

A Review of the United States Centers for Disease Control and Prevention Vaccine Management Business Improvement Project

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Batiment Avant Centre
13 Chemin du Levant
01210 Ferney Voltaire
France

Phone: 33.450.28.00.49
Fax: 33.450.28.04.07
www.path.org
www.who.int

OPTIMIZE

Immunization systems and technologies for tomorrow



World Health
Organization

Contact information:

Project Optimize
World Health Organization/PATH

Mail

PO Box 900922
Seattle, WA 98109 USA

Street

2201 Westlake Avenue, Suite 200
Seattle, WA 98121 USA

Optimize.who@path.org

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Introduction

The United States Centers for Disease Control and Prevention's (CDC's) Vaccine Management Business Improvement Project (VMBIP) represents an end-to-end reengineering of the US public-sector vaccine supply chain—from vaccine budgeting through storage and distribution. It represents the efforts of the CDC, state and local immunization program managers, and partner agencies to improve existing vaccine management processes at the federal, state, and local levels. The project was initiated in 2003 as vaccine management and inventory visibility needs grew dramatically over the course of a decade. This was due in large part to the success of the Vaccines for Children (VFC) program which expanded access for vaccines to millions of Americans, as well as the need to update the processes and technologies of antiquated supporting infrastructure. The existing system was highly decentralized and consisted of a patchwork of stand-alone computer applications and paper-based systems operated by the CDC and state and local immunization providers. With significant levels of variation, what emerged over time was a sprawling, highly complex, and fragmented supply chain that left the national government with little visibility over vaccine supply, challenging the CDC's capacity to effectively and efficiently respond to increasing vaccine shortages and other public health emergencies.

In considering the right approach to improving public-sector vaccine management, the CDC's overarching goal was to ensure that vaccine was flowing to the right places at the right time. A key requirement to making this work is the need for full visibility of the whole supply chain, from manufacturer's supply in transit to vaccine at destination and all points in between. The CDC would need to know the exact location of their inventory and when it would reach any of their 40,000 providers. In order to obtain full visibility, the management of information about inventories and shipments is required and not just physical stock.

With an ambitious goal from the start, the objectives of the VMBIP were to build a more reliable, efficient, and transparent vaccine supply chain system by improving processes that:

- Created a streamlined approach to vaccine management.
- Enabled rapid responses to changes in vaccine supply and demand at the national, state, or local level.
- Improved operational efficiency and contained rising costs.

Research objectives

This work aims to provide a high-level overview of the VMBIP, from project planning through implementation, and from multiple perspectives. It will profile:

- The components and initial results of a comprehensive, system-wide vaccine supply chain overhaul.
- The critical success factors associated with project planning and implementation.
- Considerations for its application in emerging and developing countries.

The VMBIP was a gargantuan undertaking by the CDC. As such, each of its components and dimensions could be studied in more depth than what is present in this review. Case studies on privatization and outsourcing, customer-centric supply chain systems, and successfully managing public-sector change and project implementation are potential topics of interest to the government official or vaccine program manager.

Research methodology

Multiple VMBIP stakeholder interviews were conducted with representatives from the CDC and its vaccine supply chain partners, McKesson Corporation and Booz & Company, with the purpose of gaining public- and private-sector perspectives on the planning and implementation phases of the VMBIP and the CDC's process for monitoring and measuring system performance.

A series of videoconferences were also conducted between the VMBIP stakeholders, and representatives from the Optimize project, a World Health Organization and PATH collaboration, and the United Nations Children's Fund Supply Division for the purpose of sharing the VMBIP experience and interpreting its experience for developing countries. Representatives from the Optimize project also presented their body of work and demonstration projects to the VMBIP partners.

For additional information and context, face-to-face interviews were also conducted with supply chain partners affiliated with the US President's Emergency Plan for AIDS Relief's Supply Chain Management System Project (i.e., PHD Distributors, Booz Allen Hamilton, and John Snow Inc. [JSI]).

The CDC also presented their VMBIP business case to the Optimize project as follow-up to the informal videoconferences and information exchange.

