



Conference report

Researching routine immunization—do we know what we don't know?[☆]

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ABSTRACT

Background: The Expanded Programme on Immunization (EPI), launched in 1974, has developed and implemented a range of strategies and practices over the last three decades to ensure that children and adults receive the vaccines they need to help protect them against vaccine-preventable diseases. Many of these strategies have been implemented, resulting in immunization coverage exceeding 80% among children one year of age in many countries. Yet millions of infants remain under-immunized or unimmunized, particularly in poorer countries. In November 2009, a panel of external experts met at the United States Centers for Disease Control and Prevention (CDC) to review and identify areas of research required to strengthen routine service delivery in developing countries.

Methods: Research opportunities were identified utilizing presentations emphasizing existing research, gaps in knowledge and key questions. Panel members prioritized the topics, as did other meeting participants.

Findings: Several hundred research topics covering a wide range were identified by the panel members and participants. However there were relatively few topics for which there was a consensus that immediate investment in research is warranted. The panel identified 28 topics as priorities. 18 topics were identified as priorities by at least 50% of non-panel participants; of these, five were also identified as priorities by the panel. Research needs included identifying the best ways to increase coverage with existing vaccines and introduce new vaccines, integrate other services with immunizations, and finance immunization programmes.

Interpretation: There is an enormous range of research that could be undertaken to support routine immunization. However, implementation of strategic plans, rather than additional research will have the greatest impact on raising immunization coverage and preventing disease, disability, and death from vaccine-preventable diseases. The panel emphasized the importance of tying operational research to programmatic needs, with a focus on efforts to scale up proven best practices in each country, facilitating the full implementation of immunization strategies.

1. Background

The Expanded Programme on Immunization (EPI) was launched by the World Health Organization (WHO) in 1974 with a mandate to deliver routine immunization with six antigens¹ to infants in developing countries. When EPI began, only about 5% of infants in poorer countries were receiving these low cost vaccines, despite their availability. For the past 30 years, extensive efforts have been made to maximize immunization coverage in an equitable and cost-effective fashion in every country.

Routine immunization is the basic activity that enables vaccinators to administer vaccines to infants and other target age groups at health facilities or in outreach settings on a regular basis. It comprises a complex set of inter-related activities including training, logistics, planning, management, monitoring, supervision, and

communication between health service providers and the public. It is the platform from which other special immunization strategies (e.g., eradication/control activities, introduction of new vaccines and other child survival interventions) can be launched.

A broad range of strategies, activities and practices has been developed, implemented and evaluated during the 30 years since the EPI began, many of which have been undertaken with considerable success, although this has not always been done in a systematic fashion. These strategies have included initiatives designed to improve programme management down to the peripheral level, such as the Reaching Every District (RED) strategy [1]. In addition, performance management tools, such as the coverage monitoring chart, have been developed, field-tested and incorporated into training courses undertaken throughout the world. The Effective Vaccine Stores Management (EVSM) [2] is one initiative launched to ensure a reliable supply of vaccines of assured quality; others have been designed to provide appropriate and accessible information, education and communication to health care providers and the public.

The response to these initiatives has been truly remarkable, and has resulted in the mobilization of large amounts of monetary,

[☆] Summary of an expert meeting convened by the Centers for Disease Control and Prevention on research needs for routine immunization in developing countries.

¹ Bacille Calmette-Guérin (BCG), diphtheria-tetanus-pertussis (DTP) vaccine, oral poliovirus vaccine, and measles vaccine.

logistical and human resources, and the prevention of illness, disability and death of millions of children every year. Estimated global immunization coverage² among children who have reached one year of age increased from 74% in 2000 to 82% in 2009 [3]. Despite this success, there are millions of infants who remain unreached and unimmunized. Only 25% of countries reported $\geq 80\%$ DTP3 coverage in all districts. Furthermore, the rate of coverage improvement has stagnated at higher coverage levels, with only 27% of countries reporting increases in estimated coverage between 2008 and 2009 [3]. Unimmunized and under-immunized infants are disproportionately found in the least privileged sectors of society. In response to this situation, humanitarian and political pressure has increased on agencies and national immunization services to achieve even greater successes. The most recent targets have been established within the Millennium Development Goals (MDGs) [4] and the Global Immunization Vision and Strategy (GIVS) [5].

