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Cost effectiveness analysis of elementary school-located vaccination against influenza – Results from a randomized controlled trial

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Abstract

School-located vaccination against influenza (SLV-I) has been suggested to help meet the need for annual vaccination of large numbers of school-aged children with seasonal influenza vaccine. However, little is known about the cost and cost-effectiveness of SLV-I. We conducted a cost-analysis and a cost-effectiveness analysis based on a randomized controlled trial (RCT) of an SLV-I program implemented in Monroe County, New York during the 2009–2010 vaccination season. We hypothesized that SLV-I is more cost effective, or less-costly, compared to a conventional, office-located influenza vaccination delivery. First and second SLV-I clinics were offered in 21 intervention elementary schools (n=9,027 children) with standard of care (no SLV-I) in 11 control schools (n=4,534 children). The direct costs, to purchase and administer vaccines, were estimated from our RCT. The effectiveness measure, receipt of ≥1 dose of influenza vaccine, was 13.2 percentage points higher in SLV-I schools than control schools. The school costs ($9.16/dose in 2009 dollars) plus project costs ($23.00/dose) plus vendor costs excluding vaccine

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purchase ($19.89/dose) was higher in direct costs ($52.05/dose) than the previously reported mean/median cost [$38.23/$21.44 per dose] for providing influenza vaccination in pediatric practices. However SLV-I averted parent costs to visit medical practices ($35.08 per vaccine). Combining direct and averted costs through Monte Carlo Simulation, SLV-I costs were $19.26/dose in net costs, which is below practice-based influenza vaccination costs. The incremental cost-effectiveness ratio (ICER) was estimated to be $92.50 or $38.59 (also including averted parent costs). When additionally accounting for the costs averted by disease prevention (i.e., both reduced disease transmission to household members and reduced loss of productivity from caring for a sick child), the SLV-I model appears to be cost-saving to society, compared to "no vaccination". Our findings support the expanded implementation of SLV-I, but also the need to focus on efficient delivery to reduce direct costs.

Keywords

Cost analysis; Cost effectiveness analysis; School-located vaccination against influenza; Randomized controlled trial

1. INTRODUCTION

Seasonal influenza continues to impose a substantial disease burden on children [1–3]. In 2008, the Advisory Committee on Immunization Practices (ACIP) recommended universal childhood annual influenza vaccination, including all children aged 5 to 18 years [4]. ACIP also recommends that children aged 6 months-8 years receive two doses of vaccine if they have not been vaccinated previously [4]. National influenza vaccination coverage for this age group reached 51.0% in the 2010–2011 influenza vaccination season, but has remained [5] far below the Healthy People 2020 goal of 80% [6].

Primary care practices may not have the capacity to meet the greatly expanded demand for influenza vaccination services [7], which could result in up to 42 million additional healthcare visits during a conservative 5-month window for each influenza vaccination season[8]. Along with capacity issues, primary care practices also bear financial risks related to vaccine purchase and may face inadequate reimbursement rates for administering vaccination, which might discourage some practices from expanding their vaccine provision [7, 9, 10]. For instance, practices are often fearful of ordering too many vaccine doses that they may not use and would have to discard, leading to a financial loss at the end of an influenza season [7, 11]. School-located vaccination against influenza (SLV-I) has been suggested to help improve vaccination coverage. Cawley and associates conducted a systematic literature review and concluded that SLV-I is a promising option to achieve the expanded ACIP influenza vaccination recommendation [12]. They also pointed out the need for well-controlled trials to establish the cost-effectiveness of specific influenza vaccination strategies.

To address this need, we conducted a community-based randomized controlled trial (RCT) of SLV-I among elementary school children in Monroe County, NY, during the fall of 2009 to examine the effectiveness (i.e., improvement in influenza vaccination rates), cost, and cost-effectiveness of SLV-I. The study design and the effectiveness of this demonstration

have been previously reported [13]. In this paper we report on the cost and cost-effectiveness of this model of SLV-I. Our first hypothesis is that the average cost per dose in SLV-I during the initial year of the study would be comparable or lower than that observed in medical practices. Our second hypothesis is that in a cost analysis the average net cost per dose in SLV-I would be lower than that observed in medical practices [10], when accounting for the costs to deliver vaccines and also parents' costs to visit medical practices for their child's influenza vaccination. Our supplemental hypothesis was that SLV-I could be cost-saving for society compared to "no vaccination." The following Methods section defines direct costs, net costs and societal costs to test our first, second and supplemental hypotheses, respectively.

2. METHODS

All of the effectiveness parameters and most of the cost parameters were derived from our community-based RCT, in developing our cost models and cost effectiveness models.

2.1 Overview of the community-based RCT

Study design and sample size—This study included 21 intervention elementary schools (12 urban and 9 suburban; 9,027 students) and 11 control elementary schools (6 urban and 5 suburban; 4,534 students) in Monroe County (greater Rochester), NY, which volunteered to participate in the study [13]. These schools were located in 7 school districts [13]. We randomized schools within school districts to either SLV-I or control arms.

Vaccine clinics at school—A vaccination vendor provided influenza vaccination clinics at each school, on two dates between 11/3/2009 and 12/18/2009 using a mass vaccination team that consisted of at least one registered nurse and a clerical person. The team offered both live attenuated (LAIV) and inactivated (TIV) seasonal influenza vaccines, but did not offer a separate H1N1 ("pandemic flu") vaccine in these clinics. All influenza vaccinations given in the intervention schools were recorded in the mass vaccinator's database and analyzed in this study.

