School-Located Influenza Vaccination Program Effectiveness:

An Observational, Descriptive Case Study

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Children have the highest influenza infection rates of all population groups (Fiore et al., 2010; Fiore, Epperson, Perrotta, Bernstein, & Neuzil, 2012). While the Advisory Committee on Immunization Practices (ACIP) recommends annual universal influenza vaccination of all persons ≥ 6 months of age, many school-aged children do not receive recommended vaccinations and experience influenza, which results in poor health, absences from school, and transmission of infection to family and community members (Centers for Disease Control and Prevention [CDC], 2013; Fiore et al., 2010; Fiore et al., 2012; Hull & Ambrose, 2011a & b).

In January, 2010 free vaccine became available through the federal Vaccines for Children (VFC) program via the state health department and was offered to local public health units (LPHUs) to conduct school located influenza vaccination (SLIV) clinics in 2010. A gap was identified by the LPHU planners because no evaluation strategy was in place prior to conducting the pilot. There was a need to determine the effectiveness of the program to assist decision making about the future of the initiative.

Background

School located influenza vaccination clinics are recognized as an effective method to deliver vaccinations to school-aged children (Cawley, Hull, & Rousculp, 2010; Fiore, et al., 2010; Fiore, et al., 2010; Fiore, et al., 2012; Hull & Ambrose, 2011a & b; Kwong et al., 2010; Scheiber, Kennedy, & Kahn, 2012; and Tran, et al., 2010). A SLIV program is targeted at enrolled students; provides vaccinations at clinics held before, during, or after school hours in partnerships with public and private schools, school districts and public health (CDC, 2011).

The U. S. Department of Health and Human Services [USDHHS] (2010) set a national goal to vaccinate 80% of children 2-17 years of age against seasonal influenza in the Healthy

People 2020 initiative. Vaccination rates calculated from state Immunization Information System (IIS) data for children living in this LPHU region during the influenza season of 2009-10 was 21% for those aged 5-10 years and 13% for 11-17 year olds (NDDOH, 2011). The difference between past rates and the Healthy People 2020 target revealed a need to improve rates for school-aged children.

Many early SLIV programs (2003-2006) used manufacturer sponsored live attenuated influenza vaccine (LAIV) (nasal mist) with programs including 1-244 schools and rates ranging 7-58% (Hull & Ambrose, 2011a; Tran et al., 2010). Many later clinics offered LAIV and trivalent influenza vaccine (killed virus) (TIV) or H1N1 vaccine with rates of 16.5-73% with no serious adverse events in any of the programs. Most programs averaged between 40-55% coverage with more elementary and middle school than high school students vaccinated (Carpenter, 2007; Cawley et al., 2010; Effler et al, 2010; Fiore et al., 2010; Gupta, 2011; Hull and Ambrose, 2011a; Scheiber, et al., 2012). Ambrose & Sifakis (2011) identified that during school hours clinics had significantly higher rates than after school-hours clinics.

Disparities in rates among certain populations exist. Schools with high enrollments in the National School Lunch Program and schools with greater enrollments of black students had lower rates (Carpenter, et al., 2007; Fiore et al., 2010; Tran et al., 2010). An advantage of SLIV programs is they may reach the socioeconomically disadvantaged with access to vaccine that children might otherwise miss (Hull & Ambrose, 2011a). Parents prefer access to child vaccines that do not interfere with parental work schedules (Allison, et al., 2010; Cawley, et al., 2010). Studies indicate costs of influenza illness are greater than those of prevention (Cawley, et al., 2010; Fiore et al, 2012).

The majority of schools used various combinations of volunteers, temporary staff, student nurses, school nurses, public health nurses and, in some cases, commercial vaccinators to

administer vaccines (Cummings et al., 2012; Hull & Ambrose, 2011a; Scheiber et al., 2012; Tran et al., 2010). Strong partnerships among school officials, parents, the medical community, school personnel, local and state public health, volunteer organizations, and community stakeholders is the foundation for a sustainable program (Cawley et al., 2010; Cummings et al., 2012; Fiore et al., 2012; Scheiber et al., 2012; Tran et al., 2010).

