Immunization Logistics and Supply Systems: From Vision to Action

Workshops Report
Washington, DC (July 19, 2010)
Seattle, WA (July 22, 2010)

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OPTIMIZE Immunization systems and technologies for tomorrow

PATH World Health Organization

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Optimize welcomes comments on this document as well as suggestions for any additional consultation opportunities. If you have suggestions for further work or would like to get involved, we welcome comments from interested parties (see contact information below).

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Introduction

In July 2010, workshops were held in Washington, DC, and Seattle, WA, to engage stakeholders from a wide variety of organizations related to immunization or logistics and supply chain systems in shaping the future of immunization technologies and logistics systems in low- and middle-income countries. The workshops provided a brief review of the history and current state of developing-country immunization systems and sought participant perspectives on the challenges facing current systems, the desired future state of these systems, and work streams required to reach the desired state.

While these work streams will be completed by many partners over the long term, project Optimize is catalyzing these efforts in the near term. Optimize is a five-year collaboration undertaken in 2007 by PATH and the World Health Organization (WHO) and funded by the Bill & Melinda Gates Foundation which focuses on projects that:

- **Innovate** by identifying technologies and practices likely to improve future immunization systems and promoting a policy and regulatory environment conducive to incorporating them.
- **Demonstrate** these technologies and practices in relevant countries and model the impact of implementing them on a larger scale. These efforts will help build an evidence base to support adoption of these technologies and practices, as well as transfer any lessons learned to future implementations.
- **Facilitate** by engaging key partners within immunization and across the public health spectrum to develop a joint vision and plan of action. The Small Working Group developed a draft vision and a set of supporting tenets in September 2009 which have since been reviewed and refined by the Optimize Team, Optimize Project Advisory Group members, the United Nations Children's Fund (UNICEF) Cold Chain and Logistics (CCL) Task Force, and the newly created Future Vision Think Tank at several international immunization-focused meetings.

During these workshops, Optimize also enlisted stakeholders' aid in refining the draft vision and beginning to translate the vision and supporting tenets into an action plan. Key partners cited by participants as necessary to accomplish these efforts were also identified.

While many common themes emerged from both workshops, a distinct set of participants attended each workshop and provided input that focused on their specific areas of expertise. Washington, DC, workshop participants represented a broad array of organizations, including:

- **Existing public-sector partners in global health** such as the US Centers for Disease Control and Prevention, the GAVI Alliance, Johns Hopkins University School of Public Health, PATH, UNICEF, and the United States Agency for International Development.
- **Other public-sector entities** such as the Biomedical Advanced Research Development Authority division of the US Department of Health and Human Services.
- **Nongovernmental organizations (NGOs)** such as the Center for Global Development, the Clinton Health Access Initiative, John Snow International, Management Sciences for Health, and VillageReach.

- **Independent consultants.**

Seattle workshop participants represented a smaller group of organizations including:

- The **Bill & Melinda Gates Foundation** which composed approximately two-thirds of Seattle's participants.
- **PATH.**
- **Others** such as the Clinton Health Access Initiative, Health Alliance International, Intel Corporation, and VillageReach.

Themes covered only in the Washington, DC, or Seattle workshops are documented separately to highlight the focus of each group of stakeholders.

Challenges

Participants discussed what new immunization and supply system challenges would need to be overcome given the history and current state of immunization in developing countries.