2.2 Cost analysis

Our cost analysis used the unit of cost per dose. All cost estimates were adjusted to 2009 dollar values, adjusting with the consumer price index when needed [14]. Five cost components were estimated, including three "direct costs" incurred by this study (A) school costs, (B) project costs, and (C) vendor costs. Two indirect costs of no SLV-I program, averted by having such a program, were also estimated: (D) averted parents' costs (i.e., costs to visit medical practices for a child's influenza vaccination) and (E) costs averted by disease prevention (i.e., both reduced medical costs-- because of reduced disease transmission to household members -- and reduced loss of parental productivity related to caring for a sick child). "Net cost" is defined as these three direct costs (A+B+C) less the indirect Component D (costs to parents). "Societal cost" is defined as the sum of the direct costs (A+B+C) less the indirect Component E (costs from disease).

Direct vaccine administration costs—Component A, school cost, comprises non-labor material cost (e.g., supplies and expenses associated with distributing information to parents) and labor costs to the schools themselves. Labor cost was calculated by multiplying the reported school staff hours by the national mean wage of a relevant job category as of May 2009 [15]. Component B, project cost, measured the cost incurred by coordinating activities, again including material cost and labor cost. Research and evaluation activities were excluded in this estimation. Component C, vendor costs, included the vendor's labor and material costs (e.g., vaccine purchase and supplies). C_1 represents the vendor's relevant labor costs. The vendor's vaccine purchase costs were modeled in two ways. In, our primary analysis, we assigned a vaccine purchase cost, C_2, of $10.40/dose, which is the weighted average prices of TIV (80% of doses administered in this demonstration) and LAIV (20%) as of May 2009 listed on the CDC website [16]. We also performed a supplemental analysis that estimated the costs assuming that federal Vaccine-For-Children (VFC) doses were free (C_3) as they are from the viewpoints of school districts, health departments, or insurers. In this study, 52% of students were VFC-eligible and therefore there was no charge to the vendor or families for the vaccine, but these doses were not "free" from a societal perspective.

Indirect (averted) costs—We also estimated two indirect components that are important from a broader societal perspective. These components were applied only among the children who received an influenza vaccination in the SLV-1 schools. Component D is the averted parents' costs (i.e., to visit medical practices for a child's influenza immunization). From the parent's perspective, this component is important when comparing the cost of immunizing a child in school or at a traditional medical practice setting. The dollar values for parents' time [17–19] ($41.80 for two hours at the national median hourly wage regardless of a parent's employment status) and transportation cost [20] ($6.32) were obtained from the literature. The combined value ($48.12) was discounted by 27.1% to $35.08, because our analysis of the Medical Expenditure Panel Survey (MEPS) [21] showed that 27.1% of children aged 7 to 12 years had at least one primary care visit during an influenza vaccination period between 10/1/2007 and 1/31/2008. This group might not need an additional medical practice visit solely for influenza vaccination since they would have been seen in the practice during the months when influenza vaccine would probably have been available there. We used this as a conservative estimate; some of these parents would have scheduled an additional primary care visit for influenza vaccination and, in some cases, children would not have been immunized during visits associated with acute illnesses [22].

As a supplemental analysis, we estimated Component E, the costs averted by disease prevention (i.e., both reduced medical costs-- because of reduced disease transmission to household members -- and reduced loss of parental productivity from caring for a sick child), using the assumptions derived from the literature as follows. Based on data from a large controlled clinical trial, Schmier et al. estimated the averted medical expenditure to be $117.45 (adjusted to 2009 dollars) for all members in a household during an influenza season [23]. This averted medical expenditure represents the difference in direct influenza costs between intervention and control schools. These costs include outpatient, emergency department, hospitalization, prescribed medication and over-the-counter medication [23].

Schmier et al. also calculated the averted productivity loss as $87.55 (adjusted to 2009 dollar) per household, in addition to the averted medical expenditure of $117.45 [23]. They based this calculation on assumptions regarding the forgone income of a parent who was absent from work to take care of her/his influenza-infected child. Their study reported that the difference in the vaccination rate between the intervention group and the control group was 45 percent (47% in intervention group versus 2%in controls), and that the average household size was 4.6 members (2.6 children and 2.0 adults) [23]. Thus, Component E could be inflated by 2.22 (=1/45%) times, if the difference in the vaccination rate is 100%, i.e., $455 (=2.22*($117.45+$87.55) per household.

Monte Carlo Simulation—To address the uncertainty of the cost estimates in our study, we conducted a Monte Carlo simulation in summing the component costs, (A), (B) and (C_1), to estimate subtotal costs and total costs. For each component cost we defined a triangular distribution with likeliest, minimum and maximum values based on prior studies that documented factors affecting vaccination costs [10]. The likeliest value was the overall mean of the SLV-I schools. The minimum and the maximum values were selected among the four subgroups of the SLV-I schools, based on geographic area (urban or suburban) and the intensity of communication to parents (some schools were randomized to a high intensity of communication with many parent reminders; others to low intensity)[13]. We reported the mean and the 95% confidence interval (CI) of the simulation results with 10,000 iterations.

Comparison with practice-located vaccination—This cost analysis was designed to examine our first and second hypotheses, i.e., that the cost of SLV-I is comparable or less than the cost of practice-located childhood influenza vaccination, depending on the assumptions in the cost calculation. We determined that SLV-I would be less costly if the estimated cost per dose for SLV-I were below the mean/median ($38.23/$21.44 in 2009 dollar value) cost per dose for practice-located influenza vaccination as reported in our past study [10]. For this analysis, we consistently excluded the vaccine purchase cost from both SLV-I costs and medical practices' costs [10]. Thus, vaccine costs did not affect this comparison. The mean value ($38.23) was not published in our past study, but calculated with the same subjects as in our past study [10]. To test this second hypothesis, the averted parent's cost to visit a medical practice for their child's vaccination had been subtracted from the SLV-I costs.

