted in keeping with this aim of the review.

Stage 6: Consultation exercise (optional step)

A consultation exercise is not intended for this review as its relevance to the review question and objectives is negligible. Therefore, none will be conducted.

ETHICS AND DISSEMINATION

Ethics approval is not a requirement for the review. All data will be obtained from publicly available documents, and no primary data will be generated. The scoping review forms part of the evidence synthesis phase of a doctoral research project that has obtained ethics approval from the Stellenbosch University Human Research Ethics Committee (reference number S19/01/014 (PhD)).

The review will be presented at conferences and other relevant and appropriate platforms. It will also be published in a peer-reviewed journal.

DATA STATEMENT

Data generated will be published in the review and will be publicly accessible.

Author contributions

EO led the conceptualization, design, and drafted the protocol. EDP and CSW developed the search strategy and EDP conducted the preliminary searches; HM and CSW provided supervisory overview and feedback on the methodology and the manuscript. This team of four authors give their approval to the publishing of this protocol manuscript.

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Competing interests

None declared.

Patient consent

Not required.

Patient and public involvement

Patients and the public will not be involved in the review

Ethics approval

Research ethics approval is not required for a scoping review.

Provenance and peer review

Not commissioned; externally peer reviewed.

Figure 1: PRISMA flow diagram

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Figure 1: PRISMA flow diagram