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Review

The need for targeted implementation research to improve coverage of basic vaccines and introduction of new vaccines

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ABSTRACT

The Decade of Vaccines Collaboration (DoVC) Research and Development (R&D) Working Group identified implementation research as an important step toward achieving high vaccine coverage and the uptake of desirable new vaccines. The R&D Working Group noted that implementation research is highly complex and requires participation of stakeholders from diverse backgrounds to ensure effective planning, execution, interpretation, and adoption of research outcomes. Unlike other scientific disciplines, implementation research is highly contextual and depends on social, cultural, geographic, and economic factors to make the findings useful for local, national, and regional applications. This paper presents the broad framework for implementation research in support of immunization and sets out a series of research questions developed through a Delphi process (during a DoVC-supported workshop in Sitges, Spain) and a literature review.

Contents

1. Introduction

Impressive gains in vaccine coverage have been made since the launch of the World Health Organization (WHO) Expanded Program on Immunization (EPI) in 1974 [1]. However, the benefits of vaccination have not yet reached many of those living in resource-limited countries, which carry the major burden of vaccine-preventable diseases [2,3]. In 2005, WHO and the United Nations Children's Fund (UNICEF) developed the Global Immunization Vision and Strategy (GIVS), which set a goal for all countries to achieve 90 percent national coverage and 80 percent

Abbreviations: DoVC, Decade of Vaccines Collaboration; DTP, diphtheria/tetanus/pertussis; EPI, Expanded Program on Immunization; GIVS, Global Immunization Vision and Strategy; GVAP, Global Vaccine Action Plan; IVR, Initiative for Vaccine Research; NGO, nongovernment organization; R&D, Research and Development; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

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coverage in every district for delivery of three doses of diphtheria/tetanus/pertussis (DTP) vaccines to infants. This goal has not yet been achieved universally [4]. Several new vaccines are now being introduced into national programs, but uptake of these new vaccines in developing countries faces significant challenges.

There are important differences between the development of new technologies, products, and interventions for disease control and the development of the strategies required to enhance the uptake of these approaches within their unique target communities. The R&D Working Group of the DoVC has focused on three research domains: (1) the R&D needs for enhancing coverage of existing vaccines and uptake of new vaccines (short-term R&D needs); (2) innovations in technologies for development of new and improved vaccines (mid-term R&D needs); and (3) the basic research required to develop new concepts for vaccine development (long-term R&D needs) [5].

The consultations of the R&D Working Group supplemented by a literature search inform the content of this paper. The purpose of this paper is to highlight the importance of implementation research within the Global Vaccine Action Plan (GVAP) to improve the coverage of basic vaccines as well as the uptake of desirable new vaccines with a particular focus on low- and middle-income countries [5].

We used the search terms "implementation research" and "immunization", "vaccination", "routine immunization", "global immunization", or "immunization delivery strategies" in two search engines (PubMed and BioMed Central). Our search returned 1027 articles, and we considered 55 as relevant for this article. We specifically looked for review articles that had undertaken analysis of published and gray literature on the subject.

2. What is implementation research?

Health-related implementation research is the use of science to study practices in routine clinical care and public health systems in order to improve the quality and equity of health care [6–9]. It also includes the study of factors that influence health care professionals and organizations and the factors influencing users of health care services, thus covering demand and supply. Implementation research often involves impact research, which includes research aimed at understanding what happens during the process of implementing a change in policy, program, or practice, and intervention studies, which are designed to compare different approaches to implementing change. Introducing new vaccines and ensuring they reach all people for whom they are intended is a challenging task, and the science related to implementing interventions effectively, efficiently, and with equity and high fidelity has received inadequate attention, particularly in African and Asian countries where overall research capacities are limited.

The major objective of implementation research for immunization, as discussed here, is to generate evidence that can support countries in strengthening their routine immunization programs. Implementation research can inform locally appropriate strategies by identifying the bottlenecks in vaccine procurement and delivery, handling the special needs of life course immunization, mass immunization campaigns for polio, measles, influenza, meningitis A, or other diseases, pinpointing vaccines needed during humanitarian emergencies such as floods or conflicts, and generating context-specific evidence for rational policy and program decisions [10].

Our research findings covering a wide range of topics indicate four overarching aspects of successful implementation—referred to in the literature as "active implementation frameworks"—to support health programs [11,12]. After summarizing these diverse characterizations, we propose to use them to develop a framework for research to support national immunization programs as described below.

The first aspect is that implementation requires well-thought-out changes, which require repetitive, context-specific learning in discernible stages. Implementation is a process that involves multiple decisions, actions, and course corrections to evolve new program models, innovations, and initiatives. Implementing a well-constructed, well-defined, well-researched program can take two to four years, depending on whether programs are implemented at national or district levels [13–17].

Second, implementation drivers are the core components required to support practice, organization, and system change. High-fidelity and sustainable programs occur when competency drivers, organization drivers, national systems, and leadership drivers work in partnership.

Third, implementers should connect policy and practice to ensure that learning from both informs decision-making and results in continual program improvements, including development and implementation of evidence-based policies for deployment of vaccines and allotment of funds for procurement and delivery of vaccines.

Fourth, implementation requires constant review and input from local, national, and global experts to ensure a transparent process that benefit from continuous technical innovations and cutting-edge implementation research with regular evaluation and impact assessments.

Thus, the complete iterative process may take several years as the results of the implementation research become available and the new interventions become firmly embedded within the health system [6–8,12].

During our DoVC consultations, members of the R&D working group who comprised of discovery, development and delivery experts, proposed several important topics for an implementation research agenda. These include: (1) new information technology and communication tools in immunization programs; (2) life-course immunization, where the focus should be from infancy to adults; (3) effective and efficient systems to retain clients and minimize dropout; (4) strategies to identify and reach the most disadvantaged sections of society that often comprise the lower one-third to one-fourth of the population (based on social and economic parameters) and are often missed by routine immunization; (5) mapping of vulnerable communities to develop targeted strategies for these groups; (6) establishing human resource and capacity-building programs for immunization; and (7) developing a matrix to assess short- and long-term outcomes and programmatic impact.

Suggested research strategies to accomplish these agenda goals could include: (1) social and behavioral science research to increase confidence in a vaccine; (2) an emphasis on context-specific research; and (3) establishing a network of Centers of Excellence for implementation research, including provision for core funding for such centers.

Implementation research demands an appropriate balance between internal and external validity of its findings for scaling-up of programs [18,19]. Implementation of an intervention requires changes at several steps in program management and delivery that need to be embedded into the local system to ensure acceptability and sustainability [19]. Implementation research also requires an interdisciplinary approach that includes social sciences (such as anthropology and health economics), statistics, epidemiology, policy analysis, ethics, and other relevant disciplines [20]. Employing qualitative methods helps to improve understanding of the processes, phenomena, context, inter- and intra-organizational issues, and perspectives of different stakeholders and for triangulating quantitative results. Implementation research focuses on effectiveness of the interventions in actual program settings rather than