Supplemental cost analyses of first and second SLV-I clinics—Children aged 6 months-8 years are recommended to receive two doses of vaccine if they have not been vaccinated previously [4]. Children could receive a vaccine dose at their primary care physicians' office before the first school-located clinic ("first clinic") and/or before the second school-located clinic ("second clinic"). Of the 1724 doses provided in SLV-I schools, the first clinics provided 70% of doses (1200, i.e., 1197 first-doses +3 second-doses) and the second clinics provided 30% (524, i.e., 184 first-doses + 340 second-doses). If we assumed that the total administrative costs to the vender were equally distributed between the first and second clinics for each school, the per-dose cost estimates would be much lower in first clinics since more doses were administered in these. Therefore, we conducted separate supplemental analyses for first clinics and second vaccine clinics. We

conducted additional supplemental break-even analyses to assess the threshold values at which SLV-I would be equivalent to medical practice-located vaccination in direct costs or net costs.

2.3 Effectiveness and cost parameters in the cost effectiveness analysis (CEA) model

Effectiveness measure parameters—The effectiveness measure was the receipt of at least a first dose of seasonal influenza vaccination, a metric also used by prior studies [13, 24]. This measure was adopted because our database could not distinguish which children needed two doses due to the lack of a prior seasonal influenza vaccination. The primary effectiveness measure was the difference in the percent of children vaccinated (either at school or elsewhere) at the intervention vs. control schools; i.e., the incremental vaccination rate (regardless of the setting in which influenza vaccine was given). This difference could lead to either a positive or negative change in terms of vaccination receipt. The secondary effectiveness measure was the incremental vaccination rate solely based on vaccination administered in SLV-I schools.

Cost parameters—The cost parameters of CEA followed the cost analysis illustrated earlier, i.e., the primary cost measure included the direct cost from a narrower societal perspective. The secondary cost measures included the indirect costs.

Cost-effectiveness measures—The incremental cost-effectiveness ratio (ICER) was estimated by dividing the incremental cost by the incremental effectiveness (i.e., the number of additionally vaccinated students), using either control schools or “no-vaccination” as a reference group. Two types of ICERs were estimated separately for the primary and secondary effectiveness measures, explained above.

3. RESULTS

3.1 Effectiveness measures

In SLV-I schools, 15.3% of the children received their first dose of seasonal influenza vaccination at school (our secondary effectiveness measure) (Table 1). In addition, 27.4% of the children attending SLV-I schools were vaccinated elsewhere. The overall vaccination rate, irrespective of the location of vaccination, was 42.7% in SLV-I schools (Table 1) compared to 29.5% in control schools (p-value < 0.0001). Thus, the net effect of SLV-I was a 13.2 percentage point higher influenza vaccination rate, i.e., our primary effectiveness measure. This primary effectiveness measure (13.2%) was lower than the secondary effectiveness measure (15.3% vaccinated at schools) due to the fact that the proportion of children vaccinated with influenza vaccine elsewhere was smaller among children attending SLV-I schools than control schools.

Among the 1,381 students who received their first vaccine dose in an SLV-I school, 1197 (87%) did so at their school’s first vaccine clinic rather than at the school’s second clinic. Therefore, we also calculated the effectiveness of these first clinics only, i.e., excluding second clinics. These first clinics alone increased the proportion of children receiving influenza vaccine overall (the primary effectiveness measure) by 11.2 percentage points

when compared to the control schools (Table 1). Overall, 13.3% of children attending SLV-I schools were vaccinated during the first clinics (secondary measure) (Table 1).

3.2 Cost analysis

Per dose costs by component—The mass vaccinator documented administration of 1724 vaccine doses among 1381 students initiating their first dose of the influenza series. This was used as the denominator for this cost analysis (Table 2). The school cost (Component A) was $9.16 per dose, and was composed of per-dose material costs ($4.42) and labor costs ($4.75). Per dose project costs (B) were $23.00 and vendor costs (C, including vaccine purchase and administration) were $32.67. The direct costs (school + project + vendor costs) totaled $67.13 with 95% CI ($56.91, $78.06) in our Monte Carlo simulation.

The indirect cost components –Component D, averted parents' costs, and E, costs averted by disease prevention), were estimated to be $35.08 and $455.00 (not reported in Tables) per dose, respectively.

Per dose cost comparisons—When we accounted only for direct costs without vaccine purchase, the overall cost per dose was estimated to be $54.26 with 95% CI ($44.10, $65.16) (Subtotal Cost 2, Table 2). This per dose direct cost ($54.26) is above the mean/median ($38.23/$21.44) and the 75th percentile ($38.84) direct cost for providing influenza vaccination in medical practices as reported in our previous study [10]. This estimate was against our first hypothesis that the average direct cost per dose in SLV-I during year 1 would be comparable or lower than that observed in medical practices.

Because the vaccine purchase cost (C_2) could vary substantially across schools depending on the proportion of VFC eligible children, we made separate costs estimates: (i) including the vaccine administration cost (C_1) only and (ii) additionally including the vaccine purchase cost (C_2).

When we accounted for the Component D, averted parental cost to accompany their child to a medical practice for immunization (which was averted by SLV-I), this cost declined to $19.26 (Total Cost 2, Table 2). This per dose net cost ($19.26) falls between the 25th percentile ($13.42) and the mean ($38.23) cost for providing influenza vaccination in medical practices reported in our previous study [10]. Therefore, this cost analysis supported our second hypothesis that SLV-I has lower net costs compared to conventional influenza vaccination in medical practices.

