

# Identifying factors that can be used to assess a country's readiness to deploy a new vaccine or improve uptake of an underutilized vaccine: a scoping review

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## Abstract

**Objectives** Identifying whether a country is ready to deploy a new vaccine or improve uptake of an existing vaccine requires knowledge of a diverse range of interdependent, context-specific factors. This scoping review aims to identify common themes that emerge across articles, which include tools or guidance, that can be used to establish whether a country is ready to deploy a new vaccine or increase uptake of an underutilized vaccine.

**Design** Scoping review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews (PRISMA-ScR) guidelines.

**Data Sources** Embase, CINAHL, Cochrane Library, Google Scholar, MEDLINE, PsycINFO and Web of Science were searched for articles published until 09-Sep-2023. Relevant articles were also identified through expert opinion.

**Eligibility Criteria** Articles published in any year or language that included tools or guidance to identify factors that influence a country's readiness to deploy a new or underutilized vaccine.

**Data extraction and synthesis** Two independent reviewers screened records and performed data extraction. Findings were synthesized by conducting a thematic analysis.

**Results** Thirty-eight articles met our inclusion criteria; these documents were created using methodologies including expert review panels and Delphi surveys and varied in terms of content and context-of-use. Twelve common themes were identified relevant to a country's readiness to deploy a new or underutilized vaccine. These themes were: (i) legal, political, and professional consensus; (ii) socio-cultural factors and communication; (iii) policy, guidelines, and regulations; (iv) financing; (v) vaccine characteristics and supply logistics; (vi) program planning; (vii) program monitoring and evaluation; (viii) sustainable and integrated healthcare provision; (ix) safety surveillance and reporting; (x) disease burden and characteristics; (xi) vaccination equity; and (xii) human resources and training of professionals.

**Conclusions** This information has the potential to form the basis of a globally applicable evidence-based vaccine readiness assessment tool that can inform policy and immunization program decision-makers.

## Introduction

The development of new or improved vaccines is a key vehicle to improve health outcomes across the world, with follow on benefits to equity, economic capacity, and societal function <sup>1,2</sup>. With the emergence of new diseases (e.g. COVID-19) <sup>3</sup>, or the resurgence of existing diseases (e.g. polio) <sup>4</sup>, the importance of rapid introduction or re-introduction of vaccines is increasingly evident. Effective rollout of vaccines is critical to their success – particularly where high levels of vaccination are required to control transmission <sup>5</sup>.

Vaccine rollout is affected by a multitude of interacting factors at local, district, country, and regional levels. These factors are driven by both the supply (e.g., distribution) and demand side (e.g., individual willingness to receive a vaccine). They incorporate logistical factors, governmental healthcare systems, policy, and social perceptions including confidence in vaccination, which may have been influenced by misinformation and disinformation. The combination of these factors creates an overall assessment of “vaccine readiness” for a particular region or group. For example, in the last 10 years, 86 countries have introduced rotavirus vaccines (increasing from 30 countries in 2011 to 116 countries in 2021) <sup>6</sup>. After the introduction, global coverage of the rotavirus vaccine increased from 9% in 2011 to 51% in 2022 <sup>7</sup>. However, these statistics are underpinned by significant variability between countries <sup>8</sup>. For example, as of January 2022, rotavirus vaccines have been introduced in national immunization programs in 79% of sub-Saharan African countries, 60% of countries in the Americas and in only 46% of countries in southeast Asia <sup>9</sup>. This variability is underpinned by a multifaceted set of inter-dependent factors.

The ability to assess a country's vaccine readiness for a particular vaccine is valuable for several reasons: it allows countries to self-assess and prioritize areas for improvement; it allows overarching bodies (e.g., the World Health Organization or European Commission) to identify deficiencies (or weaknesses) to prioritize support; it allows external organizations, such as non-governmental organizations (NGOs) to focus their efforts for greatest impact. More importantly, many factors affecting vaccine readiness are amenable to country-level intervention, including through communications (public information strategies) and public information strategies.

Recent work led by international organizations, and influenced by the impact of the COVID-19 pandemic, has aimed to define the factors that influence country-level vaccine readiness. Work conducted by COVAX, co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), the Vaccine Alliance, Gavi, and the World Health Organization (WHO), alongside key delivery partner United Nations International Children's Emergency Fund (UNICEF), has shown that our ability to achieve vaccine coverage targets requires effective planning, coordination and implementation strategies <sup>10</sup>. Multiple documents, including tools and decision-making platforms, have been created to aid evaluation during the COVID-19 pandemic <sup>11</sup>. For example, WHO-UNICEF issued a COVID-19 National Deployment and Vaccination Plan (NDVP) <sup>12</sup> to support countries to decide whether national readiness to deploy a specific vaccine has been established. However, readiness in a pandemic setting needs to consider specific factors, such as political prioritization, time-scrutiny, emergency authorizations and regulatory process changes, rapid updates from governments, access to emergency funding and more. Consequently, the recent focus on deploying COVID-19 vaccines, is not necessarily generalizable, and leaves a gap when considering readiness for the deployment of new routine vaccines or improving uptake of underutilized vaccines in national vaccination schedules.

