A Private Sector Review for Vaccine
Delivery Strategies in Developing Countries

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A Private Sector Review for Vaccine Delivery Strategies in Developing Countries

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Abstract

The Bill and Melinda Gates Foundation (BMGF) was founded in 2000 after Bill Gates took his first trip to India to help administer polio vaccines to children in 1997 and in conjunction with a merger with the William H. Gates Foundation shortly thereafter. His foundation was built on the belief that the power of personal computing could enable everyone, everywhere with a tool to benefit the world. Within a couple of years of its founding, the Gates Foundation began a partnership with the Global Alliance for Vaccines and Immunizations (GAVI), along with other global health organizations, policymakers, researchers, and donors. Since then, their support has involved deliveries of polio vaccines to India, HIV/AIDs prevention in India, anti-malaria research in Africa, research library development in Botswana, Lithuania, Latvia, Romania, Ukraine, and Poland; among various other medicinal and environmental initiatives. Whether in Tanzania, Niger, Pakistan or elsewhere, the need for a robust medical supply chain infrastructure is prevalent. Getting vaccines from their manufacturer to some of the most remote places on Earth requires major investment, technological innovation, cultural changes, and improvements in security to name only some of the issues.

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Literature Review

The referenced journal articles, along with several organizations' white papers, related web site information, and sources directly from the Bill and Melinda Gates' Foundation, were assembled by order of section relevance. Starting with a basic introduction to the what, why, and how of a vaccine supply chain, the articles where utilized in order to present a brief background of vaccine delivery, a review of innovative cold storage devices, and a look at the steps involved with a public-private vaccine supply chain partnership; finally concluding that there is no one solution to the logistical challenge of transporting and distributing vaccines globally. This is accomplished under the auspices of how a private-public partnership with an organization such as the Bill and Melinda Gates Foundation is beneficial to both ends of that spectrum.

Several of the journal articles were derived from the journal *Vaccines*, which proved to be indispensable as its various authors, several supporting each other on and contributing to different articles, provided some of the most comprehensive and methodical research into the issue at hand. Further, the Bill and Melinda Gates Foundation's own web site and numerous white papers lead to further information and provided extended links to other agencies, such as USAID and Doctors Without Borders, to supplement the public-private partnership endeavors. Additional journal articles from the BBC and journals involving logistics, supply chains, and even finance help further allow for additional information, while also expanding on the topic at hand. Finally, the author's own visit to the Museum of History and Industry (MOHAI) in Seattle, WA provided a physical examination of the cold storage device discussed.

Background. The need for vaccines and their delivery methods is not a new process, rather extends back in history at least 1,000 years. New methods, continuously being developed, have consistently improved their delivery, effectiveness, and impact. Starting with information

provided in several white papers from the Bill and Melinda Gates Foundation, a brief history of that organization, its goals, and mission provided a launching point for the paper. Recent BBC articles were used to explore near real-time updates on the fight to eradicate Polio from Pakistan, something that the Gates Foundation has been heavily involved with.

Authors Francis, D.P., Du, Y.P., and Precioso, A.R. (2014) provided a detailed analysis of the history of vaccine delivery programs dating back 200 years prior, noting that there have been three "eras" of innovation and successes that included 1977 with the last case of small pox, improvements in childhood vaccines from the 1950s-1970s, and the creation of the first recombinant protein vaccine for hepatitis B in 1986. They explained that the fourth era, now underway, involves improvements in middle income countries being able to produce and distribute vaccines internally. They concluded that the progress in worldwide vaccine production and application has resulted in disease control successes that have stimulated even more interest in both developing new vaccines and improving the delivery of existing ones.

The Increasing Role of Manufacturers From Middle Income Countries found in *Vaccine* 32, 5,259-5,265, provided a brief history of the vaccine development from Medieval Europe to the modern world. This allowed for a better understanding of the complexities and longevity the vaccine development, supply, and distribution have endured over several centuries.

Supply Chain Segmentation. Reviewing the global supply chain sectionally, or by individual segments, can improve delivery by taking on smaller challenges separately to achieve an overall larger success. Researchers Allain, Goentzel, Bates, and Durgavich (2010) reviewed how supply chain segmentation offers a solution to consolidate program-specific supply chains under the idea that public health initiatives do not fall under a one-size-fits-all category. Supply chain segmentation, a strategic tool, manages a wide range of products and improves efficiency

by identifying similar characteristics in the products and/or its customers, who, in this case, are the service delivery points. This is particularly important in vaccine delivery due to the frequent remote distribution destinations and obstacles in achieving delivery.

While applying the HERMES method, an article by Lee, B.Y., Connor, D.L., Wateska, A.R., Norman, B.A., Rajgopal, J., Cakouros, B.E., Chen, S.I., Claypool, E.G., Haidari, L.A., Karir, V., Leonard, J., Mueller, L.E., Paul, P., Schmitz, M.M., Welling, J.S., Weng, Y.T., and Brown, S.T. (2015) was utilized as it examined vaccine supply and distribution in three poorer countries, an underlying premise of this paper. Using this methodology, they then compared three sample countries' supply chains, comparing the cost and impact of alternative options. They concluded that a four-tiered design template could suffice, but more tailored designs are likely necessary.

Outsourcing Delivery to Remote Locations. Delivering vaccines to remote and/or Third World countries pose numerous challenges not experienced in more developed regions of the world. Being the primary research of this paper, White Paper information was extracted from various World Health Organization (WHO) and the USAID Deliver Project's efforts, in conjunction with agencies such as the Bill and Melinda Gates Foundation, in supplying vaccines to some of the poorest and remote regions of the world. This also involved a brief review of the security risks involved, a topic that could be a research paper in its own right. The USAID white paper examined the potential opportunity for public health sectors, anywhere in the world, to partner with third party (3PL) logistics providers. It provides information for supply chain managers in public health positions with the whys, what, and how to outsource public health supply chains. Several country examples are included. A 2012 White Paper from the World Health Organization (WHO) detailed various reasons why outsourcing supply chain assistance is

necessary for public institutions, particularly in low and middle-income countries. The paper also provided a comparison to help determine whether outsourcing is a viable option.

A different White Paper by Hessel (2009), examined the strain on the world's vaccine production and distribution in the event of a global influenza pandemic. Following a pandemic declaration, the priority will be to deliver as much vaccine in as short a timeframe as possible. While steps have been taken to increase the mass production of some vaccines in such an event, an equally robust and timely distribution network will also be required. This includes working with government officials to streamline key procedures, while establishing flexibility in supply formats to maximize the speed of delivery. Similarly, the deployment of large quantities of vaccines in an emergency situation requires appropriate transport infrastructure and the distribution of associated medical supplies. Further, an additional White Paper by JSI Health Logistics White Paper (2015), in partnership with the Bill and Melinda Gates Foundation, expanded upon the Decade of Vaccines goal in controlling or eliminating many diseases by 2020. The paper highlighted several supply chain solutions for delivering vaccines while reviewing the typical supply chain functional components.