Per dose costs for first and second clinics—The SLV-I vaccine net costs, accounting for averted parental cost to accompany a child to a medical practice for influenza vaccination, were $19.26 when considering all vaccine clinics (both first and second). They were $3.90 if only first clinics were included (Table 3), well below both the 25th percentile ($13.42) and the mean ($38.23) cost per dose in private medical practices [10]. If only first clinics were included (Table 3), per dose direct cost ($39.06) (without considering the averted parent's cost to visit medical practices) is comparable to the mean ($38.23) cost for providing influenza vaccination in medical practices as reported in our previous study [10].

3.3 Cost effectiveness analysis

Tables 2 and 3 present the CEA results for all influenza vaccination clinics and for first clinics alone, respectively. The CEA that included only first clinics was far more favorable for SLV-I than vaccination in medical offices. Specifically, if only first clinics were included, the estimated ICER (based only on Components A + B + C_1) decreased from $73.70 (Table 2) to $53.10 (Table 3) per-incremental-student-vaccinated.

This ICER increased depending on the additional assumptions of the vaccine purchase cost. For all influenza vaccination clinics, the ICER increased from $73.70 to $84.47 (assuming a cost of $0 for influenza vaccine provided by the VFC program from the perspectives of school districts and the local health department) to $92.50 (assuming $10.40 as the cost of a dose of influenza vaccine provided by the VFC program from a societal perspective), respectively (Table 2). The perspectives of school districts and the local health department were adopted, because these perspectives are the factors that school districts and the local health department would use in considering a future school-vaccination program (i.e., they would not consider the cost of VFC vaccine, which is government supplied).

More broadly, the ICER would decline if indirect costs averted by parents (D) are taken into account (Components A+B+C – D). If we consider the savings for parents who would otherwise need to visit medical practices for their children's influenza vaccination (Component D), the ICER of $92.50 in direct costs (including both labor and vaccine purchase) declined to $57.37 in net costs (Table 2).

Our supplemental hypothesis was that SLV-I could be cost-saving for society compared to "no vaccination." This hypothesis is supported by our findings. That is, if indirect costs averted by disease prevention (E) are taken into account (Components A+B+C – E), the ICER became negative in societal costs ((A+B+C-E) = $67.13-$455=-$387.87) (results not shown in Tables 2). The negative ICER values indicate that SLV-I is cost-saving compared to "no vaccination" from the broader societal perspective.

Additionally, we performed a supplemental break-even analysis for CEA accounting for net costs [i.e., (direct costs – parent costs) = (A+B+C – D)]. This analysis suggests SLV-I could be cost-saving to society in net costs -- even if averted costs due to medical expenditures and lost productivity are not included -- if the vaccination rate at school were to increase from the actual level in this project (15.3%) to at least 29.5%.

4. DISCUSSION

4.1 Implications based on key findings

This study provides both caution and also support for the benefit of SLV-I. In the first year of the SLV program, direct per-dose costs were higher for SLV-I ($54.26/dose) than those for pediatric practice-based influenza vaccination (previously reported mean/median cost $38.23/$21.44 per dose). However, when we factored in the averted costs for parents to have their child vaccinated by the child's primary care provider, which is averted by SLV-I, our cost analysis showed that the (average) net cost estimates per dose in the SLV-I schools were lower than those in pediatric practices, particularly for the first vaccination clinics in

the SLV-I program. Finally, because SLV-I was associated with an increase in influenza vaccination, savings from the increase in disease prevention could be included in the model. This analysis showed SLV-I to be cost-saving to society compared to "no vaccination."

Direct costs (costs to deliver influenza vaccinations)—In this SLV-I demonstration project direct costs ($A+B+C_1$=$54.26) were higher than practice-based costs ($38.23). If SLV-I could reduce the direct cost of providing influenza vaccination in school, the program could reach the break- even point (versus medical practices), irrespective of indirect costs. Our analyses identified three feasible strategies to make SLV-I less costly and more cost effective than vaccination in medical practices, even without accounting for any future indirect cost savings. The first strategy is elimination of the relatively poorly attended second dose clinics. Children eligible for a second dose could be referred to primary care. Another strategy is to maximize vaccination clinic size through better student recruitment. We believe that as schools and parents become more familiar with SLV-I, the program will attract a larger number of children and eventually achieve the break-even threshold. Specifically, if this SLV-I project could have achieved a higher vaccination rate, providing 2447 doses (42% more than the actual 1724 doses given), this SLV-I demonstration would reach the break-even point. The third strategy involves decreasing direct costs through greater efficiency. For example, streamlined utilization of SLV-I personnel may be realized with more experience. Substantial project administration time was spent on the consent process that could be streamlined in the future through the use of technology such as electronic consent. A combination of these three strategies is the most promising enhancement to SLV-I.

Net costs including averted parent costs—When averted parental costs are considered, the estimated per dose net cost ($19.26) is below the mean/median cost ($38.23/$21.44) for providing influenza vaccination in medical practices [10]. This estimate decreases to $3.90 if only first clinics were included, which is well below both the 25th percentile ($13.42) cost per dose in private medical practices [10]. These cost estimates supported our second hypothesis that SLV-I has lower net costs compared to conventional influenza vaccination in private medical practices, if averted parent costs are included in the calculation.