There is therefore a system-level evidence gap in the resources available to enable rigorous, comprehensive assessment of vaccine readiness (whether for new vaccines or to improve uptake of underutilized vaccines) <sup>13</sup>. A variety of guidance documents have been developed, of which many relate to the use of specific vaccines or specific target populations <sup>14</sup>, while other documents consider the use of vaccines in a more general context <sup>15</sup>. These guidance documents have

been created using different methodologies, targeting various geographical regions and vaccine types. To date, there does not appear to be a globally applicable, comprehensive vaccine readiness assessment approach that can be applied widely, across all vaccine-types, populations, and geographies. We believe there is an urgent need for an evidence-based tool to fill this gap.

We therefore conducted a scoping review to identify existing guidance used to assess whether a country is ready to roll-out a new vaccine or support enhanced uptake of an existing vaccine. This review had two aims. The first was to identify current tools, guidelines, checklists, or other relevant documents (herein collectively referred to as guidance documents) that have been developed to support decision-making in relation to whether a country is ready to deploy a vaccine or improve uptake of an underutilized vaccine. The second aim was to establish common themes and sub-themes that arise across these documents. This enabled us to identify a set of universal factors suitable to underpin the development of a comprehensive, broadly applicable, evidence-based tool to assess vaccine readiness. We propose that such a tool could be a foundational platform to support enhancements to vaccine rollout for new and underutilized vaccines and therefore population health. Further, enhancements could have a synergistic effect on the overall performance of the vaccination program and ecosystem more broadly.

## Methods

### Search strategy and selection criteria

Our review protocol was written according to PRISMA-P guidelines<sup>16,17</sup>, and was originally registered on the Open Science Framework<sup>18</sup> on 14th April 2023 (<https://doi.org/10.17605/OSF.IO/64Q8M>). Subsequently, changes to the protocol were made to clarify the review aims and broaden the literature search. A revised protocol indicating all updates from the original version (with tracked changes) is available on OSF (<https://doi.org/10.17605/OSF.IO/WGNFP>).

We conducted the review using the Arksey and O'Malley framework<sup>19</sup>, and report information in line with PRISMA-ScR guidelines<sup>20</sup>. The research question that we addressed was: what are the common themes across tools that can be used to assess a country's readiness to deploy a new or underutilized vaccine? Our review question is presented in PICO format in Supplementary Information S1.1 (Table S1).

Our eligibility criteria are tabulated in Supplementary Information S1.2 (Tables S2-3). We included studies and other documents that detailed country-level tools and guidance documents that related to vaccine deployment. All study designs were included from any publication year and in any language. No further limits were applied.

We searched MEDLINE, Embase, PsycINFO, CINAHL, Cochrane Library (CDSR and CENTRAL), Web of Science (SCI-EXPANDED and SSCI), and the top 200 hits from Google Scholar<sup>21</sup> on 9th September 2023. Our search strategies were independently peer-reviewed using the PRESS Checklist<sup>22</sup> by Kat Steiner and Matthew Henry, Outreach Librarians at the Bodleian Health Care Libraries, University of Oxford. All search strategies are presented in full in Supplementary Information S1.3.

The search results were deduplicated and screened using EPPI-Reviewer Web (ER-Web)<sup>23</sup>. Study selection was a two-stage process: screening on title and abstract followed by screening on full text. Screening was carried out in duplicate by two independent reviewers and disagreements settled by discussion between both reviewers. Relevant tools or guidance documents that related to a country's readiness to deploy a new or underutilized vaccine were also identified through expert opinion.

## Data analysis

### Characterizing article types and data sources

After determining each guidance document's eligibility, the following data were extracted: title, author, and date of publication; geographic scope, type or types of vaccine considered, in-text descriptor of how the information was gathered (e.g., expert review, literature review, policy brief) and in-text descriptor of the content type that was generated (e.g., checklist, tool, guideline, framework). We reviewed a wide-range of documents (collectively referred to as guidance documents) that were curated using a range of methodologies. Using this approach to gather and triangulate information across different sources provided the flexibility to draw conclusions across a wide pool of information.