To develop more efficient strategies to increase coverage, including identifying barriers to immunization, and to address the challenge of improving coverage levels, innovative efforts will be needed, especially given that fewer resources are likely to be available in the near future as a consequence of the slowed global economy. A number of important questions can be asked regarding this complex issue: Is more research needed to refine and expand routine services that are the bedrock of vaccine delivery? Is progress towards crucial global, regional and national goals blocked for want of large (or even small) research efforts? Does the international community need to develop more user-friendly tools to assist health workers in their struggle to deliver services? CDC has long been recognized as an important contributor to evidence-based knowledge about global immunization. Recognizing the critical need for coordinated strategic efforts to improve global immunization coverage, CDC convened a meeting to address potential research needs to strengthen routine immunization globally.

2. Methods

On 12 and 13 November 2009, the Global Immunization Division (GID) of CDC conducted an external review to examine current routine immunization research activities and identify areas of research required to strengthen routine service delivery in developing countries. Objectives of the review were to evaluate the nature of current CDC routine immunization research and to provide guidance on priorities for CDC's research activities needed to identify the barriers to improving current systems, as well as strategies for strengthening routine immunization systems for the next 5 years. With a broad representation of immunization experts and global partners, this review meeting provided a unique opportunity to examine global routine immunization issues and to identify priorities for future work.

A review panel³ was identified consisting of six experts in routine immunization service delivery. The panel's responsibilities were to lead the discussion period during the meeting and, after reviewing the material presented, to develop a set of recommendations for CDC on the way to move forward. In addition to the panel members, nine individuals from key international institutions were invited to serve as discussants during the review. Discussants included representatives from international, regional and national organizations and agencies⁴. The discussants' role was

to participate in deliberations on the various topics and to assist in identifying the key issues that the panel members should consider in their final report and recommendations. Panel members and discussants were chosen based on their expertise and their wide experience in issues affecting routine immunization, as well as to ensure a broad spectrum of knowledge about the different components of routine immunizations. Thirteen representatives from various Centers and Divisions within CDC, whose work relates to immunization, were invited to attend as observers along with GID technical staff. Background materials, potential questions that could be addressed, a synopsis of ongoing and proposed CDC global routine immunization projects, and a bibliography of recent CDC global routine immunization publications were distributed to the panel and discussants before the consultation.

The four strategic areas of the GIVS⁵ were used as a framework for categorizing activities and research areas, and within each goal area, research opportunities were identified using introductory presentations that emphasized ongoing research, gaps in knowledge and key questions that could be addressed during the group discussion.

To prepare the recommendations, research topics identified during the discussion among all participants (i.e., panel members, discussants, observers), were listed, consolidated and collated into summary form. Panel members reviewed this list to prioritize the research topics. While the panel reviewed the topics in private, the discussants and observers also ranked the potential research topics on a scale of 1–5 according to importance. GID staff then further categorized the research topics into those identified as priority by at least 50% of participants. This methodology permitted identification of the priorities of the review panel as well as that of the discussants and observers.

2.1. Role of funding source

CDC provided funding for the review panel, which consisted of covering the travel costs for panel members plus a consultant fee for the rapporteur.

3. Findings

Several hundred research topics were identified during the discussion periods among the panel members, discussants and observers during the two-day meeting. After consolidating related topics, 28 were selected by the panel as priorities for research (Table 1) and 18 topics were selected as priorities by at least 50% of the discussants and observers (Table 2). Among these, five (28%) had been independently identified as priorities by the research panel.

4. Review recommendations

4.1. Panel recommendations

Although there is enormous potential in a wide range of research topics that would support routine immunization (Table 1), there are relatively few questions of importance or significance for which there was consensus that immediate investment in research is

² Immunization coverage is typically measured as the proportion of children who have received at least three DTP vaccines (DTP3) during the first year of life.