Programs can operate at reasonable expense if they obtain VFC free through state health departments. Administration fees for a first dose of vaccine ranged \$6 to \$27.37 (Fiore et al., 2012; Hull and Ambrose, 2011a; Tran, et al., 2010). Program costs varied widely depending on venue, total doses, type of vaccine, community and school involvement and methods of payment.

Aims and Objectives

The purpose of this evaluation was to answer the question: Was the program effective in achieving it's goal of vaccinating 50% of children aged 5-18 in the region? A secondary objective was to improve assessment of future performance by identifying benchmarks.

Theoretical Framework

The Participatory Model for Evaluation was included in the integrated framework because it characterizes evaluation as a process that is systematic, data driven, flexible, iterative, integrative, simplified, and cyclical (Harris, 2010). Health improvement and promotion can be a "jigsaw" embedded in environments with many interacting, multifaceted variables that impact the outcomes of health programs, thus data gathering and interpretation to find plausible evidence of performance must be shaped by ethical principles (Tannahill, p. 386). Lewin's Planned Theory of Change was used for the systems change strategy to influence organizational culture to promote unfreezing. Driving and restraining forces unique to an organization can

promote or hinder change. The *moving* stage is characterized by applying a solution to the problem revealed by data analysis. *Refreezing* is when changes become established and integrated into normal practice (Burnes, 2004; Schriner, et al., 2010).

Methods

Design and Sample

An observational, descriptive, case study design was used. Budgetary limitations required a practical, low cost approach. Data was gathered from multiple sources, analyzed and triangulated to reveal evidence of program effectiveness. A nonprobability, convenience sample of 58 schools set in a mixed urban/rural setting in the upper Midwest, United States participated in a SLIV pilot program in 2010 (2010-11 school year). These schools had an enrollment of 13,356 children aged five through 18 in 2010. The school was the unit of analysis.

A knowledge/opinion/attitude survey was conducted to identify the perspectives of key participants using a nonprobability, convenience sample recruited from a total of 54 public health unit (HUP) and 1,780 school personnel (SP). Inclusion criteria were age ≥18 years old and being an employee of the LPHU or a school in the region.

A quality improvement (QI) team of four included three LPHU staff: the Director of Nursing (DON), the County Nursing Supervisor (CNS), the Immunization Coordinator (IC); and the author. Sixteen HUP RNs participated in the SLIV program as part of their regular work duties and all attended a Public Health Nursing Grand Rounds (PHNGRs).

There are 28 independent LPHUs in a 53 county state, organized in various ways: single or multi-county health districts, and city/county health departments or health districts (NDDOH, 2012a). Each LPHU was contacted by email or telephone and all but two single county LPHUs

supplied data about participation in SLIV clinics during 2011 (2011-12 school year).

Institutional Review Board (IRB) approval from a university was obtained prior to data collection which stated that research involving observation was approved under the QI category without obtaining consent, while survey or interview research was limited to adult subjects.

Setting

Six counties in this LPHU are classified as rural (non-metro, completely rural, county that does not contain a town with at least 2,500 population) and one is classified as semi-rural (non-metro county that contains a town or city with 2,500 population or more) as it has an urban center (Center for Rural Health, 2009). The term *urban schools* identifies schools within the urban center or nearby catchment area, while the remaining are *rural schools*.

Measures

The time period was September 2010 through May 2013 (school years extend from September – May). Data for 2010 and 2011 includes vaccination rates; VFC, LAIV, and TIV uptake; in vs. out of school hours clinics; program operations and fiscal data, and vaccination outcomes only for 2012 (2012-13 school year). Data were stored electronically in Microsoft (2010) Excel worksheets.

No survey tool was found that met study needs, thus a questionnaire was developed by the author and tested by two LPHU staff. It included 22 closed-ended items consisting of 5-point Likert-type scale items, five pick list items; and eight demographic items. A survey description and invitation to participate was sent out several days prior to the survey through work-site emails via the appropriate webmasters. No incentives were offered. Adult subjects were required to provide individual consent electronically prior to receiving access to survey items. Participants not meeting inclusion criteria were omitted from calculations. An internet based survey tool was purchased by the author to collect survey responses. Secure Sockets Layer (SSL) technology was

enabled to protect users.