Costs to society—Moreover, our cost analysis showed that SLV-I was cost-saving to society compared to no-vaccination. This analysis accounted for direct costs and costs averted by disease prevention (i.e., both reduced medical costs-- because of reduced disease transmission to household members -- and reduced loss of productivity from caring for a sick child) at the household level (Component E), as reported earlier. It is important to note that the magnitude of Component E can vary across influenza seasons due to year-to-year variation in both the virulence of the particular season's influenza virus and vaccine effectiveness. Due to such uncertainty, Table 2–4 did not include the results relating to this component.

4.2. Comparisons to other studies

In our SLV-I model, a for-profit vendor delivered the in-school vaccinations that were purchased through routine channels. Thus, estimates of the costs for this study tend to be larger than those in other SLV-I demonstrations. Our estimate of $54.26 per dose was substantially higher than $6.75 estimated by Schmier et al. [23], the $9.78 estimated by Hull and colleagues [25] and the $15.14 estimated by Effler and associates [24]. Among these studies, only the last study reported the detailed cost items within the administration cost. Regarding the labor cost estimates, our estimate ($37.27 per dose) was higher than $11.79 of Effler et al [24]. The study by Hull and colleagues [25] may have underestimated the true administrative cost, because their demonstration did not seek third party reimbursement (which was included as part of the vendor's administrative cost in our study). One of the reasons for this difference could be our extended time and effort that was needed to collect parents' consent forms; these forms contained detailed information about patient insurance. Material costs incurred by schools and the project coordinators were $5.40 per dose, which was comparable to $5.53 (adjusted to 2009 dollar) estimated by Effler et al [24]. However, our estimate of the vendor's material cost, $16.02 per dose, was much larger than that of $1.59 by Effler et al [24]. This gap can be partly explained by our additional inclusion of items such as the refrigerator for vaccines and non-medical supplies.

Other studies also have found SLV-I to be cost saving to society, when accounting for broader indirect costs [23, 26]. White and colleagues conducted a similar CEA among school-aged children using secondary datasets only [26]. They concluded that group-based influenza vaccination is cost-saving, i.e., saving $6.19 and $53.98 per vaccination as compared to individual-initiated vaccination (at a conventional medical practice) and no-vaccination, respectively. Their estimate about SLV-I cost (including all administrative and vaccine purchase costs) was $6.69 adjusted to 2009 dollars. This amount seems extremely low considering the vaccine purchase cost of $10.40 per dose listed by CDC [16].

Schmier et al. conducted a cost analysis of SLV-I using primary data from a large-cluster controlled clinical trial [23]. They compared the cost per household between intervention schools and control schools, and concluded that SLV-I targeting children aged 5–18 years is cost- saving to society. In their estimates, the households in intervention schools incurred an additional incremental cost to have a child receive an influenza vaccination ($40.31), which was offset by the averted medical expenditure ($117.45) and lost productivity ($87.55) per household.

4.3 Potential limitations

One potential limitation is the assumption of equal direct costs for first vaccine clinics and second clinics in the SLV-I schools. Since it was difficult to strictly allocate costs for each clinic, we assumed an equal allocation. The true cost for first clinics is likely to be between the estimates in Table 2 (first and second clinics) and Table 3 (first clinic only). Also, as mentioned earlier, the administrative cost is expected to decline over multiple seasons. Hence, our estimates in Table 2 are likely to be conservative ones.

Due to the lack of information on whether children were due for one or two doses of influenza vaccine based on the available data, our study's outcome variable was the receipt of at least one dose rather than being fully immunized.

A third limitation involves generalizability of our estimates, which may have been limited by three factors. First, our SLV-I program occurred during the 2009–2010 vaccination season during which there was the H1N1 influenza pandemic. This outbreak may have affected the vaccination behaviors of our study population in unmeasured ways. For instance, demand for seasonal influenza vaccine may have been affected by the lack of availability of H1N1 vaccine as part of the SLV-I program. Second, the effectiveness of SLV-I depends on the proportion of local children vaccinated by medical practices before the school vaccine clinics. That is, when medical practices regularly vaccinate a high proportion of children in a certain area, the SLV-I program in that area is likely to only have a small impact due to a "ceiling-effect." Therefore, our estimates of SLV-I effectiveness are likely to be most applicable to other settings where the "baseline" vaccination rates contributed by medical practices are comparable to those in our study site (29.5%). Third, seasonal influenza's severity varies across regions during the same season. Because seasonal influenza's severity may affect influenza vaccination behavior [27], SLV-I effectiveness might be different in other regions even if the baseline vaccination rates in those regions are comparable to that of our study. Additionally, we did not include costs associated with disruptions of the school day caused by SLV-I, nor cost savings associated with decreased absenteeism.

Another limitation is that the indirect cost estimates were not derived from our study, but from the literature. However, the indirect cost component (D, averted parents' costs) used a national-level median hourly wage among working adults and, hence, is likely to be reasonably applicable for our study population. Because another indirect component (E, costs averted by disease prevention) has uncertainty in the methods and the magnitude across the seasons, we did not report component E-related results in Tables.

4.4 Conclusion

Our empirical results appear to support the expanded implementation of SLV-I. Future work is needed to examine the feasibility of improving delivery efficiency by offering one clinic instead of two clinics for each school, and increasing the vaccination rate within SLV-I. Direct medical costs to conduct SLV-I (school + project + vendor costs) were high in this initial year of the SLV-I intervention, exceeding typical reimbursement rates. However, costs potentially could be decreased over time as greater efficiencies may accrue in subsequent years of the intervention. Nevertheless, costs currently favor SLV-I over the conventional influenza vaccination delivery system either when we only consider a single SLV-I clinic per school or if averted parental costs to visit medical practices are taken into account. One major challenge is that cost-savings to parents may not be a factor that is considered by schools or the medical care system when SLV-I is contemplated. Nonetheless, our findings lend support to SLV-I as a potentially promising system to raise childhood influenza vaccination rates in a cost-efficient manner.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
CEA	Cost Effectiveness Analysis
ICER	Incremental Cost-Effectiveness Ratio
LAIV	Live Attenuated Influenza Vaccine (intranasal spray)
MEPS	Medical Expenditure Panel Survey
NYSIIS	New York State Immunization Information System
RCT	Randomized Controlled Trial
SLV-I	School-Located Vaccination against Influenza
TIV	Trivalent Influenza Vaccine (injectable)
VFC	Vaccine-For-Children

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HIGHLIGHT

We estimate a school-located flu vaccination project's cost and cost-effectiveness.

