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School-Located Influenza Vaccinations: A Randomized Trial

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abstract

OBJECTIVE: Assess impact of offering school-located influenza vaccination (SLIV) clinics using both Web-based and paper consent upon overall influenza vaccination rates among elementary school children.

METHODS: We conducted a cluster-randomized trial (stratified by suburban/urban districts) in upstate New York in 2014–2015. We randomized 44 elementary schools, selected similar pairs of schools within districts, and allocated schools to SLIV versus usual care (control). Parents of children at SLIV schools were sent information and vaccination consent forms via e-mail, backpack fliers, or both (depending on school preferences) regarding school vaccine clinics. Health department nurses conducted vaccine clinics and billed insurers. For all children registered at SLIV/control schools, we compared receipt of influenza vaccination anywhere (primary outcome).

RESULTS: The 44 schools served 19 776 eligible children in 2014–2015. Children in SLIV schools had higher influenza vaccination rates than children in control schools county-wide (54.1% vs 47.4%, $P < .001$) and in suburban (61.9% vs 53.6%, $P < .001$) and urban schools (43.9% vs 39.2%; $P < .001$). Multivariate analyses (controlling for age, grade, vaccination in previous season) confirmed bivariate findings. Among parents who consented for SLIV, nearly half of those notified by backpack fliers and four-fifths of those notified by e-mail consented online. In suburban districts, SLIV did not substitute for primary care influenza vaccination. In urban schools, some substitution occurred.

CONCLUSIONS: SLIV raised seasonal influenza vaccination rates county-wide and in both suburban and urban settings. SLIV did not substitute for primary care vaccinations in suburban settings where pediatricians often preorder influenza vaccine but did substitute somewhat in urban settings.



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Dr Szilagyi conceptualized and designed the study and drafted the initial manuscript; Dr Schaffer, Dr Rand, Ms Vincelli, Ms Eagan, Dr Hightower, Ms Younge, Ms Albertin, and Dr Humiston contributed to study design and fieldwork and reviewed and revised the manuscript; Mr Goldstein and Mr Blumkin contributed to study design and fieldwork, performed much of the analyses, and reviewed and revised the manuscript; Dr Yoo contributed to study design and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

This trial has been registered at www.clinicaltrials.gov (identifier NCT02227186).

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WHAT'S KNOWN ON THIS SUBJECT: Influenza vaccination rates among school-aged children remain low. Little is known about the ability of school-located influenza vaccination to improve rates.

WHAT THIS STUDY ADDS: This school-located influenza vaccination program raised influenza vaccination rates county-wide, in suburban, and urban school districts, with substantial use of Web-based consent for vaccination; it did not substitute for practice-based influenza vaccinations in suburban settings that use mostly purchased vaccine.

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Influenza causes many deaths, hospitalizations, and emergency department and outpatient visits for adults and children.¹⁻³ In 2009 the Advisory Committee on Immunization Practices and the American Academy of Pediatrics recommended influenza vaccination for children ≥ 6 months of age.¹ However, vaccination rates remain low. During the 2014–2015 season, 62% of 5- to 12-year-olds and 47% of 13- to 17-year-olds were vaccinated.⁴

Most pediatric influenza vaccinations are administered in primary care offices, yet it is challenging to vaccinate all patients during the vaccination season.⁵⁻⁷ Practitioners order commercial vaccine months before the influenza season and are reluctant to order excess vaccine. Family barriers include time, money, and need for an extra office visit.⁸⁻¹¹ Experts have discussed schools as sites for influenza vaccination¹²; most pediatricians¹³⁻¹⁵ and parents^{7,16-18} support school-located influenza vaccination (SLIV). Additionally, schools have a stake in influenza vaccination because immunization of school-children can reduce absenteeism throughout the community.¹⁹⁻²²