Lemmens, S., Decouttere, C., Vandaele, N., and Bernuzzi, M. (2016) showed how complex supply chains become even further challenged when vaccines are the commodity being manufactured, stored, and transported. The authors developed tables and checklists for logisticians to apply when determining how best, most efficiently, and how much product should be developed and ordered given a range of uncertainties.

Financial Support and Costs. Beyond the physical challenges of delivery, the vaccine supply chain is more often than not an expensive endeavor, one not likely capable of being supported by solely private or public institutions alone. Pauly M.V. (2015) then viewed the

public-private partnership role in the vaccine supply chain from a financial standpoint. It seems that higher costs are required to develop the vaccines themselves versus actually supplying them to remote parts of the world.

An article by Reveiz K.S. (2012) from the Journal of Management in Engineering was included as he concluded that despite the costs, the roles of public and private institutions are mutually beneficial, and indeed necessary, for overcoming a variety of risk factors in developing countries.

Mvundura et al (2015) provided an additional detailed vaccine supply chain cost analysis, using Kenya and Tanzania as specific country examples. The author provided a detailed review of how public-private partnerships with regards to financing, developing and distributing vaccines can be beneficial, the central theme to this research paper. He argued that the high costs of vaccines may act as an inhibitor to supplying them to third-world countries, but that through a shared effort, those costs could be reduced, while still allowing vaccine manufactures profitability.

Yadav, Lydon, Oswald, Dicko, and Zaffran (2014) detailed that one of the primary objectives of the National Immunization Programs (NPIs) is to enhance immunization supply chains to make vaccine delivery more efficient, effective, and sustainable. They showed how integration with other supply chains may help in achieving this goal.

The remaining unknown however is whether or not cost savings can be achieved through this endeavor. Research by Assi, et al. reviewed the various levels of bureaucracy involved with most vaccine supply chains and whether or not removing even one of them would help improve efficiencies. They compared Niger's four-tier approach (central, regional, district, and integrated

health centers) to a three-tiered process by removing the regional level. The group concluded that removing the regional level from Niger's vaccine supply chain could substantially improve vaccine availability as long as certain adjustments to shipping policies and frequencies are implemented parallel to the change.

Charkaoui, Ouahman, and Bouayyad (2012) continued this examination by showing that logistics in Morocco as the country is in the early stages of developing a supply chain program that does not solely involve international assistance. They noted that the country has three inherent constraints involving structural, organizational, and institutional concerns. By partnering with private sector in-country, Morocco is aiming to overcome these challenges by developing a national network of logistics zones, optimizing supply flow, incentivizing emerging logistics agencies, improving educational training programs for the logistics trade, and installing a measurement and regulatory regime.

Lydon, P., Raubenheimer, T., Arnot-Kruger, M., and Zaffran, M. (2015) aimed to shed light on the value proposition of outsourcing by documenting the specific experience of the Western Cape Province of South Africa. The results from this analysis confirmed some of the theoretical benefits of outsourcing to the private sector. However, there are several policy and practice implications that developing countries should be mindful of when considering engaging the private sector. While outsourcing can help improve the performance of the vaccine supply chain, it actually has the potential to do the reverse if done incorrectly.

Kumar and Blair (2913) applied a macro-level comparison of U.S. healthcare as a business system to that of the nation's food supply chain operations. Supply chain strategies for reducing the cost of transportation, improving the quality and longevity of food, and a total cost of ownership are shown to potentially be equally beneficial to the healthcare industry as it is to

the food supply chain. They noted that improving the medical supply chain in the United States could result in savings similar to those experienced by food suppliers.

Keeping in-line with the focus on costs, Mvundura, M., Lorenson, K., Chweya, A., Kigadye, R., Bartholomew, K., Makame, M., Lennon, T.P., Mwangi, S., Kirika, L., Kamau, P., Otieno, A., Murunga, P., Omurwa, T., Dafrossa, L., and Kristensen, D. (2015), examined a variety of costs associated with vaccine supply chains, including resource-use data from cold chain, distribution systems, and health care worker time in Kenya and Tanzania to determine the costs against service delivery points (SDPs). Data on the annual quantities of vaccines distributed to each facility, and the occurrence and duration of stockouts were collected from stock registers. They concluded that the average cost per dose of vaccine was less than the supply chain costs associated with distributing the vaccine and that both countries incurred month-long stockouts. The authors also noted that the government of Tanzania made investments in preparation for planned vaccine introductions following the study, which lead to declines in the per dosage costs.

Storage Options. While costs and delivery methods are integral parts of the vaccine delivery challenge, there are various storage and container distribution options. As such, the paper then examined the types of storage devices required, along with innovations for, the cold storage of vaccines. While the Bill and Melinda Gates Foundation's site and white papers, along information gathered from the MOHAI, provided most of the details, additional information was found in articles from Kristensen et al (2016), Karp (2015), Yadev (2014), and Haidari et al (2015). Kristensen, Lorenson, Bartholomew, and Villadiego assessed the challenges with storing temperature-controlled vaccines, the need to improve vaccine stability, and potential for short-term storage and transportation of vaccines in a controlled-temperature supply chain. The authors noted that improving cold storage and delivery alone, while extremely important, will not

suffice, rather the need to improve the vaccine stability themselves will also greatly aid in this endeavor. Again, most of these articles came from the journal Vaccine, which provided a plethora of information on the topic being reviewed.

Cheng, S-L., Norman, B., RAjgopal, J., and Lee, B. (2015) expanded upon the insight provided by the Gates Foundations' vaccine cold storage device, what they termed as PCDs. The group examined cases with real use data from a representative country and presented a model that captured the various tradeoffs that must be considered in developing a suitable PCD, and also provided further guidance on what would constitute a useful, robust and economical design.

Haidari, Conor, Wateska, Brown, Mueller, Norman, Schmitz, Paul, Rajgopal, Welloing, Leonard, Chen, and Lee (2013) reviewed the emphasis typically placed on stationary storage needs for temperature-controlled vaccines versus the interplay with transporting such goods. They group studied how to relieve transportation bottlenecks which increases vaccine delivery. They concluded that there needs to be a mix of storage facilities combined with a robust delivery system. Additional research by Haidari, et al. considered how the design of the primary container may affect the distribution of the vaccine, its resulting cost, and whether the vial is ultimately utilized. To accomplish this, the group partnered with the WHO to study the results from the delivery of different vaccine containers in the Republic of Benin. The group concluded the size of the vaccine container can have a considerable impact on the logistics costs, delivery reach, and bottleneck reductions but that the size needs to be determined by the goal of the outreach program being undertaken to utilize the best containerized method.