### Thematic analysis

A thematic analysis was conducted to identify and analyze commonalities that emerged across guidance documents, and to interpretate patterns that arose across key themes. As Vaismoradi and colleagues described<sup>24</sup>, conducting a thematic analysis using a descriptive approach allows data reduction to be conducted in a flexible and positive way. Data synthesis was conducted whereby a list of themes and subthemes were developed that accurately reflected key factors associated with a country's readiness to deploy a new or underutilized vaccine. Firstly, key factors relating to vaccine readiness were extracted from each text and tabulated using grounded theory to inductively interpret the empirical material, through an iterative and reflexive process<sup>25</sup>. These were collated to form a comprehensive list of key factors and synthesized to explore patterns identified across guidance documents, which would contribute to overarching themes. Factors relating to each theme were then grouped, and themes were reviewed to ensure clarity and consistency in terms of terminology and meaning. Assessments of the grouping within each theme were developed and reviewed through regular discussion in team meetings. Where required, themes were refined and redistributed to produce a final set of distinct and individual themes. Factors within each theme were then categorized to develop subthemes, which represented the scope of the theme. This enabled distinct overarching themes to be produced, with a core list of subthemes within each theme.

### Role of funding source

Employees of the funder were involved in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

## Results

### Article selection and article characteristics

We identified 38 articles<sup>12–15,26–48,48–59</sup> that were eligible for this review: 28 from databases and 10 from other sources identified through expert opinion. The article selection process is displayed in Fig. 1. Specific characteristics for each included article are presented in the Supplementary Information (Table S4), with summaries of the characteristics presented in Fig. 2–3 and Tables 1,2, and S5. The 38 articles included in the final review, met our inclusion criteria because they described a tool, policy document, guideline, framework, checklist, or process for decision making, that can be used to consider whether a country is ready to administer a new vaccine or improve the uptake of an underutilized vaccine.

The 38 identified articles were published between 2004 and 2023 (See Fig. 2a), with (19 out of 38; 50%) published between 2020–2022, highlighting the timeliness of this research area. Articles captured research conducted across six continents (Africa, Asia, Australia, Europe, North and South America), and although some of the articles were country-specific, several considered vaccine readiness in a global context (13 out of 38; 34%) (Table S4, Column 3). Most articles (67%) were created in the context of whether a country is ready to deploy a *specific* vaccine(s), such as vaccines for the prevention of influenza, meningitis, or measles, whereas 33% of articles were not vaccine-specific and considered all vaccine types (see Fig. 2b).

Across the 38 articles, a variety of methodologies were used to gather information. This included expert review, literature review, and policy analysis. In most cases, information was gathered based on expert review (68%). The different approaches used to gather the relevant information, as described in-text by the authors, are summarized in Fig. 2c. The document types were described within the articles using a range of in-text descriptors, such as a checklists, tools, guidelines or frameworks, as well as more general terms such as ‘factors for consideration’ and ‘recommendations’. Figure 2d shows the different in-text descriptors used to describe each set of guidance documents. The most common type of guidance document was a framework (n = 9), followed by guidelines (n = 8) but other terminology such as a ‘decision-support platform’ (n = 1) was also used.

### Common indicators and themes emerged across the different guidance documents

A thematic analysis was conducted to identify common themes that emerged across the different guidance documents. In brief, key factors associated with vaccine readiness were extracted and collated into a comprehensive list so patterns that emerged across different indicators could be evaluated. This facilitated the creation of a final set of 12 distinct overarching themes that are relevant for consideration when assessing whether a country is ready to deploy a new vaccine or improve uptake of underutilized vaccines. Figure 3 summarizes the core themes that emerged and ranks each theme according to the number of articles where each topic was discussed. A summary description of each of the 12 themes is given in Table 1 and the sub-components that emerged within each theme are given in Table 2.

## Discussion

A scoping review was conducted to identify articles that have been created to help establish whether a country is ready to deploy a new vaccine or improve uptake of an underutilized vaccine. The review identified several common themes and sub-themes that consistently emerged across articles, despite the breadth of source materials considered, in terms of the geographical locations, types of vaccine, and target populations. This led to the development of 12 overarching themes, which each contained multiple sub-themes, reflecting the scope of each topic. Only two articles included topics that were relevant to all the themes identified in this scoping review<sup>30,38</sup>.

Socio-cultural factors and communication emerged as the most prominent theme across the guidance documents. This highlights that engaging the public and having culturally informed communication plans in place are critical to the success of immunization programs, as well as the acceptance and uptake of vaccines. This aligns with the concept that vaccine hesitancy is context and culturally specific and interventions must be tailored for the target audience to elicit an impact<sup>60</sup>. The frequency in which social-cultural and communication factors were raised, and depth to which they were discussed, increased with time. This reflects an increased appreciation of the importance of this topic and the current status-quo, where communities expect to be carefully and appropriately informed about public health interventions. Given the public focus on COVID-19 vaccination programs during the pandemic, and the likely corresponding increase in general vaccine awareness and hesitancy, the importance of developing community-informed communication strategies has become a prominent factor in guidance documents. It is apparent that, even if the practical aspects related to vaccine supply, infrastructure, and financing are in place, clear communication strategies and tailored public engagement are essential for vaccine deployment success. The WHO Risk Communication Engagement Tool<sup>54</sup> highlights the importance of this; the associated guidance documents focus on how to engage the public and generate trust and transparency in the context of immunization programs. Negative press and misinformation related to vaccine use can affect vaccine uptake<sup>61</sup>. As such, countering this with trustworthy information presented accurately, empathetically, and with integrity, is critical and its equally critical that consistent messages are communicated by diverse and trusted messengers. This is particularly important during the program implementation phase to prevent the spread of misinformation and maintain engagement with the public using culturally appropriate and regionally-specific strategies<sup>62–64</sup>.