Grand rounds is defined as a participatory teaching/learning method that originated in medical residency training to improve clinical reasoning skills by examining clinical problems (MedicineNet, Inc., 2012) and was adapted for RNs to critically examine a public health problem. Nursing grand rounds were used in an academic hospital system, an acute care hospital, a community hospital, and school and public health setting, with participants satisfied that grand rounds effectively improved nursing practice (Burnie & Parks, 2008; Furlong, D'Luna-O'Grady, Loveland, 2005; Macari-Hinson, O'Connel, Perez, & Pierson, 2007; Odedra & Hitchcock, 2011; & Wolak, Cairns, & Smith, 2008). An analysis of the pilot SLIV baseline outcomes and benchmarks were examined with the expected outcome improved care to this population.

Benchmarking aids performance assessment by comparisons with similar organizations on reference points (JISC, 2012). No generalizable indicators were available, thus a need to identify and report benchmarks of local program success was revealed. Data about 2011 participation was collected January to April 2012 from state LPHUs and several private agencies that conducted clinics in four counties where LPHUs did not. County level rates for 5-18 year olds for Sept. 1 – Dec. 31, 2010 and 2011 was obtained from the state IIS after completing a data use agreement. This time frame included the active SLIV programs in schools plus 30 days to allow for data entry to the IIS (NDDOH, 2012b).

Analytic Strategy

Analysis was done using Microsoft (2010) Excel (Service Pack 3). Descriptive statistics were calculated including frequencies, means, rates, ranges and change in the variables between two seasons. The LPHU received results in detailed, granular form to assist decision making about SLIV clinics for each school, at the county level, and in aggregate.

Results

Baselines for 2010 Pilot Program

Vaccination rates.

The mean vaccination rate was 21% for 58 clinics (see Appendix Table 1: Results of School Located Vaccination Clinics in 2010, 2011, and 2012). In urban schools, clinics were during Sept. 27-Oct. 29 (≈5 weeks) and in rural schools, Sept. 29-Nov. 4 (≈6 weeks). Second dose clinics were not scheduled routinely, but 190 second doses were given.

During school-hours vs. out of school-hours clinics rates.

A natural experiment with a non-probability, convenience sample included 19 clinics conducted after school hours only, resulting in a mean rate of 16.27% (SD=7.47). All other 39 clinics were conducted during school hours resulting in a rate of 30.38% (SD=7.02), t(56)=7.03, p<.01, one tailed test (pooled t-test).

Operational baselines.

Twenty-two paid staff worked 1,942 hours (mean 88.3 hours) at program activities and 23 volunteer staff contributed 84 hours (mean 3.6 hours). It took 39 minutes of paid staff time to provide one unit of vaccine.

Fiscal baselines.

Administration fees of \$13.90 per dose were charged. Costs included \$47,572.87 for salaries plus benefits, \$3,103.54 for printing, \$1,641.20 for mileage, \$733.11 for supplies, and \$88.50 for postage. Net cost to deliver one unit of vaccine was \$17.57 resulting in a net program loss of \$11,105.62.

Benchmark baselines.

The state IIS data produced vaccination rates of 38% for 5-10 year olds and 28% for 11-17 year olds for Sept. 1, 2010-May 31, 2011 in the LPHU region (NDDOH, 2011).

Survey of School and Public Health Unit Personnel

Survey data was extracted May 21, 2011, from the Survey Monkey© site into Excel 2010 work sheets. Response was low from SP (n=70, 3.9%) and higher from HUP (n=28, 51.9%). A total score was obtained by summing items, with higher scores indicating support for the item premise. The overwhelming majority (both SP and HUP) were female, white and worked in a semi-rural county. Fifty-six percent of SP reported age as 50-69 while 67% of HUP were <30-49. Ninety-one percent of SP and 54% of HUP stated educational preparation at the master's or baccalaureate level. Fourteen percent of HUP and 8% of SP reported a management or supervisory role. About half of SP and HUP stated being in their current role and worksite ≥ 10-21 years. Sixty-eight percent of HUP and 83% of SP reported direct interaction with parents in their work position.

Public Health Nursing Grand Rounds and Recommendations for Improvements

Registered nurses who work as PHNs identified facilitators and barriers, and described lessons learned from planning and conducting the program. The QI team derived recommendations for program improvements from analysis of patterns in the information obtained from RNs, program baselines, the HUP and SP survey, and discussions amongst the QI team.

