



Global Vaccine Shortage: The Threat To Children and What To Do About It

A White Paper

Exploring Lessons from the
Sabin Vaccine Institute's 9th Annual Vaccine Colloquium

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The mission of the Albert B. Sabin Vaccine Institute is to save lives by stimulating development of new vaccines and increasing immunization rates throughout the world. Founded in 1993, the Institute pursues Dr. Albert Sabin's vision of a world protected from disease by vaccines. Sabin Institute colloquium convenes leaders in academia, government, industry, and philanthropy to explore solutions to problems in vaccine research and development, and promote dialogue to prevent infectious diseases and treat cancer. As an immunization advocate, it helps policy makers shape sound public health policies and informs the public about the importance of vaccinations. The Sabin Institute's Hookworm Vaccine Initiative is working to develop a vaccine to prevent an infection that afflicts more than one billion individuals, and is a leading cause of anemia and malnutrition in the developing world.

The Institute is indebted to the Bill and Melinda Gates Foundation for funding the 2002 Sabin Vaccine Colloquium, and to Cold Spring Harbor Laboratory and their gracious staff. We gratefully acknowledge indispensable contributions of time and expertise extended by co-chairs Lance Gordon, PhD, and Lewis Miller, and co-organizers Nancy Tomich and Heidi Larson, PhD.

Global Vaccine Shortage: The Threat To Children and What To Do About It

The Sabin Vaccine Institute convened its ninth annual vaccine colloquium from October 23 to 25, 2002, at Cold Spring Harbor Laboratory's Banbury Conference Center on Long Island, New York. The fragility of national and global vaccine supplies brought experts to the table to generate strategies to rescue this vital resource for public health. The Cold Spring Harbor meeting reinforced numerous suggested pathways to a stronger vaccine supply and developed new approaches to this issue.

Vaccines—Weapons of Mass Protection

The colloquium adopted the catchphrase that vaccines are global “weapons of protection” that save the lives of children and adults. Periodic shortages of needed vaccines in the U.S. and in developing countries impede goals for preventing and eradicating dangerous infectious diseases.

The national and global vaccine supply continues to be threatened and fragile. Vaccine shortages reported for the past two years represented a crisis for manufacturers and health care providers, and caused inconvenience and confusion for the public. Anecdotal evidence indicates that recent shortages left some children vulnerable to preventable diseases. While catch-up efforts have temporarily alleviated these recent shortages, the conditions that led to the supply crisis continue to concern public health experts and all those who are vested in the development, production, delivery, and regulation of vaccines.

The Sabin Vaccine Institute colloquium identified potential pathways to resolving vaccine-supply concerns, as well as factors that lie beneath those concerns. These pathways and factors are enumerated in subsequent sections of this white paper.

Pathways to Vaccine Supply Solutions

Emphasize the Value of Vaccines

National and global advocacy is needed, with emphasis on the fact that the return on investment from vaccines in terms of public health benefit is probably the highest of any health care expenditure.

Explore Inventory Management

Methods of inventory management ought to be explored, including stockpiling, that will substantially reduce the risk of a sudden disruption in the supply of one or more vaccines that would lead to a health risk to a population. More appreciation is required of the impact different methods for inventory management may have, including revolving stocks of products. Further, awareness is needed of the fact that the divergence of products for various national markets results in non-interchangeability and requirement for multiple stocks of different formulations to prevent the same diseases.

Enhance Capacity

While the notion of increasing stockpiles is attractive, intermediate logistical issues require resolution. Capacity of vaccine production will benefit from identifying and implementing improved methods for forecasting long-term vaccine demand in developed and developing countries.

Promote Innovations in Financing

A more predictable demand for vaccines will have a positive effect upon the ultimate supply, since vaccine production timelines are lengthy and cannot be hastened if an urgent demand arises. It is therefore important to identify and promote innovative approaches to financing vaccine purchases so that long-term commitments can be negotiated to provide a predictable and reasonable rate of return to manufacturers.

Harmonize Regulatory Processes and Vaccine Schedules

The regulatory requirements to which manufacturers must adhere for licensing and production are necessary, however, the requirements for vaccine licensure differ from country to country. Some individual country regulatory decisions have global implications. To address regulatory issues for the entire industry, a global agency to harmonize vaccine administration schedules and manufacturing regulations ought to be considered.

Examine Product Divergence Trends

Product harmonization would benefit the broader vaccine market, since combinations of vaccines entering the market are more expensive. There should be an examination of the causes of product divergence by market and ways to reduce it, including the possibility of developing generic standards by product category.

Build Mechanisms for Stronger Communication

Overall, the vaccine market would benefit from mechanisms to improve communication among public health authorities nationally and globally, and in turn with manufacturers. As part of this improved communication, it will be important to develop an early-warning system to report problems in production and/or regulation that affect supply.

