Obtaining Parental Consent In An Elementary School-Located Influenza Vaccination Program: Year 2

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Background

MCSKIPP (Monroe County School Kids Influenza Prevention Project) is a school located influenza vaccination (SLV) program to evaluate the feasibility and acceptability of SLV administered by an independent mass vaccine provider in Monroe County, NY. MCSKIPP tested parent notification and consent methods in urban and suburban elementary schools. We randomized schools to two levels of intensity of parent notification (Low and High) and to Controls.

Reported here are findings and experience associated with obtaining written parental consent in Year 2.

Other MCSKIPP workshops this week:
- o Vaccine rates -- Tuesday 4 pm (Dr. Humiston)
- o Economic evaluation – Thursday 9 am (Dr. Yoo)

Parent Notification

Low and High notification schools received:
1. Packets to send home in backpacks: flu facts, and VISs and one consent form
2. Information in newsletters and websites
3. Autodialer messages about consent forms and MCSKIPP vaccination dates
4. Extra forms available in school office

High notification schools ALSO received:
1. A mailed Flu clinic post card before school started
2. A second consent forms sent home in backpacks in October
3. An extra autodialer message with school vaccine clinic date

Participants and Roles

Schools 18 Urban: 6 high & 6 low notification, 6 control
14 Suburban: 2 high & 7 low notification, 5 control

Vendor An experienced mass vaccinator agreed to participate and bear financial risk

Payers NYS DOH and NYS Medicaid allowed the vendor to provide VFC vaccine and bill an administration fee. Most local insurers accepted billing from the vendor.

MCSKIPP Team Implementation, managed consents

University of Rochester Evaluation

SLV Consent Problem

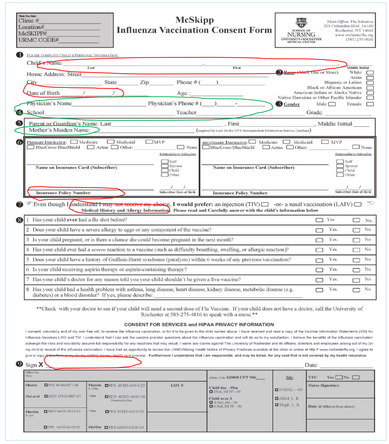
Low Response in Year 1 -- only 21% returned consent forms, 28% of which were incomplete.

On Vaccine Day – children without completed consent forms cannot receive vaccine. Parents are not present to answer questions or to complete the missing elements of the consent form.

Consent forms missing key elements:
- Reduce the % of students who can be vaccinated in school
- Prevent billing and cost recovery for providers
- Increase the personnel time needed to contact parents

Changes in Year 2:

1. Consent forms were simplified and were also available in Spanish
2. Autodialer messages were added to all parent notification groups. **and**
3. H1N1 was not making news!


McSkipp
Influenza Vaccination Consent Form

Information needed to vaccinate:

Child's identity and DOB
Parent signature
Medical information
Billing information

Information not essential to vaccinate:

Mother's maiden name
School, teacher, physician name and phone, etc

Year 2 Consent Process

- Classroom teachers distributed forms to children.
- Parents returned consents to school via children.
- MCSKIPP team collected consents and reviewed for completeness
- MCSKIPP team called parents to collect missing elements– 688 phone calls (3 weeks)

Consent status after follow-up

- **None** – No consent received
- **Complete** – Ready to vaccinate
- **All missing data collected by phone**– Ready to vaccinate
- **Parents not reached by phone, but missing only data not essential for vaccination** – Ready to vaccinate
- **Incomplete with key medical or insurance data still missing** – Cannot vaccinate

RESULTS: Consents in Year 2

	Number in School	Number (%) consents returned to school by parents
Urban High	2675	453 (17%)
Urban Low	2262	428 (19%)
All Urban	**4937**	**881 (18%)**
Suburban High	737	184 (25%)
Suburban Low	3473	616 (18%)
All Suburban	**4210**	**800 (19%)**

Year 2 Consent Follow-Up

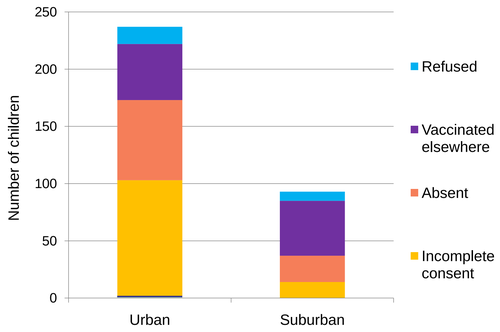
	# Consents returned to school	% Complete at start	% Complete after follow- up	% Incomplete after follow-up
Urban High	453	49%	88%	12%
Urban Low	428	50%	89%	11%
All Urban	**881**	**49%**	**88%**	**12%**
Suburban High	184	72%	95%	5%
Suburban Low	616	77%	99%	0.7%
All Suburban	**800**	**76%**	**98%**	**1.7%**

What factors predicted children having complete consent forms both when they were first collected and after follow up?
Complete and eligible:

	All Urban	vs	All Suburban
At start	49%		76%*
After follow-up	88%		98%*
	All High	**vs**	**All Low**
At start	56%		66%
After follow-up	90%		95%
	Grades K-2	**vs**	**Grades 3-6**
At start	62%		62%
After follow-up	94%		93%

Location was highly significant at start and after follow-up *(p<.0001). but **intensity** and **grade level** were not significant predictors.

Reasons children who returned consents did not get vaccinated in school



Conclusion

Even with clearer language and Spanish language versions, many consents were not complete.

In urban schools with high rates of incomplete consents **and** with high demand for SLV (average 25% returned consent forms,) half the children required follow-up. After follow-up, 16% of children who requested vaccine were still not eligible.

The main reason children had incomplete information after follow-up was their families could not be reached by telephone.

Missing information essential to consent and vaccine eligibility would prevent any provider from vaccinating, including school nurses, so the work of assuring accurate consent must be done by someone for successful SLV programs.

The number of children expected at school based clinics was also reduced by absence, refusal, and children who had been vaccinated elsewhere. Providers have a minimum number of vaccinations to deliver and bill to cover their costs, another reason consents must be complete before clinic day.

Implications

In a setting where parents will not be present during vaccination…we need better methods to
- ★ Distribute and collect consent forms
- ★ Help families with health literacy limitations to accurately and thoroughly complete consent forms
- ★ Reach parents who did not fill in all needed parts of the consent

Innovative technologies and collaboration with providers could improve the SLV consent process.

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