Nevertheless, only 6% of childhood influenza vaccinations occur at school.²³ SLIV poses logistical challenges: obtaining parental consent, ordering and administering vaccine, and billing.^{12,24-29} Further, there is limited evidence that SLIV increases immunization rates population-wide. Most studies involved manufacturer-supported trials with donated vaccine and nursing services,^{19,24,30} or focused on Vaccines for Children (VFC)-eligible children.³¹ A previous randomized controlled trial performed by our group over 2 seasons (2009–2010 H1N1 pandemic season and 2010–2011) revealed 10 percentage point higher influenza vaccination rates of children in schools randomized to SLIV versus usual care schools.³²⁻³⁴

A nonrandomized SLIV program in 19 schools in Denver vaccinated one-third of children attending those schools.³⁵ Authors noted that SLIV was inefficient^{33,35} due to the time-consuming process of communicating with parents and obtaining parental consent via backpack fliers (mailings via student backpacks). Finally, a potential concern is that SLIV may substitute school-based vaccination for vaccination in primary care.

Many parents use Web-based and electronic media to access information, communicate with schools, and conduct financial transactions. Yet little is known about the degree to which parents would use Web-based notification or provide informed consent online for SLIV. We created a blended model of SLIV that used both paper and electronic means to notify parents and gather informed consent and insurance information. The study aims were to assess (1) the impact of SLIV on overall influenza vaccination rates (vaccination anywhere, primary outcome) for elementary school children, (2) the impact of SLIV in suburban and urban school districts, (3) the impact of SLIV on vaccination in primary care offices, and (4) the use of Web-based informed consent by parents.

METHODS

University of Rochester's Research Subjects Review Board approved the study on July, 24, 2014.

The setting was Monroe County, New York (2013 population 709 606), which includes Rochester and surrounding suburbs.

Selection of Schools and Randomization

After approaching school district superintendents, we selected the Rochester City School District (urban) and 6 suburban school districts that expressed interest; these represent 7 of 19 school

districts, serving 43% of Monroe County's schoolchildren (Fig 1). We stratified school districts into urban/suburban because suburban children have higher influenza vaccination coverage.³²

Within each school district, we paired all possible elementary schools by: grade span (eg, kindergarten to sixth grade), percent of students eligible for free/reduced cost school lunch, and number of students per school. We selected these matching factors because influenza immunization rates vary by child age⁴ and poverty status,³⁶ and logistics of SLIV vary by school size. Within each school pair, we used a computer-generated random number to randomly allocate schools to SLIV versus usual care (henceforth "control schools"). The school directory (names of all enrolled students on October 1, 2014) comprised the study population.

SLIV Intervention

Program Teams

The university team coordinated activities and performed the evaluation. The county Department of Public Health (DPH) team ordered/stored vaccine, staffed vaccine clinics, billed Medicaid and commercial payers, and entered vaccination data into the New York State Immunization Information System (NYSIIS). The informatics team developed a Web-based application for parental consent for influenza vaccination, and a tracking system to remind consented parents about upcoming vaccine clinics. Schools provided information to parents about vaccine clinics, space, and personnel to accompany children to/from vaccine clinics. A Community Advisory Board included school experts, primary care practitioners, and public health experts.