Issues Impacting the Vaccine Market

The Economics of Vaccine Supply

Fair rate of return on investment is critical to the stability of the vaccine supply.

Vaccines are purchased privately and also as public commodities. In the latter case, these purchases are made principally by a small number of public agencies, the CDC in the U.S., PAHO in Latin America, and UNICEF—and to a lesser degree by the Global Alliance for Vaccines and Immunization—for other developing nations. These agencies are often under-funded, and their purchasing power is characterized by short-term financing. They lack the capability to create reliable long-term demand.

As a privately manufactured products, vaccines generate a marginal return on investment. Manufacturing costs are not limited to raw product and assembly, but are amplified by the investment required in research and development, licensing, regulation and liability protection. The pharmaceutical companies that manufacture vaccines achieve far greater return on investment in their pharmaceutical versus vaccine products, since pharmaceuticals are used in great volume to treat chronic conditions, whereas vaccines achieve their effect in a minimal number of doses.

Globally, poorer nations or their purchasing agents can't or won't buy newer, more effective vaccines because they are more costly. This reliance on older, less-expensive products is leading to a divergence in products by market and decreasing economies of scale for the purchases of vaccines.

Regulating the Vaccines In Supply

The regulatory process, though essential for public safety, exacerbates vaccine supply fragility.

Regulatory requirements that are changed abruptly can disrupt vaccine production and adversely affect vaccine supply. Manufacturers often cannot rapidly change production processes fast enough to accommodate either regulatory change or product design improvements.

From an international perspective, regulation can pose unanticipated incongruencies. The regulatory standards for vaccines are established, for the most part, by officials in the developed world, for the benefit of the population of a developed country. These standards indirectly affect the developing world, often with adverse consequences. Some developing countries are venturing into generic vaccine manufacture, raising issues of international standards and regulatory costs.

Maintaining a Robust Supply of Vaccines

Adequate capacity in vaccine production rests in fewer manufacturers today than in the past. This smaller number of producers deals in products that are fraught with biological production challenges.

Vaccine supply is compromised when producers are unable to rapidly ramp up to sudden increases in demand. Compounding the problem is the fact that agencies in various public health sectors in the U.S. and globally fail to maintain adequate communications and coordination among themselves as well as with manufacturers.

Sustaining Vaccines' High Profile

Vaccines need to be elevated to a national priority, in every country. Most governments, including that of the United States, undervalue the contribution of vaccines to the health and well being of their people — and what is undervalued easily can be lost. There must be a concerted effort to make policymakers and the public aware of the disease burden that is prevented by vaccination, as well as the resultant cost-savings.

Appendix I

Task Force Initiative

The Sabin Vaccine Institute will begin a further examination of key issues surrounding strengthening the vaccine supply domestically and globally. Seven task forces will revisit each issue exposed during the colloquium during the coming year. Following is a description of the task force topics and the goal to be achieved by each:

Task Force on Communications. To develop a proposal for an ongoing framework of regular communications among national and global public health agencies and from that network to industry, with a particular focus on an early warning system to report problems in production or regulation that may affect supply.

Task Force on Stockpiling. To develop a proposal for U.S. and global stockpiling that will substantially reduce the risk of vaccine shortages in event of a sudden, but temporary, disruption of supply.

Task Force on Forecasting Demand. To develop a proposal for a system of demand forecasting for the U.S. and developing countries that can be implemented over the next three to five years in order to lay the groundwork for long-term commitments from purchasing agencies to manufacturers.

Task Force on International Commission on Harmonization (ICH) on Vaccines. To develop a proposal to create and finance an agency that can effectively promote harmonization of administration schedules and manufacturing regulations around the world.

Task Force on Financing. To propose innovative approaches to long-term financing of vaccine purchases that will provide reasonable rates of return to manufacturers.

Task Force on Public Advocacy. To propose ways to strengthen public advocacy of vaccines, emphasizing to the people of many nations and their governments the high cost benefit value of vaccines in preserving health.

Task Force on Divergence of Products by Market. To examine the cause of product divergence between markets and what can be done to reduce it.

Appendix II

Colloquium Methodology

In the months leading up to the colloquium, the Sabin Vaccine Institute accessed recent studies and analyses of the status of vaccine production for domestic and global markets. Included were the 2002 Institute of Medicine report, *Calling the Shots: Immunization Finance Policies and Practice*; the fall 2002 reports of the U.S. General Accounting Office, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges* and the National Vaccine Advisory Committee, *Strengthening the Supply of Routinely Recommended Vaccines in the United State*; as well as the Global Alliance for Vaccines and Immunization-commissioned 2002 report, *Lessons Learned: New Procurement Strategies for Vaccines*. Each report added perspective to the nature of the problems in the vaccine market and the need for systemic solutions. Each also solidified confidence that a colloquium focused on vaccine supply was timely. The objective of the meeting was to stimulate a discussion of pathways to systemic remedies to the domestic and global vaccine supply problem.