The importance of adequate and sustainable finance being in place to initiate and maintain vaccine programs has been highlighted in this scoping review. Many articles recognized that financial and economic factors underpin our ability to facilitate actions required to successfully rollout a new vaccine or improve uptake of an underutilized vaccine. This draws attention to the high degree of interdependence across themes. Taking action to improve communication strategies, train personnel, organize adequate transport and waste management systems requires funding, which is in turn is dependent on political will. The tremendous impact that organizations, such as the Global Vaccine Alliance (Gavi), have had on protecting people’s health by increasing

equitable and sustainable use of vaccines, in part through the provision of financial support, is well recognized<sup>65</sup>. Another key factor that emerged was the importance of considering vaccination equity within a country from the outset. A systematic review of the uptake of the Measles, Mumps and Rubella (MMR) vaccine in Europe found associations between ethnicity, low income and education levels with lower MMR vaccine uptake<sup>66</sup>. However, in lower income countries, other indicators including characteristics, such as gender and number of children, maternal age, and religious beliefs are indicators of vaccine uptake. Lower educational level and lower income of a child's caregiver is also related to lower vaccine uptake<sup>67-69</sup>. Ensuring that equity is considered from the outset, requires proactive measures to be in place to actively evaluate factors, such as accessibility and vaccine distribution, before vaccine deployment<sup>70,71</sup>. This theme frequently emerged across guidance documents, where there was often a focus on reaching vulnerable populations, such as children<sup>57</sup>, pregnant women<sup>35</sup> and older adults<sup>48</sup>. Although, vaccination equity is recognized as an important aspect for consideration when deploying new vaccines or improving the uptake of underutilized vaccines, specific systems, and processes for establishing equity are often not readily available<sup>72</sup>. This is important because while the importance of vaccination equity is well recognized, this knowledge does not necessarily translate into practical steps to ensure that people who are underserved by vaccination programs are adequately provided for. The sub-themes identified in this scoping review that address vaccination equity lack detail compared with other topics, such as 'Vaccine Characteristics and Logistics'. Guidance with clear methods and systematic approaches to ensure vaccination equity in global and regional contexts are needed to improve application of this critical component of all immunization programs.

In the modern era, the occurrence of the COVID-19 pandemic was a watershed moment for exploring readiness to deploy new vaccines. This led to a substantial increase in the number of guidance documents that have been created to support the introduction of vaccines across the globe<sup>13,31,35,46,48,53,73</sup>. Unsurprisingly, readiness to deploy COVID-19 vaccines represented a substantial proportion of vaccine-specific work published in the 2020–2022 period. Guidance documents that were written following the COVID-19 pandemic, differ substantially from previous documents, in terms of the level of detail provided and the specificity of the recommendations. Guidance has become more focused and action-oriented; for example, the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT/VRAF 2.0)<sup>11</sup> generated during a pandemic, included regulatory guidance to ensure COVID-19 vaccines can be administered to individuals within specified timeframes. In addition, while there was an obvious focus on COVID-19 vaccines during this period, guidance was also more often developed with a view to global applicability, compared to earlier documents that often referred to vaccines within a specific country or region<sup>28</sup>.

This scoping review has several limitations. While common themes and sub-themes that occur across various guidance documents have been identified, substantial heterogeneity between document types and intended context of use, meant that the terminology within each document is highly variable, and therefore challenging to synthesize. For example, extracting salient information that was common to both generic global guidance documents and highly specific local, regional advice led to a high degree of heterogeneity in considered advice. As similar topics were often described using different terms, careful judgement was needed when synthesizing information to establish whether the articles were focused on similar themes. This was further complicated as the scoping review considered both prospectively created articles and retrospective reflections, such as barriers to successful delivery of immunization programs. Importantly, while common themes that emerged were summarized and synthesized, the lack of inclusion of a specific topic does not negate its importance, as these indicators may be of critical importance in some contexts and/or environments. While a careful search strategy was designed and tested using specific search techniques such as text analyzers to identify words that occur more than once within a predetermined list of tools, and MeSH tools to identify terms that match titles of the guidance documents, this approach did not identify a range of relevant guidance documents that were later found through reference lists and expert knowledge. Over 6,000 articles were identified in the original search strategy, demonstrating the challenge of finding the appropriate level of specificity and sensitivity in the search strategy.