Background

In 2008, vaccine-related activities accounted for 30 percent (\$3.7 billion) of the CDC's annual budget. The VFC—the largest financier of two national immunization programs run by the CDC—was providing 43 percent of all childhood vaccines in the country. This large entitlement program, which was established through legislation enacted by the US Congress in 1993, drove policies that expanded access to immunization services to millions of Americans under the age of 18, raising coverage rates across the nation to record levels, around 90 percent. The program went from administering six vaccines, at an annual cost of \$200 million in 1994, to administering 12 vaccines in 2008 at a cost of \$3 billion.¹

What also came with the expansion was significant burden placed on federal, state, and local health care agencies, as the details of VFC implementation were left up to them.

¹ Copeland MV. Smarter medicine. *Strategy and Business*. 2008;52(08307). Available at: www.strategy-business.com.

Each US territory (64 geographical areas) was required to build a system infrastructure designed to budget, procure, store, distribute, and deliver vaccines for their respective populations. The complexity extended across these 64 areas with over 400 storage depots supplying approximately 40,000 individual provider clinics, hospitals, and pediatric/general practices. Vaccine was subsequently ordered and transported through a number of different public- and private-sector distributors, under individual contracts with any of the 40,000 provider sites and 64 territories. Funding and information flows, therefore, were not visible to the national vaccine managers.

This highly decentralized and fragmented structure posed several challenges to the CDC in Atlanta. With limited visibility over national vaccine supply at any given time, they were vulnerable and without adequate response capabilities in the event of a vaccine shortage or outbreak. For example, if there was a shortage of measles, mumps, and rubella vaccine, and Philadelphia was completely out of stock, in order to locate available vaccine, CDC headquarters would have to manually call the 64 territories that would then need to contact their local-level providers. It was not unusual for vaccine allocated for one region to sit idle on storage shelves while other regions were in short supply. This vulnerability was highlighted several times from 2000 through 2005 when unprecedented numbers of vaccine shortages occurred, challenging the CDC's ability to rapidly locate and reallocate vaccine to where it was most needed.

Overall, a convergence of factors drove the need and support for major change to the vaccine supply chain system and the VMBIP. At the national level, there were new requirements for the CDC to implement and maintain a national pediatric stockpile. On a political level, there were the President's Management Agenda and the Department of Health and Human Services' goals to drive efficiency and reduce costs. The public was also demanding greater response capabilities after major events such as the terrorist attacks on September 11, 2001, followed by anthrax scares, and fears of a pending pandemic. At an operational level, there were changes in state funding flows and an ongoing need to improve vaccine management activities.

Critical success factor 1: Identify strong motivators for change.

Critical success factor 2: Design a supply chain system that maximizes visibility over the entire system.

VMBIP

Key components

There are several major critical components of the VMBIP, and the process by which they were developed is described in the planning section. The VMBIP project plan was divided into the following four components in order to focus operations: centralized distribution, vaccine management technology system, funds management, and stockpile.

Centralized distribution: The centralized distribution of vaccine from two or three locations eliminates the need for multiple state and local depots. It reduces storage risk and distribution cost, while allowing more visibility into vaccine supply. The centralized distribution contract is held at the federal level.

Vaccine management technology system: The Vaccine Tracking System is a new vaccine management technology system currently under development. It is a resilient, recoverable, standardized enterprise system that will replace several legacy systems used at CDC and at state and local grantees. It will include web-based provider ordering technology with automated grantee approval; however, grantees will have overall control of the level of visibility and usage by their providers.

Funds management (internal efficiencies): The first focus was on funding (streamlining accounting lines). Funds now flow through two funding accounts instead of 64 grantee vaccine purchase accounts. As a result, there is improved inventory management and enhanced vaccine visibility at the national level which produces significant cost savings and reduces administrative processes. The second key area was on implementation of industry standards such as economic order quantity, prior order monitoring, grantee-specific process improvement initiatives, etc.

Stockpile: The stockpile process includes a migration of a portion of the national pediatric stockpile held by vaccine manufacturers to the centralized distributor for CDC full access and use in the event of an emergency. This policy also allowed the manufacturers to recognize revenue for the sale of stockpiled vaccines. Finally, this process reduces storage costs and ensures vaccine availability at the federal level.