The Sabin Vaccine Institute prepared for the colloquium by first implementing a multi-round survey, or Delphi exercise, to gather input regarding vaccine supply from more than 100 individuals affiliated with a range of vaccines stakeholder organizations. The respondents to this Delphi study included members of academia, advocacy organizations, the medical community, industry, U.S. federal government (the Center for Disease Control and Prevention, Department of Health and Human Services, Federal Regulatory Administration, and legislative offices), and international organizations and foreign agencies. Respondent comments on key issues, identified from the literature on vaccine supply, yielded a broad spectrum of responses and illuminated four issues that served as the focus of the colloquium.

Appendix III

Individual Recommendations of Colloquium Participants

- Ensure that all players agree to the immediate disclosure of information that could impede the immunization of the world's children.
- Determine the feasibility of stockpiles.
- Give public advocacy in education a more general form.
- Address/learn lessons from the lack of success by public health in establishing its relationship with and in comparison to that of industry and government.
- Advocate the value of vaccines as an international priority.
- Explore tax incentives in the U.S. and EU to expand manufacturing capacity for developing countries.
- Develop a strategy to manage the uncertainty of liability exposure.
- Demonstrate the need for predictability and stability through greater transparency in the timelines, costs and licensure in a development of a vaccine.
- Improve long-term demand forecasting.
- Improve understanding of industry to the public health sector.
- Improve understanding of stockpiles.
- Set up a task force to effective plan for stockpiling.
- Demonstrate the importance of good communication.
- Place immunization and vaccines in the global context. (i.e.: anti-vaccine activity is universal)
- Thus there is a need for a few focal points from this colloquium to liaise with the GAVI task forces, i.e.: The Advocacy and Communication Task Force, ACTF.
- Address the question of how to make vaccine markets more global by focusing on regulatory harmonization.
- Look at the pros and cons of standardization of vaccine products.
- Create a long-term and sustainable public education/awareness campaign on the value of vaccines.
- Create a multi-agency task force.
- Recognize that advocacy of immunization is multi-year and two-tiered (public education and political). Thus, much importance must be placed on who will be the "face" of the advocacy group to address the government and the Department of Defense on immunization issues.
- Initiate an academic study that would create a better model for valuing vaccines.
- Examine the tracking of supply versus demand and the need for better planning at a country level.
- Translate the concern over bio-terrorism into an opportunity for advocacy of immunization's value to a country's security
- Commission a study, which includes all players, on stockpiles.
- Create a task force to promote information sharing in an attempt to increase the ability to forecast.
- Develop vaccines as a national and global priority through a body with global interests. (National priorities can be integrated into global priorities).

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- Challenge the assumptions of divergence of products and address the need for standardized products that can be used around the world.
- Set up a task force to harmonize global and US regulatory processes, schedules and movement of vaccines.
- Address the question of how to communicate the value of vaccines to the public (advocacy).
- Educate the larger medical community to address the gap between the public health community and private medical community.
- Address the question of how we can translate the value of vaccines into political terms to ultimately ensure long-term funding.
- Provide capacity to developing countries for better forecasting.
- Create a multinational long-term fund/commitment.
- Set up a task force, to include government and industry, with the aim of ensuring greater communication and transparency.
- Embark upon a public education campaign
- Address the need for a global enterprise.
- Increase communication between industry and other players
- Address the question of how to get the issues surrounding vaccine supply into the political arena where it matters.
- Address the question of how public policy has created the industrial structure of today. Example: U.S. drives innovation yet the supply chain is over-fragile. The absence of U.S. suppliers in the global market and the relationship between government and industry should be studied.
- Set up GAVI and UNICEF as a revolving fund (with bonds) to ensure long-term funding.
- Create greater communication between all partners including industry.
- Improve capacity of developing countries to purchase vaccines through a series of incentives and infrastructural aid from the U.S.
- Create incentives for industry to continue long-term, innovative vaccine development through grant programs.
- Address harmonization, divergence and product regulation issues.
- Understand and find mechanisms to ensure long-term financial reliability to Ministries of Health and Donors.
- Prioritize the value of vaccines.
- Create a discussion between the public and the private sectors with a focus on procurement, the role of competition, and the role of international forecast and supply.
- Convene a conference, hosted by CDC and Sabin etc., to examine stockpile feasibility.
- Set up a task force/study group/mini-ICH that would examine what concretely can be done to ensure easier access to vaccines.
- Initiate “Policy Planning Meetings” where institutionalization of vaccine policies will be debated with industry.

Colloquium Participants

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