


BMJ Open Health actor approaches to financing universal coverage strategies for pneumococcal and rotavirus immunisation programmes in low-income and middle-income countries: a scoping review protocol

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ABSTRACT

Introduction Sustainable financing of immunisation programmes is an important step towards universal coverage of life-saving vaccines. Yet, financing mechanisms for health programmes could have consequences on the design of universal approaches to immunisation coverage. Effective implementation of immunisation interventions necessitates investigating the roles of institutions and power on interventions. This review aims to understand how sustainable financing and equitable immunisation are conceptualised by health actors like Gavi, and government-related entities across low-income and middle-income countries (LMICs) and how financing mechanisms can affect universal coverage of vaccines.

Methods and analysis This study protocol outline a scoping review of the peer-reviewed and the grey literature, using established methodological framework for scoping review. Literature will be identified through a comprehensive search of multiple databases and grey literature. All peer-reviewed implementation research studies from the year 2002 addressing financing and universal coverage of immunisation programmes for the pneumococcal conjugated vaccine and rotavirus vaccines immunisation interventions will be included and grey literature published in/after the year 2015. For the study scope, population, concept and context are defined: Population as international and national health stakeholders financing immunisation programmes; Concept as implementation research on pneumococcal conjugate and rotavirus vaccination interventions; and Context as LMICs. Findings will be quantitatively summarised to provide an overview and narratively synthesised and analysed. Studies that do not use implementation research approaches, frameworks or models will be excluded.

Ethics and dissemination Ethics approval is not required for this scoping review. Findings and recommendations will be presented to implementation researchers and health stakeholders.

Strengths and limitations of this study

- The review will take a thorough approach to synthesise academic and grey literature on sustainable financing and equitable immunisation and use the reach, effectiveness, adoption, implementation, maintenance framework to enhance conceptual clarity of the findings.
- The use of an implementation science framework facilitates the quality and rigour of our study on immunisation interventions.
- It is expected that the dearth of implementation science literature addressing sustainable financing may limit the findings.
- Pneumococcal and rotavirus vaccines are considered new and underused as such may pose a challenge in getting sufficient literature and data for cross-country comparison more so that many low-income and middle-income countries are in the process or yet to introduce these two vaccines.

INTRODUCTION

To achieve global equity in access and coverage of vaccines, national ownership of immunisation programmes and financing mechanisms are critical. This can in turn contribute to the sustainability of immunisation programmes. One of the critiques of the Global Vaccine Action Plan (GVAP) 2011–2020 was its top-down process.¹ It has recently been realised that GVAPs agenda-setting, policy formulation and programme interventions did not sufficiently address unique country circumstances including national programmes, financial and technical needs, and implementation outcome determinants. In line with the global commitment to leave no one behind, the WHO's Immunisation

Agenda 2030² has detailed seven strategic priorities as guiding principles. Specifically, strategic priority three addresses coverage and equity, and priority six addresses sustainable financing for immunisation programmes. Related objectives include ‘to advance and sustain high and equitable immunisation coverage nationally and in all districts’, and ‘to ensure sufficient financial resources for immunisation programmes in all countries, increase immunisation expenditure from domestic resources in aid-dependent countries, and when transitioning away from aid, secure government funding to achieve and sustain high coverage for all vaccines’.²

Sustainable financing is ‘the ability of a country to mobilise and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunisation performance in terms of access, utilisation, quality, safety and equity’.³ However, the majority of low-income and middle-income countries (LMICs) remain dependent on bilateral, multilateral, international financial institutions and non-state actors (eg, non-governmental organisations) for vaccine development, procurement or financing of immunisation programmes. While these financing methods—most notably, through WHO, UNICEF and Gavi, the vaccine alliance—may contribute to quantifiable vaccination coverage and availability, they are fiscally unsustainable without greater domestic investment from national governments.^{4 5} Increased domestic immunisation financing can sustain vaccination coverage and improve the efficiency of immunisation programmes.¹

Countries adopt universal immunisation programmes to promote equitable vaccination coverage.⁶ However, the adoption of new vaccines into national immunisation programmes and related policy implementation has been found to be influenced by donors and technical agencies.^{7 8} Undue reliance on international organisations for access, financing and procurement of vaccines, may imply that adopted immunisation programme plans may not always be the national priority.^{7 9} A recent systematic review shows that in addition to the burden of disease data and vaccine prices, funding from Gavi strongly determines the decision to adopt vaccine programmes in LMICs.¹⁰ The review further notes that programmatic considerations such as feasibility, accessibility and equity were less significant for decision making. Therefore, linking available evidence on immunisation financing to immunisation services coverage (and equity) could provide clarity on implementation bottlenecks.