Performance highlights

Operational efficiencies and cost containment

Through a phased rollout which began in 2007, the VMBIP delivered operational success on many levels in its first year of implementation. It demonstrated its ability to gain efficiencies by decreasing overall complexity within the vaccine supply chain, freeing up resources required to manage vaccine operations and funding. The number of unique supply chains, budgeting processes, and inventory locations were reduced, as well as delivery times and inventory and distribution costs. The efficiencies gained are shown through the following set of indicators:

Table 1. Post-VMBIP reduction in supply chain complexity and associated costs

| Indicators | 1994 | 2008 |
|-----------------------------------|------|--------|
| Number of unique supply chains | 64 | 1 to 3 |
| Number of separate vaccine grants | 449 | 0 |
| Number of inventory locations | 400+ | 2 to 5 |

| Indicators | 1994 | 2008 |
|-----------------------------------|---------|----------------|
| Number of funding lines of credit | 64 | 1 |
| Number of touches per shipment | 4 to 10 | 4 |
| Delivery time | 4 weeks | 3 to 8 days |
| Ordering and distribution costs | \$33M | \$13M to \$22M |
| System-wide inventory | \$1.45B | \$1.32B |

Source: Booz & Company, 2009 VMBIP presentation (unpublished data)

Although it was not the primary goal, the financial performance of the VMBIP was also impressive. As early as 2008, its overall return on investment was estimated at \$400 million, with annual savings in perpetuity of \$19.5 million beginning in 2012.²

Supply availability

Supply reliability was achieved through centralizing and outsourcing vaccine distribution through a third-party logistics (3PL) provider. There were exceptions, however, in those territories that had geographical limitations or regulatory requirements, in which case distribution remained in the hands of the public sector. Distributor performance is monitored through a national system designed to report the weekly status of vaccine distribution and returns for all 64 territories and vaccine stockpile levels maintained for the federal government.

A weekly metric scorecard was established to enhance visibility at the national level and report specifically on the following performance metrics:

- Percent of shipments without backorder lines and delivered within three days.
- Percent of shipments without backorder lines and delivered within five days.
- Order quality.
- Cold chain quality.
- Stockpile inventory levels and operating expiration dates.

An unpublished VMBIP metric scorecard from May 2009 reported fulfillment levels of 99.96 to 100 percent for each of the reported metrics listed above.³

² Copeland MV. Smarter medicine. *Strategy and Business*. 2008;52(08307). Available at: www.strategy-business.com.

³ VMBIP presentation to UNICEF Supply Division, K. Lane, September 2009

Information technology

While the need to upgrade the VFC's outdated legacy information technology (IT) system was identified at the onset of VMBIP planning as a major target for change, it was recognized that its development would need to occur within the context of the broader system changes that were likely to occur. As of 2009, while still in development, the CDC's proprietary ordering system is being built to enable ordering and payment to be conducted on the same web-based system, and have it be accessible to the 64 individual territories and thousands of doctors' offices. Borrowing from industry best-practices, such as Walmart and Amazon, an additional goal is to possess a wealth of data for scientists, health care workers, and manufacturers, so that one could analyze demand and other patterns of need and behavior. From the CDC's perspective, this could lead to better demand predictability and stronger negotiation power with manufacturers. From the manufacturing perspective, greater predictability could lead to more accurate forecasting, minimizing over-production risk. With more reliable data and information, this improvement would be a win-win for both sectors.

Planning

Business plan development

VMBIP planning began in early 2003 and was led by CDC's Kimberly S. Lane, who was the chief operating officer for what was then called the National Immunization Program and responsible for all the activities and systems that kept it running. The VMBIP introduced several major changes to the public-sector vaccine management system in the form of solutions such as outsourcing, IT systems integration, and consolidation of funding flows and processes. These solutions, while one can argue are essential to any well-functioning supply chain, are only applied successfully when designed to meet the specific needs and requirements of the system environment in which it operates. Understanding this concept, Lane and colleagues took a thorough approach to mapping and understanding the needs of key stakeholders involved in vaccine management, which meant every state and US territory, tens of thousands of doctors, and thousands more health care workers. This would ensure that relevant needs would be considered in the development stage of the new supply chain. Planning took the form of live meetings with the full range of stakeholders over the course of 18 months, often in airport hotels with 20 to 25 people. Needs assessments were conducted as well as much needed socialization of recommendations and advocacy building among the key public health departments in all states and large cities.

