## A REPORT OF THE CSIS GLOBAL HEALTH POLICY CENTER

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WILL THE PROMISE OF VACCINES BE FULFILLED?

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# the future of global immunization will the promise of vaccines be fulfilled?

Stephen L. Cochi<sup>1</sup>

#### Introduction

In January 2010 at the World Economic Forum (WEF), the Bill and Melinda Gates Foundation launched the Decade of Vaccines by pledging \$10 billion over the next 10 years, in addition to the \$4.5 billion that the foundation had already committed, to support worldwide efforts to develop and deliver vaccines to the world's poorest countries during the next decade. The foundation also challenged other global partners to demonstrate their continuing commitment and, in so doing, to dramatically reduce child mortality by the end of the decade. The 2010 WEF heralded an effort to maintain and enhance the momentum of progress achieved over the previous decade to make lifesaving vaccines available to the world's children, including through the work of the Global Alliance for Vaccines and Immunization (GAVI Alliance), which had been launched almost exactly 10 years earlier at the same forum.

In June 2011, the GAVI Alliance announced the success of its pledging conference, with donor commitments of \$4.3 billion in new funds for the period 2011–15, bringing total available GAVI Alliance resources for that period to \$7.6 billion.<sup>3</sup> These positive developments represented a turnaround for the GAVI Alliance, which had previously struggled for funding and faced major funding gaps in meeting its commitments through 2015. Flush with these additional resources and bolstered by new leadership in the form of both a new board chair and a new chief executive officer, the alliance is now strategically positioned to increase its impact over the next five years.

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 <sup>&</sup>lt;sup>2</sup> "Bill and Melinda Gates Pledge \$10 Billion in Call for Decade of Vaccines," January 29, 2010, http://www.gatesfoundation.org/press-releases/Pages/decade-of-vaccines-wec-announcement-100129.aspx.
 <sup>3</sup> "Donors Commit Vaccine Funding to Achieve Historic Milestone," June 13, 2011, http://www.gavialliance.org/library/news/press-releases/2011/donors-commit-vaccine-funding-to-achieve-historic-milestone-in-global-health/.

Although these new funding commitments are unprecedented in magnitude, nonetheless they represent only a small part of what is needed to address the many priorities and demands in global immunization that lie ahead.

In May 2011, the 64th World Health Assembly (WHA) endorsed the Decade of Vaccines (DoV) vision and called for the development of a Global Vaccine Action Plan through a DoV collaboration process, on which work had begun in late 2010.<sup>4</sup> The DoV collaboration created four working groups—delivery, global access, public and political support, and research and development—to devise a strategic framework for the next 10 years with consultation and inputs from key stakeholders. The final plan will be submitted for approval by the WHA in May 2012.

### Realizing the Vision

Childhood immunization is one of the most successful and cost-effective of all health interventions, especially for reducing infant and child morbidity and mortality globally.<sup>5</sup> In the past two decades, immunization has prevented an estimated 20 million deaths worldwide from vaccine-preventable diseases. Current estimates are that more than 2.5 million child deaths per year are prevented through vaccination. Still, nearly 2 million children die of vaccine-preventable diseases every year, representing approximately 25 percent of all deaths among children younger than five years of age. Deaths due to rotavirus diarrhea and invasive pneumococcal disease and pneumonia top the list of priorities, as well as further reducing measles-related deaths after a decade of remarkable progress on this front.<sup>6</sup> New vaccines currently under development have the potential to prevent millions of additional deaths. The next decade offers a tremendous opportunity for transforming global health and could have significant consequences for child survival while expanding the impact of vaccines across the lifespan.

### Challenges

With so many opportunities to prevent additional disease, disability, and death due to vaccinepreventable diseases, a great deal is at stake. There is no easy formula for success. How a number of challenges are addressed will be critical to success or failure in the next decade and to the most

<sup>&</sup>lt;sup>4</sup> "Global Vaccine Action Plan—An Immunization Agenda for the Decade (draft)" (paper presented at meeting of the WHO Strategic Advisory Group of Experts on Immunization, Geneva, Switzerland, November 8–10, 2011), http://www.dovcollaboration.org/.

<sup>&</sup>lt;sup>5</sup> D.E. Bloom, D. Canning, and M. Weston, "The Value of Vaccination," *World Economics* 6 (2005): 15–39. <sup>6</sup> P.M. Strebel, S.L. Cochi, E. Hoekstra, P.A. Rota, D. Featherstone, W.J. Bellini, and S. L. Katz, "A World without Measles," *Journal of Infectious Diseases* 204 (Supplement 1 2005): S1–3; and "The Measles Initiative Vaccinates One Billion Children in First Decade," http://www.measlesinitiative.org/.