Implementation research studies use mixed research methods to investigate the roles of context, actors, ideas, institutions, and power in the implementation of health interventions.¹¹ These studies are appropriate for a review since global health interventions, such as immunisation programmes, are ‘implemented in contexts where domestic resources are scarce and power issues resulting from dependence on international aid are present’.¹² For instance, opportunities for financing are well known to influence evidence-informed decision making for

immunisation programmes.¹³ Reliance on global health actors for funding (wholly or partially) often implies that the design of health policies, such as universal coverage approaches, may differ from national interests or be aligned with international funding priorities.¹⁴ Unsustainable financing for vaccines could have consequences on a country’s ability to ensure equitable immunisation coverage. Decision-makers including national governments and stakeholders from donor organisations, responsible for implementing immunisation programmes may adopt different approaches on the road to universal coverage.^{13 15–17} This can include progressive universalism that prioritises vulnerable subgroups proportionate to the level of disadvantage from the onset while ensuring universal coverage and direct scarce resources to health systems that serve them before they are depleted,¹⁸ or population-wide health coverage that emphasises access to services and financial protection to the population.¹⁹ The effects of adopting different approaches may not always be immediately evident. Therefore, linking available evidence on immunisation financing to immunisation services coverage could provide clarity on implementation bottlenecks.

To date, the roles of both sustainable financing, and universal coverage of immunisation programmes have not been investigated and analysed for cross-country comparison. This study will contribute to our knowledge on financing strategies for equitable immunisation coverage relevant to foster continuous political and financial commitment after donor-funding stops. Therefore, we will add to the body of literature on universal coverage of immunisation programmes and related financing challenges affecting LMICs. This review aims to understand how sustainable financing and equitable immunisation are considered in the implementation of interventions by health actors like Gavi, United Nations Children’s Fund (UNICEF) or similar government-related entities across LMICs and how financing mechanisms in place can affect universal coverage of vaccines. Immunisation programmes against pneumococcal disease and rotavirus are selected due to the high disease burden and coverage disparities particularly in low resource settings.^{20 21} It was estimated that in 2016, pneumococcal disease-related deaths amounted to about 500 000 among children under-5 years of age,²⁰ while rotavirus disease resulted in over 215 000 deaths among children under-5 mostly in LMICs.²¹ Data of pneumococcal conjugate vaccines (PCV) unvaccinated children from the International Vaccine Access Centre shows 35 countries that have between 200 000 and 2 million PCV unvaccinated children²² and 47 countries that have over 200 000 children without rotavirus vaccine (RV).²² Additionally, pneumococcal and rotavirus vaccinations are relatively new compared with other available vaccines. They are, therefore, funded only by organisations such as Gavi in many countries, which makes them a good focus for this review

There are differences in financing mechanisms for immunisation programmes within and across these

countries. To address this aim, the research questions developed are:

1. How are sustainable financing and universal coverage of immunisation programmes operationalised in the implementation of pneumococcal and RVs across LMICs?
2. What are the barriers and facilitators to sustainable financing and universal coverage of immunisation programmes for pneumococcal disease and rotavirus in LMICs?

METHODS

Study design

We have selected a scoping review method to examine available academic and grey literature to map key concepts and identify evidence gaps. Grey literature is mainly produced by stakeholders in health and is included as an important supplement to academic literature. The scoping review methodology is useful to achieve our aim since it facilitates the mapping of key concepts in a research area and collection of disparate evidence sources while ensuring a comprehensive review.^{23 24}