Identified challenges common to both workshops

- **Separate logistics systems exist within the health sector.** While acknowledging that there are no "one size fits all" systems and that individual accommodations will need to be made, participants agreed that opportunities for increased efficiency exist and the costs and benefits of integration should be evaluated on a systems basis rather than in a vertical top-down or bottom-up approach.
- **Immunization systems are insufficiently flexible and agile.** Participants also agreed that immunization systems must be sufficiently flexible and agile to respond to emerging technologies, changing system and country needs (new product introduction, climate change, etc.), local customs (e.g., pharmacists administering vaccines in addition to physicians), and the economic and development context within which the system operates (e.g., growing middle class and expansion of private-delivery services covering progressively more remote areas).
- **The lack of comprehensive information management systems and decision support tools.** Many cited the need to improve the quality, not just the amount, of data available and transmitted between various levels of the immunization system and the timeliness with which the information is shared.
- **Human resource gaps are present.** Participants noted that logistics management is insufficiently professionalized as a career and has a low status in many societies. Human resource gaps throughout the system, both in quantity and training of workers, were raised as a concern.
- **Infrastructure challenges exist.** Participants noted the existing cold chain does not have sufficient capacity to absorb the dozen or more new products available between 2000 and 2019. Some mentioned that maintaining product safety and quality is already challenging because of the lack of systems to monitor and control temperature throughout the value chain, and additional, more expensive products will only exacerbate existing problems.

Additional challenges—Washington, DC, workshop

The Washington, DC, workshop focused more intensely on policy- and advocacy-related challenges:

- **The potential global and national policy impact on immunization system design has not been assessed.** Washington, DC, participants discussed the need to determine whether current policies drive system design or whether the desired system drives policy change.
- **Tradeoffs between macroscopic system coordination and more direct but piecemeal interactions with specific parts of the system are not well understood.** Some participants noted that global policy can result in significant positive impact, as in the cases of the WHO multidose vial policy, autodisable syringe requirements, and the practice of bundling sufficient numbers of autodisable syringes with vaccine doses at the point of procurement. Others believed more decentralized efforts, such as direct supplier-country negotiations, could result in more rapid innovation.
- **The need for greater political will and greater support for immunization from parents and health care providers.**
- **The need to examine potential policy implications of the ever-greater monetary value of vaccines in cold storage.**

The Washington, DC, workshop also identified several challenges beyond policy and advocacy such as financing and absorbing and transmitting lessons learned:

- **More innovative financing mechanisms are needed to support immunization.**
- **Lessons learned from successes at the district/subnational level and from countries that have successfully graduated from donor assistance need to be compiled and transferred.**

Additional challenges—Seattle workshop

The Seattle workshop focused more on the challenges associated with product characteristics, planning, and procurement:

- **Not all products are designed to minimize cold chain requirements.** In particular, lyophilized products that require reconstitution prior to being administered add to cold chain requirements, but efforts to mandate that all products supplied to developing countries are ready to administer remain controversial.
- **In spite of target product profiles (TPPs), marketed products may not keep up with technological advancements and developing-country needs.** Developing TPPs requires making decisions now that will drive how products are developed and used well into the future. The immunization landscape and technological context (and thus developing-country needs, available technologies, and potential solutions) may have changed by the time these products actually become available.

Desired future state

Participants discussed the desired characteristics of a 2025 immunization logistics and supply chain system.

Identified themes common to both workshops

By 2025, participants stated they would like to see a system in which:

- **Public-sector logistics and supply systems are more integrated.** Various components of the public-sector logistics and supply system would be more integrated and would better leverage the private sector, wherever practical, for support services, outsourcing, and collaborations.
- **System effectiveness and efficiency are increased.** Some system redundancy would be incorporated as a means to maximize reliability, but system efficiency can and should increase.
- **Public-sector systems incorporate best practices and concepts from the private sector.** Systems would be locally empowered, adaptable to new technologies, and contain monitoring and evaluation feedback loops to support continuous improvements. Government funding for strengthening systems would be treated as an investment on which a tangible return (i.e., cost savings, increased coverage, etc.) would be expected.
- **Improved data systems support better decision-making.** State-of-the-art data systems using consistent, interoperable tools would allow seamless, real-time information sharing among all levels of the system and facilitate vaccination and procurement decisions.
- **Workers are valued, supported, and more effectively used by the system.** A valued and professionalized logistics work force would be in place, with adequate certification, training, and paths for career advancement. Workers would be empowered to suggest or make changes (especially at the local level), adequate management and oversight would be in place, and accountability would be ensured while still promoting appropriate risk taking.