Parental Notification About SLIV

Parents of children in SLIV schools received information about the

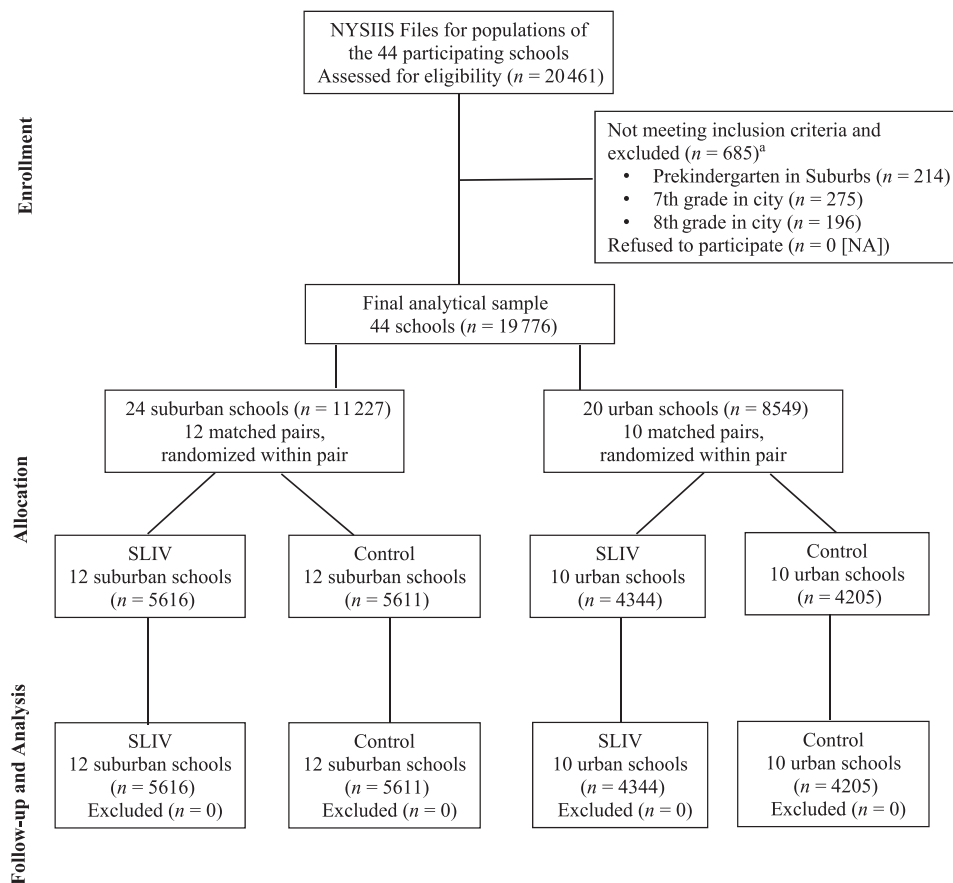


FIGURE 1

CONSORT diagram. ^aSome elementary schools had a prekindergarten grade, seventh grade, or eighth grade. If these schools could not be matched with another school within the same school district that had the identical grade span, we eliminated the outlying grade. As an example, if 1 school from a pair had a prekindergarten grade, we eliminated prekindergarten from that school's numerator and denominator if the matched pair school did not have a prekindergarten grade.

importance of influenza vaccination, availability and timing of vaccine clinics, and how to consent. Based on preference by each school, these notifications were sent via (1) e-mail only, (2) backpack flier only, or (3) both e-mail and backpack flier. Extra fliers were available in the school's main office. For all methods, initial notifications contained a 2-page information sheet about the SLIV program and how to provide consent that included a "Frequently Asked Questions" sheet plus a 1-page Flu Facts sheet (information from Centers for Disease Control and Prevention Web sites). The last rounds of notifications contained these sheets plus a 2-page information sheet about the study, and a 2-page vaccine consent form,

plus a seasonal influenza vaccine information statement form and DPH Health Insurance Portability and Accountability Act and Patient Bill of Rights forms.

Parental Consent for Vaccination

Web-based consent system: A secure Web site (www.fluvax4kids.com) described the SLIV program and contained influenza vaccine information statement forms and a consent form mirroring the DPH paper consent. The online consent included questions about child demographics, primary care provider, insurance (for billing and eligibility for VFC vaccine), potential contraindications to vaccination, and questions to identify eligibility for the default live attenuated vaccine or

need for injectable vaccine. Parents created a log-in and provided their full name and their child's name and birthdate (to match with a school database) to verify they were the guardian, and signed consent forms electronically; they could print copies. If they received a PDF attachment to an e-mail notification, they could sign that attachment and return consents to schools. Paper consent system: We sent paper versions of the same materials via children's backpacks for schools that preferred this method. Parents returned signed consent forms to schools.

