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WORLD HEALTH ORGANIZATION

GLOBAL VACCINE ACTION PLAN

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Introduction

As the world community confronts frightening headlines about the rapid spread of infectious diseases and viruses such as dengue fever, Ebola, HIV/AIDS, measles, and tuberculosis (TB), including multi-drug resistant tuberculosis (MDRTB) and extensive drug resistant tuberculosis (XDRTB), to name just a few, the demands for most affordable, effective, and widely available vaccines have increased commensurately. Vaccine development represents very significant opportunities for both public health advancements as well as potential profitability for those medical personnel and companies that create and market them. The World Health Organization recently reported that deaths from traditional vaccine-preventable diseases, such as diphtheria, measles, neonatal tetanus, pertussis, and poliomyelitis, were more than halved between 2000 and 2010, dropping from approximately 900,000 deaths annually in 2000 to approximately 400,000 in 2010.¹ Developing and disseminating affordable, effective, and safe vaccines throughout the world also directly addressed the Millennium Development Goals (MDGs), particularly goals 4-6 (reduction of child mortality; improving maternal health; combating HIV/AIDS, malaria, and other infectious diseases), and provides critical support for achieving Millennium Development Goals 2 and 3 (achieving universal primary education; promoting gender equality and empowering women and girls). In the post-2015 Sustainable Development Goals (SDGs), vaccine development and distribution are vital elements to meeting Goal 3 (Ensure healthy lives and promote well-being for all at all ages). Ensuring that the Global Vaccine Action Plan (GVAP) is implemented successfully throughout the world will require greater cooperation and coordination between national governments, particularly their respective health ministries, international organizations, including the WHO and the UN System, medical providers at all levels, the private sector, particularly pharmaceutical manufacturers and distributors, and interested civil society partners.

Scale of the Problem

The urgency of more rapid development and distribution of vaccines can be most readily reflected in the litany of news stories in recent years about the need for vaccines to combat

¹ World Health Organization (WHO), "Global Vaccine Action Plan 2011-2020" 2013 p. 16. The entire Global Vaccine Action Plan (GVAP) report may be accessed at: http://www.who.int/immunization/global vaccine action plan/GVAP doc 2011 2020/en/

cholera, Ebola², HIV/AIDS, various strains of influenza, poliomyelitis,³ shingles, and swine flu. WHO estimates that vaccines prevent approximately 2.5 million deaths annually⁴ and the benefits of these prolonged and enhanced lives are immense to their families, their communities, their countries, and to humanity as a whole. Enormous advances have been made in recent decades, but the stark reality is that vaccine coverage and distribution is very uneven. In 2010, "only 13% of the total high-income country birth cohort lived in countries that did not have pneumococcal vaccines in their immunization schedules. Of the total low-income country birth cohort, 98% lived in countries that did not have pneumococcal vaccines in their immunization schedules."⁵ While the variance in vaccine schedules is not always as vast as the above noted statistic for pneumococcal vaccines, it is abundantly evident that vaccine distribution and scheduling is far less common and/or comprehensive in the developing countries, especially the Least Developed Countries (LDCs), than in middle-income and high-income countries. Income, educational attainment of mothers, geographic distance from health centers and providers, and even cultural, ethnic, and religious differences all contribute to the wide variances seen in global vaccine development and distribution. Additionally, vaccines for diseases that traditionally affect poorer countries, and particularly tropical regions, are often not high priorities for pharmaceutical companies based in the highly developed world.

The Global Vaccine Action Plan

At the World Health Assembly (WHA) in May 2012, 194 member states of WHO agreed to the Global Vaccine Action Plan 2011-2020. In the process, these member states committed themselves to achieving the following 5 goals during the second decade of the twenty-first century: 1) achieving a polio-free world; 2) meeting vaccination targets in every region, country, and community; 3) exceeding the reductions in childhood mortality called for in Millennium Development Goal 4; 4) meeting global and regional elimination targets; and 5) developing and introducing new and improved vaccines and technologies.⁶ The following sections will examine the progress made as well as the remaining challenges to achieving these goals for the Global Vaccine Action Plan (GVAP).