Additional themes—Washington, DC, workshop

Washington, DC, participants described a high-level view of the 2025 system:

- **Incentives exist that encourage manufacturers to make products more suitable for developing countries.**
- **Long-term national strategies are used to plan in advance for several vaccine introductions at once.** Because so many new products will reach the market in the coming years, it will be especially important to evaluate potential introductions in a portfolio context.
- **Political will in support of immunization is strong.**
- **The value proposition of improving immunization systems is well understood.** A strong understanding of the value of immunization and the cost of not addressing inefficient system components should drive system investment and improvement.

Additional themes—Seattle workshop

In contrast, Seattle participants focused more on the details of a 2025 system view, including product-related developments, financing, and efficiency:

- **TPPs are refined and user-driven.**
- **Products do not require reconstitution.**
- **More combination vaccines and more products administered orally are available.**
- **Measures are in place to mitigate the risk of counterfeiting and ensure product safety and quality.**
- **Sustainable vaccine financing** allows immunization coverage goals to be set at 95 to 100 percent of the eligible population.
- **Efficiency is embraced in the context of both cost savings and environmental stewardship** by reducing wastage of vaccines and supplies, adequately managing medical waste resulting from immunization, and reducing fuel and energy consumption.

Key work activities

Participants discussed what work would need to be done to address the gap between the current state and the desired future state.

Identified activities common to both workshops

- **Increase private-sector involvement in immunization logistics.** Participants emphasized the importance of determining where and how the private sector currently participates in the immunization logistics system, evaluating the benefits of this participation, and incentivizing further private participation where beneficial.
- **Build automated, electronic means of collecting and transmitting data.**
- **Make vaccine products that are easier to administer (e.g., intranasal or transdermal vaccine administration).**

Additional activities—Washington, DC, workshop

- **Clearly articulate the value proposition of improving immunization logistics.** Participants recommended developing one or more metrics to quantify the cost savings realized by moving from the current state to the desired state.
- **Establish performance monitoring systems to inform donor investment and future policy.**
- **Create a policy environment that reflects and can adapt to the latest technologies.**
- **Pursue regulatory solutions.** Relicensing vaccines for storage and/or use out of the cold chain would be particularly helpful, since Optimize has demonstrated that many vaccines are stable for one to several months at well above ambient temperatures.

- **Increase communications and advocacy activity/investments.** Recommended activities included increasing financial investments in advocacy, increasing participation from GAVI, WHO, and other related organizations in logistics, and leveraging the larger community to motivate progress (e.g., civil society organizations).
- **Increase the efficiency of activities done for and by donors.** Participants noted the importance of standardizing data requests from donors and creating incentives for synergies among donors and country partners.

Additional activities—Seattle workshop

Seattle participants described essential activities that would improve immunization supply system effectiveness and efficiency:

- **Agree on a common definition of a "highly empowered, flexible, responsive system."** This would allow partners to determine what promotes or impedes such a system and what solutions are optimal in the context of individual countries.
- **Garner lessons learned from developing-country introduction and use of mobile technology.** Learning how mobile technologies have been leveraged in developing countries and taken to scale would guide future system improvements.
- **Assess the appropriateness of the currently collected health indicators as a foundation for standardization.** If common data are collected across countries, it may be simpler to design common systems to store, process, and transmit these data.
- **Agree on a common data-system architecture.**
- **Create inventory and stock management systems** in order to decrease emergency procurement activities and help clarify supply and demand for better long-term planning.
- **Build accreditation systems** in order to help document and teach the basic personnel and equipment requirements of an immunization clinic.
- **Build evidence for the cost-effectiveness of integrated health logistics systems.** By realizing cost savings through integration, these resources can be reallocated to address other health-related needs.
- **Pilot investments in transportation and distribution infrastructure within countries**, from ports of entry to individual health facilities. This part of the value chain is often the most challenging to improve because individual country-relevant solutions are needed.

Seattle participants also stressed the critical nature of financing-related activities:

- **Continue GAVI Alliance vaccine financing.**
- **Create training programs to enhance the ability of country ministries of health to negotiate budgets with country ministries of finance.** This would allow countries to secure more national resources to cover health-related expenses which could reduce country reliance on donors.