Critical success factor 3: Map and conduct a thorough assessment of stakeholders' needs and requirements.

With stakeholders engaged, the baselining of existing VFC processes was initiated, modeling existing systems with the purpose of uncovering the variations in system requirements, current practices, and limitations across territories. For example, some remote parts of the country could not access reasonably priced third-party providers for vaccine distribution, and therefore, outsourcing was not an option. Also, some regions,

while without geographic or economic limitations, were unable to outsource distribution because of worker's union requirements.

The process continued with stakeholder engagement in further developing and vetting high-level recommendations, quantifying potential benefits, and developing the operational model that would define requirements, roles, and responsibilities. From there, Lane and her team developed a business plan to ensure that all of the many different aspects and challenges within the vaccine supply chain system had been adequately considered and addressed in the recommendations and solutions they would put forward. A step-by-step approach to project planning, implementation, and evaluation was developed and further vetted with stakeholders. Without this plan, Lane has noted that, "they would have been highly vulnerable to budget cuts and be unable to defend the project against uncontrollable external influences, such as scope creep and political and/or social resistance to change."⁴

Critical success factor 4: Develop a stakeholder aligned business plan that demonstrates an understanding of existing systems (baselining) and rationale for the recommended solutions (cost-analysis).

The VMBIP business plan focused on structuring solutions around the following needs and requirements identified as critical for improving US public-sector vaccine management: achieve visibility by centralizing distribution, enable better coordination of functions by upgrading the IT system, gain administrative efficiencies by streamlining the funding process, and ensure reliable vaccine supply by establishing a national vaccine stockpile.

To address these needs, targeted solutions were developed based upon results from baselining existing systems and their associated costs. They included the privatization/outsourcing of vaccine distribution and stockpile management to a third-party provider, integration of provider functions (ordering, tracking, and payment) through a single IT platform, and centralization of vaccine funding. According to a VMBIP partner at Booz & Company, "It is invaluable to understand the range of current processes before attempting to make significant improvements," highlighting the importance of baselining and establishing a process to systematically collect information.

Streamlining, outsourcing, and IT integration

VMBIP implementation was conducted by internal CDC teams in addition to several private-sector partners that were selected by the CDC through their standard vendor bidding and selection process. Two key partner organizations involved in the implementation of the VMBIP are the logistics provider, McKesson Corporation, and the IT systems provider, SAP. Important to note is that the vendor selection process, in

⁴ Excerpt from interview with Kim Lane, the CDC, August 10, 2009.

addition to contract and vendor management, was critical to implementation success of the operation even though it is not part of this review. In order to gain full appreciation of the critical decision-making processes that occurred in these areas, an in-depth study is required.

Streamlining

The administrative burden contained within the vaccine budgeting and procurement process contributed to frequent funding bottlenecks and vaccine shortages within the US supply chain. The complexity was enormous with more than 430 depots spread across the country and more than 100,000 pediatricians and clinicians requiring vaccine. Among the 40,000 provider locations within the 64 territories, many orders required approval at the county or city level before they were forwarded to the state for another step in the approval process. Therefore, the VMBIP sought to streamline the funding process, and through presidential and congressional support, the CDC was able to establish new policies that reduced the 64 different funding flows down to one line of credit, against which territories could order vaccine. This efficiency gain provided sustainable financing that guaranteed funding for territories and secured supply with manufacturers. It also added a level of predictability that supported private-sector forecasting, with both distributors and manufacturers.

Critical success factor 5: Support policies that enable private-sector engagement and success.