Achieving a Polio-free World

The debilitating, and paralyzing, effects of polio (poliomyelitis) are today almost completely unknown throughout the vast majority of the world, other than references in history and medical textbooks. Just 25 years ago, however, the vast majority of the world's population lived in countries that had not eliminated polio; at the end of 2014, the World Health Organization (WHO), national health agencies, including the US Centers for Disease Control (CDC), and nongovernmental organizations (NGOs) such as Rotary International, are concentrating their efforts on eliminating polio in 3 countries: Afghanistan, Pakistan, and

² Joel Achenbach, "WHO reports that Dec. 1 goals for Ebola treatment and safe burials may not be met" *Washington Post* November 26, 2014.

³ Donald G. McNeil, Jr., "Polio's Return After Near Eradication Prompts a Global Health Warning" *New York Times* May 5, 2014.

⁴ WHO, "Global Vaccine Action Plan" 2013 p. 12.

⁵ WHO, "Global Vaccine Action Plan" 2013 p. 19.

⁶ WHO, "Global Vaccine Action Plan" 2013 p. 28.

Nigeria. Eliminating polio in these 3 countries will require a concerted partnership between all relevant stakeholders; one prominent recent example that these countries and the international community may look to is that of India's March 2014 announcement of polio elimination.

WHO's March 2014 pronouncement that India had accomplished 3 consecutive years without any new polio cases was justifiably greeted with both admiration and a desire to systematically analyze the contributing factors and reasons for India's success. Health professionals and international organizations assert that while many factors contributed to India's efficacy in preventing new polio cases, including sustained political will from government officials and civil society groups, the most important factor "belongs to the strong network of field workers, community health specialists and volunteers who worked tirelessly to ensure that no part of the country was too inaccessible, no child too far away to vaccinate."7 Other observers, including *The Wall Street Journal*, argue that the India's government and health providers' willingness to reach out to the Muslim minority community in India was essential to polio elimination. India's extensive use of data and "micro plans" about each community formed part of the "holistic" approach to eliminating polio that included the 2010 introduction of a bivalent vaccine that protected against multiple types of polio as well as a reinvigorated emphasis on personal hygiene, including frequent hand washing, exclusive breastfeeding of infants under 6 months and improved sanitation.⁸ India's success will only be sustained through continued vigilance regarding potential outbreaks as well as the elimination of polio in neighboring countries, including Afghanistan and Pakistan.

Meeting Vaccine Targets in Every Region, Every Country, Every Community

In order to eliminate some of the most glaring differences in health outcomes both between and within countries, national health ministries, health care providers, and related civil society partners, including private sector representatives such as pharmaceutical companies must fully commit themselves to reaching all vulnerable communities, particularly communities that have been traditionally underserved. The goal for 2015 is 90% vaccine coverage for all countries, with all communities achieving at least 80% coverage.⁹ Achieving and maintaining these levels of vaccine coverage will require that countries commit to immunizations as a health care priority that is integrated into their overall health system and that national health ministries and health care providers communicate more effectively with individuals and communities who fear that immunizations may lead to severe, long-term health hazards and impairments, including reproductive problems.¹⁰

Expanding vaccine coverage will also require very significant and sustained financial investments over the next 6 years. WHO projects that the cost for expanding vaccine coverage in the 94 low to lower-middle income countries will rise from between \$3.5 billion USD to \$4.5 billion to between \$6 billion USD and \$8 billion USD by 2020.¹¹ National governments must

⁷ Paromita Pain, "How India won over polio drop by drop" *AlJazeera* March 28, 2014.

⁸ Patralekha Chatterjee, "How India managed to defeat polio" *BBC News* January 13, 2014.

⁹ WHO, "Global Vaccine Action Plan" 2013 p. 26.