Reminders to Consented Parents

One week and again 1 day before vaccine clinics, consented parents

were sent e-mail or telephone (autodialer) reminders about upcoming vaccine clinic days and were asked to contact the program if their child had already been vaccinated or if they now declined SLIV.

Vaccine Clinics

These occurred late in the vaccination season (December 1, 2014, to December 18, 2014) to allow ample opportunity for primary care providers to vaccinate children. Because a second vaccine clinic day may have low attendance,³² we provided 1 clinic day per school with 4 to 10 DPH personnel depending on number of vaccinations. Before clinics, the county DPH team checked NYSIIS to ensure children had not been vaccinated. School personnel escorted children wearing nametags from class to the vaccine clinics where county DPH nurses verified children's identity, administered VFC or commercial vaccine, and provided children with vaccination documentation to bring home. School personnel escorted children back to class.

Postvaccination Procedures

The DPH billed insurers for vaccine and/or administration fees, and entered vaccination information into NYSIIS, which all primary care providers can access.

Data Collection and Analysis

The key independent variable was study group (SLIV or control). Covariates included independent predictors of vaccination³² to improve estimation efficiency (child age, school's grade-span, suburb/urban district, and receipt of influenza vaccination during the previous 2013–2014 season).

The primary outcome measure was receipt of ≥ 1 influenza vaccination (from any location) during the study year ("vaccination anywhere"). After the vaccination season, we matched

child names and birthdates with NYSIIS records to obtain influenza vaccination data for the current and previous seasons. State law requires all immunization of children ≤ 18 years to be recorded in NYSIIS within 14 days.

Analysis

Our unit of analysis was the student (child), whereas the intervention was at the school level. We used an intention-to-treat paradigm for all analyses unless otherwise specified. To account for the matched pair randomization process, we included indicator variables for each of the 22 school pairs in all models; we excluded an urban district pair as a reference and performed sensitivity analyses to evaluate whether results varied by choice of reference. To account for lack of independence among students within a school and associated intracluster correlation, we employed multilevel logistic regression modeling in all models; the random effects of our models were students nested within schools. To assess Aims 1 and 2, we compared vaccination rates (vaccinated anywhere) between SLIV and control groups utilizing χ^2 tests. We performed bivariate multilevel logistic regression models of our primary outcome by study group and each covariate with matched pair fixed effects and school random effects. We performed multivariate multilevel logistic regression with the full set of covariates. We performed our analyses with multiple model specifications (ie, with and without both matched pair fixed effects and school random effects); the intervention effects were substantively identical. We then stratified analyses by suburban and urban school for Aim 2.

To investigate the impact of SLIV on vaccination in primary care offices (Aim 3), we performed multilevel logistic regression utilizing vaccination outside of school as the

dependent variable and study group (SLIV or control) as the independent variable. The analysis was run with matched pair fixed effects, school random effects, and the above covariates.

To assess Aim 4, we tabulated use of online consents. Also, as an exploratory analysis, we compared the rates of online consent and influenza vaccination with different notification methods utilizing multilevel logistic regression.

RESULTS

Baseline Characteristics

Seven school districts (6 suburban, 1 urban) participated. The 44 schools served 20 616 students in 2014–2015; 20 461 (99.15%) were matched with children in NYSIIS. After excluding students predetermined to be ineligible (Fig 1), the final analytical sample was 19 776. SLIV and control schools were similar for student age (Table 1). There were no adverse events.

SLIV Vaccination

Seven percent of all SLIV school students, 5.3% of suburban SLIV school students, and 9.2% of urban SLIV students were vaccinated at SLIV clinics (Table 2).

Impact of SLIV on Influenza Vaccination Anywhere

The proportion of students who were vaccinated anywhere was greater at SLIV schools versus control schools across the county (54.1% vs 47.4%, $P < .001$), in suburban schools (61.9% vs 53.6%, $P < .001$), and in urban schools (43.9% vs 39.2%, $P < .001$; Table 2, Aims 1–2, primary outcome).

