Delivering Vaccines: A Case Study of the Distribution System of Vaccines for Children

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Objective: To evaluate the efficacy of the centralization by the Centers for Disease Control and Prevention of their pediatric vaccine distribution system.

Study Design: In March 2007, the Centers for Disease Control and Prevention began a pilot program to reform the Vaccines for Children (VFC) program. All California VFC providers were required to place vaccine orders under the centralized logistic system of the Vaccine Management Business Improvement Project (VMBIP). For this study, VFC ordering, use, and delivery data were collected from 2 large southern California healthcare providers that collectively served more than 200,000 children. Data collection occurred between January 2005 and June 2008.

Methods: This case study measures the change in the mean VFC delivery times before and after the VMBIP. The data underwent simulation to estimate the number of days per year a provider would have zero VFC inventory before and after the VMBIP.

Results: After the VMBIP was implemented, delivery times increased from 1.6 to 12.3 business days (P <.001). The probability that VFC deliveries took longer than 1 week increased from 7% before the VMBIP to 89% afterward. Our simulation demonstrates that for 7 of 11 vaccines investigated there was a statistically significant increase in the number of days a provider would be without VFC (P <.01).

Conclusion: Although the VMBIP was implemented to save costs, this study finds that during the VMBIP's initial implementation timeline, providers experienced longer delivery delays and a higher probability of a VFC stockout.

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In the early 1990s, more than 11% of American children (8.9 million) were uninsured, and an additional 29% were insured under the State Children's Health Insurance Program and Medicaid.[1] To ensure that vaccination services were affordable for all children, the federal government established the Vaccines for Children (VFC) program. Enacted in 1993 under Title XIX of the Social Security Act,[2] the VFC program of the Centers for Disease Control and Prevention is the largest supplier of childhood vaccines. With an estimated 2009 budget of $2.8 billion, VFC provides approximately 43% of all routinely recommended childhood vaccines.[3,4] Researchers estimate that having children complete the entire routine vaccination schedule yields a net societal savings of $43.3 billion.[5,6] If the VFC program can improve coverage rates, this will create significant societal savings. Therefore, any major changes to the VFC logistic system will directly affect vaccine availability at the provider level, as well as overall societal welfare.

One such change in vaccine delivery logistics was the creation of the Vaccine Management Business Improvement Project (VMBIP). Because of reporting requirements stemming from the Government Performance Results Act of 1993, the Centers for Disease Control and Prevention has focused on reducing waste and fraud.[7] Two mechanisms were used to achieve this goal. The first was the implementation of electronic order entry. The second, the subject of this study, was the creation of the VMBIP, a centralized vaccine distribution system.

Before the VMBIP, there were various ordering and distribution methods that differed among states.[8] Previous ordering and distribution systems permitted vaccines to be distributed directly to the provider from a local vaccine depot or via a contracted distributor. Also, healthcare organizations could redistribute vaccines readily among organizational sites. Under the VMBIP, local depots were eliminated. Instead, vaccines are shipped directly from 1 of 2 distribution centers to each provider site. In an attempt to better account for these vaccines, redistribution of VFC-provided vaccines within a healthcare organization has been disallowed. Furthermore, most provider offices are restricted to ordering with 1 month's lead time to prevent excessive ordering and fraud.[9] Although the changes enacted under the VMBIP have the potential to substantially reduce overhead costs, their effects on vaccine delivery delays[10] and on provider vaccine inventory levels have not been sufficiently studied.

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Although the Vaccine Management Business Improvement Project (VMBIP) was implemented to save costs, this study finds that during its initial implementation timeline, providers experienced longer delivery delays and a higher probability of a Vaccines for Children (VFC) stockout.

- After VMBIP was implemented, VFC delivery times increased from 1.6 to 12.3 business days ($P<.001$).
- The probability that VFC deliveries took longer than 1 week increased from 7% before the VMBIP to 89% afterward.
- Our simulation demonstrates that for 7 of 11 vaccines investigated, there was a statistically significant increase in the number of days a provider would be without VFC ($P<.01$).

METHODS

Data Source

The data for this study were collected from a convenience sample of the vaccine ordering behavior of 2 large southern California healthcare organizations. In particular, the data include vaccine ordering and delivery behavior from a San Diego County provider between January 2005 and June 2007, as well as data from an Orange County provider between January 2007 and June 2008. Collectively, these 2 providers represent 14 locations and served more than 200,000 children during the study period.

