

Executive Summary for April 2012 SAGE Meeting: Published Literature Review

Impact of New Vaccine Introduction on the Immunization and Health Systems: a Review of the Published Literature

Terri Hyde¹, Holly Dentz^{1,3}, Susan Wang², Sandra Mounier-Jack⁴, Helen Burchett⁴, W. Scott Gordon⁵, Logan Brenzel⁶, Jessica Shearer⁷, Michael Favin⁸, Susan Goldstein¹, Jacqueline Gindler¹ Carsten Mantel² as part of the SAGE ad hoc working group on the Impact of New Vaccine introduction on the Immunization and Health Systems*

1. Global Immunization Division (GID), United States Centers for Disease Control and Prevention, Atlanta, GA USA
2. Immunizations, Vaccines and Biologicals (IVB), World Health Organization, Geneva Switzerland
3. Innovations for Poverty Action, 101Whitney Ave, New Haven, CT 06510, USA
4. London School of Hygiene and Tropical Medicine, Global Health Development, Public Health and Policy, 15-17 Tavistock Place, London WC1H 9SH, UK
5. Program for Appropriate Technology in Health (PATH), Seattle, WA USA
6. Consultant, Bill & Melinda Gates Foundation, Seattle, Washington, US.
7. Centre for Health Economics and Policy Analysis, McMaster University, Canada
8. The Manoff Group, participated in this work through the USAID/MCHIP project

Introduction

The introduction of a new vaccine can have both positive and negative impacts on the immunization system and the broader health system. It may add stress to an already weak infrastructure or, alternatively, it may provide opportunities and resources to strengthen the existing system. Evidence of impact of new vaccine introduction on health and immunization systems has not been systematically reviewed and summarized. Based on a request in 2010 from the Strategic Advisory Group of Experts (SAGE) on Immunization that guides the World Health Organization (WHO) on global immunization policies, we conducted a systematic review of the published literature to examine these impacts.

Methods

Search strategy

We developed search terms to identify articles that included information describing the impact of new vaccine introduction on immunization systems and health systems. Developed with input from immunization experts, we selected the search terms to be comprehensive. They were divided into two broad categories: vaccines, and immunization and health systems.

We searched six publication databases (Medline, Embase, Nursing Update, West African Journal of Nursing, CINAHL, Web of Science and Global Health) that are known to be relevant to vaccines and immunization programs, and that were likely to also contain reports from developing countries. We attempted to use identical terms to search each database; however, as each database had certain specifications, it was sometimes necessary to modify some of the terms. We limited the search to human subjects published in any language. The final search date was September 29, 2010 and was not limited to a beginning year.

Published articles were reviewed and organized according to the WHO Framework for Action; this framework was created by WHO in 2007 to promote a common understanding of health systems by providing a systematic means for considering the essential functions of a health care system. The Framework comprises six building blocks: service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance.

Results

Search and abstraction

The search yielded 24,768 articles from 1911 through to September 29, 2010, among which 8,925 (36%) were found to be duplicates. Reviewers applied the inclusion criteria to the remaining 15,795 titles and abstracts. Among these, 654 (4%) articles met the inclusion criteria and were reviewed for relevancy; 49 of these were in languages other than English. One hundred and thirty-five (20%) were found to be

relevant and data were abstracted for the analysis. In addition, one key article known to the authors and not identified by the systematic search was included, for a total of 130 articles.

General overview

Among the 130 studies included in this review, the majority were from highly industrialized countries: 97 (75%) were from high-income countries (by World Bank Definition); 21 (16%) were from middle-income countries; and only 4 (3%) were from low-income countries. Vaccines targeting 10 diseases (hepatitis A (3; 2%), hepatitis B (24; 19%), *Haemophilus influenzae* type b disease (28; 22%), human papilloma virus infection (13; 10%), influenza (1; 1%), Japanese encephalitis (1; 1%), meningococcal meningitis (17; 13%), *Streptococcus pneumoniae* disease (28; 22%), Rotavirus diarrhea (14; 11%) and typhoid (2; 2%)) were represented in the studies, with multiple formulations and different combinations. Over half of the studies (64; 56%) considered vaccine introductions that took place between 2000 and 2008.

