Vaccine Storage Practices in Primary Care Physician Offices

Assessment and Intervention

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Purpose: To assess the proportion of primary care physician (PCP) offices meeting vaccine storage guidelines, identify factors associated with low compliance, and evaluate whether a quality improvement (QI) activity improves compliance.

Methods: We examined compliance with guidelines of 721 PCP offices contracted with a national managed care organization in four cities. A QI activity (educational materials, written feedback, and distribution of thermometers) was conducted at baseline and a follow-up assessment occurred within 3 months.

Results: Baseline compliance was relatively high, with >80% adherence to most guidelines. For example, 89% of offices had a thermometer; and 83% of temperatures were appropriate. Most units did not have vaccines stored in the door or food/biological materials in the unit (80% and 96%, respectively). Almost all vaccines had not expired. Multivariate analysis indicated that practice location, type of physician, participation in vaccine programs, and using guidelines were associated with compliance. For most of the compliance measures, pediatric offices had the highest compliance. Adherence to guidelines improved after the QI activity; the net change between pre- and post-intervention ranged from +1% to +19%. Measurements most impacted included temperature log posted (19% improvement in refrigerator; 16% improvement in freezer) and no vaccine stored in refrigerator door (14% improvement).

Conclusion: Despite generally high compliance, there are some opportunities for improvement in how PCPs store vaccines. Incorporating an intervention program in existing practice activities can improve storage practices. Further research is needed to determine the possible benefits of targeting interventions to certain types of providers who may be less knowledgeable about recommended guidelines.

Medical Subject Headings (MeSH): guideline adherence, immunization, intervention studies, physicians' offices, primary health care, quality indicators, healthcare, risk assessment, vaccines (Am J Prev Med 2002;23(4):246–253)

Introduction

The success of immunization programs depends on both high vaccination coverage rates and effective vaccines. Preserving the cold chain during distribution is critical. Since most vaccines can survive at room temperature for only short periods of time,[1] failure to adhere to handling and storage recommendations can reduce or destroy a vaccine's effectiveness.[2–4] In one localized outbreak of measles in the 1970s, illness was associated with previous vaccination at a physician's office where measles vaccine was stored on the door shelf of a refrigerator rather than in its central core.[5] During the 1989–1990 measles epidemic,[6–8] more than half of measles cases occurred among appropriately vaccinated children aged 5 to 19 years.[9] Primary vaccine failure was proposed as one of several reasons for the occurrence of measles in this group.[9–11] In Australia, some suggested that poor vaccine storage may have contributed to the resurgence of pertussis in 1996–1997.[12]

In the United States, approximately 52% of children's vaccines are distributed by or on behalf of public

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health departments,[13] and individual state health departments are responsible for monitoring the quality of vaccine storage in public clinics. With the exception of providers and clinics that participate in government programs such as Vaccines for Children (VFC), little monitoring exists in the private sector. Previous assessments of vaccine storage practices have been small studies, which found that knowledge about vaccine storage in provider clinics is low and that compliance with storage recommendations is often lacking.[2,14–25]

In the few studies that have examined the impact of interventions on adherence to vaccine storage guidelines, results varied depending on the type of intervention used.[14,24,26] In a recent study[14] of private providers, there was no significant difference in the vaccine storage practices of office staff who were mailed educational material compared to those who had not been mailed the educational material. In one small Australian study, storage practices in 32 randomly selected physician offices improved following temperature monitoring and direct feedback to office staff.[24]

This study was undertaken to assess vaccine storage practices in primary care physician (PCP) offices contracted with a national managed care organization (MCO). Specifically, we determined the proportion of PCP offices meeting various vaccine storage guidelines recommended by the Centers for Disease Control and Prevention (CDC) and assessed factors related to compliance with guidelines. We also evaluated the effectiveness of a quality improvement (QI) activity among PCP offices.

Methods

Study Locations

PCP offices contracted with a national MCO in four metropolitan areas were selected to participate in this study. All PCP offices, including pediatrics, family practice, and internal medicine were initially eligible for participation in the study. The number of PCP offices eligible for inclusion in the study varied by study location. In the two smaller health plans (Locations I and II), we attempted to survey all contracted PCP offices (265 and 140 offices, respectively). In the two larger health plans (Locations III and IV), we selected a random sample of offices, with the sample size designed to balance the need for a manageable data collection workload and the need for a reasonable degree of precision in estimating the proportion of offices complying with vaccine storage guidelines. Because it was anticipated that we would be unable to reach approximately 10% of the study sample for logistical reasons, our sample sizes included 20 extra offices for Locations III and IV. In Location III, we randomly selected 255 of 753 offices; in Location IV, we randomly selected 223 of 734 offices. These sample sizes were expected to result in a precision of ±5.5% for estimates of compliance proportions.