Outsourcing—McKesson Corporation

Before the VMBIP, vaccine distribution was managed completely by grantees using various models—either in-house, third-party, or hybrid. None of these systems had the capacity to fully integrate the various vaccine management functions (such as funding flows, procurement, and tracking). The CDC’s decision to outsource distribution to a third-party provider was driven by several factors. First, they understood that vaccine logistics should not be nor try to become a core competency of the public health system, despite its responsibility residing in the hands of many health care workers for years. They recognized the need to employ best practices from FedEx, Walmart, and Social Security to fully upgrade the vaccine supply chain. Second, from a cost perspective, the math made sense as well. Through outsourcing, providers would not have to spend health care resources maintaining delivery trucks and vans or assume the risk of losing millions of dollars of vaccine if a refrigerator or van breaks down. Already, many VFC providers had acquired the experience and realized the benefits from outsourcing to a 3PL provider. According to Lane, all these benefits combined meant that public health professionals could focus all their attention on health care, on improving immunization rates, and other things they did not always have the time to do before third-party distribution.

The CDC decision to outsource to only one distributor required a significant amount of analysis and debate over the inherent risks associated with dependency on a single supplier. After an extensive due diligence process, the contract was awarded to

McKesson Corporation, who was able to demonstrate two important functions: (1) expertise in supply chain management and just-in-time distribution of fragile and highly valuable drugs to private hospitals and physicians, and (2) capacity to maintain business continuity under the most extreme circumstances.

IT Integration—SAP

SAP was chosen for the Vaccine Tracking System because it provided an enterprise-wide system that enabled integration of all pieces of vaccine supply chain into one product including: inventory management, contracts management, and provider fulfillment.⁵ It provided strong authentication and security to meet government needs and is also used by several vaccine partners, such as the pharmaceutical industry and vaccine distributors. It is also leveraged in a number of government agencies, including department of defense logistics implementations.

Implementation

“When trying to drive improvements in communities of common, but different, stakeholder groups (like states in the US and countries in the emerging world), pilots are very useful in establishing credibility and creating champions for a new model.” Booz & Company

As with any large operation, a project plan was developed to facilitate a smooth transition from the old to the new system. It was built into the overall business plan so that responsibilities were clear and that a feasible timetable for implementation existed. From the CDC perspective, it was vital that clear visibility of the implementation process existed.

The CDC chose to implement their new supply chain model in a phased rollout approach. They used a pilot to prove the VMBIP concept on a small scale to reduce risk, ease grantee concerns, and create champions. This also enabled the CDC and McKesson to take customer (grantee) feedback and modify policies/processes prior to full system rollout.

The selected pilots had noteworthy characteristics that contributed to their selection. They were selected based on their ability to represent the diverse set of regions that made up the majority of the United States, considering their different funding and distribution mechanisms, labor requirements, and policies and regulations. To maximize chances for success, final implementation with all regions was also phased and based on a grantees level of interest and implementation complexity. The full transition involving 64 grantees took approximately 13 months.

⁵ Lane K. VMBIP presentation. Presented at: Project Optimize Conference, June 1, 2009; Ferney, France.

Critical success factor 6: Conduct a pilot(s)/proof of concept to visibly demonstrate system capabilities and benefits.

Monitoring and evaluation

The main reason for monitoring project operations is to measure whether the operation is meeting set service levels at an acceptable cost. While there are a number of different ways of monitoring logistics operations (i.e., balanced scorecard [SCOR] model), more specific metrics can be used for operations that are outsourced. Some of the main methods for monitoring and managing a 3PL provider include: monitoring against a contract or service level agreement, budgetary control, management information, activity forecasts, audits through open book, and a constructive review process to include continuous improvement.

The VMBIP business plan included a formal approach to the management and monitoring of performance indicators that are also contract requirements. The primary indicators monitored weekly by the CDC, received in a scorecard format, fall into one of four categories: distribution, returns, receiving, and stockpiling. With regard to distribution, the CDC knows the percentage of vaccine that arrives in three days versus five days to customers and with or without backorders. Returns are intended to measure quality control and the effectiveness of the cold chain. Stockpiling signals reserve stock and expiring vaccine. Continuous quality improvement projects are also in progress and additional projects have been identified for the near future.

In interviews, the CDC and McKesson teams credit their close and frequent interactions as fundamental to the success of VMBIP. Their outsourcing arrangement is managed by designated people on each side, as they recognize and appreciate the need for sound management, defined roles and responsibilities, and agreed-upon expectations.