Table 3 presents results of bivariate multilevel logistic regression, controlling for age, grade, and vaccination in the previous season with matched pair fixed effects and school random effects. The study arms did not differ by any of the

covariates, so they were included in multivariate analyses because of their potential impact on the primary outcome (vaccination anywhere). On bivariate analysis across the full study sample, students in SLIV schools had higher odds of receiving an influenza vaccination than students in control schools (odds ratio [OR] = 1.28, confidence interval [CI]: 1.20–1.38). SLIV was associated with increased vaccination rates in both suburban (OR = 1.34, CI: 1.23–1.47) and urban schools (OR = 1.21, CI: 1.08–1.35). From the multivariate analysis for suburban and urban districts combined, the odds of vaccination were higher among students attending SLIV schools than among students attending control schools (OR = 1.32, CI: 1.23–1.42). On stratified analysis, vaccination rates were higher among SLIV schools in both suburban districts (OR = 1.38, CI: 1.27–1.51) and the urban district (OR = 1.23, CI: 1.10–1.38).

Impact on Vaccination in Primary Care (Aim 3)

Bivariate Analysis (Table 2): Across suburban and urban school districts combined, there was no significant difference in vaccination in primary care physician's offices by SLIV status (47.0% vs 47.4%; $P = .59$). Suburban SLIV school students were more likely than suburban control school students to receive an influenza vaccination at their primary care physician's office (56.6% vs 53.6%; $P = .002$); but the opposite effect was noted among urban SLIV versus urban control school students (34.7% vs 39.2%; $P < .001$). Multilevel logistic regression analysis: Table 4 presents bivariate and multivariate analyses predicting vaccination outside of school. On bivariate analysis, SLIV was not significantly associated with vaccination outside of school county-wide (OR = 0.96, CI: 0.89–1.03), with an insignificant increase in suburban schools (OR = 1.07, CI: 0.97–1.18) and a significant decrease in urban schools (OR = 0.82,

TABLE 1 Baseline Characteristics of SLIV and Control Schools and Children, by Suburban or Urban Location

Characteristic	SLIV Schools	Control Schools	<i>P</i>
Suburban schools			
	<i>N</i> = 12 schools	<i>N</i> = 12 schools	
No. of students	5616	5611	.28
Mean student age, quartiles	8.08	8.07	.72
Eligible for free or reduced cost lunch, %	27.2	29.5	.008
No. (%) students receiving ≥ 1 influenza vaccination during the 2013–2014 season (pre-SLIV)	2571 (45.8)	2457 (43.8)	.03
Urban schools			
	<i>N</i> = 10 schools	<i>N</i> = 10 schools	
No. of students	4344	4205	.28
Mean student age, quartiles	8.32	8.39	.14
Eligible for free or reduced lunch, %	91.4	88.2	<.001
No. (%) students receiving ≥ 1 influenza vaccination during the 2013–2014 season (pre-SLIV)	1393 (32.1)	1405 (33.4)	.19

TABLE 2 Number (%) of Students in SLIV Versus Control Schools Given Influenza Vaccine During the Study Period by Suburban or Urban Location

	2014–2015 Vaccination Season (SLIV Year)		<i>P</i> ^a
	SLIV Schools	Control Schools	
All schools			
Vaccinated at school	699 (7.0)	0 (0.0)	—
Vaccinated elsewhere ^b	4685 (47.0)	4655 (47.4)	.59
Vaccinated anywhere	5384 (54.1)	4655 (47.4)	<.001
Suburban schools			
Vaccinated at school	300 (5.3)	0 (0.0)	—
Vaccinated elsewhere ^b	3177 (56.6)	3007 (53.6)	.002
Vaccinated anywhere	3477 (61.9)	3007 (53.6)	<.001
Urban schools			
Vaccinated at school	399 (9.2)	0 (0.0)	—
Vaccinated elsewhere ^b	1508 (34.7)	1648 (39.2)	<.001
Vaccinated anywhere	1907 (43.9)	1648 (39.2)	<.001

^a *P* values were not calculated since control schools did not receive SLIV clinics.