³ Dr. Ciro de Quadros, Chair, Dr. John Clements, Rapporteur, Mr. Robert Steinglass, Dr. Robin Bielik, Dr. Deborah McFarland, Dr James Hadler.

⁴ Jon Andrus (Pan-American Health Organization), Nancy Binkin (UNICEF Headquarters), Rudi Eggers (World Health Organization), Satish Gupta (UNICEF-India),

Peter Hansen (GAVI Alliance), Alan Hinman (Task Force for Global Health), Dan Kress (Bill and Melinda Gates Foundation), Richard Mihigo (World Health Organization, African Regional Office), Elizabeth Zell (Division of Bacterial Diseases, CDC).

⁵ GIVS1-Protecting more people in a changing world, GIVS2- Introducing new vaccines and technologies, GIVS3-Integrating immunization, other linked health interventions and surveillance in the health systems context, GIVS4-Immunizing in a context of global interdependence. Global financing, communication and partnership).

Table 1

Routine immunization research topic recommendations of the external review panel, routine immunization research review meeting, 2010.

GIVS	Category	Questions that require further research
1	Protecting more people in a changing world.	<p>How can routine administrative data be validated periodically at the district level?</p> <p>How can the vaccine coverage monitoring chart used at the local level be better used to improve coverage levels?</p> <p>How can monitoring at sub-district levels be used as a strategy by health workers to track and improve their performance?</p> <p>Can improved, standardized methods be developed to evaluate the quality of routine immunization services through periodic reviews?</p> <p>How can the impact of training be measured?</p> <p>How can hard-to-reach and under-immunized infants be better identified and reached?</p> <p>Can school-based immunization be used to improve coverage?</p> <p>How can the involvement of the community, and in particular women's networks, best be included in the process of raising vaccine coverage?</p> <p>Can reasons be identified for positive deviance at community and health facility levels?</p> <p>What is the role of the private sector?</p> <p>How can best practices for the implementation of immunization services be identified and evaluated?</p> <p>What are the factors that lead to "left-outs" and "drop-outs", and which of them are amenable to intervention?</p>
2	Introducing new vaccines and technologies.	<p>What is the impact of adding new vaccines on immunization coverage levels?</p> <p>Can a protocol be developed that would facilitate the evaluation of a national programme before and after the introduction of a new vaccine?</p> <p>How can the most cost-effective strategies and best practices be identified that will achieve a smooth and seamless introduction of a new vaccine?</p> <p>What are the non-vaccine related costs associated with the introduction of new vaccines?</p> <p>What interventions will maximize positive effects and minimize negative effects resulting from the introduction of new vaccines?</p>
3	Integrating immunization, other linked health interventions and surveillance in the health systems context	<p>What are the options at global and country levels for optimal integration of other health initiatives with routine immunization?</p> <p>How can overall coverage be measured accurately in settings with periodic intensified routine immunization (PIRI) strategies such as Child Health Days?</p> <p>Can the impact of integrating routine immunization with other services be evaluated?</p> <p>Are different children reached by child health days than are reached by routine immunization services?</p> <p>What are the characteristics of successful vs. unsuccessful integration efforts?</p> <p>Can the vaccine coverage chart be used to monitor administration of other commodities?</p> <p>How should GID engage participants in the World Bank eight pilot projects on performance-based financing to ensure the finalized projects are rolled out at country level?</p>
4	Immunizing in a context of global interdependence.	<p>What are the best methods of purchasing vaccines?</p> <p>What has been the impact (if any) on service delivery as a result of changes in funding patterns, e.g., bilateral donors providing funds directly to GAVI, IFFim or AMC instead of directly to countries?</p> <p>What are the key drivers that shape the vaccine market?</p> <p>How can the potentially negative effects of vaccine administration be minimized through communication?</p>

needed. On the contrary, it is clear that a large amount of research has already been completed successfully over the 30-plus year period of EPI's existence. The result has been a tremendous repository of knowledge about how to run immunization services in all parts of the world. However, these evidence-based best practices and extensive country experiences have not been fully shared, adopted and rigorously or completely implemented, particularly in those countries with lowest coverage levels. In the next few years, the challenge will be to find ways of increasing political commitment, transferring experience gained in one country and applying it to others, and scaling up the best of the proven approaches [6].