Conceptual framework

The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework²⁵ will be used to guide this research and analysis. This framework is useful since it addresses the relevant aspects of intervention implementation and can be used retroactively. Thus, the RE-AIM framework is suitable for our aim which is to understand the conceptualisation of sustainable immunisation financing and equitable immunisation. Adapting dimensions described in Holtrop, Rabin and Glasgow to our review of immunisation programmes²⁵: reach addresses who the beneficiaries are, characteristics of the beneficiary population covered; effectiveness addresses what the intended patient outcomes of the programmes are; adoption addresses whether and where the programmes were applied and who applied/implemented them; implementation addresses how the programmes were delivered, extent to which the intervention was implemented, and how they will be adapted; and maintenance addresses when the programmes became operational, the duration or extent the intervention is sustained during and beyond funding. Since sustainable financing and universal coverage could have different implications for different health stakeholders, and be conceptualised differently, our primary outcomes are maintenance and reach of pneumococcal and rotavirus immunisation programmes. Secondary outcomes are the adoption and implementation of PCV and RV immunisation initiatives. Evaluating these dimensions will enhance conceptual clarity in the analysis of findings.

Protocol

We use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews Checklist (see online supplemental appendix 1).²⁶ The

draft protocol has been reviewed by all the members of the research team and revised. The final protocol was submitted to the Open Science Framework on 5 April 2020 (<https://osf.io/jdztg6/>).

Identifying the research question

We follow the population, concept, context framework tool to construct research questions for scoping reviews.²⁷ We define the ‘population’ as national and external health actors, programme implementers and health policy-makers. The ‘concept’ of interest is implementation research on financing mechanisms and coverage for PCV and RV immunisation interventions; The ‘context’ is any country classified as LMIC based on the World Bank classification.

Information source and search strategy

To find relevant research publications the databases that will be searched include the Cochrane Library, Econlit, EMBASE, Global Health Database (EBSCO), JSTOR, Medline, Web of Science, and Scopus. The search strategy will use search terms relevant to implementation research to capture relevant literature. Vaccine action plans are likely to be policy-related documents, relevant websites of global health actors including International Finance Facility for Immunisation, Institute for Health Metrics and Evaluation, UNICEF, WHOLIS (WHO Library Database), PAIS Index, ProQuest, Gates Foundation, and Gavi, the vaccine alliance will be searched for implementation related reports. This is done to include peer-reviewed articles and grey literature on pro-poor approaches to vaccination initiatives funded by global health actors. The search will cover peer-reviewed literature from the year 2002 to match the start of the accelerated development and introduction plans for pneumococcal vaccines and RVs. Grey literature published from 2015 will be retrieved to match the start of the Sustainable Development Goals when the focus on inequality became more explicit. A combination of the synonyms for the population, concept and context will be used to develop the search strategy. (The search strategy is shown in online supplemental appendix 2). The study will be undertaken from May 2021 through January 2022.

Eligibility criteria

To assess the literature identified through the search strategy, the inclusion and exclusion criteria summarised below in [box 1](#) will be applied.

Selection process

Search results will be imported and stored in the Covidence platform (an online web application for screening systematic reviews). The software will be used to facilitate the review process including importing citations; removing duplicate entries; programming the number of reviewers; recording reviewer decisions; assigning conflict resolution when reviewers disagree; title and abstract inclusion/exclusion criteria and keywords.²⁸ Using the

Box 1 Eligibility criteria

Inclusion

- ▶ Empirical studies at the country level that use implementation research designs, models, theories, or frameworks for examining pneumococcal conjugated vaccine (PCV) or rotavirus vaccine (RV) immunisation interventions. These are not limited to studies that report on adoption, feasibility, fidelity, implementation cost, coverage, equitable access and sustainability.
- ▶ Studies on specific populations who are intended beneficiaries of PCV or RV vaccination interventions. Eligibility and access to vaccine initiative based on being a part of a population group (eg, children under 5 years, mothers delivering at home, individuals who refuse vaccination), or determined by selection criteria (eg, health status, discriminated individuals or low socioeconomic status)
- ▶ Studies that include at least one country in the low-income and middle-income country World Bank classification.
- ▶ Published primary studies and unpublished (grey literature) are restricted to the English and French language.

Exclusion

- ▶ Editorials, conference abstracts and proceedings, and dissertations.
- ▶ Experimental studies are not relevant, and therefore, not included since they do not reflect real-life contextual conditions, may not be fully implemented.

above eligibility criteria, the search results will be selected based on titles, abstracts and full texts as applicable.