¹⁰ Shaimaa Khalil, "The parents refusing to vaccinate their children against polio" *BBC News* November 22, 2014. ¹¹ WHO, "Global Vaccine Action Plan" 2013 p. 75.

consider appropriate funding mechanisms for immunization campaigns, including from donor governments. This is also an area where civil society partners, including NGOs such as the Gates Foundation, may provide substantial assistance. A critical example of the effective collaboration between international organizations, including WHO, the United Nations Children's Fund (UNICEF), and the World Bank Group, national governments, and private sector and civil society partners, such as the Bill and Melinda Gates Foundation, is GAVI, the Vaccine Alliance. Canada recently pledged \$500 million Canadian dollars (approximately \$438 million USD as of early December 2014) to fund immunization efforts in developing countries.¹²

Increasing and regularizing vaccine funding for many diseases, particularly neglected tropical diseases (NTDs), is a vital component of any long-term strategy for meeting vaccine targets in countries and regions. Ensuring that existing vaccines are also effectively distributed is essential as well. During the 2009-2010 global swine flu pandemic, highly developed countries generated far more vaccine doses than required for their populations but after at least 10 months of concern and warning, only 2 of the 95 countries that originally reported not being able to access the vaccine had received any.¹³ Overcoming the lack of funding and prioritization of neglected diseases remains a critical goal; in 2013, only 4% of new drugs and vaccines approved since 2001 were for neglected diseases, including malaria and tuberculosis (TB).¹⁴ Governments, pharmaceutical companies, and citizens of highly developed, higher-income countries have many reasons to increase the funding for and improve the timely distribution of vaccines for neglected [tropical] diseases [(NTDs)], including that these diseases are increasingly found in higher income countries such as the United States, Japan and many European countries.¹⁵

Exceeding the Millennium Development Goal for Reduced Childhood Mortality

When the international community approved the Millennium Development Goals (MDGs), the 2015 target was a two thirds reduction in childhood mortality rates from 1990 levels. As progress was achieved throughout the 2000s, the international community resolved to exceed the 2015 targets for childhood mortality by 2020. Even with the very considerable progress made during the 15 years of the Millennium Development Goals (MDGs), the world failed to achieve a 2/3 reduction in childhood mortality by 2015; according to a September 2014 report released by UNICEF, in collaboration with other UN agencies and the World Bank, childhood mortality rates have been cut almost in half as compared to 1990 rates.¹⁶ While several regions, including Latin America and the Caribbean and East Asia and the Pacific, met their overall targets for achieving Millennium Development Goal #4, according to UNICEF, without even greater progress in many countries, and particularly throughout sub-Saharan Africa as well as the 5 individual countries that account for approximately half of all childhood deaths before

¹² GAVI, The Vaccine Alliance, "Canada commits C\$ 500 million to support immunisation in developing countries" November 28, 2014.

¹³ Donald G. McNeil, Jr., "Progress is Slow on Moving Surplus Swine Flu Vaccine to Countries that Need It" *New York Times* February 1, 2010.

 ¹⁴ Donald G. McNeil, Jr., "Neglected Diseases Are Still, Well, Neglected" *New York Times* October 28, 2013.
¹⁵ Donald G. McNeil, Jr., "Europe: Increase in Tropical Diseases is Aided by Migration and Weak Economies" *New York Times* August 1, 2011.