- **Explore alternative financing mechanisms.** Designing appropriate market-based mechanisms to improve health financing and instituting a global health tax to finance health care were options raised.

Several human resource-related activities were also cited as essential:

- **Train and adequately professionalize health care workers prior to service.**
- **Develop comprehensive training programs for logisticians.**
- **Establish an independent professional network or association for logisticians.**
- **Provide technical personnel and incorporate quality improvement programs at the district level.** Where these programs already exist in developing countries, they are most often confined to the central government level.
- **Implement feedback and accountability loops in health system organizational structures.**

Education/communication initiatives were also mentioned:

- **Develop a marketing and education campaign to grow consumer demand for vaccination and improved health care.** If the general population were more aware of the benefits of vaccination and improved health care, they would likely advocate more strongly for it. Participants mentioned that since many developing-country diseases disproportionately affect children, mothers would be particularly tenacious advocates.
- **Educating policymakers and technocrats to enable more evidence-based decision-making on vaccines.** Advocacy is likely to be more effective if the decision-makers and implementers thoroughly understand the benefits of vaccination.

Several additional work streams were also classified as essential at the Seattle workshop:

- **Establish policies or guidelines to ensure vaccine vial monitors are on all vaccines.**
- **Evaluate the impact of TPPs on the vaccine market.**
- **Assess how private-market channels may evolve over time and how these would impact public-market channels.**

Vision alignment and feedback

The current vision statement is intended to unite and align the work of all partners engaged in the effort to improve the impact of immunization.

By 2025, state-of-the-art supply systems meet the changing needs of a changing world in order to enable the right vaccines to be in the right place, at the right time, in the right quantities, in the right condition, and at the right cost.

Participants agreed that a vision statement is critical and that it should be aspirational and motivate people to strive for more ambitious goals. In the context of immunization, “ambitious goals” were characterized as a system that can handle the availability and introduction of

multiple vaccines. Participants suggested the statement be flexible, adaptable, and broad enough to cover the necessary points but also sufficiently concrete to clearly convey a goal.

While participants agreed that the vision statement accomplished its stated purpose, they suggested improvements that involved clarifying language or adding additional explanatory detail:

- **Shorten the timeframe from 2025 to 2020.** This would align the goal with the Decade of Vaccines declared by the Bill & Melinda Gates Foundation, as well as help maintain a sense of urgency and ensure that partners do not become complacent in their activities.
- **Add language to convey:**
  - **The value proposition associated with immunization logistics (i.e., "save lives and save money").**
  - **Sustainability.** To some, "enabling" immunization means only making sure the program begins, while "sustaining" immunization conveys a more long-term focus on both starting and maintaining immunization programs.
  - A sense of collaboration among partners.
- **Incorporate the human element.**
- **Describe vaccination as service delivery through a dynamic, responsive system rather than simply supplying vaccine products.**
- Set a tangible goal (e.g., x% vaccine coverage by 2020/2025).

Supporting tenet alignment and feedback

Through the collaborative work to date, five supporting tenets intended to represent the most critical areas required to ensure long-term success of immunization programs were articulated. These tenets are listed below, along with the workshop feedback linked to each specific tenet.

1. *Vaccine products and their packaging are designed with characteristics that best suit the operational needs of countries.*

   - **No additional feedback.** Participants agreed with the importance of this tenet and stated that there was nothing further they wished to add on this topic.

2. *Immunization supply systems are designed to maximize effectiveness and efficiency and are built around mechanisms that support continuous learning to improve system performance.*

   - **Combine the second and third tenets.** Participants agreed with the importance of this tenet, but they suggested that most of the ideas described in the third tenet were already covered by the second tenet, so the two tenets could be combined as described below.

3. *Immunization supply systems are part of an integrated health supply system that maximizes synergies and makes the most appropriate strategic links with the private sector.*

    - **Combine the second and third tenets by moving the reference to engaging the private sector to tenet 2.** Integrating systems and maximizing synergies could be considered a means to the end of maximizing efficiency.