Data from the San Diego County provider were collected from before and after the implementation of the VMBIP. Data from the Orange County provider were collected only after the VMBIP was instituted. Although the Orange County data should not be used to make causal inferences regarding the VMBIP's effect on delay times, the data provide a more precise picture of VFC delays after the implementation of the VMBIP. Excluding the Orange County data would increase the magnitude of the effect of the VMBIP on delays and would decrease precision.

Variables collected include quarterly vaccine use, vaccine ordering dates and quantities, the dates the vaccine shipments were received, and the vaccine inventory levels at the times the orders were placed. These data were collected for the following 11 vaccines: (1) polio; (2) hepatitis A; (3) hepatitis B; (4) tetanus and diphtheria; (5) *Haemophilus influenzae;* (6) meningococcal vaccines; (7) measles, mumps, and rubella; (8) diphtheria, tetanus, and pertussis; (9) tetanus, diphtheria, and pertussis; (10) pneumococcal conjugate vaccine; and (11) the combination of diphtheria, tetanus, and pertussis; hepatitis B; and polio. Data for varicella vaccines were collected but were not included because of missing data. In March 2007, California was 1 of 4 pilot states that began the VMBIP distribution.[8] Because of the early enactment date in California, we have 27 months of data before the VMBIP start date and 15 months of data after the VMBIP was implemented.

Statistical Analysis

Analysis began with determining the mean duration between the date vaccines were ordered and the date they were received under the old and new distribution systems. For each of 11 vaccines, differences in the mean delivery times before and after the VMBIP were tested for statistical significance using standard *t* tests. Also estimated are the median delivery times and the probability that a vaccine delivery will take more than 1 week.

To calculate the number of business days per year that a provider will have zero vaccine inventory on hand, a simulation method is used. A provider will run out of vaccines if the number of doses used between the vaccine order and delivery dates is higher than the vaccine inventory levels at the time an order is placed. The inventory levels at the time of order are known from the data collected; however, vaccine use data were only available on a quarterly basis. To estimate daily vaccine use, it was assumed to be distributed according to a negative binomial distribution. Because it fit the data better, a normal distribution was assumed for 1 vaccine (the combination of diphtheria, tetanus, and pertussis; hepatitis B; and polio). The negative binomial distribution adequately deals with the overdispersion in the daily vaccine use data. Furthermore, the variables of this distribution were set so that the simulated data's expected mean quarterly use and expected quarterly standard deviation matched those of the actual data collected. However, this method will underestimate or overestimate stockouts if daily vaccine demand is more or less volatile than predicted by our model.

Using historical ordering schedules and actual inventory levels at the time an order was placed, we begin the simulation. A random level of daily vaccine demand was drawn from the simulated negative binomial distribution already described. To model delivery delays, actual delivery delay data are bootstrapped separately before and after the VMBIP implementation. To calculate the number of business days per year that a provider will have zero vaccine inventory, we simulated 42 months of vaccine ordering, inventory, and delivery data 10,000 times.

RESULTS

Mean Delay Time

Table 1 gives summary statistics for vaccine delivery times. After the VMBIP was implemented in California, the mean

Table 1. Vaccine Delivery Statistics

Variable	Business Days			Probability for >1 Week Delivery, %	Months of Data
	Mean	Median	SD		
Total					
After VMBIP	12.3	13	6.3	89	15
Before VMBIP	1.6	1	2.4	7	27
Δ	10.7	12	3.9	82	—
P	<.001	<.001	<.001	<.001	—
San Diego County Provider					
After VMBIP	13.5	13.5	10.6	100	3
Before VMBIP	1.6	1	2.4	7	27
Δ	11.9	12.5	8.2	0.93	—
Orange County Provider					
After VMBIP	12	13	5.7	86	15
Before VMBIP	—	—	—	—	—
Δ	—	—	—	—	—

VMBIP indicates Vaccine Management Business Improvement Project.

vaccine delivery time increased from 1.6 to 12.3 business days. Furthermore, the probability that a vaccine delivery arrived more than 1 week after an order was placed increased from 7% to 89%. A *t* test for equality of means was strongly rejected (P <.001). By way of comparison, benchmarks for distribution centers for biologic products include an order fill time of 24 hours with an additional "dock to stock" time of 8 to 24 hours.[11,12] This benchmark corresponds to a 2-day delay for the data given in Table 1. Delivery delays before the VMBIP met these expectations, but delivery times after the VMBIP were much longer than this 2-day benchmark. Therefore, the evidence shows that during the initial phases of implementation the VMBIP significantly increased vaccine delivery delays.