A randomized controlled trial of urban and suburban vaccination provides our data.

The direct per-dose cost of this project exceeded that of office-based vaccination.

When we include broader averted costs, the program was less costly than office-based vaccination.

Our findings support expanded program implementation and suggest efficiencies.

Table 1

Vaccination rates in school-located seasonal influenza vaccination (SLV-I) schools and control schools during the 2009–2010 season

	SLV-I schools		Control schools		Difference in
	Students	**% Total Students**	**Students**	**% Total Students**	**% Total Students**
Total students	9,027	100%	4,534	100%	0
Not vaccinated	5,172	57.3%	3,195	70.5%	−13.2
Vaccinated elsewhere [a]	2,474	27.4%	1,339	29.5%	−2.1
All clinics in SLV schools					
Received 1st dose [b]	1,381	15.3%[c]	n/a	n/a	15.3[c]
Total Vaccinated	3,855	42.7%*	1,339	29.5%*	13.2[d]
First clinic only in SLV schools					
Received 1st dose [b]	1,197	13.3%[c]	n/a	n/a	13.3[c]
Total vaccinated	3,671	40.7%**	1,339	29.5%**	11.2[d]

n/a: not applicable

[a] Identified as receiving at least the 1st dose outside the SLV-I schools in the New York State Immunization Information System (NYSIIS) data

[b] Identified as receiving at least the 1st dose at the SLV-I schools in the New York State Immunization Information System (NYSIIS).

[c] Secondary effectiveness measure included in our cost-effectiveness analysis model

[d] Primary effectiveness measure included in our cost-effectiveness analysis model

* 42.7% was significantly greater than 29.5% (p-value < 0.0001).

** 40.7% was significantly greater than 29.5% (p-value < 0.0001).

Table 2

Cost analysis and cost-effectiveness analysis of school-located seasonal influenza vaccination (SLV-I) during the 2009–2010 season (2009 dollar value)

	Cost analysis [a]	Cost-effectiveness analysis [b]	
		Vaccinated at school	Vaccinated anywhere [c]
	Cost ($ per dose)	ICER [d] ($-per-incremental-student- vaccinated)	
COMPONENT COSTS [e]			
(A) School Cost [f]	$9.16 ($5.92, $13.61)	$11.45 ($7.39, $17.01)	$13.29 ($8.90, $16.84)
(B) Project Cost [g]	$23.00 ($14.85, $34.17)	$28.73 ($18.55, $42.68)	$33.37 ($22.35, $42.29)
(C) Vendor Cost (= C_1+ C_2)	$32.67 ($25.63, $42.34)	$40.81 ($32.01, $52.87)	$47.40 ($37.87, $55.11)
(C_1) vaccine administration [h]	$19.88 ($12.84, $29.55)	$24.84 ($16.04, $36.90)	$28.85 ($19.32, $36.56)
(C_2) vaccine purchase (VFC dose =$10.40[i]	$12.79	$15.97	$18.55
(C_3) vaccine purchase (VFC dose = $0)[i]	$7.31	$9.13	$10.61
(D) Averted parents' costs (i.e., to visit medical practices for a child's influenza vaccination)	$35.08	$35.08	$35.08
SUBTOTAL COSTS [j]			
Subtotal Net Cost 1: (A + B) - (D)	−$1.53 (−$9.47, $6.92)	$6.90** (−$2.92, $17.54)	$10.62*** ($2.05, $18.88)
Subtotal Direct Cost 2: (A + B + C_1)	$54.26 ($44.10, $65.16)	$67.86 ($55.06, $81.71)	$73.70 ($62.67, $84.60)
Subtotal Direct Cost 3: (A + B + C_1 + C_3)	$61.66 ($51.36, $72.58)	$76.97 ($63.91, $90.58)	$84.47 ($73.48, $95.06)
TOTAL COSTS [j]			
Total Direct Cost 1: (A + B + C)	$67.13 ($56.91, $78.06)	$83.67 ($70.83, $97.40)	$92.50 ($81.47, $103.24)
Total Net Cost 2: (A + B + C_1) - (D)	$19.26* ($8.70, $30.10)	$32.74 ($20.00, $46.48)	$38.59 ($27.57, $49.30)
Total Net Cost 3: (A + B + C) - (D)	$31.97 ($21.78, $42.97)	$48.70 ($35.65, $62.58)	$57.37 ($46.26, $68.11)

[a] Based on 1724 doses.

[b] Based on 1381 students, identified as receiving at least the 1st dose at the SLV-I schools in the vendor's data.

[c] Broader perspective accounting for the fact that among children attending SLV-I schools a smaller proportion of children were vaccinated elsewhere (i.e., their primary care doctor's office) than control schools. Namely, Incremental effectiveness declined from 15.3% to 13.2% ICER for components (A/B/C_1) inflated by (15.3%/13.2%).