Karp, Lans, Esparza, Edson, Owen, Wilson, Heaton, Levine, and Rao (2015) combined efforts to review that the need to keep vaccines cold despite often being used and transported in high temperature environments requires vaccines that are more temperature robust. This is

especially true in low and middle-income countries, often with limited access to electricity. They examined a variety of options, included cold chain technology and supply chain system designs, and estimated that such transportation means do not necessarily have to be costly.

An article written by Brown, S.T., Schreiber, B., Cakouros, B.E., Wateska, A.R., Dicko, H.M., Connor, D.L., Jaillard, P., Mvundura M., Norman, B.A., Levin, C., Rajgopal, J., Avella, M., Lebrun, C., Claypool, E., Paul, P., and Lee. B.Y. (2014) examined the costs associated with new vaccine introductions and the strains that can place on vaccine supply chains. In partnership with the government of Benin, the group compared four options against a computational model that included: consolidating the commune level to a health zone level, removing the commune level completely, removing the commune level and expanding delivery to a dozen department stores, and adding shipping loops during delivery. The authors concluded that while a combination of any of the approaches lead to improvements, the best approach involved merging health zone change with enhanced delivery loops. This continues the theme throughout the paper expounding the need for public-private partnerships for innovation, improved efficiencies, and reducing costs.

Public-Private Partnerships. As previously noted, it has been shown that vaccine delivery is likely not able to be supported by public institutions alone. The need for public-private partnership is acute. Articles by Mkoka et al (2014) and Sturchio et al (2012) were utilized as they examined a more operational flow for manufacturing and distributing vaccines to not only Third World countries, particularly in Africa, but also as part of the United States' plan for AIDs relief. Mkoka, Goicolea, Kiwara, Mwangu, and Hurtig (2014) studied the drug and medical supply constraints experienced by medical professionals, particularly those providing obstetric care, in Tanzania. They noted that the unreliability of necessary drugs and other

medical supplies, insufficient budgets, and lack of governmental support challenges the maternal health care system in the country. The article's goal was to raise awareness, while also pointing to readily available areas for support, for those offering outside assistance.

Stuchio and Cohen (2012) detailed how the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), established in 2003, is touted as being a successful bilateral program that successfully integrated public and private collaborations. As an example, the authors noted how PEPFAR's Supply Chain Management System utilized private industry's best logistics practices.

Rebeiz (2012) examined the acute rise in public-private partnership (PPP) in developing countries. He noted how these collaborations are typically complex in nature, require capital, require technological innovation, incur high risks, and usually involve long-term relationships. However, PPP project represents a unique opportunity to leverage its core competency and achieve competitive advantage in both domestic and foreign markets.

Finally, items included in the conclusion were found in BBC articles, through a study of a recent UPS drone program, and from the European Influenza Working Group provided by Hessel et al (2009). That conclusion being that is takes an understanding from all of the above mentioned topics, along with joint public-private partnerships, to successfully manufacture, supply, and distribute life-saving vaccines that require cold storage temperatures to some of the most in-need and hard to reach places on the planet.

Introduction

As the sun reaches its zenith, blasting those beneath it in a scorching heat, making the already dry land somehow even more arid, a long line of people are waiting. They are not waiting for food or water, rather they are waiting for life-saving medicines to vaccinate against diseases such as Polio. Many are skeptical, not only of the drugs being administered, but also due to the ever-present threat of attacks from militants who see such medicine as being against their religious beliefs.

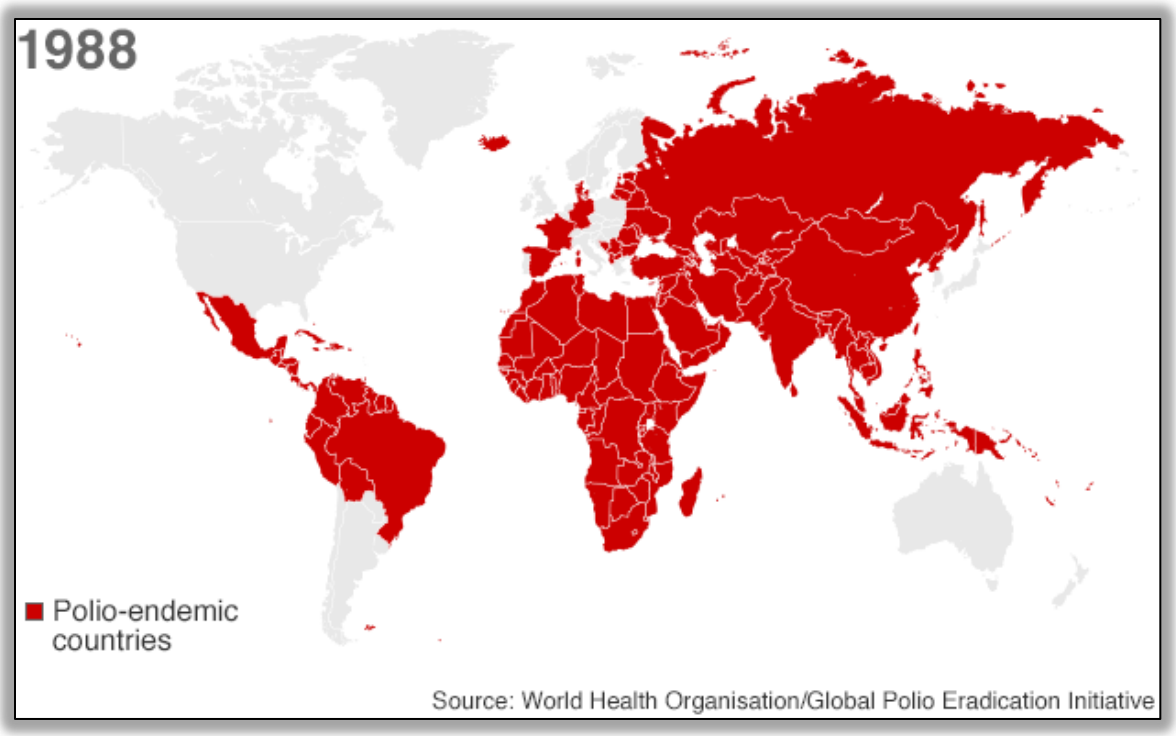
For much of the world, diseases, such as polio, measles, and others no longer pose any major risks to the populace. However, in many Third-World countries, such as Pakistan, Afghanistan, and much of Africa, particularly Nigeria, disease long-since eradicated elsewhere remain a daily threat these country's citizens. In 1988, 125 countries had circulating poliovirus, with only 4 countries considered to be undergoing a polio endemic by 2010 (Gates Foundation White Paper 2011). Concurrently, the Western Hemisphere was certified polio-free in 1994, and the larger Western Pacific region, free by 2000. For example, Pakistan reported its highest number of case of Polio in late 2014 in more than 15 years (BBC News 2014). Most of this volume came from north-western tribal areas that are highly contested by a variety of militant groups. Suspicions over vaccine delivery programs particularly took a turn for the worse following the United States' tracking and ultimate termination of al-Qaeda leader Osama Bin Laden in Pakistan in 2011. Many are suspicious over rumors that the U.S. government used such aid programs to cover its tracking activities; an accusation the government has not necessarily refuted (BBC News 2014). The decline in polio in the remaining parts of the world is attributable to an overall increase in polio vaccines and education, but also through the development of better

vaccines, such as the oral polio vaccine (OPV), and innovative distribution techniques are helping to ensure people are receiving the necessary medicines, even in conflict zones.