Critical success factor 7: Establish a weekly/monthly metric scorecard with agreed-upon key performance indicators and other expectations.

Critical success factor 8: Establish consistent and open communication channels between grantor and provider.

Application for emerging and developing countries

Regardless of whether product is flowing through a developed or developing nation, supply chain management is highly complex and, therefore, any effort to reduce complexity within a system has the potential to improve performance and minimize supply disruptions. The CDC took this approach with VMBIP in recognition that sustainable solutions needed to be system-based instead of isolated to any one particular area of the chain in need of fixing. Experienced vaccine program managers know that

plugging a hole in one area without addressing the root cause inevitably leads to increased pressure and leaks somewhere else.

While vaccine supply chain needs in emerging and developing countries are likely to be similar to those in the United States, their requirements and limitations for enabling adequate solutions will typically vary. Because the main issues in developing countries for logistics are the poor transport infrastructure, the inexperienced and untrained labor market, and the lack of guaranteed product flows, selecting the most appropriate solution(s) will need to take into account these variables. For example, outsourcing to a 3PL provider or maintaining a stockpile may neither be possible nor appropriate in some regions, depending on the reasons for why this may be the case. In some countries, it could be that the private sector is not incentivized or supported by a healthy commercial environment and, therefore, 3PL providers have not had the opportunity to flourish in their current environment. Reasons for this can range from things like poor tax policies and trade barriers to poor road construction and financing. If the root causes for an immature 3PL provider market can be identified, it might be that supply chain strategies can target efforts to strengthen the commercial environment, such as advocating for new government policies and tax structures or facilitate cross-sector collaboration to elevate interest and incentives (i.e., engaging transportation and financial sectors.)

In other areas such as communication needs, certain IT platforms may be more appropriate solutions than others (i.e., global positioning system versus wireless capable). In areas where safety, theft, or quality control is of concern, tracking and monitoring devices can be cost-effective supply chain solutions that can minimize wastage and safety concerns.

As mentioned in critical success factor four, the exercise of baselining existing processes and costs to understand the full range of system needs and requirements is crucial for getting it right. The process allows for the complexity within the supply chain to be deconstructed into manageable and transparent elements that represent sources of “stress” within the system and which can be targeted for change or improvement. This process of deconstruction is done at all levels, national, regional, and local, and can reveal a range of stress points, such as budgeting hurdles, multiple storage and transaction points, and non-integrated critical functions, (i.e., ordering, tracking, and distribution). As observed in the VMBIP, once these stress points were identified and requirements mapped out, solutions could be evaluated based on their implementation feasibility.

The importance of stakeholder management throughout the development and implementation of the VMBIP cannot be underestimated. With such a large and diverse mix of stakeholders across the United States and various sectors, it was a critical element to its success. Aside from the improvements that the VMBIP would bring to vaccine management overall, the change that the VMBIP would bring to the entire vaccine supply chain would inevitably effect people’s jobs and environments in which they practiced for decades. Accepting this type of change is not always easy or welcomed, and while the CDC team faced some level of resistance along the way, they anticipated this dynamic and hence included a process in their business plan to ensure that change would be thoughtfully managed. This translated into live meetings with the 64 different territories,

frequent visits to provider sites, and continuous engagement with partner companies. In developing countries, the same stakeholder dynamic occurs when change is on the horizon. Therefore, adequate engagement that addresses the concerns and questions of those impacted by that change should be considered from the start of any project.

Recommendations for future collaboration

Complementary to this report are three proposals and presentations developed by PHD, Booz & Company, and JSI Deliver to be considered as practical solutions, tools, and approaches to supply chain strengthening efforts.

PHD's proposal is intended to provide insight into the benefits of outsourcing to 3PL providers in developing countries. They also describe unique models for purchasing and storing vaccine (i.e., regional hub facilities and vaccine purchasing on a consignment basis).

Booz & Company's proposal emphasizes the importance of baselining current processes and costs before implementing a supply chain solution. Their recommendation is to conduct these assessments in regions where there is adequate willingness for change.

JSI Deliver's presentation is for the purpose of describing a new modeling tool developed to design and simulate a more efficient distribution network across many variables.