[d] ICER = incremental cost-effectiveness ratio [$-per-incremental-student-vaccinated at least 1st dose in the school-located seasonal influenza vaccination (SLV-I), compared to control schools]

[e] The values in the rows for COMPONENT COSTS indicate the triangular distributions defined by the likeliest value, (minimum value and maximum value). The likeliest value is the overall mean of the SLV-I schools. The minimum and the maximum values were selected among the four subgroups of the SLV-I schools, based on geographic area (urban or suburban) and the intervention intensity (high or low).

[f] Composed of material cost and labor cost. Material cost includes information distribution (to parents) costs such as paper, mailing, and phone. Labor cost was calculated through "the time spent for the project by school staffs" multiplied by "category-specific hourly wage (national average)" as of May 2009 [15].

[g] Time cost for collection of consent forms, and meeting with school staffs, and vendors. Evaluation research cost was excluded.

[h] Composed of the vendor's material and labor costs.

[i] 52% of the administered doses that were provided by Vaccine-for-children (VFC) for free. From a societal perspective, we assigned $10.40 per dose as the vaccine purchase cost, which is the weighted average prices of TIV (80% of doses administered in this demonstration) and LAIV (20%) as of May 2009 listed in the CDC website [16].

[j] The values in the rows for subtotal costs and total costs indicate the mean and 95% confidence interval of Monte Carlo Simulation results (10,000 iterations) using the distributions defined in the rows for component costs.

[*] Falls between the 25th percentile ($13.42) and the median/mean ($21.44/$38.23) cost [per dose] for providing influenza vaccination in private pediatric practices estimated by Yoo et al. [10].

[**] Below the lower limit of the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].

[***] Falls within the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].

Table 3

Cost analysis and cost-effectiveness analysis of the "first clinics" in school-located seasonal influenza vaccination (SLV-I) during the 2009–2010 season (2009 dollar value)

	Cost analysis [a]	Cost-effectiveness analysis [b]	
		Vaccinated at school	Vaccinated anywhere [c]
	Cost ($ per dose)	ICER [d] ($-per-incremental-student- vaccinated)	
COMPONENT COSTS [e]			
(A) School Cost [f]	$6.58 ($4.25, $9.77)	$8.22 ($5.31, $12.22)	$9.55 ($6.39, $12.10)
(B) Project Cost [g]	$16.52 ($10.67, $24.54)	$20.64 ($13.33, $30.66)	$23.97 ($16.05, $30.38)
(C) Vendor Cost (= C_1+ C_2)	$27.08 ($22.02, $34.02)	$33.81 ($27.49, $42.48)	$39.27 ($32.43, $58.69)
(C_1) vaccine administration [h]	$14.29 ($9.23, $21.23)	$17.84 ($11.52, $26.51)	$20.72 ($13.88, $26.26)
(C_2) vaccine purchase (VFC dose =$10.40)[i]	$12.79	$15.97	$18.55
(C_3) vaccine purchase (VFC dose = $0)[i]	$7.31	$9.13	$10.61
(D) Averted parents' costs (i.e., to visit medical practices for a child's influenza vaccination)	$35.08	$35.08	$35.08
SUBTOTAL COSTS [j]			
Subtotal Net Cost 1: (A + B) - (D)	−$10.99 (−$16.67, −$4.80)	−$4.94** (−$12.02, $2.65)	−$2.28*** (−$8.52, $3.55)
Subtotal Direct Cost 2: (A + B + C_1)	$39.06 ($31.57, $46.93)	$48.76 ($39.42, $58.69)	$53.10 ($44.99, $60.90)
Subtotal Direct Cost 3: (A + B + C_1 + C_3)	$46.38 ($39.07, 54.24)	$57.86 ($48.57, $67.62)	$63.74 ($55.89, $71.44)
TOTAL COSTS [j]			
Total Direct Cost 1: (A + B + C)	$51.79 ($44.37, $59.63)	$64.67 ($55.46, $74.34)	$76.27 ($65.12, $89.26)
Total Net Cost 2: (A + B + C_1) - (D)	$3.90* (−$3.52, $11.74)	$13.67 ($4.45, $23.35)	$18.05 ($9.85, $25.86)
Total Net Cost 3: (A + B + C) - (D)	$16.69 ($9.44, $24.50)	$29.63 ($20.34, $39.34)	$41.12 ($30.05, $54.27)

[a] Based on 1724 doses.

[b] Based on 1381 students, identified as receiving at least the 1st dose at the SLV-I schools in the vendor's data.

[c] Broader perspective accounting for the fact that among children attending SLV-I schools a smaller proportion of children vaccinated elsewhere (i.e., their primary care doctor's office) than control schools. Namely, Incremental effectiveness declined from 15.3% to 13.2% ICER for components (A/B/C_1) inflated by (15.3%/13.2%).

[d] ICER = incremental cost-effectiveness ratio [$-per-incremental-student-vaccinated at least 1st dose in the school-located seasonal influenza vaccination (SLV-I), compared to control schools]

[e] The values in the rows for component costs indicate the triangular distributions defined by the likeliest value, (minimum value and maximum value). The likeliest value is the overall mean of the SLV-I schools. The minimum and the maximum values were selected among the four subgroups of the SLV-I schools, based on geographic area (urban or suburban) and the intervention intensity (high or low).

[f] Composed of material cost and labor cost. Material cost includes information distribution (to parents) costs such as paper, mailing, and phone. Labor cost was calculated through "the time spent for the project by school staffs" multiplied by "category-specific hourly wage (national average)" as of May 2009 [15].

[g] Time cost for collection of consent forms, and meeting with school staffs, and vendors. Evaluation research cost was excluded.

[h] Composed of the vendor's material and labor costs.