- Schedule clinics in the month of October with September as a second choice.
- Conduct clinics on Tuesday or Wednesday, with Thursday as a lesser preferred day.
- Schedule clinics during school hours within morning or afternoon class times.
- Do not require parental presence.
- Post materials on school websites with links to forms: supply paper forms as needed.

- Encourage uptake of needleless LAIV as parents may find this a more acceptable option.
- Track distribution and return of completed consent forms to establish best timing.
- Consider a strategy to collect day of clinic return of completed parental consent forms.
- Send reminders to parents twice (a week before and a day before) clinics via school systems.
- Increase utilization of volunteers such as student nurses.
- Explore billing alternatives and vaccine sources for children not qualified for VFC.
- Refer students who require second doses of vaccine to their PCPs or county PH offices.
- Enter complete data into the state IIS within 30 days of vaccination.
- Standardize terminology and measures that may indicate program effectiveness.
- Develop a dashboard of program effectiveness and provide it to stakeholders.
- Encourage school participation in state school ILI surveillance system.

Planning for program success includes expecting risks related to personnel, technical, ethical and financial factors but environmental events are another matter. A flood inundated the urban center and caused the evacuation of 11,000 people and the destruction of 4,115 homes in summer of 2011 (City of Minot, 2012). An elementary and a large middle school were destroyed and students moved to temporary facilities indefinitely. The program was compromised by the disaster because though the same RNs participated in planning and conducting SLIV clinics as in 2010, their activities were limited by diversion of public health to community disaster management. Clinics were mostly held during October on Tuesday or Wednesday, all during school hours and none required parental presence. No second dose clinics were conducted. Communication with parents, schools and the community were streamlined. Volunteer activity of student nurses at clinics increased. One form was used from consent, administration of vaccine, billing, to data entry into the state IIS. The LPHU used existing agreements with

underwriters to recover vaccine purchase costs and collect administration fees for insured children.

Outcomes for 2011 SLIV Program

Vaccination rates.

The outcome objective was evaluated February 24, 2012. The mean rate was 19% for all 54 SLIV clinics. In urban schools, clinics were conducted Sept. 22-Oct. 25 (≈6 weeks) and in rural schools, Sept. 20-Nov. 2 (≈7 weeks). Only ten second doses were given. Change between seasons is demonstrated in Table 2.

Table 2.

Ranges in Clinics, Mean Rates, Enrollments, Vaccinations, LAIV^a, TIV^b, and VFC^c at Schools

Category	2010	2011	Change in 2011
	Rural Schools	Rural Schools	
Clinics	N=29	N=28	-1
Mean Rates	8-48%	7-51%	(-1%) to (+3%)
Enrollments	31-577	22-598	(-9) to (+21)
Vaccinations	8-185	7-208	(-1) to (+23)
LAIV	2-86	1-112	(-1) to (+26)
TIV	4-108	3-96	(-1) to (-12)
VFC	All	0-36	
	Urban Schools	Urban Schools	
Clinics	N=29	N=26	-3
Mean Rates	3-50%	1- 41%	(-2%) to (-9%)
Enrollments	50-968	60-966	(+10) to (-2)

Vaccinations	18-112	6-130	(-12) to (+18)
LAIV	8-70	2-82	(-6) to (+12)
TIV	6-50	3-48	(-3) to (-2)
VFC	All	2-63	

Note. ^aLive attenuated influenza vaccine. ^bTrivalent influenza vaccine. ^cVaccines for Children. Sources of data: LPHU (2012).

Operational outcomes.

Nineteen paid staff worked 946.5 hours (mean 49.8 hours) on planning or program activities and 23 volunteer staff contributed 168 hours (mean 6.7 hours). It took 22 minutes of paid staff time to provide one unit of vaccine.

Fiscal outcomes.

Qualified children received 704 doses of VFC administered for \$13.90 per dose. There were 890 doses of non-VFC TIV purchased for \$8.15 each and administered for \$30 per dose. There were 1003 doses of non-VFC LAIV purchased for \$18.75 each and administered for \$40 per dose. Other costs were \$21,741.63 for salaries plus benefits, \$1,590.00 for printing, \$1,707.75 for mileage, \$659.56 for supplies, and \$27.52 for postage. Net cost to deliver a unit of vaccine was \$19.94. Net income to administer a unit of vaccine was \$29.50 resulting in a positive program balance of \$24,819.39.