¹⁶ Rick Gladstone & Somini Sengupta, "Despite Declines, Child Mortality and Hunger Persist in Developing Countries, UN Reports" *New York Times* September 16, 2014.

the age of 5 (India 21%; Nigeria 13%; Pakistan 6%; Democratic Republic of the Congo 5%; and China 4%), the world will not achieve the 2/3 reduction from 1990 childhood mortality rates until 2026.¹⁷

Exceeding the Millennium Development Goals/post-Millennium Development Goals target of a 2/3 reduction in childhood mortality will require enhanced and improved vaccine distribution to specifically address the most problematic health concerns for infants and young children. WHO estimated that in 2013 there were still 1.5 million vaccine preventable childhood deaths globally, many from diseases such as diphtheria-tetanus-pertussis (DTP), malaria, measles, pneumococcal disease, and rotavirus.¹⁸ While vaccine coverage for DTP improved to 84% worldwide, nearly 22 million children were still not vaccinated in 2013; 10 countries (Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Mexico, Nigeria, Pakistan, South Africa, and Viet Nam) accounted for 70% of all the children not vaccinated against DTP in 2013.¹⁹ Ensuring that all of these countries and their respective regions meet their elimination targets for these vaccine preventable diseases will require a sustained emphasis on achieving a truly equitable distribution of vaccines, with a particular emphasis on protecting the most vulnerable populations, including children.

Meeting Global and Regional Elimination Targets

Reaching the appropriate global and regional elimination targets for vaccine preventable diseases will require improved coordination and collaboration between national ministries of health as well, WHO, and the respective WHO regional health organizations, such as the WHO Regional Office for the Americas/Pan American Health Organization (PAHO). Governments and their regional and civil society partners must also emphasize the importance of constant and accurate reporting and monitoring of relevant health and vaccine statistics to ensure that global and regional elimination targets are met and continue to be met in the future. Accurate reporting of vaccine rates are critical to maintaining public trust, particularly given the prevalence of concerns about potential side effects of vaccines, including the much publicized, and disputed, claims linking the measles, mumps, and rubella (MMR) vaccine to increased risk of autism spectrum disorders in children.²⁰ In the case of vaccines for the human papillomavirus (HPV), resistance to obtaining vaccines that may be highly effective in protecting against cervical cancer often stems from concerns about adverse health and physical side effects as well as concerns by some parents and religious authorities that the vaccine may increase promiscuity amongst teenagers and young adults.²¹

Developing and Introducing New and Improved Vaccines

¹⁷ UNICEF, "UNICEF Data: Under Five Mortality" 2014.

Found at: http://data.unicef.org/child-mortality/under-five

¹⁸ WHO, "Global Immunization Data" July 2014. Found at:

http://www.who.int/immunization/monitoring_surveillance/global_immunization_data.pdf?ua=1

¹⁹ WHO, "Global Immunization Data" July 2014.

²⁰ Gardiner Harris, "British Journal Retracts 1998 Paper Linking Autism to Vaccines" *New York Times* February 2, 2010.

²¹ Sabrina Tavernise, "A Push for HPV Vaccinations" New York Times March 25, 2013.

In cases where there is no vaccine or suitable medicine to treat a disease, pharmaceutical firms and academic research organizations must fulfill their missions to find one. However, neglected tropical diseases (NTDs) are neglected specifically because they do not provide these institutions with incentives to invest in the necessary research and development. In recent months, the starkest example of this lack of attention to a tropical disease is the recent Ebola outbreak in West Africa. In the mid-2000s, American and Canadian researchers announced that they had developed an Ebola vaccine that was 100% effective in monkeys but no human trials were conducted for nearly ten years.²² Dengue fever, a very serious health threat in the Amazon and many other tropical areas, is finally reaching the stage where clinical trials for vaccines are being conducted.²³