^b Vaccinated elsewhere (almost always in physicians' offices because NYS did not allow pediatric influenza vaccinations at pharmacies, and influenza vaccination programs at malls or other settings in Monroe County were for adults only). Denominators of SLIV and control schools are in Table 1.

TABLE 3 ORs of Influenza Vaccination Anywhere

	OR (95% CI)
Bivariate analysis^a	
All SLIV versus control schools	1.28 (1.20–1.38)
Suburban SLIV versus control schools	1.34 (1.23–1.47)
Urban SLIV versus control schools	1.21 (1.08–1.35)
Multivariate analyses^b	
All SLIV versus control schools	1.32 (1.23–1.42)
Suburban SLIV versus control schools	1.38 (1.27–1.51)
Urban SLIV versus control schools	1.23 (1.10–1.38)

^a With matched pair fixed effects and school random effects.

^b Controlling for age, grade, and vaccination in the previous season with matched pair fixed effects and school random effects.

CI: 0.75–0.90). Multivariate results were nearly identical to bivariate results county-wide (0.95, CI: 0.89–1.02), in suburban schools (1.06, CI: 0.96–1.16), and in urban schools (0.83, CI: 0.76–0.91).

To further assess for substitution of vaccination, we performed a

subanalysis comparing vaccination rates outside of school before/after SLIV notifications began (Supplemental Table 5). The beginning of SLIV notifications was the cutoff because SLIV information may have affected practice vaccination in either direction.

TABLE 4 ORs of Influenza Vaccination Outside of School

		OR (95% CI)
Bivariate analysis ^a	All SLIV versus control schools	0.96 (0.89–1.03)
	Suburban SLIV versus control schools	1.07 (0.97–1.18)
	Urban SLIV versus control schools	0.82 (0.75–0.90)
Multivariate analyses ^b	All SLIV versus control schools	0.95 (0.89–1.02)
	Suburban SLIV versus control schools	1.06 (0.96–1.16)
	Urban SLIV versus control schools	0.83 (0.76–0.91)

^a With matched pair fixed effects and school random effects.

^b Controlling for age, grade, and vaccination in the previous season with matched pair fixed effects and school random effects.

Suburban districts: Compared with the same time period in the previous season, the vaccination rate after notifications increased by equivalent amounts in SLIV and control schools (+5.9%), implying SLIV notifications did not impact vaccinations outside of school. Urban district: The vaccination rate after notifications increased compared with the same time period in the previous season by a greater amount in control versus SLIV schools (+6.1% and +3.7%, respectively), suggesting SLIV notifications reduced vaccination slightly outside of school.

Use of Web-based Consent (Aim 4)

Suburban schools: Among the 5616 children in suburban SLIV schools, 3478 families received paper notifications only (62%); 239 (7%) consented for SLIV; and 113/239 (47%) consented online indicating that parents accessed the Web site noted on the paper notifications. Among the 1702 families who received e-mail notifications only, 66 (4%) consented for SLIV; 59/66 (89%) consented online; and 7 (11%) printed out and returned written consent forms. Among the 436 children notified both ways, 31 (7%) consented and 22/31 (71%) consented online. Urban schools: Among the 4344 children at urban schools allocated to SLIV, all children received paper notifications only, 443 (10.2%) consented for SLIV, and 53/443 (12%) consented online.

As an exploratory analysis, we assessed the likelihood of influenza vaccination anywhere as a function of

notification type. Suburban schools: Vaccination rates were paper notification only (58% vaccinated), e-mail notification only (70%), or both paper and e-mail notification (63%), compared with control (54%). Utilizing multilevel logistic regression with matched pair fixed effects and school random effects, and controlling for the previous year's influenza vaccination to adjust for the propensity to be vaccinated, the odds of receiving a vaccination in the current year were higher for paper-only notification (OR = 1.42, $P < .001$) and e-mail-only notification (OR = 1.38, $P < .001$) but not for paper and e-mail combined notification (OR = 1.12, $P = .43$). Urban schools: Paper only notification was associated with a 44% vaccination rate compared with 39% for controls (OR = 1.23, $P < .001$).