Benchmarks.

Both single county and multicounty LPHUs that conducted SLIV clinics in all schools in 2010 and 2011 had higher vaccination rates than similar LPHUs that either did not, or had only a very limited program (a few schools at limited times or after school hours) (see Table 3). Multicounty LPHUs that had clinics in all schools had mean coverage of 26.5% (22-32%) in 2010, and 31% (24-43%) in 2011.

Table 2.

Vaccination Rates of School-aged Children in 2010 and 2011 in Single and Multi-county Local Public Health Unit^a Service Regions that Did or Did Not Have School Located Clinics

Local Public Health Unit Type	Did have	e clinics	Did not have clinics			
	2010 ^b	2011°	2010	2011		
		Mean (R	ange) %			
Single county LPHU	32 (19-44)	31 (19-50)	18 (13-24)	19.5 (17-19)		
Multi-county LPHUs (per county)	30 (16-43)	30 (10-45)	18 (11-25)	21 (12-29)		
Multi-county LPHU (includes all	26.5 (22-32)	31 (25-43)	24 (22-25)	24.5 (24-25)		
counties in the LPHU)						

Note. ^aLocal public health unit. ^bN=41, no data was supplied for 12 counties for 2010 clinics and these were removed from the calculation. ^cN=51, no data was supplied for two counties participation in 2011 clinics and these were removed from the calculation. Sources of data: NDDOH (2012b); US Census Bureau (2012); personal communications with state LPHUs (2012).

In 2011, there were 636 cases (43% of all state cases) of influenza in the 34 counties with clinics in all schools whether conducted by a LPHU or private provider with a mean of 19 cases per county. There were 812 reported cases (55% of all cases) of influenza in the 16 counties that had no clinics or had limited partial or after school clinics with a mean of 36 cases per county. No case data was provided for 3 counties.

In 2009-2010, 69.4 % of the total cases of influenza in the state occurred in those 0-19 years of age. In 2012-2013 the percentage of cases of influenza occurring in 0-19 year olds was 51.6% (see Table 4).

Table 4.

Influenza Cases During 2009-13 in all Age Groups in the State and Local Public Health Unit
Region, and in those Aged 0-19 in the State

	Influenza Seasons ^{a,b}									
	Frequency, % of Total Cases in the State									
State or region and age group	2009-10	2010-11	2011-12	2012-13						
State (all age groups)	3259	2089	1487	4831						
Seven county LPHU (all age	327, 10.0%	182, 8.7%	161, 10.8%	505, 10.4%						
groups)										
State (children 0-19 years of age)	2263, 69.4%	1140, 54.6%	678, 45.6%	2494, 51.6%						

Note. ^a 2009-12 seasons confirmed cases fully reported. ^b 2012-13 Confirmed cases to July 6, 2013. Source of data: NDDOH (2013).

Discussion

This initiative was designed to support decision making for program continuation in ensuing seasons. The pilot program rate was 21%, far from the goal of 50% coverage for children aged 5-18 in the region. Substantial LPHU staff time and resources were expended in 2010 resulting in financial loss. In 2011, reductions in staff time and resources, and increases in administration fees for non-VFC doses resulted in financial gain, though coverage was 19%. Uncontrollable variables such as vaccine availability and effectiveness, influenza attack rates and unforeseeable events can have an impact on outcomes.

Limitations

There were limitations to this evaluation. This was a non-probability study and no effort was made to control for extraneous or confounding variables. Interactions among contextual factors might have affected internal validity. Clinics were operated by varied sets of staff rather than one clinic in one setting with exactly the same staff each time. Several schools did not receive clinics in 2011 and 2012 due to small enrollments. Possible threats to internal validity of the survey may be selection bias, attention bias, recall bias, and interaction among respondents.

Threats to external validity of the results were the small sample sizes of schools, LPHU participants, school participants, and state LPHUs. The survey may not have been valid for both populations as it was not tested with SP prior to use, though the QI team reviewed the HUP/SP survey prior to collecting data for content and face validity.