<sup>&</sup>lt;sup>7</sup> O.S. Levine, D.E. Bloom, T. Cherian, C. de Quadros, S. Sow, J. Wecker, P. Duclos, and B. Greenwood, "The Future of Immunization Policy, Implementation, and Financing," *Lancet* 378 (2011): 439–48; and H. Rees and S.A. Madhi, "Will the Decade of Vaccines Mean Business as Usual?" *Lancet* 378 (2011): 382–85.

effective use of available resources. What are some of these challenges? The following are, in no particular order, 10 important issues.

#### Need for Focus and Agility amidst Competing Priorities

The scale of what is needed to improve immunization services and provide new vaccines previously available only to industrialized countries can give rise to an endless list of "priority" activities and objectives. Enterprises with many stakeholders often face these competing priorities, which have to be countered by a laser focus on impact, a top tier of high priorities, and the ability to take decisive and quick actions when the circumstances require.

The fact that it will take nearly two and a half years from the launch of the Decade of Vaccines in January 2010 to the endorsement of a Global Vaccine Action Plan by the WHA in May 2012 illustrates the dilemma faced and the limitations of top-down global initiatives. Such processes can potentially undermine or dampen the inherent excitement, enthusiasm, and momentum that an extraordinarily worthy cause generates.

#### Reaching Unvaccinated and Undervaccinated Children

Despite improvements in routine vaccination coverage during the past decade worldwide, regional and local disparities in vaccination coverage resulting from limited resources, competing heath priorities, poor health system management, and inadequate monitoring and supervision continue. The reasons for undervaccination and nonvaccination are multifaceted and often complex, and it is the most vulnerable populations in the low-performing, low- and lower-middle-income (LMIC) countries that are not receiving immunization services. These reasons may relate to immunization system factors and access to services or to parental knowledge and attitudes, cultural mores, and religious beliefs and are often specific to local circumstances.

Thus, the challenge is not only to document who is being missed but also to diagnose the "why" and to design innovative and targeted approaches to reach these children. Communications and social marketing research will be essential to achieving success. Civil society organizations, with their on-the-ground networks and know-how, will play a critical role in overcoming these barriers. The goal is to achieve equity in the availability and use of vaccines as a human right and core component of primary health care.

<sup>&</sup>lt;sup>8</sup> Centers for Disease Control, "Global Routine Vaccination Coverage, 2010," *Morbidity and Mortality Weekly Report* 60 (2011): 1520–22.

<sup>&</sup>lt;sup>9</sup> J.J. Rainey, M. Watkins, T.K. Ryman, R. Sandhu, A. Bo, and K. Banerjee, "Reasons Related to Non-vaccination and Under-vaccination of Children in Low and Middle Income Countries: Findings from a Systematic Review of the Published Literature, 1999–2009," *Vaccine* 29 (2011): 8215–21; and H. Rees and S.A. Madhi, "Will the Decade of Vaccines Mean Business as Usual?" *Lancet* 378 (2011): 382–85.

#### Strengthening Immunization and Health Services

One of the biggest challenges in the global immunization arena is to find links or synergies between the specific vaccine initiatives and the overall strengthening of the systems through which these vaccines are delivered. It is difficult to move beyond ideological and conceptual frameworks to measurable, practical interventions and solutions that have impact, particularly since in many instances these solutions are country and community specific. Clearly, "the devil is in the details"; essential elements of success include a rigorous diagnosis of the problems and creative, innovative, and sustained approaches to overcoming the system weaknesses and barriers that have been identified.

The GAVI Alliance's ill-fated initial effort to create an \$800 million health systems strengthening funding window had poorly defined objectives, vague and ineffective links between investments and measurably improved vaccination results, and little in the way of tangible outcomes; it provides a cautionary example of what not to do. The alliance has recovered from this misstep, has agreed to devote 15–25 percent of its program resources to cash-based programs aimed at strengthening country-level health systems as part of these countries' multiyear immunization plans, and now oversees a performance-based funding scheme focused on immunization systems that track immunization indicators, including degrees of coverage.

#### Maintaining Public Confidence in Vaccines

Unfounded fears about the safety of vaccines are a growing threat to the future of global immunization in the age of the Internet and social media, which allow mass dissemination of misinformation and opinions regardless of their accuracy or authenticity. <sup>10</sup> The emerging crisis of public trust in vaccines is no longer a phenomenon of the developed countries only, as antivaccination groups become more sophisticated and extend their global reach. The increasing number of vaccines in use and the complexity of vaccination schedules heighten the potential for public concerns and questioning.

To face these emerging challenges, countries and global immunization partners must make it a priority to build public trust and confidence in vaccines for the future, through implementation of such approaches as vaccine risk communication methodology, timely and accurate communication of information, implementation of surveillance systems for monitoring adverse events following immunization, ongoing public engagement to hear and better understand public concerns, and communications research to gain insights into the factors that affect public trust in vaccines.