Security risks remain extreme for many of the regions receiving vaccination aid, however as equally complex is the logistical process for getting temperature sensitive medicine to often arid and remote locales. Delivery programs require a collaborative effort between public and private organizations to achieve safe, sustainable, and effective delivery. Where all of the population is accessible and cold supply chain is maintained, at least 90% of the 40 million or so children are inoculated repeatedly during five to six monthly campaigns (Khan 2015). Formed in 1988, the Global Polio Eradication Initiative (GPEI) has reduced incidences of polio down by 99% through use of supplementary immunization activities (SIAs) (Gates Foundation White Paper 2011). However, as the BBC reported from Pakistan in 2014-2015, the threat has not been entirely removed. Partnerships between governments in these hard-struck areas with organizations, such as the Bill and Melinda Gates Foundation, have led to the eradication of smallpox globally. Now, the Gates Foundation is aiming at removing other diseases, especially polio, from the Earth as well. The Gates Foundation has invested more than one billion dollars in polio eradication through GPEI. While not the sole private organization driven to stop diseases, the Gates Foundation is on the leading edge of investing in and developing vaccine supply chain delivery. Based at the World Health Organization (WHO), GPEI has the coordinating function for the global effort in polio eradication through partnerships with private organizations, Rotary International, the U.S. Centers for Disease Control and Prevention (CDC), and the United Nations Children's Fund (UNICEF). Additional sources of private-public support come from agencies as the Global Alliance for Vaccines and Immunizations (GAVI), USAID, Doctors Without Borders, and Medecins Sans Frontieres (MSF).

Vaccines are often expensive for the world's poorest countries, and unreliable transportation systems and storage facilities further increase the difficulty in preserving vaccines that require refrigeration to remain effective. While such organizations have learned that polio delivery requires a multi-pronged approach involving overcoming cultural, geographical, and security risks, this paper attempts to highlight the innovation employed under public-private collaboration involving the Bill and Melinda Gates Foundation's development of a cold storage device that has greatly aided in the delivery of polio vaccines to some of the most inhospitable regions of the Earth.

"Vaccines do not behave like commodity goods," Lemmens, Decouttere, Vandaele, and Bernuzzi explained in a 2016 research paper. ". The complexity of supply chain design increases," the authors continued, "with the number of stages, products and integrated decision levels" Lemmens, et al. 2016). This already complex process because even more so when requirements, such as cold transport and storage, are required as with vaccines. Vaccines differ from other products in the chemical and pharmaceutical industry. The active ingredient of a vaccine is an antigen which is typically a large complex molecule that is difficult to characterize in vitro (Moalla 2007).



Map 1: Global Polio Cases, 1988

Map 2: Global Polio Cases, 2015

Vaccine Delivery Background

There are several important eras, along with specific dates, in the history of successful vaccine delivery. October 1977 saw the last case of community-acquired smallpox globally, several childhood diseases, such as polio, were eradicated in most of the world during the 1950s-1970s, and 1986 witnessed the licensing of the first vaccine for hepatitis B (Francis, Du, and Precioso, 2014, 5,259). The scientific advances made with vaccines over the past 200 years, "enabled production of a low cost, heat stable vaccine that was easy to reconstitute and deliver. The supply of millions of doses of…highly effective vaccine[s] enabled the successful eradication of [several] deadly disease[s]" (Francis, et. al. 2014, 5,259). The 1980s introduced a new era of global vaccine manufacturing and delivery. "The primary focus at that time aimed at the delivery of the recommended routine immunizations to all children of the world" (Francis, et. al. 2014, 5,261). Smallpox eradication became an early target, followed by whooping cough vaccine (DTP), malaria, polio, and many more. The success in distributing DTP for example, showed a particularly impressive increase from about 20% of the world's children being administered to 75% by 1990 (Francis, et. al. 2014, 5,261).

For further example, Figures 1 and 2 show the advancement of polio vaccines globally in a span of a little less than three decades. The remaining areas of concern, most involving extremely difficult logistical challenges, are where private-public partnerships, such as that with the Bill and Melinda Gates Foundation, remain aggressive in combating diseases.

The success of these efforts were not the sole work of various governments, rather a combination of public and private organizations working (and learning) together lead to such positive results. In India for example, one study showed that of the three original government run vaccine manufacturing endeavors, only one had signs of success. Whereas, private manufactures

produced and distributed far more vaccines (Francis, et. al. 2014, 5,264). China too has seen successes, although the form of government control over the vaccine industry is a debatable discussion being truly public-private. “The progress in worldwide vaccine production and application,” one group of researchers surmised, “has resulted in disease control successes that have stimulated even more interest in both developing new vaccines and improving the delivery of existing ones” (Francis, et. al. 2014, 5,265).

Image 1: The Museum of Human Achievement and Innovation in Seattle, WA has a wall-size map depicting the global reach that the Gates Foundation has regarding vaccine delivery. Source: Author’s photo.

About the Bill and Melinda Gates Foundation

With a goal of preventing, "more than 11 million deaths, 3.9 million disabilities, and 264 million illnesses by 2020 through high, equitable, and sustainable vaccine coverage and support for polio eradication" the Bill and Melinda Gates Foundation has set the bar in creating collaboration between governmental and private organizations, while also challenging innovation to allow their goals to be achieved. An estimated 1.5 million children die each year, one every 20 seconds, from vaccine-preventable diseases such as diarrhea and pneumonia, and tens of thousands of other children suffer from severe or permanently disabling illnesses (Gates Foundation.org).

> ***"First you have to have money. You have to be able to buy vaccinations for children. And sometimes they only cost 13 cents. Sometimes they cost about $4. But if we use an alliance that we have, a public-private partnership, to procure those vaccines, pharmaceutical companies will make them and the supply chain actually works in these countries to get vaccines out. It's amazing but it does."*** – Melinda Gates, Bloomberg TV, March 10, 2011

The Bill and Melinda Gates Foundation was founded in 2000 after Bill Gates took his first trip to India to help administer polio vaccines to children and a merger with the William H. Gates Foundation. His foundation was built on the belief that the power of personal computing could enable everyone, everywhere with a tool to benefit the world. (Gates Foundation.org).