[i] 52% of the administered doses that were provided by Vaccine-for-children (VFC) for free. From a societal perspective, we assigned $10.40 per dose as the vaccine purchase cost, which is the weighted average prices of TIV (80% of doses administered in this demonstration) and LAIV (20%) as of May 2009 listed in the CDC website [16].

[j] The values in the rows for subtotal costs and total costs indicate the mean and 95% confidence interval of Monte Carlo Simulation results (10,000 iterations) using the distributions defined in the rows for component costs.

[*] Below the 25th percentile ($13.42) cost [per dose] and the median/mean ($21.44/$38.23) cost [per dose] for providing influenza vaccination in private pediatric practices estimated by Yoo et al. [10].

[**] Below the lower limit of the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].

[***] Below the lower limit of the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].

Table 4

Cost analysis and Cost-effectiveness analysis of the "second clinics" in school-located seasonal influenza vaccination (SLV-I) during the 2009–2010 season [2009 dollar value]

	Cost analysis [a]	Cost-effectiveness analysis [b]	
		Vaccinated at school	Vaccinated anywhere [c]
	Cost ($ per dose)	ICER [d] ($-per-incremental-student-vaccinated)	
COMPONENT COSTS [e]			
(A) School Cost [f]	$15.07 ($9.73, $22.39)	$18.84 ($12.16, $27.98)	$21.86 ($14.64, $27.71)
(B) Project Cost [g]	$37.84 ($24.43, $56.21)	$47.26 ($30.52, $70.21)	$54.89 ($36.76, $69.57)
(C) Vendor Cost (= C_1+ C_2)	$45.51 ($33.92, $61.40)	$56.83 ($42.36, $76.67)	$66.01 ($50.33, $78.70)
(C_1) vaccine administration h	$32.72 ($21.13, $48.61)	$40.86 ($26.39, $60.70)	$47.46 ($31.78, $60.15)
(C_2) vaccine purchase (VFC dose =$10.40)[i]	$12.79	$15.97	$18.55
(C_3) vaccine purchase (VFC dose = $0) [i]	$7.31	$9.13	$10.61
(D) Averted parents' costs (i.e., to visit medical practices for a child's influenza vaccination)	$35.08	$35.08	$35.08
SUBTOTAL COSTS [j]			
Subtotal Net Cost 1: (A + B) - (D)	$20.12 ($7.42, $33.72)	$33.86** ($17.53, $50.88)	$40.08*** ($25.97, $53.56)
Subtotal Direct Cost 2: (A + B + C_1)	$89.36 ($72.63, $106.89)	$111.76 ($90.71, $133.63)	$121.68 ($103.02, $139.11)
Subtotal Direct Cost 3: (A + B + C_1 + C_3)	$96.74 ($79.78, $114.56)	$120.97 ($99.65, $143.78)	$132.33 ($113.90, $149.74)
TOTAL COSTS [j]			
Total Direct Cost 1: (A + B + C)	$102.22 ($84.99, $119.94)	$127.69 ($106.54, $150.24)	$140.15 ($121.80, $158.10)
Total Net Cost 2: (A + B + C_1) - (D)	$54.48* ($37.64, $72.41)	$76.39 ($55.11, $98.95)	$86.41 ($68.49, $103.60)
Total Net Cost 3: (A + B + C) - (D)	$67.20 ($50.61, $85.42)	$92.69 ($71.49, $114.90)	$105.00 ($86.49, $122.90)

[a] Based on 1724 doses.

[b] Based on 1381 students, identified as receiving at least the 1st dose at the SLV-I schools in the vendor's data.

[c] Broader perspective accounting for the fact that among children attending SLV-I schools a smaller proportion of children vaccinated elsewhere (i.e., their primary care doctor's office) than control schools. Namely, Incremental effectiveness declined from 15.3% to 13.2% ICER for components (A/B/C_1) inflated by (15.3%/13.2%).

[d] ICER = incremental cost-effectiveness ratio [$-per-incremental-student-vaccinated at least 1st dose in the school-located seasonal influenza vaccination (SLV-I), compared to control schools]

[e] The values in the rows for component costs indicate the triangular distributions defined by the likeliest value, (minimum value and maximum value). The likeliest value is the overall mean of the SLV-I schools. The minimum and the maximum values were selected among the four subgroups of the SLV-I schools, based on geographic area (urban or suburban) and the intervention intensity (high or low).

[f] Composed of material cost and labor cost. Material cost includes information distribution (to parents) costs such as paper, mailing, and phone. Labor cost was calculated through "the time spent for the project by school staffs" multiplied by "category-specific hourly wage (national average)" as of May 2009 [15].

[g] Time cost for collection of consent forms, and meeting with school staffs, and vendors. Evaluation research cost was excluded.

[h] Composed of the vendor's material and labor costs.

[i] 52% of the administered doses that were provided by Vaccine-for-children (VFC) for free. From a societal perspective, we assigned $10.40 per dose as the vaccine purchase cost, which is the weighted average prices of TIV (80% of doses administered in this demonstration) and LAIV (20%) as of May 2009 listed in the CDC website [16].

[j] The values in the rows for subtotal costs and total costs indicate the mean and 95% confidence interval of Monte Carlo Simulation results (10,000 iterations) using the distributions defined in the rows for component costs.

[*] Above the median/mean ($21.44/$38.23) and the 75th percentile ($38.84) cost [per dose] for providing influenza vaccination in private pediatric practices estimated by Yoo et al. [10].

[**] Above the upper limit of the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].

Above the upper limit of the cost range ($11.21, $16.81) [per child vaccinated] in the reminder program (using letters and/or automated telephone message) estimated by Lieu et al. [28].