Additional Findings

Across SLIV and control groups combined with matched pair fixed effects and school random effects, influenza vaccination was higher among suburban versus urban students (OR = 1.53, $P = .01$) and younger versus older students (with a 1-year increase in age, the odds of vaccination decreased by 4%; OR = 0.96, $P < .001$). Vaccination in the previous season was strongly predictive of vaccination in the current season (OR = 4.05, $P < .001$).

DISCUSSION

We were able to implement SLIV across 7 school districts, including

22 schools serving >10 000 children, with the guidance of a community-based partnership.^{32,35} We found that SLIV resulted in a modest increase in influenza vaccination rates across the county and in both suburban and urban schools, equaling the impact of some other interventions such as patient reminder-recall.^{37,38} Type of consent (paper or Web-based) did not appear to markedly affect the impact of SLIV. Our study is novel in that we used Web-based parental consent, and examined the impact of SLIV upon vaccination in primary care offices.

We assessed whether SLIV substituted for practice-based vaccination¹³ since primary care practitioners must preorder and purchase commercial vaccines at a substantial cost. We found that in suburban schools serving mostly commercially insured children,³² SLIV did not substitute for practice-based vaccination. Notably, we designed our SLIV program to offer clinics in December, after practitioners had a chance to vaccinate their populations and use up vaccine supplies. In the urban school district where 88% of SLIV vaccinations involved VFC vaccine, we did note some substitution; however, it is possible that since VFC vaccine does not require up-front vaccine purchase, substitution may be less concerning to urban practitioners who serve mostly VFC-covered patients. In sum, neither this study nor a previous one¹² demonstrated substitution in settings that use primarily commercial vaccine.

Whether notified about SLIV by backpack fliers or e-mail, most suburban parents who consented used the Web-based consent process. We feel online consent is now a potentially viable option for SLIV because most US residents have daily access to computers.³⁹

Study strengths include a robust randomized controlled trial study design to measure impact of SLIV,

multiple school districts that enhances generalizability, large numbers of children included, and accurate assessment of influenza vaccination via the state immunization registry. The study also has limitations. It was conducted in a single county that may not be representative, and not all school districts participated. SLIV and control schools had slightly different baseline characteristics; thus we controlled for influenza vaccination rates in the previous year. For both SLIV and control schools, NYSIIS may have lacked influenza vaccinations for children who immigrated to NYS just before the study; however, this should be balanced across study groups. Schools selected how to notify parents rather than by randomization. We did not assess reasons why parents selected SLIV or why they used paper or Web-based consent. Further, we were unable to measure with certainty the level of substitution of SLIV vaccination for practice-based vaccination; thus we estimated substitution by using multiple analytic

strategies. For all SLIV schools, the initial notification to parents included a brief summary of the study, which may have affected parental behavior in unmeasured ways. Finally, this study was fairly resource-intensive although much of the resources involved initial development of the online-based system and school-based SLIV processes to allow SLIV in multiple school districts.

CONCLUSIONS

In 1 large county in upstate New York, an SLIV program that used both paper-based plus Web-based information and consent increased children's influenza vaccination rates county-wide and in both suburban and urban schools. SLIV did not substitute for primary care-based influenza vaccination in suburban districts; some substitution occurred in the urban district. SLIV, using Web-based consent, is a potential strategy to improve influenza vaccination coverage among large populations of children.

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ABBREVIATIONS

CI: confidence interval
DPH: Department of Public Health
NYSIIS: New York State Immunization Information System
OR: odds ratio
SLIV: school-located influenza vaccination
VFC: Vaccines for Children

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