Accordingly, the panel recommended that the focus of routine immunization research in the next five years should be predominantly on efforts to help bring the best practices to each country, and to assist struggling countries to upgrade and fully implement their strategic immunization plans. The panel selected a small number of high priority research topics that it hoped will make a positive contribution to routine immunization. But the panel stressed emphatically that it is the full implementation of strategic plans, rather than the results of proposed research that will have the greatest impact on raising global immunization coverage and preventing disease, disability, and death from vaccine-preventable diseases. Furthermore, any additional research should, from the outset, have the goal of implementation once its results become

available. CDC, WHO and other lead agencies should ensure there is coordination in research and avoid duplication of effort.

4.2. Recommendations from discussants and observers

Research topics selected as priorities by the non-panel discussants and observers varied widely. There was little consensus about research priorities, with only 18 of several hundred possible topics identified as priorities by at least half of participants. Selected priority topics common to both panel and non-panel participants included the need for immunization data validation methods and data use at district and sub-national levels, the concept of positive deviance (why it is that some programmes achieve excellent results while others with similar resources do not), the role of the private sector in immunization service delivery, and new vaccine introduction.

4.3. Commonalities

There were prioritized topics that were common to both panel and non-panel participants. The need for methods that validate administrative immunization coverage data and their use at district and sub-national levels was identified as a priority, as was the concept of positive deviance. Learning more about the role of the private sector (both for-profit and not-for-profit) in strengthening

Table 2
Routine immunization research topics identified as priority by at least 50% of discussants and observers, routine immunization research review meeting, 2010.

GIVS Strategy	Category	Questions that require further research
1	Protecting more people in a changing world.	<p>What factors are associated with under-vaccination at all administrative levels? What is the validity of the existing sources of vaccination coverage data and how can it be improved? What are the practical survey method alternatives to replacing the WHO 30- cluster survey? What indicators best assess success of interventions? How should service quality be defined and measured? What factors are associated with under-vaccination at all administrative levels? Can performance-based funding and health care worker incentives be used to improve coverage? When are pilot study results sufficient to warrant scaling up, and what factors enhance/encourage successful scaling-up of pilot projects? What methods can be used at sub-national levels to measure program performance and to provide periodic validation of routine administrative data?^a Why do some countries/areas achieve excellent results, while others do not (positive deviance)?^a What is the role of private sector (for-profit and not-for-profit sectors) in providing immunization services?^a</p>
2	Introducing new vaccines and technologies.	<p>What support do countries need to introduce new vaccines? How can the most cost-effective strategies and best practices be identified that will achieve a smooth and seamless introduction of a new vaccine?^a What is the impact of adding new vaccines to the schedule on immunization coverage levels and other aspects of routine immunization services?^a</p>
3	Integrating immunization, other linked health interventions and surveillance in the health systems context	<p>What is the effect of integration on each intervention (including immunization) and on the whole health system and immunization sub-system? Can integrated services serve as an incentive to increase coverage? How can integration improve coverage of immunization and other services in hard-to-reach populations?</p>
4	Immunizing in a context of global interdependence.	<p>Vaccine financing: What are the costs to developing countries of introducing new vaccines? How will new vaccines be financed? How much should developing countries contribute to EPI? What indicators should be used to measure sustainability (e.g., 80% coverage in districts for 3 or more years)?</p>

^a Also selected by the panel as a priority area.

routine immunization services was identified as a research need. In addition, the introduction of new vaccines and new technologies poses special problems for routine immunization services that can be greatly helped with a sound research agenda.