Simulation Results

Once the vaccine delivery delays were estimated, a simulation method was implemented to determine how changing vaccine delivery times affect vaccine availability throughout the year. Table 2 gives the results of the simulation. There is a large increase in the number of days a provider would have zero vaccine inventory for hepatitis A, tetanus and diphtheria, *Haemophilus influenzae*, and pneumococcal conjugate vaccine. In each of these cases, providers would be without the vaccine for more than 2 months of the year. Vaccine availability is much higher under the old system, and these results are statistically significant at the 1% level. The decrease in vaccine availability under the VMBIP is also statistically significant at conventional levels for polio; measles, mumps, and rubella; and the combination of diphtheria, tetanus, and pertussis; hepatitis B; and polio. On the other hand, the longer delays of the VMBIP have little effect on vaccine availability for hepatitis B; meningococcal vaccines; diphtheria, tetanus, and pertussis; and tetanus, diphtheria, and pertussis. Variation in these results across vaccines is due to differences in vaccine demand and typical inventory levels.

DISCUSSION

This case study of 2 large healthcare organizations indicates that the VMBIP increased vaccine delivery delays, resulting in clinic spot shortages. Coincident with and compounding the increase in the mean vaccine delivery times was a dramatic increase in the variability of expected arrival time for vaccine delivery. As summarized in Table 1, the standard deviation of the delivery delay increased from 2.4 days before the VMBIP to 6.3 days after the VMBIP. Increased variability can create vaccine ordering challenges, particularly for high-volume sites. Because the Centers for Disease Control and Prevention now generally restrict ordering to a 1-month supply, it is no longer a viable option to increase vaccine order quantities in response to increased volatility.

Although a centralized vaccine distribution system may decrease the federal government's overhead costs, the results of this study suggest that centralization may create costly vaccine delivery delays for providers. Periodic vaccine stockouts may increase the number of children who miss a necessary vaccination. Further research in this area is merited to de-

Table 2. Simulated Days per Year With Zero Vaccine Inventory

Vaccine	Days per Year With Zero Vaccine Inventory				Mean Vaccines per Month
	After VMBIP	Before VMBIP	Δ	*P*	
DtaP	0.7	0.0	0.7	.46	182.1
DtaP/HepB/IPV	31.3	0.0	31.3	.001	198.6
HepA	95.7	2.3	93.4	.001	162.6
HepB	3.1	0.0	3.1	.07	141.8
HIB	122.1	4.8	117.3	.001	318.3
IPV	6.1	0.0	6.1	.004	134.3
MCV	0.0	0.0	0.0	>.99	6.0
MMR	18.5	0.0	18.5	.001	156.6
PCV	137.8	6.8	130.9	.001	327.7
Td	62.7	1.6	61.1	.001	54.7
Tdap	0.0	0.0	0.0	>.99	5.4

DtaP indicates diphtheria, tetanus, and pertussis; HepA, hepatitis A; HepB, hepatitis B; HIB, *Haemophilus influenzae*; IPV, polio; MCV, meningococcal vaccines; MMR, measles, mumps, and rubella; PCV, pneumococcal conjugate vaccine; Td, tetanus and diphtheria; Tdap, tetanus, diphtheria, and pertussis; VMBIP, Vaccine Management Business Improvement Project.

termine whether administrative cost savings outweigh additional costs to providers and patients. Besides the effect on routine childhood vaccinations, the data also question the present capacity of the centralized distribution system to meet unexpected demand in a pandemic or bioterrorist scenario.

There are several limitations to this study. The case study uses data from 2 large multisite healthcare organizations. Although the data provide a glimpse on how the VMBIP is affecting providers, the data are not nationally representative, and there is no information on vaccine waste. Furthermore, the data were collected during the start-up phase of the VMBIP; subsequent changes to the program may or may not have shortened delivery delays.

It is unknown whether the increased delays actually resulted in decreased vaccination coverage rates for these sites. For instance, providers may use their private vaccine inventory to accommodate VFC shortages. In the long run, having providers tie up more capital in private vaccine inventory to backfill VFC demand will reduce provider incentives to participate in the VFC program. What can be stated with certainty is that the VMBIP led to increased inconvenience for families and for healthcare organizations.

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