4. *The environmental impact of energy, materials, and processes used in immunization supply systems from the international to local levels is assessed and minimized.*

    For a variety of reasons, some participants suggested this tenet should not be included as one of the "critical areas required for long-term success:"

    - **An immunization system could be quite successful in terms of reducing morbidity and mortality even if its processes are not environmentally friendly.**
    - **Environmental impact is a developed-world concept framed primarily in terms of resource use and carbon emissions and is not relevant to developing countries.** Participants noted that reducing environmental impact can mean adopting technologically advanced solutions that are more difficult or more expensive to implement. Given scarce financial resources developing countries are less likely to measure the impact of their immunization program in environmental terms or choose to reduce environmental impact if it will reduce health impact.
    - **Environmental impact is notoriously difficult to quantify.** This would complicate costing and any efforts to make tradeoffs necessary to objectively consider environmental impact.
    - **The environmental impact message can easily be misinterpreted or conveyed poorly.** While there have been individual cases of developing countries prioritizing "green" technologies (e.g., Tunisia supporting solar electricity to reduce reliance on fossil fuels even though grid electricity is nationally reliable and available), global partners must ensure that the environmental impact message is not conveyed or interpreted as the developed world paternalistically dictating to developing countries how to manage their resources.

    In contrast, others strongly supported retaining a tenet devoted to reducing environmental impact:

    - **Reducing environmental impact could be conceptually reframed to be more relevant to developing countries.** This would include using local product sources wherever possible, reducing fuel consumption, and reducing broadly defined environmental impact in the context of increased efficiency. As currently written, this tenet does not capture cost-effectiveness or efficiency, which could be used as a means to reduce environmental impact and make the most effective use of all types of program resources.

    Collectively, project Optimize and its partners will have to determine if reducing environmental impact is a noncritical aspiration or if "meeting the changing needs of a changing world" as described in the vision necessitates designating environmental impact reduction as critical.

5. *Data produced by effective, affordable, and sustainable information systems and technologies are used to inform and drive immunization supply systems.*

    - **No additional feedback.** Participants agreed with the importance of this tenet and stated that there was nothing further they wished to add on this topic.

The tenets are supported by cross-cutting enablers such as financing, policy, and human resources. Some participants also recommended adding procurement as a cross-cutting enabler.

Overall, participants considered the tenets valuable because they provide a framework to develop a more detailed work plan, and most of the key work activities listed by participants mapped well to one of the tenets or the cross-cutting enablers. However, participants suggested several additional improvements not linked to a specific tenet:

- **Focus more clearly on the value proposition of vaccines.**
- **Emphasize more strongly quality, accountability, and a focus on results.**
- **Charter an organization to oversee efforts and hold partners accountable.** Participants stressed that preserving institutional memory and ensuring progress toward logistics-related goals will be difficult to accomplish without a coordinating body. Some participants suggested that Optimize should be named and their mandate should continue but in a scaled-down form, while others recommended designating a secretariat or smaller group to act as a cross-organizational coordinator after Optimize's tenure. Others suggested naming the partners who have been engaged and have incorporated logistics-related goals into their work plans once those steps are complete.
- **Use the word "sustaining" to describe immunization.** This was perceived as being broader and more inclusive than simply enabling immunization.

Participants also discussed whether the cross-cutting enablers were sufficiently critical to warrant their own tenets. Consensus was not reached on whether human resource needs warranted its own tenet. Some suggested human resources may ultimately be the most important tenet and is often the most under-assessed. Others stated that human resources should not be placed above financing, policy, and advocacy by raising it to the level of tenet while the others remained enablers. Some also suggested rewriting existing tenets to encompass human resources rather than establishing a whole new tenet. However, participants agreed that procurement should not be covered as a separate tenet because it can either be subsumed into existing tenets two and/or five, or new technologies may render the current procurement paradigm obsolete.

Key partners necessary for future success

It is essential for Optimize to engage key partners that will carry on this work beyond its time-limited mandate. Washington, DC, participants suggested general categories of partners but focused primarily on partner engagement strategies. In contrast, Seattle participants focused on determining the most appropriate specific partners to engage and the rationale for seeking their input and expertise. By combining these outcomes a comprehensive picture of whom to engage and how to engage them emerged.

