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

## Sharon Humiston, MD, MPH<sup>1</sup>, Tahleah Chappel, MS<sup>2</sup>, Christine Long, MPH<sup>2</sup>, Kimberly DiMattia, BA<sup>2</sup>, Peter Szilagyi, MD, MPH<sup>3</sup>, Stanley Schaffer, MD, MS<sup>3</sup>, Andrew Doniger, MD, MPH<sup>4</sup> and Maureen Kolasa, RN, MPH<sup>5</sup>

<sup>1</sup>Emergency & Urgent Care Division, Children's Mercy Hospitals and Clinics, Kansas City, MO, <sup>2</sup>Center for Community Health, University of Rochester Medical Center, Rochester, NY, <sup>3</sup>Department of Pediatrics, University of Rochester Medical Center, Rochester, NY, <sup>4</sup>Monroe County Dept. of Public Health, Rochester, NY, <sup>5</sup>Health Services Research and Evaluation Branch, CDC, Atlanta, GA

#### 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:

- Vaccine rates -- Tuesday 4 pm (Dr. Humiston)
- Economic evaluation Thursday 9 am (Dr. Yoo)

#### **Parent Notification**

#### Low and High notification schools received:

- Packets to send home in backpacks: flu facts, and VISs and one consent form
- Information in newsletters and websites
- Autodialer messages about consent forms and MCSKIPP vaccination dates
- Extra forms available in school office

#### High notification schools ALSO received:

- 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**

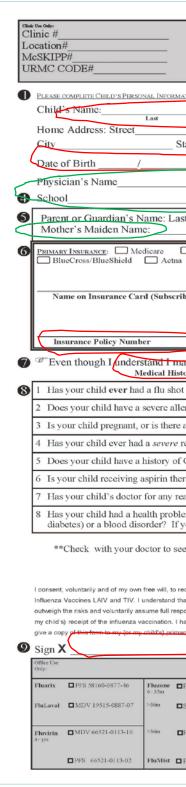
Low Response in Year 1 -- only 21% returned consent forms, 28% of which were incomplete.

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

- in Spanish
- notification groups. and
- 2. Autodialer messages were added to all parent 3. H1N1 was not making news!



#### Information needed to vaccinate

Child's identity and DOB Mother's maiden name Parent signature Medical information Billing information

 Prevent billing and cost recovery for providers Increase the personnel time needed to contact parents

## **Changes in Year 2:**

. Consent forms were simplified and were also available

### 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

Influen	McSkip za Vaccination	op 1 Consent Form	SCHOOL NURSI UNIVERSITY#RO MEDICAL CO	OF Ro NG ww	flice: Flu Initiative nden Blvd. 1w160 chester, NY 14642 w.rochesterflu.org (585) 275-0636
	,	First		,	Middle Initial
			2 Race: (Ma	rk One or More)	White Asian
State Zip	Phone # (	)		Hispanio Black or African	American
	Age.:			can Indian or Ala ian or Other Pacif	
	Physician's Phone # (		3 Gender	Male 🗔	Female
	Teacher			Grade:	
ist		, First		, Middle I1	nitial
	(requi	red by Law for the NYS Immunization Infor	nation Service Databa	ise)	
Medicaid C Other:		ACONDARY ISSURANCE: Medica BlueCross/BlueShield	Aetna 🔲 Other		tionship to Subscriber Self Spouse Child Other
	/ / Subscriber Date of Birth			Eat	/ / scriber Date of Birth
	y choice, I would pref	Insurance Policy Number		accination (L	
ot before?				Yes	□ No
lergy to eggs or any	component of the vaccin	ne?		Yes.	□ No
e a chance she coul	d become pregnant in the	next month?		Yes.	No No
reaction to a vaccin	ne (such as difficulty brea	thing, swelling, or allergic rea	ction)?	Yes.	No No
f Guillain-Barré syı	ndrome (paralysis) within	6 weeks of any previous vacc	ination?	Yes.	No No
erapy or aspirin-co	ntaining therapy?			Yes.	No No
eason told you your child shouldn't be given a live vaccine?					□ No
lem with asthma, lung disease, heart disease, kidney disease, metabolic disease (e.g. Yes. No Yes, please describe: No					No No
Roc CONSENT receive the influenza vacci that I can ask the vaccine sponsibility for any reaction have had an opportunity	chester at 585-275-4816 to FOR SERVICES and HIF ination, or for it to be given to the provider questions about the influ ns that may result. I waive any clai to review the URMC/Strong Health	In Vaccine. If your child does o speak with a nurse.** PAA PRIVACY INFORMATION child named above. I have received and enza vaccination and will do so to my si ms against The University of Rochester a Notice of Privacy Practices available at am responsible, and may be billed, for	I read a copy of the V atisfaction. I believe and its officers, direc the clinic or online a any cost that is no	Vaccine Information S the benefits of the in tors and employees a at http:// www.rochest at overed by my he	tatements (VIS) for fluenza vaccination trising out of my (or erflu.org. I agree to
				Date:	
PFS 49281-0010-25 SDV 49281-0010-10 Preservative free	LOT #	Admin Code: G0008 CPT 906 Child 6m - 35m 25mL IM PP55 Child over 3 0.5mL IM -58 0.5mL IM PR-65	Site NASAL—60 ARM L R Thigh L R	VFC Yes Nurse Signature:	
■PFS 49281-0010-50 -		0.5mL IM PF-56		Date (If different fro	