Data Collection

Professional services coordinators (PSCs) collected data between October and December 2000. PSCs function in a liaison role between the physicians (PCPs and specialists) and the MCO in an assigned territory. Because PSCs typically make quarterly visits to each office in their territory, office personnel are familiar with them and accustomed to their visits. Data for this project were collected during the PSCs' regularly scheduled office visits. All on-site coordinators and PSCs at the study locations participated in a training session prior to beginning data collection. Throughout the study, ongoing meetings and e-mail communications with the four study coordinators addressed questions and facilitated consistent and thorough data collection.

Each PSC was provided a list of offices to survey. The PSC called each office to confirm eligibility. Offices that were no longer contracted with the MCO, had location issues, did not immunize patients, or had no PCPs were not eligible to participate. The PSC informed each eligible office that during the next visit he or she would conduct a survey of vaccine storage practices as part of the MCO's patient safety program.

The baseline office visit included an 18-item survey completed through a combination of in-person interview and visual inspection of the vaccine storage refrigerators and freezers. On arrival at the office, the PSC interviewed the person responsible for storing vaccines to ascertain the following:

1. Number of people in the office responsible for vaccines;
2. Type of PCP;
3. Size of office;
4. Participation in any state or federal vaccine program; and
5. Use of published guidelines for vaccine storage practices.

Following the in-person interview, the PSC inspected the vaccine refrigerator(s) and freezer(s) according to a standard protocol. In each office, the PSC observed up to two refrigerators and two freezers used to store vaccines. If there were more than two refrigerators or freezers, the PSC assessed the one that was closest to the reception desk and the one that was farthest away. To ensure consistency among locations, the temperature of the central core of each vaccine storage unit was measured with a Fisherbrand Traceable® Monitoring Thermometer, which is accurate to ±1°C. (Calibration was certified by Control Company, 308 West Edgewood, Friendswood, TX 77546.)

The visual inspection of the vaccine storage units assessed the following:

1. Whether a thermometer was present;
2. Temperature;
3. Whether a temperature log was posted;
4. If a log was posted, how often the temperature was measured and recorded, and if daily recorded temperatures were within an acceptable range for the last 30 days for the refrigerator(s) (2 to 8°C) and freezer(s) (≤15°C);
5. Whether varicella vaccine was stored in refrigerator;
6. Whether any diluents or other vaccines besides varicella were in freezer;
7. Whether vaccines were stored in the door of the storage units; and

Table 1. Participating PCP offices by U.S. region and study location

Assessment	Southeast I	Southwest II	Midwest III	Southwest IV	Total
Total number of offices	265	140	753	734	1952
Number of offices targeted	265	140	255	223	883
Baseline assessment					
Number of non-eligible offices[a]	36	37	40	15	128
Number eligible	229	103	215	208	755
Number of completed surveys	225	100	205	207	737
Post-intervention assessment					
Number of non-eligible offices[a]	3	1	1	9	14
Number eligible	226	102	214	199	741
Number of complete follow-up surveys	222	99	202	198	721
Overall response rate[b]	98.2%	97.0%	94.4%	99.5%	97.3%

[a]Not eligible: offices that did not immunize, offices that were no longer contracted with the managed care organization, location issues (office closed, wrong address, administrative/billing location, nursing home, hospital-based, practice moved, office under construction), no PCPs at office.
[b]Completed both baseline and post-intervention assessments.
PCP, primary care physician.

8. Whether food or open containers of biological materials were in the storage units.

Finally, for each storage compartment, the PSC did a spot check of vaccine expiration dates (two vials/packages from the front and two from the back of the compartment).

Quality Improvement (Intervention) Activity

Following the survey assessment, the PSC gave the office staff a summary of CDC guidelines for vaccine storage and handling; a sample temperature log that could be duplicated and used in the future; and a Cooper Instrument thermometer for use in the vaccine storage refrigerator and freezer, if the office did not currently have a thermometer. In addition, the PSC completed a feedback checklist indicating which vaccine storage guidelines (if any) the office was not meeting; the office was given a copy of the checklist. Office staff was also informed that a follow-up assessment would be conducted at the next PSC visit. Office visits to assess vaccine storage practices averaged 22 minutes.