Limitations

Only published papers were included, although much of the information about the impact of new vaccine introduction is, in fact, contained in the grey literature. In addition, because the information related to the impact of new vaccine introduction was rarely the main focus of the reviewed studies, we were unable to compare studies or evaluate the quality of the data. Most papers were from high-income countries; therefore, it is difficult to generalize those experiences to low-income countries. Although the majority of papers reviewed were published during the past decade, we also included reports of introductions from more than 20 years ago; these reports may be less relevant to current introductions of new vaccines. Findings related to impact on the larger health system were limited. While it is likely that the impact of vaccine introduction on a country's existing immunization and health system reflected the underlying system strength, evaluating this was beyond the scope of this review. Few reviewed papers were designed to evaluate impacts on immunization systems or health systems. The information relevant to our review was frequently an incidental finding noted in the discussion section of the papers. Our conclusions, therefore, need to be interpreted in the context of these caveats.

Findings

We found that new vaccine introduction had mixed effects on – and often provided opportunities to strengthen – existing components of the immunization system. The impact of introduction differed according to the delivery platform and vaccine formulation. When vaccine introductions made use of existing delivery strategies, such as routine infant immunization, the costs and impact on staffing needs were substantially less than when vaccines were introduced through newly-created platforms. School-based programs were documented to be effective platforms for introducing new vaccines to school-aged children and adolescents, although additional staff was required, even for existing programs. Venues outside the school were sometimes needed to complete the vaccination series in a timely fashion. Combination vaccines that added the new antigen or antigens to an existing vaccine were less costly and more efficiently introduced than those that required an additional injection.

New vaccine introduction had an impact on vaccine program logistics and technology. Disruptions in routine vaccination services were reported, related to insufficient on-hand stock of vaccine when programs commenced, and in lower-income countries, to funding shortfalls. Disruptions have also been reported related to global vaccine shortages. A commonly-reported impact of new vaccine introduction was the need for increased cold chain capacity, such as with the introduction of early rotavirus vaccine formulations.

Reduced disease incidence following new vaccine introduction led to reported declines in the use of curative health services related to vaccine-preventable diseases. Decreased use of antibiotics potentially reduced antimicrobial resistance, and herd immunity extended benefits to populations not targeted by the vaccines. An important benefit to the health system facilitated by new vaccine introduction was the widespread use of AD syringes and awareness of injection safety.

Existing infrastructure was utilized and often strengthened. In many countries, established health information and disease surveillance systems were enhanced to collect data for policy development, program advocacy, and impact assessment. In other countries, new systems were developed, especially to monitor vaccination coverage, safety and effectiveness.

The importance of social mobilization for public awareness, and training and education for health care workers was frequently noted. The introduction of new vaccines led to the establishment of legislation intended to improve vaccine delivery or program assessment, including mandatory newborn vaccination or school entry laws and national vaccine registries. There is some evidence in high-income countries that new vaccine introduction is associated with lower use of ambulatory and hospital services and reduced costs. However, in low-income countries, introduction of HepB/tetavalent and pentavalent vaccines was associated with substantial cost increases for the national program. Funding gaps of up to 25% of required needs were found.

Additional Comments

While new vaccine introduction often includes an assessment of disease burden and impact on morbidity and mortality, a component of future evaluations should include the systematic and objective assessment of how a vaccine introduction affects a country's immunization system and broader health system, especially in lower-income countries.

A comprehensive assessment of cold chain capacity should be included in all pre-vaccine introduction assessments in low and middle income countries. New vaccine introductions have highlighted existing shortfalls in the cold chain and logistics systems. As a result of early introduction experiences with inadequate infrastructure, effective vaccine management (EVM) assessments and regular cold chain inventories are now a precondition for new GAVI support in order to assure system readiness for the new vaccine.

The new or enhanced disease surveillance systems should be expanded and adapted to improve disease surveillance.

Health programs in developing countries rarely have predictable, long-term funding support from donors. Financial sustainability of programs with costlier new vaccines remains a concern, particularly in the poorest countries.