In the past decade, new and underutilized vaccines have been added to immunization programmes. These include vaccines against hepatitis B, *Haemophilus influenzae* type b (Hib) disease, mumps, pneumococcal disease, rotavirus, rubella, and in endemic countries – yellow fever and Japanese encephalitis. A need to identify the most cost-effective and best practices to prepare countries for a smooth introduction of new vaccines and the need for assessment of the impact of new vaccines on immunization coverage and routine service delivery was identified as a priority research area. Post-introduction evaluation offers an opportunity to review the immunization system's overall strengths and weaknesses and can provide evidence of impact that can be used to increase advocacy and resource mobilization towards further improvement of immunization coverage and reduction in the numbers of unimmunized and under-immunized.

5. Interpretation

The presentations and discussions during the research review reinforced observations that much is already known about the reasons for failure to fully immunize children. Recent comprehensive literature reviews of reasons for non-immunization and under-immunization [7,8] in low- and middle-income countries during the last 10 years found both supply-side and demand-side reasons, but no major unexpected risk factors. These findings suggest that there is adequate documentation of the reasons for under-immunization. However, information is lacking about which interventions work, how to implement them in the most

cost-effective manner, and how to evaluate them [9,10]. The review panel identified a need to translate research into action as a priority, a concept that has been termed “implementation science” [11].

There was a wide range of suggestions for additional research, which was not surprising given the diversity of participants' (both panel and discussants/observers) professional experiences, interests and perspectives. Because the discussant/observer group was larger than the panel, there was an even broader range of topics, as well as less agreement on priority topics in this group. The heterogeneity and lack of consensus about a short list of research questions reflects the complex and multifaceted nature of routine immunization service delivery, especially in the context of broader health systems.

There is a need for improved dissemination of information about routine immunization research and translational or programmatic activities. Although publication of findings is an important activity, earlier information sharing about planned or ongoing research could result in more collaboration among partners and could help minimize duplicative efforts. “Piggybacking” onto existing recurrent meetings of partners involved in immunization or separate meetings dedicated to routine immunization research could serve as potential forums for information dissemination.

This review provided an opportunity to discuss research as it interfaces with implementation and the scale up of interventions to improve routine immunization. Ideally, research and implementation should not operate independently from each other. Rather, an optimal balance between the two would have research needs identified and findings translated into interventions that improve immunization delivery. Optimal coordination and communication between researchers and those responsible for implementation, albeit challenging, is essential to achieve this balance.

The effectiveness of many interventions purporting to improve health in poor populations in the developing world remains untested and therefore unproven [12]. One notable exception is immunization: over many decades, multiple randomized controlled trials of vaccines have been meticulously documented throughout the world, leading to the development and implementation of the immunization programmes that today save millions of lives every year. But delivering an immunization service is much more complicated than purchasing effective vaccines. The many other facets of immunization programmes oftentimes fall into the unproven category of “good ideas”. There is, therefore, a need for more implementation science to build an appropriate body of knowledge of what works, how, and under what circumstances. Even then, what works in one setting may not be applicable across the globe, and may need to be tested in multiple settings [11]. Furthermore, scientifically demonstrating the effectiveness of an intervention does not automatically ensure its use in practice. Indeed, in an analysis of the evidence of currently available interventions for child health, the Bellagio Child Survival Study Group [13] estimated that scaling up existing interventions could prevent almost 55% of global deaths in children younger than 5 years.

Interventions shown to be effective in industrialized countries may not be so in developing countries; this reinforces the necessity for local research. Research can often be undertaken very well in developing countries by existing institutions, universities and NGOs, in collaboration with institutions in industrialized countries. However, such institutions frequently lack sufficient resources, have not set their priorities, and often do not effectively disseminate their findings to ensure policy changes for the better.

Evidence on sustainability of interventions and their impact following the completion of trials is limited. For example, in carefully controlled trials, insecticide-treated bed nets have been shown to reduce malaria transmission, but the sustainability and long-term impact of this intervention is unknown [14]. Similarly, documenting evidence of the sustainability and long-term impact of interventions to improve immunization service delivery is vital.