Within a couple of years of its founding, the Gates Foundation began a partnership with the Global Alliance for Vaccines and Immunizations, along with other global health organizations, policymakers, researchers, and donors (see more about GAVI below). Since then, their support has involved deliveries of polio vaccines to India, HIV/AIDs prevention in India,

anti-malaria research in Africa, research library development in Botswana, Lithuania, Latvia, Romania, Ukraine, and Poland; among various other medicinal and environmental initiatives. In 2010, the Gates Foundation declared the Decade of Vaccines, in which it pledged $10 billion dollars over the next 10 years to develop, research, and deliver vaccines to the world's poorest countries (Gates Foundation.org).

Global Alliance for Vaccines and Immunization (GAVI)

The Global Alliance for Vaccines and Immunizations (GAVI) is a public-private global health partnership that aims to increase access to vaccines for the world's poorest countries. To be GAVI eligible, a country's Gross National Income (GNI) per capita must be at or below an equivalent U.S. dollar rate of $1,520.00 dollars (Lee, Connor, Wateska, Norman, Rajgopal, Cakouros, Chen, Claypool, Haidari, Karir, Leonard, Mueller, Paul, Schimtz, Welling, Weng, and Brown 2015, 4,452). This means that as of 2015, there are 57 GAVI-eligible countries (Lee, et al 2015).

A recent study conducted by Lee, et al (2015) reviewed the supply chain infrastructure of those 57 eligible countries. They found that there was a wide variance in logistics infrastructure by region, but that most of the countries vaccine supply chains consisted of four levels. This means the vaccines traverse through at least that many touch points (e.g. potential bottlenecks) before getting dispersed. Not surprisingly, the countries with the least amount of cold storage capability to warehouse vaccines suffered the highest mortality rates (beyond just the polio vaccine). The group found that while having a variety of distribution sources may help, it is typically not ideal, cost effective, or efficient to disperse the cold storage vaccine supply chain in this manner (Lee, et al. 2015). This is where the Gates Foundation technological innovation and

expertise can greatly aid the battle against diseases by improving the way vaccines are introduced and transported within GAVI countries.

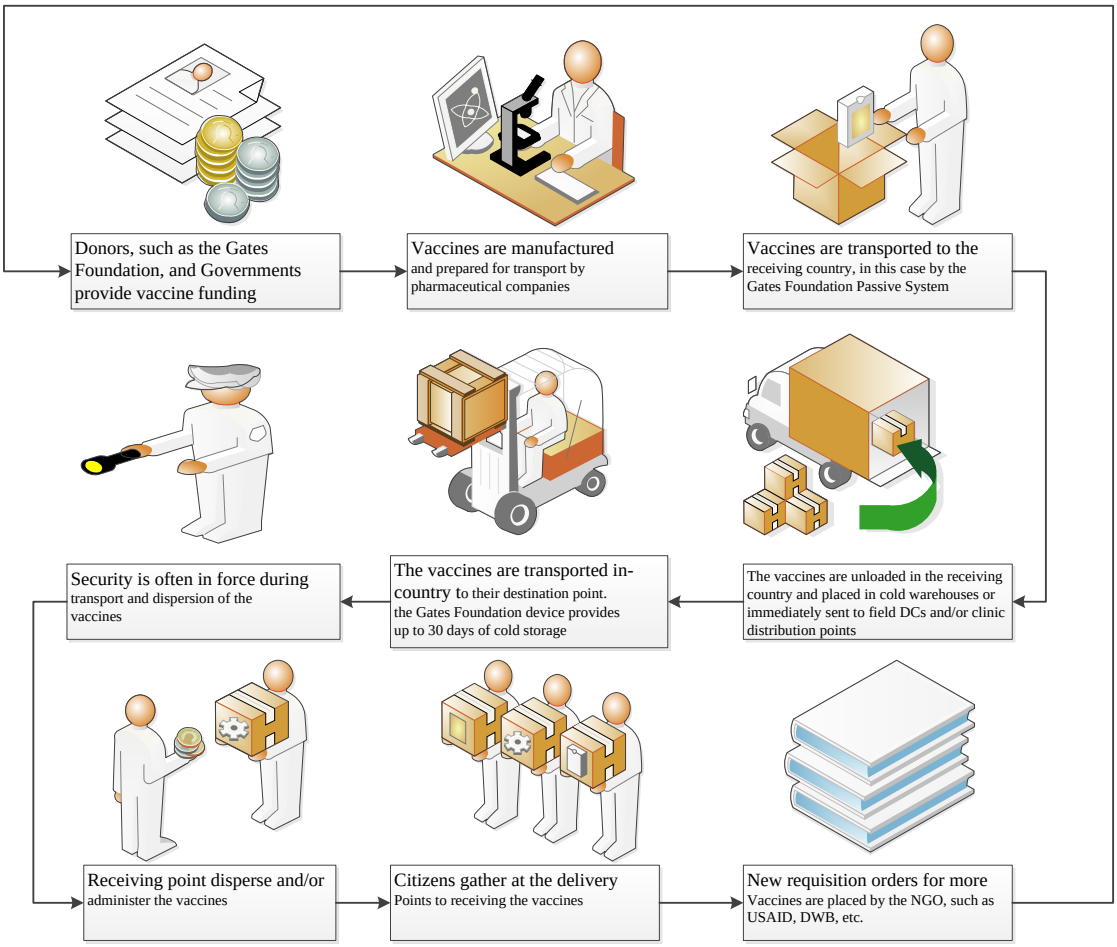


Figure 1: Typical Vaccine Delivery Supply Chain Process Flow

Outsourcing Vaccine Delivery

During the past several decades, a significant number of companies and organizations have expanded the use of third party providers (3PLs) for functions that fall outside their core capacities. Typically, organizations outsource parts of their business when the need for functions beyond their main business or mission exceeds their ability or utility. The once vertical model of companies managing all their logistics functions has moved toward reliance on companies whose

primary focus is logistics services, allowing the company to focus its efforts elsewhere, such as growth. Reasons for outsourcing vaccine supply chains may involve assistance in:

- Managing introduction of newer, more expensive vaccines
- Ensuring vaccine quality throughout the supply chain
- Ensuring vaccine availability at delivery points
- Utilizing financial resources to drive logistics system innovation
- Ensure a skilled labor pool
- Promote best practices, policies, while driving change and innovation (World Heather Organization, 2012).