4 | the future of global immunization

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<sup>&</sup>lt;sup>10</sup> H.J. Larson, L.A. Cooper, J. Eskola, S.L. Katz, and S. Ratzan, "Addressing the Vaccine Confidence Gap," *Lancet* 378 (2011): 526–35.

#### **Eradicating Polio**

Achieving and sustaining the eradication of polio through closer links to other global immunization initiatives is a moral imperative. Failure is not an option, given the negative impact it would have on the credibility of global public health for failing to achieve its objectives and the likely resurgence of polio. Despite many delays and setbacks, progress continues toward global polio eradication, including the historic absence of polio cases in India for more than 10 months (last case in January 2011).<sup>11</sup>

However, in its October 2011 quarterly report the Independent Monitoring Board overseeing progress toward achieving strategic milestones in polio eradication expressed its dissatisfaction with progress toward the end-2012 target date; it stated: "Polio simply will not be eradicated unless it receives a higher priority....We continue to believe that polio eradication should be treated as a global health emergency....To fail now would unleash widespread suffering and death on the world's most vulnerable children." Achieving polio eradication is a test of the global community's ability to achieve the other global immunization goals and objectives it has established.

#### Other Vaccines and Global Eradication

Other vaccine-preventable diseases, including measles and rubella, are on the horizon as candidates for global eradication, and these initiatives are learning lessons from the global polio eradication initiative, as well as from its mistakes. Such initiatives need to examine carefully the feasibility of eradication based on biological and technical factors, societal and political support, economic considerations, ethical issues, and links to health systems and delivery of other health interventions. In November 2010, the Strategic Advisory Group of Experts on Immunization (SAGE) of the World Health Organization (WHO) concluded that measles can and should be eradicated with a target date to be established in the near future, based on progress toward 2015 interim global and regional targets, and the WHO Executive Board agreed in January 2011.

Endemic transmission of rubella virus was interrupted in the Americas in February 2009, and major progress continues toward control of rubella and the prevention of congenital rubella

<sup>&</sup>lt;sup>11</sup> Centers for Disease Control, "Progress toward Interruption of Wild Poliovirus Transmission–Worldwide, January 2010–March 2011," *Morbidity and Mortality Weekly Report* 60 (2011): 582–86; and Centers for Disease Control, "Progress toward Poliomyelitis Eradication—India, January 2010–September 2011," *Morbidity and Mortality Weekly Report* 60 (2011): 1482–86.

<sup>12</sup> Reports from and information about the IMB are available at http://www.polioeradication.org/.

<sup>&</sup>lt;sup>13</sup> S.L. Cochi and W.R. Dowdle, "The Eradication of Infectious Diseases: Understanding the Lessons and Advancing Experience," in *Disease Eradication in the 21st Century: Implications for Global Health*, ed. S.L. Cochi and W.R. Dowdle (Cambridge, MA: MIT Press, 2011), 1–10.

<sup>&</sup>lt;sup>14</sup> Strebel et al., "A World without Measles"; and World Health Organization, "Meeting of the Strategic Advisory Group of Experts on Immunization, November 2010: Summary, Conclusions, Recommendations," *Weekly Epidemiological Record* 86 (2011): 1–16.

syndrome. <sup>15</sup> These global initiatives need to go forward as an integral part of the GAVI Alliance agenda and priorities. The recent decision by the GAVI Alliance Board to open a window of financial support for rubella vaccination campaigns, with rubella vaccine given in combination with measles vaccine (measles-rubella vaccine), will help intensify progress with measles while reducing congenital rubella syndrome in high-incidence countries. <sup>16</sup>

#### Achieving a Truly Global Alliance

Clearly, it is appropriate for the GAVI Alliance to focus mainly on the 71 low-income countries that qualify for GAVI support (this number will gradually become 57 countries as the rest, including India, transition away from eligibility for GAVI support). However, the global immunization community, with support from the GAVI Alliance, must be increasingly willing to take on issues collectively that transcend individual countries and that have regional and global implications. For example, the majority of the unvaccinated and undervaccinated children in the world soon will live in the LMIC countries, which are not eligible for GAVI support (with India's impending "graduation" from GAVI eligibility).

Furthermore, these countries also do not qualify for the considerably reduced prices available to the low-income countries for the new, more expensive vaccines that have been negotiated by GAVI with manufacturers, creating the paradoxical effect that low-income countries have been able to introduce new vaccines at a faster rate than the LMIC countries, which are having problems with affordability. Finally, global disease-specific initiatives and the infrastructure to support the overall vaccination enterprise, including vaccine-preventable disease surveillance and vaccination coverage assessment, would all benefit from a holistic approach and adequate, sustained investment.