Key partners to engage

- **Existing public- and private-sector partners in global health.** Vaccine manufacturers and the product development partnerships with which manufacturers work are essential to ensure the right products are developed for diseases affecting developing countries. Trade associations such as the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Country Vaccine Manufacturers Network (DCVMN) are a critical link to manufacturers; DCVMN was cited as a particularly important partner because the organization "behaves" differently than its constituent companies do individually. Bilateral and multilateral donors provide much of the funding necessary to implement any logistics-related initiatives. Broad coalitions such as the GAVI Alliance and the International Health Partnership can help ensure activities are well coordinated and sustainably financed. Individual organizations within these coalitions such as WHO, UNICEF, and various United Nations agencies, plus a number of NGOs within and outside these coalitions, have strong presences in country and can share many lessons learned from their work.
- **Government.** Politicians can act both as decision makers and champions for health-related causes, but mid-level officials within ministries of health, finance, and transportation can be especially helpful in advancing immunization logistics needs. Non-finance ministries can also develop more effective negotiating skills to use in budget and planning cycles with ministries of finance.
- **Professional/expert groups.** TechNet and similar organizations of logistics professionals provide important forums to share best practices.
- **Front-line implementers (e.g., health care workers and trainers).** As these will ultimately be the people responsible for determining the success or failure of any immunization-related effort, it is important to engage them both to ensure smooth rollout and program function and to ensure lessons learned and ideas for improvement are transmitted back up the value chain.
- **Media, advocacy groups, and the general public.** Advocacy to governments, donors, and key opinion leaders will no doubt be critical, but the general public can also act as a powerful voice when motivated to demand efficient delivery of higher-quality health care, especially health care for children.
- **Academics and advanced systems "thinkers."** Academic innovators such as the Massachusetts Institute of Technology/Zaragoza Logistics Center can help professionals extend their training and incorporate the latest research into their activities. Other academic groups can generate bold new ideas for infrastructure and system integration that operational-level professionals can pilot and implement if successful.
- **International standards bodies.** Ensuring systems interoperability may best be accomplished by organizations such as the American National Standards Institute (ANSI) and the International Organization for Standardization (ISO) that specialize in standardization and certification.
- **Private-sector supply systems and the industrial design community.** Lessons learned from the food and beverage industry cold chain, the just-in-time processes employed by a

Engagement strategies

- **Document and publicize immunization successes rather than failures.** In particular, pneumococcal and rotavirus vaccines are safe and highly effective products and could be cited as examples of how logistics needs to be addressed as a means to achieve the health impact these vaccines can provide.
- **Frame investments in immunization logistics as protecting the significant investments in new vaccine introduction and ensuring they have the maximum possible health impact.** By quantifying the costs of system inefficiencies or failures in financial and health impact terms, the return on logistics investment will become clearer.
- **Ensure logistics efforts are integrated into immunization and health systems and then further amalgamated into larger maternal and child health efforts such as the Millennium Development Goals.** By linking immunization logistics to the success of larger, more well-known efforts, more people are likely to recognize and advocate for the value of logistics.
- **Align immunization logistics and systems with existing programs that already have policy momentum and financial support.** For example, emphasizing the environmental benefits of reducing medical waste and reducing resource consumption (packaging, transport, etc) by improving immunization system efficiency could garner support from the worldwide environmental movement.

Next steps

To ensure the momentum generated by these workshops is effectively channeled into developing an action plan for each tenet, tenet-specific working groups are being established. These groups are currently composed of members of the UNICEF-led CCL Task Force and Optimize Project Advisory Group and are seeking additional members, as well as recommendations for key people who should be asked to participate. These working groups also welcome any additional thoughts on activities or evidence they should examine.

Optimize and the working groups plan to share their work, solicit feedback, and engage additional partners at several immunization-related meetings, including the:

- TechNet meeting (Kuala Lumpur, December 2010).
- Global Immunization Meeting (New York, February 2011).
- International Conference on Logistics for Health (Burkina Faso, February 2011).