The success of an immunization program's deployment of a new vaccine or efforts to improve uptake of an underutilized vaccine, is critically dependent on the program's readiness to do so. While indicators identified in this scoping review have not been shown to be predictive of successful vaccine roll-out, an example of the benefit of having guidance documents in place was elegantly demonstrated by the Ministry of Health and Family Welfare in India<sup>74</sup>. Across India, multiple geographical locations were identified as not being ready to deploy routine immunization schedules, but use of a checklist in each location enabled corrective action to be taken, such that 69% of the locations were eventually considered to be ready to deploy the immunization schedule<sup>74</sup>. It is plausible that the factors identified in this scoping review could be further refined to form the basis of an approach that could be used to assess a country's readiness to deploy a new or underutilized vaccine.

## Conclusion

A country's success in supporting new vaccine deployment and vaccine uptake is dependent on the readiness<sup>48</sup>. This scoping review has identified numerous guidance documents that aim to identify these factors. Of the 38 texts identified in this review, only two<sup>30,38</sup> (which were focussed on a specific disease (e.g. influenza) or population group (e.g. pregnant women), respectively) discussed all 12 overarching themes that were identified based on a detailed synthesis of the available literature. Each theme was discussed in at least half of the guidance documents, and we believe all 12 themes are critical for establishing the successful introduction, deployment, and administration of new vaccines and to improve underutilized vaccine uptake. As such, a new innovative evidence-based vaccine readiness assessment tool could be developed which comprises the themes and subthemes identified here. If such an approach were adopted, the relevance of these indicators would have to be established through formalized processes, validated by experts, and field tested to ensure global applicability outside of a pandemic setting. In summary, this work has identified key themes that emerge across guidance documents that could be used to form the basis of a vaccine readiness assessment tool that could be used globally in preparation for the deployment of any new vaccine or improved vaccine uptake.

## Strengths and limitations of this study

- **Strength 1:** The scoping review used a comprehensive search for articles in peer-reviewed journals, with all search strategies being independently peer-reviewed using the PRESS Checklist.
- **Strength 2:** Synthesizing data from national and international vaccine readiness tools and various guidance documents provided a methodology to create an evidence-based framework with broad applicability that can be used to assess a country's vaccine readiness.
- **Limitation 1:** Similar concepts were described in a myriad of ways making data synthesis a challenging and iterative process.
- **Limitation 2:** The comprehensive search strategy (that considered over 6,000 articles across 7 databases) was unable to find 10 specific documents that had been pre-identified as relevant, therefore some articles were manually identified through expert input.

## Declarations

### Contributors

VM Accessed and verified the underlying data, analyzed the data and wrote the manuscript.

AIB was involved with study conceptualization and reviewed and edited the manuscript.

AE Reviewed and edited the manuscript.

LH Project administration, reviewed and edited the manuscript.

NH Reviewed and edited the manuscript.

MC Reviewed and edited the manuscript.

LB Reviewed and edited the manuscript, accessed, and verified the underlying data, methodology.

SV Project administration, Supervision, Reviewed and edited the manuscript.

RM was involved with study conceptualization and reviewed and edited the manuscript.

RS Supervised, drafted, reviewing, and edited the manuscript.

AoB Accessed and verified the underlying data, methodology, analyzed the data, reviewed, and edited the manuscript.

All authors had full access to all the data in the study, contributed to data interpretation, critically reviewed the manuscript, and had final responsibility for the decision to submit for publication.

Our search strategies were independently peer-reviewed using the PRESS Checklist by Kat Steiner and Matthew Henry, Outreach Librarians at the Bodleian Health Care Libraries, University of Oxford.

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### Competing interests

LH, AIB, AE, NH, and RM are current employees of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, and may hold equity interest in Merck & Co., Inc., Rahway, NJ, USA. MPC, LB, and AoB were compensated for activities related to execution of the study. SV, VM and RS declare no competing interests. No other disclosures were reported.

### Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

### Patient consent for publication

Not applicable.

### Data availability statement

The completed data extraction form, which is the source data for results figures and tables, is publicly available on GitHub, along with the code required to generate the results: <https://github.com/lukebax/readiness>.

### Ethics

This systematic review of already published and non-identifiable data was considered exempt from ethics review.

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## Tables

Table 1  
A summary description of each of the 12 themes.