When pharmaceutical firms decide to embark on a project to develop a treatment for a particular illness, they perform a financial analysis to see whether the project is profitable. The firm estimates the probability of discovering a drug or vaccine as well as the cost of developing it. Development is often the most expensive phase, because it involves performing large scale clinical trials in which the drug must be administered to a wide population (that both have and do not have the targeted disease). These trials are often spread into three different phases. Together these trials will help the firm, the regulatory agencies (such as the FDA in the U.S) and other agencies that are paying for the ultimate drug (such as Medicare or in the case of a neglected tropical disease (NTD), a nonprofit) determine whether the new drug is safe, more efficient at treating the disease than current treatments, and or easier to prescribe and administer than current drugs. According to the Center for Information and Study on Clinical Research Policy (CISCRP), these trials can make up 60% of total drug development costs.²⁴ Given the large investment needed in both research and development, many diseases are neglected simply because the payout does not justify the investment. In the case of vaccines, not only is the research expensive, but the manufacturing costs can also be high. Many firms have chosen to donate drugs at cost (or even sometimes for free) to governments of poor countries but this apparent charity is not very sustainable.²⁵ While research and development (R & D) costs are often significant factors for pharmaceutical companies, it is important to bear in mind that in many instances, taxpayer-funded research grants often pay for substantial elements of pharmaceutical research and development (R & D); in 2011, US-based pharmaceutical companies spent \$39 billion USD on research while the National Institutes of Health (NIH) contributed an additional \$31 billion USD.²⁶

²² Denise Grady, "Ebola Vaccine, Ready for Test, Sat on Shelf" New York Times October 23, 2014.

²³ Andrew Pollack, "First Vaccine for Dengue Fever Shows Promise in 2nd Big Trial" *New York Times* September 3, 2014.

²⁴ <u>http://www.ciscrp.org/professional/facts_pat.html#2</u>

²⁵ <u>http://www.cptech.org/ip/health/neglect/</u>

²⁶ Peter Whoriskey, "As drug industry's influence over research grows, so does the potential for bias" *Washington Post* November 24, 2012.

Conclusion

Achieving greater overall health outcomes for the world's people is essential to achieving sustainable human development and to realizing the lofty ideals of the previous Millennium Development Goals (MDGs) and the contemporary Sustainable Development Goals (SDGs), even if those goals will not be met by 2020 or even 2030. Improving vaccine coverage for the poorest and most vulnerable communities must become a true global priority and this will be reflected in improvements in the development and delivery of affordable, effective, and safe vaccines, particularly for previously ignored or neglected tropical diseases (NTDs). Successful implementation of the Global Vaccine Action Plan (GVAP) will require sustained political will and substantial, and possibly growing, financial commitments over the next 5+ years but the rewards for the world's countries and peoples are of inestimable benefit and value.

Guiding Questions

What are the most prevalent and/or life-threatening vaccine preventable diseases and viruses affecting your country? What are the most prevalent and/or life-threatening vaccine preventable diseases and viruses affecting neighboring countries and/or your region?

How effectively is your country providing vaccine coverage for these various diseases and viruses? Has your country achieved 90% national vaccine coverage and at least 80% vaccine coverage in every community as called for in the Global Vaccine Action Plan (GVAP)?

What steps has your government taken in recent months and/or years to improve vaccine coverage or to develop new and better vaccines? What steps have been taken by the respective regional offices of WHO and related civil society partners to improve vaccine coverage?

How might the UN System, including WHO and UNICEF, and the larger international community most effectively encourage and/or induce pharmaceutical manufacturers and distributors to increase their focus on traditionally neglected tropical diseases (NTDs)?

How might the international community most effectively achieve the 5 major goals enumerated in the Global Vaccine Action Plan (GVAP) by 2020? What are the most significant obstacles that the individual countries and the international community in general are likely to confront as they seek to achieve these strategic immunization goals?

As the global community approaches 2020 and the end of this decade for the Global Vaccine Action Plan (GVAP), what are the most promising and important steps, initiatives and/or projects that the international community, including WHO, need to consider and/or adopt for the future?

World Health Assembly Resolutions:

World Health Assembly 70/25, "Global vaccine action plan" March 20, 2017.

World Health Assembly 70/20, "Addressing the global shortage of, and access to, vaccines" April 24, 2017.

World Health Assembly 65/22, "Draft vaccine action plan" May 11, 2012.



Immunization coverage with DTP3 vaccines in infants (from <50%), 2016



Source: WHO/UNICEF coverage estimates 2016 revision, July 2017. Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization. 194 WHO Member States. Date of slide: 19 July 2017

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