As private sector companies continue to make significant advances with technology, their capacity to achieve supply chain success often surpasses what is possible within the public sector. Rather than attempt to keep pace with these advances, it may make sense for government systems to benefit from that capacity by outsourcing specific functions to the private sector. This falls perfectly into what the Gates Foundation is attempting to accomplish in their Decade of Vaccines declaration (USAID Deliver Project). The Gates Foundation has the technological and economic know-how, but needs the support of governments in countries such as Pakistan and Nigeria to support the cultural and security aspects of vaccine delivery. "Further," as a recent USAID report noted, "because of growing populations and a rising number of health services and facilities, [government health agencies] in developing countries often invest increasing amounts of scarce resources in supply chain management for the public sector as the number of service delivery points expand, patient access/demand grows, health supplies and suppliers increase, and volumes increase" (USAID Deliver Project 2010, 4). With varying commitments by donors and governmental support, challenges in expanding warehousing, data, transportation,

equipment, and trained delivery personnel all need to be addressed through the combined public-private efforts. Particularly with the delivery of vaccines, observations have shown that most often the clinicians responsible for administering medicine have also had to be become proficient in the logistics of getting those very medicines to them in the first place. “The objective of a public health supply chain is to get the right health commodities, of the right quality, at the right time, in the right quantity, to the right place, and for the right cost” (USAID Delivery Project 2010,5).

There are two outsourcing models employed, although neither is exclusive as one or multiple supply chain functions can be outsourced. The best potential for each model involves either the service provider managing one or more tasks as a service to the government (procurement, importing, storage, transport, etc.), or the provider leases equipment to the government and/or provides continual support (equipment, leasing, fuel, etc.) (World Health Organization 2012). The Gates Foundation seeks a hybrid approach through providing technological assistance in the way vaccines are transported and stored and through additional funding of educational and administration training.

From the financial side, there are generally two ways of viewing vaccine supply: Supply-Side versus Demand-Side. Supply-side stakeholders depend on capital, knowledge, the vaccines themselves, and administering the vaccines. Demand-side on the other hand, involves the public sector financing vaccine demand; along with the other items mentioned prior. “No foolproof method for securing financing for vaccine production or development has yet been developed” (Pauly 2005, 689). It is essentially free-market capitalism against government-controlled markets; where the actual solution lies somewhere firmly in between.

Risk Factors

Public-private partnerships (PPP) are an attractive way to solve problems such as delivering vaccines in Third World countries. This is particularly acute in emerging countries due to population growth and increased urbanization. Further, such partnerships are typically necessary due to the high degree of complexity involved, requiring large capital expenditures, incurring extended durations, and involve utilizing sophisticated technology. As seen in Afghanistan and Pakistan, risks however are as equally prevalent. These may encompass issues with unfamiliarity with geography, geology, and the environment; along with differing local customs, cultural, and religious expectations (Reveiz 2012).

Unfortunately, vaccine supply chains may have to incorporate some degree of security protection as part of the process. Countries such as Pakistan where 303 policemen guarding vaccine campaigns were killed in 2014, highlight the pressing need to not only deliver vaccines in a temperature-controlled environment, but also one that is highly secure (Khan, 2015). In June 2012, the Taliban banned polio vaccinations drives in areas under their control in northwestern Khyber Paktunkhwa province and the adjoining Federally Administered Tribal Areas along the Afghanistan/Pakistan/India borders (Khan 2015). 70,000 health workers were reportedly being guarded by Pakistani security forces during a Spring 2016 drive to vaccinate 10 million children in Khyber Pakhtunkhwa and areas of south-west Balochistan provinces (BBC News.com, 16 May 2016). However that is topic for an entire research paper in its own right, but must at least be mentioned in passing here.

Innovative Delivery Device

Several vaccines are labelled, "Store from +2°C to +8°C. Can be stored up to 37°C for 30 days of less. Do not freeze" (Kristensen et al 2016, 901). While discussion to this point has been about cold storage for vaccines being needed, is important to note that cold storage may also be need to actually keep vaccines *warmer* than the surrounding environment as well. Of 159 participant countries interviewed in on recent study, 73% noted that there could be circumstances where cold storage and/or transport (controlled-temperature chain, or CTC) would be necessary (Kristensen et al 2016, 901). Likewise, about 27% of the same group interviewed by noted that CTC would not be beneficial for all vaccines ((Kristensen et al 2016, 901). As one group of research authors explained it, "Unquestioned optimism about the value of increased vaccine thermostability led the Bill & Melinda Gates Foundation, and the global public health community in general, to make large investments in improving vaccine thermostability" (Karp, Lans, Esparza, Edson, Owen, Wilson, Heaton, Levine, and Rao (2016, 3,742).

Image 2: Exterior view of the vaccine cold storage device designed in partnership with the Gates Foundation. Source: Author's photo.

Image 3: Exterior view of the vaccine cold storage device. Source: Author's photo.

To address the challenge regarding the requirements noted on most vaccine labels, the Gates Foundation brought together a diverse group of rocket scientists, health experts, and industrial engineers to develop a device that would keep vaccines at the appropriate temperature for up to a month or more with repeated vaccine retrievals and no need for electricity. After

several test trials, the group created a cold storage device that met or exceeded all of the requirements. The final design (Images 2 and 3), the Passive Vaccine Storage Device, makes it 10-15 times better than other current methods of keeping vaccines cool for transport to remote areas (Figure 1). The device can be transported via container, airfreighted, and/or via truck transport with relative ease. Refrigerated container transport further extends the vaccine's life cycle, but most of the GAVI countries do not have sufficient infrastructure to support reefer operations once in-country.