#### Emphasizing Evidenced-based Decisionmaking and Quality Data

More than ever before, the development of global immunization policy must rely on quality data for decisionmaking. Fortunately, WHO restructured and fortified its primary advisory group (SAGE) in 2005, and it has since done an excellent job of providing policy and strategy recommendations on the use of specific vaccines, publishing WHO vaccine position papers, and

<sup>&</sup>lt;sup>15</sup> C. Castillo-Solórzano, C. Marsigli, P. Bravo-Alcántara, B. Flannery, C. Ruiz-Matus, G. Tambini, S. Gross-Galiano, and J. K. Andrus, "Elimination of Rubella and Congenital Rubella Syndrome in the Americas," *Journal of Infectious Diseases* (Supplement 2, 2011): S571–78; and S.E. Reef, P. Strebel, A. Dabbagh, M. Gacic-Dobo, and S. Cochi, "Progress toward Control of Rubella and Prevention of Congenital Rubella Syndrome—Worldwide, 2009," *Journal of Infectious Diseases* 204 (Supplement 1, 2011): S24–27.
<sup>16</sup> "Measles Initiative Hails GAVI Decision to Fund Rubella Campaigns," http://www.measlesinitiative.org/; and "GAVI Takes First Steps to Introduce Vaccines against Cervical Cancer and Rubella," http://www.gavialliance.org/library/news/press-releases/2011/gavi-takes-first-steps-to-introduce-vaccines-against-cervical-cancer-and-rubella/.

giving technical advice to WHO, the GAVI Alliance, and global partners. <sup>17</sup> In its deliberations, SAGE convenes working groups composed of SAGE members and experts in the specific fields under study to develop the most informed, evidence-based policies and recommendations. It also conducts transparent biannual plenary meetings that are open to members of the vaccine community. This favorable global environment is complemented by technical advisory groups for each WHO region and a major push to develop and support the work of independent national immunization technical advisory groups to advise their respective governments.

This tiered infrastructure (global-regional-national) for evidence-based immunization policy development is indeed worthy of sustained support. As noted above, sustained investments in vaccine-preventable disease surveillance, measurement of the disease burden, and the infrastructure for measuring vaccination coverage at the national and local levels are essential elements of the package of quality information and data needed for informed decisionmaking and for tracking the program impact of vaccines.

#### Closing the Vaccine Financing Gap

Immunization funding needs will grow markedly in the coming decade. <sup>18</sup> The global recession and resulting fiscal austerity have exacerbated the situation. Because new vaccines are the largest cost driver, financing the introduction of these vaccines will likely be the major challenge in low-and middle-income countries. Strong encouragement must continue, as well as improved accountability mechanisms, for countries to establish or expand their national budget lines and sustain their commitments to vaccine and immunization systems as a "contractual" condition for receiving funding from international partner organizations.

#### Achieving Country Ownership and Accountability

No factor is more important to achieving success in the coming decade than the willingness of countries to fully embrace the comprehensive agenda of immunization goals and objectives that lie ahead and to assume full ownership over their national immunization programs to achieve these goals. This commitment includes not only increased political will on the part of national authorities but also stepped up cofinancing; investments in the health workforce, including frontline health workers; strengthening the structures, processes, laws, regulations, and policies that support immunization programs so that they can reach every community; and putting in place an accountability framework with monitoring and supervision to ensure that best practices are emulated and that low performance has consequences.<sup>19</sup>

<sup>&</sup>lt;sup>17</sup> Levine et al., "The Future of Immunization Policy, Implementation, and Financing."

<sup>&</sup>lt;sup>18</sup> Ibid.; and Rees and Madhi, "Will the Decade of Vaccines Mean Business as Usual?"

<sup>&</sup>lt;sup>19</sup> "Global Vaccine Action Plan—An Immunization Agenda for the Decade (draft)."

## The Way Forward

The list of challenges presented above is not meant to be all inclusive, but it provides a glimpse of some of the major challenges global immunization partners and countries face as we collectively move ahead to address the global vaccine and immunization agenda. Licensed vaccines are available and in widespread use to prevent more than 20 different vaccine-preventable diseases, <sup>20</sup> with many more new vaccines soon to be available within the next several years. This development is a remarkable change from the situation only 10 years ago and is a tribute to what has been accomplished in the past decade.

While we can appreciate the successes and achievements of the past 10 years, this discussion brings us back full circle to the question of how the global community can best build on these successes, learn from its mistakes, and be most effective in using its resources wisely to extend the benefits of vaccines even further in the coming decade.

<sup>&</sup>lt;sup>20</sup> The list of diseases includes cholera, diphtheria, pertussis, Haemophilus influenzae type b, hepatitis A, hepatitis B, HPV, influenza, Japanese encephalitis, measles, mumps, polio, rubella, tuberculosis, yellow fever, meningococcal disease, pneumococcal disease, rotavirus, tetanus, typhoid, and varicella.



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