In summary, there is an enormous range of research that could be undertaken to support routine immunization. However, the panel concluded that there were relatively few key research topics for which there was consensus that immediate investment is warranted. Future research that might be undertaken should be directly tied to programmatic needs. There should be a focus on efforts that will bring the best practices to each country, allowing them to fully implement strategic immunization plans that will have the greatest impact on raising global immunization coverage and preventing disease, disability, and death from vaccine-preventable diseases.

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Clements CJ 17 years as a member of WHO's global immunization team; 8 years as consultant to UNICEF, World Bank and other international organizations working in routine immunization; author of over 100 peer-reviewed articles on immunization; specializing in training country teams in the practice of routine immunization.

de Quadros CA 32 years as staff member of WHO including smallpox eradication in Brazil and Ethiopia. Director Division of Vaccine and Immunization of PAHO until 2002 where he led the successful initiatives to eradicate polio and measles from the Western Hemisphere. Author of over 70 peer-reviewed articles on disease control and immunization.

Biellik RJ 35 years in international public health, including 25 years working directly with developing country immunization programmes as a staff member with WHO, UNICEF and CDC, especially in Africa, Latin America and southeast Asia; specific experience with measles elimination and new vaccine introduction; author of over 50 peer-reviewed journal articles mainly on vaccines and immunization; membership of immunization expert committees.

Hadler JL 24 years as the State Epidemiologist and Director of Infectious Diseases in Connecticut, overseeing implementation and evaluation of vaccine preventable disease programmes, and 4 years on CDC's Infectious Disease Board of Scientific Counselors. Author of more than 30 peer-reviewed articles on vaccine-preventable diseases.

McFarland DM 25 years in health systems strengthening in over 40 countries, with emphasis on building platforms for health care delivery on disease control programmes including EPI; 12+ years as health financing and health economist on WHO technical advisory groups for disease control and integration; author of over 20 related articles on health systems strengthening, financing and integration.

Steinglass R 38 years work in immunization, including smallpox eradication in Ethiopia and Yemen; 10 years as WHO immunization advisor in Yemen, Oman and Nepal; 24 years with John Snow, Inc. leading immunization efforts of USAID-funded projects (REACH, BASICS, IMMbasics, and MCHIP); work in 45 under-developed countries on routine immunization strengthening. Author of 12 peer-reviewed immunization articles.

C. John Clements*

The University of Melbourne, Australia

Margaret Watkins

*Strengthening Immunizations Systems Branch,
Global Immunization Division, National Center for
Immunization and Respiratory Diseases, Centers for
Disease Control and Prevention, Atlanta, GA, United
States*

Ciro de Quadros

*Albert B. Sabin Vaccine Institute, Washington, DC,
United States*

Robin Biellik
Consultant Epidemiologist, Geneva, Switzerland

James Hadler
*Public Health Consultant, New Haven, Connecticut
and CDC Office of Infectious Diseases Board of
Scientific Counselors, United States*

Deborah McFarland
*Rollins School of Public Health, Emory University,
United States*

Robert Steinglass
*Maternal and Child Health Integrated Program/John
Snow Inc., Washington, DC, United States*

Elizabeth Luman
*Strengthening Immunizations Systems Branch,
Global Immunization Division, National Center for
Immunization and Respiratory Diseases, Centers for
Disease Control and Prevention, Atlanta, GA, United
States*

Karen Hennessey
*Strengthening Immunizations Systems Branch,
Global Immunization Division, National Center for
Immunization and Respiratory Diseases, Centers for
Disease Control and Prevention, Atlanta, GA, United
States*

Vance Dietz
*Strengthening Immunizations Systems Branch,
Global Immunization Division, National Center for
Immunization and Respiratory Diseases, Centers for
Disease Control and Prevention, Atlanta, GA, United
States*

* Corresponding author. Tel.: +61 3 9775 2931.
E-mail address: john@clem.com.au (C.J. Clements)

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