Theme	Theme Descriptor
Legal, political, and professional consensus	Input from stakeholders and the impact of their involvement (such as professional bodies, national decision-making bodies, NITAGs, and government advisory committees), at different levels of decision-making (including legal implications, government position and the scientific community).
Socio-cultural factors and communication	Communication (e.g., guidance, outreach, and materials) to prepare the public for the vaccine and approaches for deployment with an awareness of societal and cultural factors.
Policy, guidelines, and regulations	Policy measures to ensure consistency, quality, rigor and regulatory approvals for vaccine management and deployment.
Financing	The feasibility and sustainability of short- and long-term financing of the program, and other program aspects that have financial implications.
Vaccine characteristics and supply logistics	Physical and biological considerations for management of the vaccine, procuring and maintaining its supply (e.g., manufacturing and storage), and its distribution (e.g., cold chain capacity and transportation).
Program planning	Detailed strategies for the preparation, introduction, and coordination of the national immunization program.
Program monitoring and evaluation	Program evaluation methods to maintain oversight of the program, assess success, and explore means for improvement.
Sustainable and integrated healthcare provision	Practicalities of incorporating and maintaining the immunization program within an existing healthcare system (e.g., flexibility and resilience of the healthcare system).
Safety surveillance and reporting	Systems in place to monitor and record safety of the vaccine, and vaccine administration, including the reporting of adverse events.
Disease burden and disease characteristics	Disease characteristics which may impact the vaccination program, disease surveillance, and burden of disease at a national and social level.
Vaccination equity	Strategies in place to ensure equitable access to vaccination services, including vaccines, for all individuals in the target population.
Human resources and training of professionals	Availability of a sufficient workforce, access to appropriate training packages, and supervision for staff at various levels involved in the program to meet vaccine demand.

Table 2  
Sub-components of each theme that emerge across guidance documents.

<b>Sub-components of each theme that emerge across guidance documents</b>
<b>Legal, political, and professional consensus</b>
Establish a legal framework for vaccine deployment
Determine political will for vaccine / vaccination program
Determine consensus for vaccine recommendation amongst medical and scientific communities
Ensure commitment from stakeholders to support the vaccine/vaccine program introduction and continued deployment
Create stakeholder advocacy and lobbying plans
Confirm commitment to accurate and responsible data collection and sharing
<b>Socio-cultural factors, and communication</b>
Consider the acceptability of the vaccines and any perceived risks
Ensure development of a communication plan
Ensure distribution of awareness campaigns, information dissemination (including media and social media) and public education
Establish demand planning and demand generation strategies
Consider social mobilization strategies
<b>Policy, guidelines, and regulations</b>
Ensure conformity with established global guidelines
Establish national guidelines and a consensus statement
Ensure there is consensus between stakeholders
Ensure the program is standardized and verified
Develop and enforce regulations and quality assurance processes
Set up a regulatory mechanism to register and approve vaccines and ensure a quality system is in place
<b>Financing</b>
Evaluate the cost-effectiveness of the program (including government expenditure on vaccines and projected savings in healthcare) and ensure that this is within acceptable national thresholds
Consider the cost to existing healthcare programs
Ensure there is adequate financing in place to initiate the vaccine program i.e., to set up and introduce the program
Ensure there is adequate financing in place to maintain the vaccine program
Develop a strategy to ensure financial sustainability for the maintenance of the vaccine program i.e., to ensure the long-term continuation of the program
Secure approval for vaccine program costs in the government budget (e.g., line items for the purchase of vaccines)
<b>Vaccine characteristics and logistics</b>
Consider vaccine pharmacological properties which may impact the design of a vaccination program (e.g., thermostability)
Conduct demand forecasting
Set up storage and thermostability facilities
Ensure an adequate transport system is available to deliver vaccines
Organize a waste management system
Consider overall logistics i.e., designate a responsible party for ensuring that the physical vaccine is managed and administered appropriately e.g., overall co-ordination of storage and liaison with transport systems and vaccination centers, PPE management, security systems etc.
Coordinate supply of vaccine related consumables
Arrange long term supply of vaccines
<b>Program planning</b>
Create a national technical working group with terms of reference and roles and responsibilities
Create a top-level organization chart to establish roles and responsibilities within the program
Establish a scope, prioritization, and goal setting plan with a project timeline

<b>Sub-components of each theme that emerge across guidance documents</b>
<b>Legal, political, and professional consensus</b>
Prepare a vaccine introduction plan
Create a macro and micro program plan and make decisions based on evidence
Develop a long-term immunization strategy, including catch-up and booster vaccines
<b>Program monitoring and evaluation</b>
Evaluate the short-term impact of vaccination on disease burden, and evaluate the long-term impact through epidemiological surveillance
Ensure there is a management information system in place and have a mechanism to report data
Develop a monitoring framework, or adapt an existing monitoring framework, to incorporate recommended advice and provide a mechanism to incorporate feedback
Implement a monitoring plan to chart how the implementation and rollout of the vaccination program is progressing
Supervise the implementation of the program
Establish a mechanism to evaluate the implementation of the program, to ensure sustained immunity in the target population
Use the program to learn and improve understanding of deployment of a large-scale healthcare event, through developing R&D, conducting operational and/or effectiveness research, and an impact assessment
<b>Sustainable and integrated healthcare provision</b>
Country commitment to delivering a sustainable and effective vaccine program (e.g., demonstrable of good stewardship and implementation of national health plans, previous success of vaccine introduction)
Determine the relevance to the public health and public health value attributed to the program
Determine the likelihood of implementing the vaccine program through a formal feasibility assessment
Ensure a sustainable vaccine program, which is resilient, fit-for-purpose and responsive
Integrating the vaccine program into existing healthcare programs and current immunization schedules
Identify regional and geographical gaps in healthcare provision and develop a plan to create equal access to the vaccination program across all regions
Ensure that front line staff who will deploy the vaccine are healthcare providers and integrated within current healthcare and vaccination systems
<b>Safety surveillance and reporting</b>
Assess the acceptability of the adverse event profile of the vaccine by healthcare professionals and by the public
Establish safe vaccination principles
Ensure adequate tools are available for planning, conducting, and reporting pharmacovigilance activities and findings
<b>Disease burden and characteristics</b>
Evaluate characteristics of the disease relevant for developing a vaccination program (e.g., transmissibility, antigenic variation etc.)
Evaluate the burden of disease in the population
Mechanism for disease surveillance
<b>Vaccination equity</b>
Evaluate accessibility and availability of vaccines, and implement strategies to ensure greater reach to, receipt by, under-represented groups
Determine the ethical considerations of vaccine administration
Establish a mechanism to facilitate coordination and share data between stakeholders
<b>Human resources and training of professionals</b>
Establish adequate human resources and financing to provide support
Training plans in place
Ensure professional are trained and relevant accreditations are in place
Ensure support for professionals