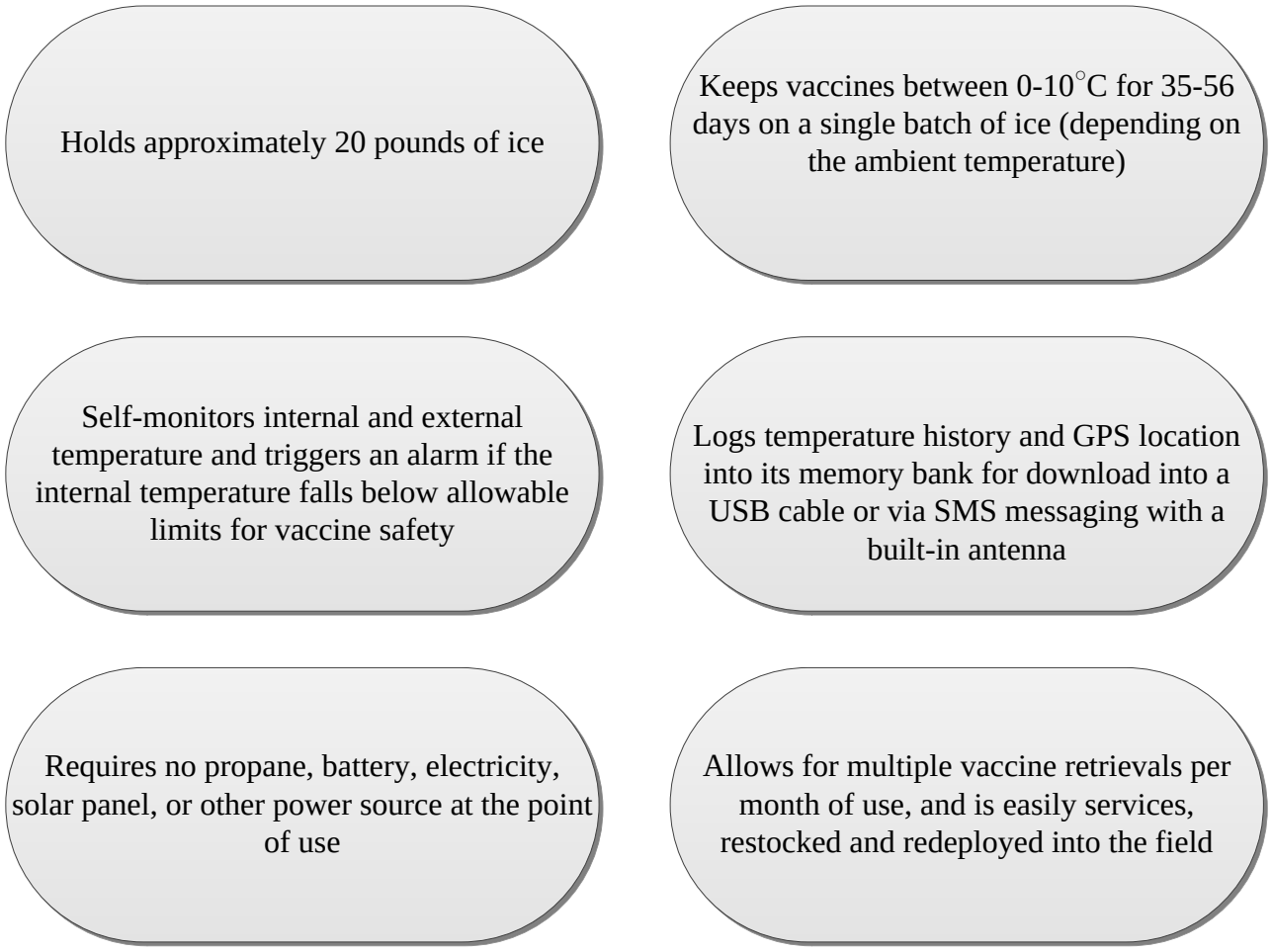


Figure 2: Gates Foundation's Passive Vaccine Storage Device Benefits

Other organizations and even individuals have created and continue to develop alternate, albeit similar, capabilities. This includes the more recent example of Will Broadway, an engineering student in the United Kingdom, who invented a backpack-sized version of the Gates Foundation's device. The device, branded as "Isobar", uses heated ammonia and water to create ammonia vapors which get released into the capsule, keeping temperatures around two to eight degrees for up to 30 days (Baggs, BBC.com). Similarly, to what Bill Gates realized after trips to Third World countries, Mr. Broadway developed his idea after visiting Cambodia and recognizing a need for cold storage devices for vaccine supply chains. The best part of this budding public-private partnership is that he refused to patent his device, making it accessible to global manufacturers (Baggs, BBC.com). For his efforts, Mr. Broadway was presented with the James Dyson Award in 2016.

Image 4: Will Broadway's "Isobar" is a cold storage vaccine device that can fit in a backpack. Source: BBC.com

Multi-Source Delivery Methods Needed and Alternatives

This paper has primarily focused on the partnership and results enjoyed between the Gates Foundation and polio vaccine delivery. It is important to note however that there are a variety of other initiatives underway globally. For example, of the objectives of the National Immunization Programs (NIPs) is to ensure, "uninterrupted availability of high quality vaccines to immunization service delivery points" in Tunisia and Senegal (Yadav, et al. 2014, 6,727).

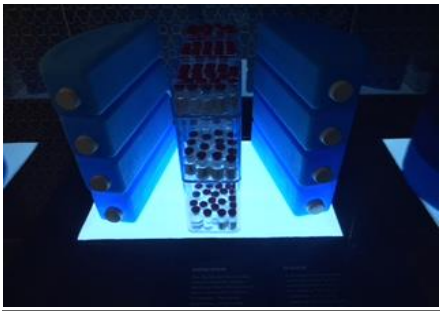


Image 5: Interior view of the ice pack arrangement. Source: Author's photo.

In these cases, a similar cold storage need was present, however the public-private partnership was able to integrate a common supply system by warehousing and delivering temperature controlled and dry health goods together. A case study in Senegal involved specially designed cold storage trucks termed "moving warehouses" that carried temperature-controlled vaccines with other essential supplies, medical professionals could then stock from as the "warehouse" drove through their areas (Yadav, et al. 2014, 6,728). As most of the vaccines in these countries were distributed by UNISEF, many of the same concepts and innovations performed by the Gates Foundation applied, however NIP's approach to distributing them varied.

Much as reported above, this particular study also examined opportunities for integrating vaccine supply chains with those of other health commodities. Areas investigated included:

- Quantification – Involves vaccine demand planning
- Procurement – Vaccines (primarily through UNISEF) and other medical supplies are procured differently
- Requisition/Ordering – Vaccines ordering schedules have to be well-established, whereas other medical supplies may not adhere to as rigid order schedules
- Storage – This area may have one of the best places for improving integration as most vaccines and medical supplies need to be (or can be) stored in temperature-controlled environments
- Transport – Here too, transport vessels, whether the cold storage device created by the Gates Foundation's team or otherwise, have a strong potential for further integration

- Information Systems – A common Logistics Management Information System (LMIS) should be readily available dependent upon training and experience of those utilizing it (Guillermet, et. al., 2014).
    - Transaction Level – Initiates and records individual logistics activities.
    - Management and Control System – Measuring performance and reporting.
    - Decision Analysis System – Modeling and analyzing tools.
    - Strategic Planning System – Develop and refine logistics strategies (Nazila & Alibabaei, 2015).

The Gates Foundation innovations primarily reside with improving the shipping method for vaccines, along with distributing the marketing and message of why vaccines are needed to the people who need them the most. An additional study conducted in Niger by Haidari, Connor, Wateska, Brown, Mueller, Norman, Schmitz, Paul, Rajgopal, Welling, Leonard, Chen, and Lee (2013) utilized the Highly Extensible Resource for Modeling Supply Chains (HERMES) software package-generated simulation to examine if adding stationary cold storage facilities along the distribution route was beneficial enough in increasing transportation capacity to mitigate bottlenecks. The model represented the logistical components of a typical supply chain, including the kind of transport devise, regulatory concerns, order frequencies, and vaccine storage temperatures (Haidari, et al. 2013, 2). However, even the HERMES model admittedly could not take into account all possible logistical scenarios, such as inclement weather or security risks. The study showed that cold storage likely needs to expand to meet increasing demands in conjunction with improving transportation routes and methods to some of the most inhospitable regions of the Earth.