Post-Intervention Data Collection

Within 3 months of the initial intervention, the PSCs returned to the PCP office and conducted a post-intervention assessment. With the exception of a slightly modified survey instrument (described below), data collection for the post-intervention assessment was completed in the same manner as the pre-intervention assessment.

During the post-intervention assessment, the following four questions evaluating the QI activity were added to the survey:

1. Whether the office had received a thermometer as part of the QI activity;
2. Whether the thermometer was in use (if applicable);
3. Whether the interviewee remembered receiving the educational materials and thermometer (if applicable); and
4. Aspects of the QI activity that the office had found to be helpful.

We assumed that many of the office characteristics (e.g., specialty of physicians) had not changed since the pre-intervention assessment; thus, we were able to remove 11 questions.

Data Analysis

We examined the frequency distributions of office characteristics from the in-person interview and the proportion of PCP offices complying with each guideline. Differences between study locations were assessed by chi-square analysis. To explore factors associated with compliance, we conducted univariate and multivariate analyses. Univariate analysis examined whether selected variables were related to compliance with storage guidelines, and significant associations were assessed by chi-square tests. Multivariate logistic regression analysis was used to test whether significant variables from the univariate analysis were associated with vaccine storage compliance after controlling for the other variables. The main outcome variables were compliance with selected vaccine storage guidelines. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. For all analyses, a p value of 0.05 was used to determine statistical significance.

To determine the extent of change between pre- and post-intervention, we conducted repeated measure analyses on key variables, including thermometer present in unit, thermometer in appropriate range, log posted on or near unit, frequency of log recording, and vaccines stored in door of unit. McNemar's chi-square test was used to compare adherence to guidelines before and after the intervention; a p value of 0.01 was used to determine statistical significance. All data analysis was completed using the SAS package, Version 6.12 (SAS Institute, Inc., Cary, NC).

Results

A total of 721 offices completed both the baseline and post-intervention assessment, for a response rate of 97% (Table 1). Response rates per location were very high, ranging from 94% to almost 100%.

Almost half (48%) of the individuals who completed the in-person survey were office staff (i.e., administra-

Table 2. Distribution of information about offices, by study location

Office information	I		II		III		IV		Total	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Number of completed follow-up surveys	222		99		202		198		721	
Person interviewed*										
Clinical[a]	56	(25.2)	35	(35.3)	35	(17.3)	30	(15.2)	156	(21.6)
Medical assistant	55	(24.8)	26	(26.3)	65	(32.2)	70	(35.3)	216	(30.0)
Office staff	111	(50.0)	38	(38.4)	102	(50.5)	98	(49.5)	349	(48.4)
No. of people who order vaccines										
1	174	(78.4)	71	(72.5)	154	(76.6)	141	(71.2)	540	(75.1)
2+	48	(21.6)	27	(27.5)	47	(23.4)	57	(28.8)	179	(24.9)
No. of people who store vaccines										
1	123	(55.4)	45	(45.9)	94	(46.8)	95	(48.0)	357	(49.6)
2+	99	(44.6)	53	(54.1)	107	(53.2)	103	(52.0)	362	(50.4)
No. of people who administer vaccines										
1	53	(23.9)	18	(18.4)	49	(24.4)	45	(22.7)	165	(22.9)
2+	169	(76.1)	80	(81.6)	152	(75.6)	153	(77.3)	554	(77.1)
Type of primary care physician*										
Pediatrics	58	(26.1)	35	(35.4)	49	(24.2)	48	(24.2)	190	(26.4)
Internal medicine	35	(15.8)	22	(22.2)	68	(33.7)	36	(18.2)	161	(22.3)
Family practice	109	(49.1)	22	(22.2)	61	(30.2)	96	(48.5)	288	(39.9)
Multispecialty	20	(9.0)	20	(20.2)	24	(11.9)	18	(9.1)	82	(11.4)
Practice size*[b]										
1 physician	122	(54.9)	40	(40.4)	75	(37.1)	100	(50.5)	337	(46.8)
2 physicians	47	(21.2)	10	(10.1)	55	(27.2)	40	(20.2)	152	(21.1)
3 physicians	18	(8.1)	14	(14.1)	31	(15.4)	18	(9.1)	81	(11.2)
4+ physicians	35	(15.8)	35	(35.4)	41	(20.3)	40	(20.2)	151	(20.9)
Participation in programs[c,*]										
0	92	(41.4)	27	(27.3)	79	(39.1)	66	(33.3)	264	(36.6)
1	51	(23.0)	26	(26.3)	58	(28.7)	82	(41.4)	217	(30.1)
2+	79	(35.6)	46	(46.4)	65	(32.2)	50	(25.3)	240	(33.3)
Use of guidelines[d]										
None	66	(29.7)	34	(34.3)	48	(23.8)	54	(27.2)	202	(28.0)
One	55	(24.8)	29	(29.3)	73	(36.1)	53	(26.8)	210	(29.1)
Two or more	101	(45.5)	36	(36.4)	81	(40.1)	91	(46.0)	309	(42.9)
No. of Refrigerators*										
One	211	(95.0)	87	(87.9)	196	(97.0)	182	(91.9)	676	(93.8)
Two or more	11	(5.0)	12	(12.1)	6	(3.0)	16	(8.1)	45	(6.2)
No. of Freezers										
None	84	(37.8)	41	(41.4)	68	(33.7)	64	(32.3)	257	(33.6)
One	136	(61.2)	55	(55.6)	132	(65.3)	131	(66.2)	454	(63.0)
Two or more	2	(1.0)	3	(3.0)	2	(1.0)	3	(1.5)	10	(1.4)