To support internal validity the QI team met regularly to validate interpretation of data analysis. Additionally, PHNGRs was utilized for peer consultation to pool observations and lessons learned from RN participants that conducted clinics. These activities were not measured to assess their direct impact on the program.

Interpretation

One plausible explanation for the rate decrease in 2011 is the seasonal nature of the problem. Stakeholders may lose interest as a result of time, though disaster response may be the more likely cause in this case. Clinics conducted after school hours required parental presence in 2010 and were urban schools. In 2011 and 2012, all rural and urban school clinics were held during school hours, but rural results were greater all three years. The rurality of most other schools and parental presence may have influenced the outcome rather than the during or out of school timing of clinics. More study is recommended.

The LPHU might have used the money it lost conducting the pilot program for other valuable initiatives. However, lessons learned in 2010 and applied in following years seem appear to have improved in fiscal outcomes in 2011 and rates in 2012.

In this mostly rural setting remote from PCPs and clinics, access to vaccinations without SLIV clinics is challenging. The SLIV clinics operated by the seven county LPHU were responsible for 66-94% (2010), 62-80% (2011), and 71-91% (2012) out of all vaccinations for children aged 5-18 during Sept. 1-Dec. 3 reported by the state IIS for these counties. This suggests these clinics provided greater access to vaccinations than all other venues. Urban and rural schools vaccination rate proportions were 16:31% (0.52), 15:28% (0.54), and 24:34% (0.71) in 2010, 2011 and 2012 respectively which may indicate improved consistency and integration across all sites as practice improved.

Conclusions

A case study approach relies on subjective interpretation and thus is not compatible with hypothesis testing. Results are only useful for improvement of services to a specific population. Though LPHUs that conducted SLIV clinics had higher vaccination rates than those that did not, more rigorous studies that include calculation of averted burden and prevented fraction may be warranted to increase knowledge discovery on the value of SLIV as an intervention and to benchmark between sites.

Kostova et al. (2013) developed a method to estimate the direct impact of influenza vaccination programs using national surveillance data. The averted burden is defined by frequencies of influenza disease, hospitalizations, and medically attended cases together called "outcomes" (p. 2). Prevented fraction is defined as "the proportion of averted outcomes out of potential outcomes in the absence of vaccination" (p. 2), calculated using averted burden and vaccination coverage, vaccine efficacy, and rate of illness that season. These may be measures that would be worth including in future studies on school located influenza vaccination programs.

It would have been useful to evaluate indirect benefits of vaccination on school attendance. Encouraging schools to participate in the state school ILI surveillance system would increase the data for that purpose. Private (internal) and public (external) data integration is challenging because of variability in definitions and reporting. It takes persistence when studying population interventions to see effectiveness over time. This evaluation may contribute knowledge to shape local and state policy on universal influenza vaccination of populations, and provide evidence of public health nursing contributions to population health.

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Appendix

Table 1.

Results of School Located Vaccination Clinics in 2010, 2011, and 2012

	Total s	chool enrol	llments	Mean s	chool enro	llments	Frequen	ncy first dos	se clinics	VFC	doses	VFC	rate
School Sites	2010	2011	2012	2010	2011	2012	2010	2011	2012	2011	2012	2011	2012
Urban	8930	8816	9309	308	339	358	29	26	26	335	635	26%	29%
Rural	4426	4663	4912	153	167	189	29	28	26	369	502	28%	30%

	Frequ	iency first	doses	Mean	first doses	/school	Mean	vaccinatio	on rates	Rate r	eceiving l	LAIV ^c	Rate	receiving	TIV ^d
School Sites	2010	2011	2012	2010	2011	2012	2010	2011	2012	2010	2011	2012	2010	2011	2012
Urban	1470	1281	2226	51	49	86	16%	15%	24%	53%	57%	59%	47%	43%	41%
Rural	1364	1306	1688	47	47	65	31%	28%	34%	49%	51%	52%	51%	49%	48%

Note. Results rounded to nearest whole number. ^aVaccines for Children (VFC). ^bRate receiving VFC. ^cRate receiving live, attenuated influenza vaccine (LAIV) weakened, nasal mist. ^dRate receiving trivalent influenza vaccine (TIV) killed vaccine, injection. Source of data: LPHU (2012, 2013).