Additional research in the availability of obstetric drugs in Tanzania has shown that health facility managers frequently deal with unreliable medicine replenishment resulting in the need for multiple approaches being required in delivering and administering drugs there as well. While not entirely similar to the needs associated with polio vaccine distribution, an estimated 99% death rate for all maternal deaths, during child birth, that occur in developing countries are attributable to inadequate medical supplies (Mkoka, Goicolea, Kiwara, Mwangu, and Hurtig (2014, 3).

Using the United States President's 2003 Emergency Plan for AIDS Relief (PEPFAR) as an additional example, such public-private partnerships (PPPs) continue to prove successful beyond the Gates Foundation's drive to eradicate polio. "PEPFAR has made creative and extensive use of a wide range of public-private partnerships to expand interventions, integrate programs fully into country plans, and complement the resources and skills that the US government and its country partners bring to bear on program implementation" (Sturchio and Cohen 2012, 1,451). Specific to this study, PEPFAR's Supply Chain Management System has shown to be a successful collaboration between government agencies and private-sector logistics best practices. In this case, antiretroviral drugs needed to be delivered in large quantities in sub-Saharan Africa. The partnership between JSI Research and the U.S. Government brought together a diverse group of agencies, faith-based, governmental, and private logistic providers such as UPS, to deliver the necessary medicines, HIV test kits, and other supplies efficiently and effectively. UPS was able to utilize is pre-existing supply chain channels to drive costs down with improved customs clearances and freight forwarding services. Additional partner companies used social media to promote dispensation points, spread educational materials, and provide support for supply chain management systems. These shared tasks and knowledge helped

improve demand planning, warehousing needs, inventory, distribution, and quality assurance (Sturchio and Cohen 2012, 1,453). By the end of 2012, the feedback appreciated through the group's efforts reportedly resulted in savings of more than one billion dollars and reduced HIV treatment costs from $1,000.00 dollars per patient per year to about $335.00 dollars per patient (Sturchio and Cohen 2012, 1,453).

A comprehensive study by each agency or country should really be accomplished to best determine which method(s) is most effective for its needs. Evaluations of the vaccine thermostability, the type of cold chain equipment available; along with the country's ability to deliver and administer vaccines needed to be taken as a whole. Savings may not always result, and costs could possibly increase depending on the volume and type of requirements needed to safely, securely, and sufficiently maintain a robust vaccine supply chain.

Additionally, vaccine manufacturers are seeing further success in (re)locating their manufacturing operations closer to and/or within the vicinity of the hardest hit areas where many of the world's disease have otherwise been eradicated. Initially, vaccines were "manufactured" by using scabs taken from previously infected humans and passed on to the next person through human-to-human contact. This inevitably lead to further health issues as further diseases were spread while combating the initial cause. In 1810, an Italian doctor implemented a different manufacturing method. "Here, the vaccine production "factory" was the underside of a cow that was scratched and inoculated with vaccinia-containing fluid. Days later, as vaccinia-filled pustules developed on the cow's skin, the puss was harvested and vialed as vaccine" (Francis, et. al. 2014, 5,260). Over the next 200 years, vaccine manufacturing improved significantly from humans to animal to laboratory development. Each advancement made inoculation, delivery, and success that much stronger.

Conclusion

Whether in Tanzania, Niger, Pakistan or elsewhere, the need for a robust medical supply chain infrastructure is prevalent. Getting vaccines from their manufacturer to some of the most remote places on Earth requires major investment, technological innovation, cultural changes, and improvements in security to name only some of the issues. Many of these concerns can be mitigated through good collaboration between private industry and public resources to mitigate diseases, deaths, and support the Decade of Vaccines initiative.

Further discussions are needed regarding the cost of the vaccines themselves, which can sometimes incur high expenses than the logistics involved in dispersing the medicine. For example, one study concluded that the costs of a vaccine compared to the necessary cold chain and its subsequent distribution network; along with healthcare labor cost more for Kenya and Tanzania in 2012 was less expensive than the medicines themselves (Myundura, et al, 20, 2015).

Private organizations, such as the Bill and Melinda Gates Foundation, in partnership with non-governmental organizations, such as the Doctors Without Borders, USAID, Rotary International, the World Health Organization, and Medecins Sans Frontieres; along with support from the United Nations and whatever governmental bodies exist in even the most poorest of countries, have proven the be one of the most effective methods overall for vaccine delivery to Third World regions globally. While the storage and transportation device is adequate to sustain the polio vaccine, challenges remain over developing a vaccine that can sustain temperature extremes on its own.

One of the underlying themes uncovered while assembling this research was the high degree of uncertainty involved with vaccine supply chains. Whether due to environmental, governmental, security, or other human causes, the vaccine supply chain has several crucial, and

susceptible, bottlenecks. Collaboration from the public and private sectors is needed to overcome all of these. Vaccine shortages may result from any number of causes such as those just reviewed. "With an improved understanding of the gaps in current information on the causes of shortages and noting the benefits of global communication, countries may also consider supporting the development of a global early warning shortage notification system to identify substitutes, alternative suppliers, or other mitigation measures" (Swathi, Hedman, Forte, and Hill, 2016, 3).

As stated, perhaps one of the biggest lessons learned through innovation such as that of the Passive Storage Device entailed, and through public-private partnerships, is that no one agency, country, or organization needs to solve their problems alone. A detailed study regarding the response required for a global influenza pandemic concluded that government officials should look to already established processes from organizations such as the Red Cross, UNICEF, and Medecins sans Frontieres for best practices (Hessel, et al. 168, 2009). Collaboration can lead to some highly innovative ideas, not all literally requiring rocket scientists to help resolve, which can help save lives. For example, a pilot program funded by the UPS Foundation and in partnership with GAVI, a private company called Zipline, and the Rwandan government, successfully tested delivering vaccines to remote parts of Rwanda by drones (Pharmaceutical Commerce, 2016).

To highlight a further victory from the efforts discussed above, the BBC recently reported that Pakistan is on the verge of eradicating polio within months (as of May 2016). One WHO doctor estimated that, "'This is the lowest toll of cases in history. We expect to be within months of polio elimination in Pakistan'" (BBC News.com May 16, 2016). While several battles in the fight to save lives through vaccinations have been won, the war continues. It will take both

private and public partnerships and innovation to ensure further successes, such as those seen with the Polio vaccine promoted heavily by the Bill and Melinda Gates Foundation, continue to accumulate victories.

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