The results of the search will be checked for duplicates and subsequently removed. Using the eligibility criteria outlined above, the titles and abstracts of peer-reviewed studies will be screened and full texts of documents from grey literature will be checked. This is done to remove irrelevant studies/documents. Through each phase of the review, the screening and data extraction will be conducted by two independent reviewers, and discrepancies in included studies will be resolved by another member of the research team.

Data collection process

Data to be extracted include information on study characteristics (eg, study design, year, author), agenda/policy documents characteristics (eg, organisation(s), year, implementation period, country), immunisation programme characteristics (eg, the objective of intervention, resources committed, beneficiaries/target population, eligibility criteria), funding organisation (eg, aim, mission and target population), and outcomes (eg, barriers, facilitators, strategies adopted). We will use the RE-AIM framework described above to structure the data extraction.²⁵ We will only extract results on reach, adoption, implementation, and maintenance, thereby omitting effectiveness. In this review, we do not focus on immunisation programme outcomes aimed at patients, for example, effectiveness of the pneumococcal or RVs. Information on immunisation coverage and equity will be catalogued under the reach dimension, indicating which populations and settings are the immunisation intervention reaching, and why or why not. Data will be extracted into a form on an Excel spreadsheet using Microsoft Excel 365 (Excel V.2102) between September and November 2021.

Two independent reviewers will pilot the extraction form with a purposive sample of six papers (three peer-reviewed studies and three documents from the grey literature). If there are disagreements about study eligibility, the two reviewers will discuss the matter and if a consensus cannot be reached, a third investigator will be involved until agreement is reached. Data extraction will be concluded by one reviewer and one verifier. The authors of the studies/documents will be contacted if needed to provide additional information when data is lacking.

Risk of bias assessment

We will not perform methodological quality or risk of bias assessments because this is a scoping review. This is consistent with guidance on scoping review conduct.²⁴

Patient and public involvement

The design of this scoping review protocol did not involve patients nor any other members of the public.

RESULTS SYNTHESIS

Retrieved information will be summarised using quantitative analysis (to provide an overview of the studies/documents characteristics) and qualitative analysis (narrative synthesis to facilitate our understanding of the conceptualisation of sustainable financing and equitable immunisation coverage for immunisation programmes among health actors and in line with relevant aspects of the RE-AIM framework). Narrative synthesis can be useful for conceptual triangulation.²⁹ This will be done to address the conceptualisation question of sustainable financing among health actors involved across LMICs. The four key elements of narrative synthesis are adapted as below:

- ▶ Narrative synthesis is useful to develop a theory of how the intervention works, why, and for whom. This is useful in our research, for example, data under the reach domain would be instrumental in understanding the conceptualisation of targeting approaches based on who the beneficiaries of immunisation programmes are when classified under the relevant approaches to the pro-poor pathway (eg, universal or progressive universal approach).
- ▶ To develop a preliminary synthesis. Tables will be used to present included information on study design/document characteristics, intervention characteristics, intervention details, location/setting.
- ▶ Exploring relationships within and between studies will facilitate the development of conceptual groups across/within data. We will explore variability in intervention design and study population. Data under the *intervention* domain would be useful will be highlighted.
- ▶ Assessing the robustness of the synthesis: a critical reflection of the data will be done on given the description of the vaccine interventions and suitability for the targeted population and context.

In sum, this will facilitate the conceptual triangulation of targeted immunisation programmes among global health actors.

Ethics and dissemination

This scoping review does not require research ethics approval. Results will be disseminated at appropriate national or international conferences, and in a peer-reviewed journal publication.

This study is part of a research project on the global governance of vaccines funded by the Dalla Lana School of Public Health Interdisciplinary Cluster on Implementation Science, University of Toronto and the Center for Vaccine-Preventable Diseases, University of Toronto. This research will serve to guide how implementation science frameworks can inform such reviews in a published methodology paper. This will be beneficial to researchers interested in applying implementation science models or frameworks. The research methods and findings will be of interest to researchers and stakeholders in health. The findings will also be published in a peer-reviewed journal. We will present these at international conferences, University-sponsored webinars and to key health system stakeholders.

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Contributors OJO and EDR conceptualised and designed the study. OJO, SF, PB and EDR contributed substantially to the drafting and revision of the study. All authors approved the final manuscript.

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