#### Information not essential to vaccinate:

School, teacher, physician name and phone, etc

### **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%)





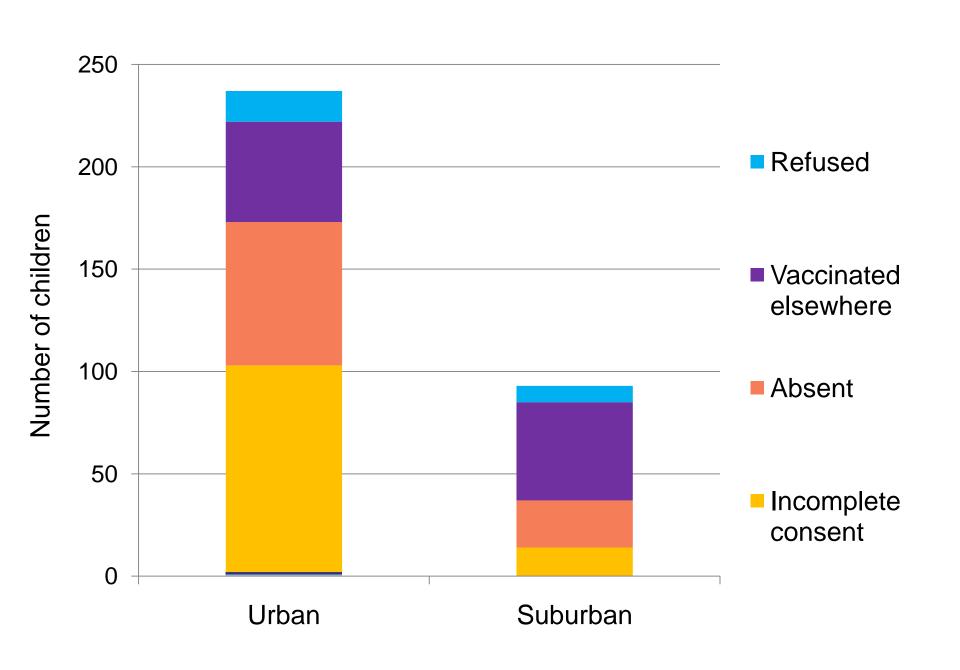
	# Consents returned to school	% Complete at start	% Complete after follow- up	% Incomplete after follow-up
Urban High	453	49%	88%	12%
Urban Low	428	50%	89%	11%
All Urban	881	49%	88%	12%
Suburban High	184	72%	95%	5%
Suburban Low	616	77%	99%	0.7%
All Suburban	800	76%	98%	1.7%

### Year 2 Consent Follow-Up

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

Complete and ongible	•	
	<u>All Urban</u>	vs <u>All Suburban</u>
At start	49%	76%*
After follow-up	88%	98%*
	<u>All High</u> v	vs <u>All Low</u>
At start	56%	66%
After follow-up	90%	95%
	Grades K-2	vs <u>Grades 3-6</u>
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

**Corresponding author: sghumiston@cmh.edu** 



### 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.