*$p<0.05$ for differences between study locations.
[a]Clinical staff includes physicians, nurses, and clinical managers.
[b]Includes full- and part-time physicians; i.e., two part-time physicians=1 full-time physician.
[c]Includes participation in any of the following programs: Vaccines for Children, State immunization programs, Children's Health Insurance Program (CHIP), or Medicaid.
[d]Includes any of the following guidelines: Centers for Disease Control and Prevention, federal or state manuals, American Academy of Pediatrics.

tive staff and office managers), 30% were medical assistants, and 22% were clinicians (Table 2). Seventy-five percent of the offices had one person responsible for ordering the vaccines, almost 50% had one person responsible for storing the vaccines, and 77% had two or more people administering vaccines. Twenty-six percent of the offices were comprised of pediatricians only, and 47% were solo practices. Slightly more than one third (37%) did not participate in any vaccine programs, while another third participated in two or more programs. Seventy-two percent of the offices used at least one recognized guideline for vaccine storage. Almost all (94%) of the offices had only one refrigerator unit, and 63% had one freezer unit for vaccine storage. Several of these characteristics varied by study location ($p<0.05$).

At baseline, 89% of offices had a thermometer in their storage refrigerator (Table 3). Of those offices that did not have a thermometer, the primary barrier reported was that they did not know how important it was to measure temperatures. According to the study thermometer, 83% of refrigerator temperatures were in the appropriate range (2° to 8°C). Almost three quarters of the offices kept a temperature log, and 92% of those offices using logs recorded temperatures at least once a day. The majority of refrigerator units did

Table 3. Baseline compliance with CDC vaccine storage guidelines, by study location

	I		II		III		IV		Total	
Baseline compliance[a]	***n***	**(%)**	***n***	**(%)**	***n***	**(%)**	***n***	**(%)**	***n***	**(%)**
Refrigerator										
Thermometer present*	194	(87.4)	90	(90.9)	197	(97.5)	160	(80.8)	641	(88.9)
Study temperature appropriate	182	(82.0)	82	(82.8)	145	(89.0)	159	(90.3)	568	(83.3)
Temperature log posted*	138	(62.2)	79	(79.8)	177	(87.6)	134	(67.7)	528	(73.2)
Frequency of recording temperatures*										
<1/day	13	(9.4)	5	(6.3)	16	(9.0)	8	(6.0)	42	(7.9)
1/day	92	(66.7)	69	(87.4)	120	(67.8)	43	(32.1)	324	(61.4)
2+/day	33	(23.9)	5	(6.3)	41	(23.2)	83	(61.9)	162	(30.7)
Varicella not stored	220	(99.1)	99	(100.0)	198	(98.0)	194	(98.0)	711	(98.6)
Vaccines not stored in door*	180	(81.1)	70	(70.7)	176	(87.1)	149	(75.2)	575	(79.7)
No food or open container of biological materials	211	(95.0)	96	(97.0)	195	(96.5)	193	(97.5)	695	(96.4)
No expired vaccines*	220	(99.5)	97	(98.0)	199	(99.5)	191	(96.5)	707	(98.5)
Vaccine date order*										
Front older than back	107	(50.5)	31	(33.7)	85	(46.7)	19	(9.7)	242	(35.5)
Back older than front	47	(22.2)	42	(45.6)	53	(29.1)	24	(12.3)	166	(24.4)
Same date	58	(27.3)	19	(20.7)	44	(24.2)	152	(78.0)	273	(40.1)
Freezer										
Thermometer present*	107	(77.5)	47	(81.0)	127	(95.0)	111	(82.8)	392	(84.5)
Study temperature appropriate	116	(84.1)	48	(82.8)	80	(87.9)	102	(76.1)	346	(82.2)
Temperature log posted*	91	(65.9)	37	(63.8)	127	(94.8)	104	(77.0)	359	(77.2)
Frequency of recording temperatures*										
<1/day	7	(7.7)	5	(13.5)	11	(8.7)	3	(2.9)	26	(7.2)
1/day	58	(63.7)	30	(81.1)	83	(65.3)	29	(27.9)	200	(55.7)
2+/day	26	(28.6)	2	(5.4)	33	(26.0)	72	(69.2)	133	(37.1)
Other vaccines in freezer*	134	(97.1)	56	(98.2)	121	(90.3)	109	(82.6)	420	(91.1)
Vaccines not stored in door	135	(97.8)	57	(98.3)	132	(98.5)	126	(94.0)	450	(97.0)
No food or open container of biological materials	131	(94.9)	57	(98.3)	133	(99.2)	125	(93.3)	446	(96.1)
No expired vaccines	115	(97.5)	51	(98.1)	101	(100.0)	118	(99.2)	385	(98.7)
Vaccine date order*										
Front older than back	15	(24.6)	12	(30.8)	35	(51.5)	24	(21.3)	86	(30.6)
Back older than front	3	(4.9)	4	(10.3)	5	(7.3)	11	(9.7)	23	(8.2)
Same date	43	(70.5)	23	(58.9)	28	(41.2)	78	(69.0)	172	(61.2)