## Figures

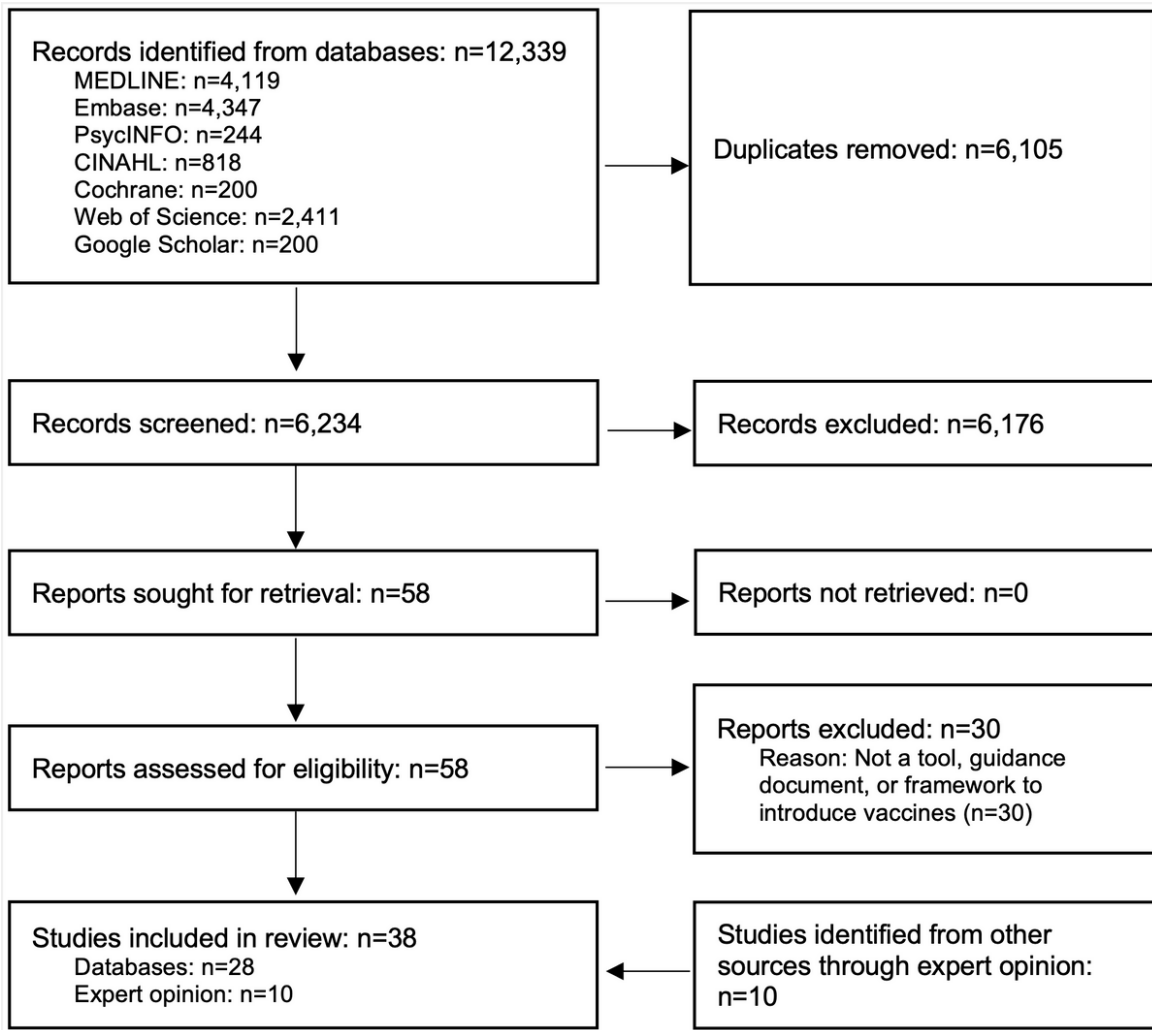
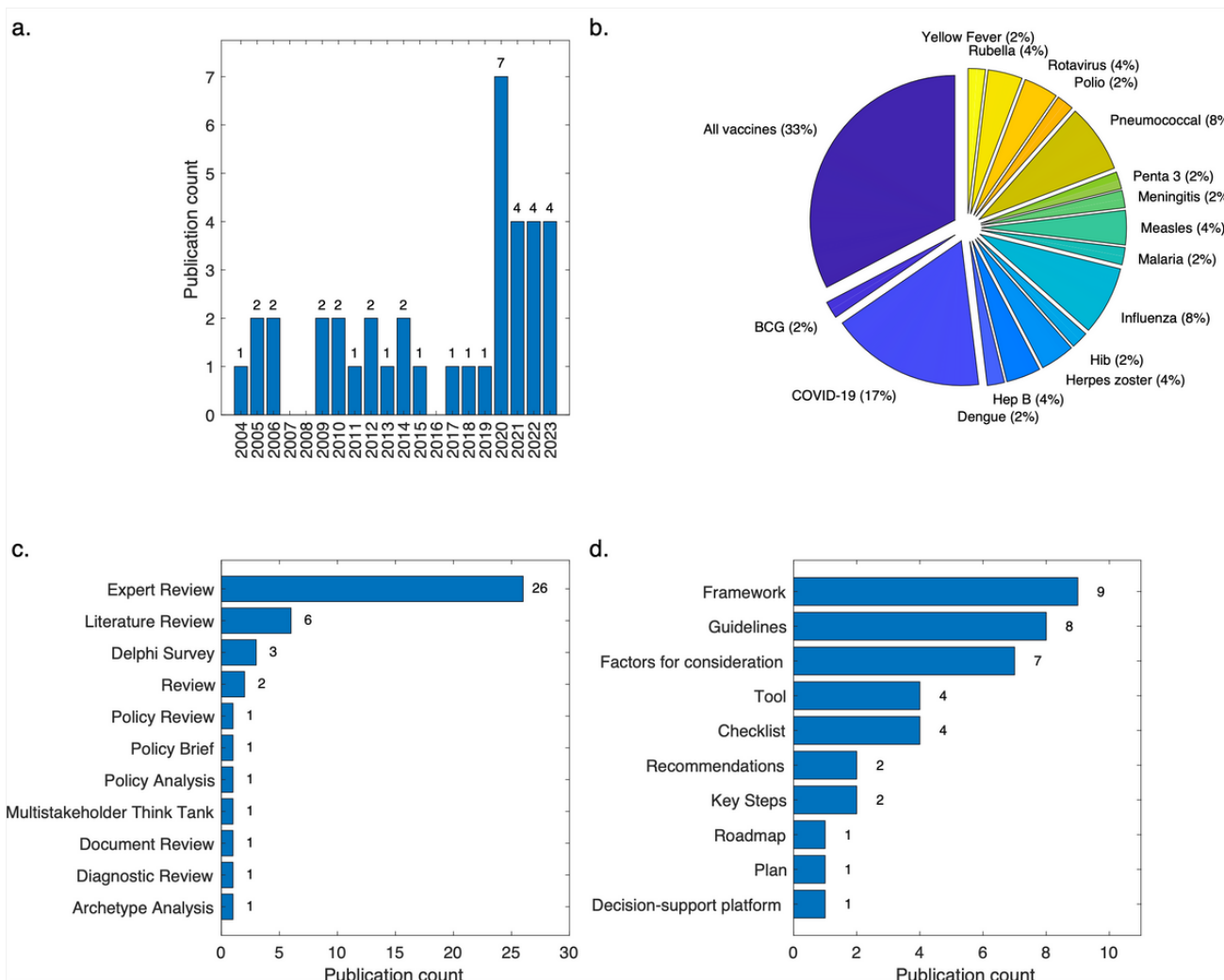


Figure 1

PRISMA flow diagram of study selection process.



**Figure 2**

**a.** Summary of years when articles were published. **b.** Summary of the vaccine type for which the article was relevant. Twenty-three articles referred to multiple vaccine types: 17 to all vaccines and 6 to more than one specifically listed vaccine. Abbreviations: Hep B = Hepatitis B; HPV = Human Papillomavirus; Hib = Haemophilus influenzae type B. **c.** Summary of approaches used to gather information for guideline creation (five articles used multiple information gathering approaches). **d.** Summary of in-text descriptors used to describe each individual guidance document (one article described two publication types).



Figure 3

Summary overarching themes that emerged across articles (n=38), ranked according to the frequency in each document.

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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