*$p < 0.05$ for differences between study locations.
[a]For practices with >1 vaccine storage unit, only 1 unit was included.
CDC, Centers for Disease Control and Prevention.

not have vaccines stored in the door or food/biological materials in the unit (80% and 96%, respectively). Almost all (99%) of the vaccines were within their expiration date; however, 24% of the units stored older vaccines in the back rather than in the front of the refrigerator shelf. Similar data were shown for freezer units. There was some variation in compliance with guidelines by study location ($p<0.05$).

Because compliance was relatively high for most of the guidelines, we conducted multivariate analysis only for the guidelines with lower compliance rates for *both* the refrigerator and freezer units. Study location was significantly associated with compliance to guidelines in all the multivariate models (Table 4). For both refrigerator and freezer units, the type of physician office was associated with having a thermometer and keeping a temperature log. For example, pediatric offices were more likely to have a thermometer in their storage units than internal medicine offices (OR=5.2, 95% CI=1.9–14.3). Being involved in immunization programs and using guidelines were associated with having a freezer thermometer and logbook.

Adherence to vaccine storage guidelines improved for all measurements after the QI activity (Table 5). The net change between the pre- and post-intervention assessments ranged from +1% to +19%. For each office and guideline, compliance was measured as "yes" or "no." Four patterns were observed: (1) office meets CDC guideline at both pre- and post-intervention assessments (column A); (2) office does not meet CDC guideline at pre-intervention assessment but meets guideline at post-intervention assessment (column B); (3) office meets CDC guideline at pre-intervention assessment but not at post-intervention assessment (column C); and (4) office fails to meet CDC guidelines at either the pre- or post-intervention assessments (column D). The level of pre-intervention adherence to CDC guidelines is measured as column A plus column C, while post-intervention adherence is column A plus column B. The net change is measured as column B

Table 4. Multivariate analysis of factors predicting compliance with CDC vaccine storage guidelines

Factors predicting compliance	Refrigerator			Freezer		
	Thermometer	Study temp app	Log	Thermometer	Study temp app	Log
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Study location						
I (Southeast)	1.8 (1.0–3.3)	1.1 (0.7–1.9)	0.8 (0.5–1.3)	0.7 (0.5–1.3)	1.6 (0.9–3.1)	0.5 (0.3–0.9)
II (Southwest)	2.8 (1.2–6.6)	1.4 (0.7–2.7)	1.8 (0.9–3.6)	0.6 (0.2–1.5)	1.1 (0.5–2.7)	0.3 (0.1–0.7)
III (Midwest)	15.0 (5.4–41.4)	2.2 (1.2–4.1)	5.0 (2.7–9.1)	4.6 (1.7–12.3)	2.6 (1.1–6.0)	6.5 (2.5–16.7)
IV (Southwest)	Referent	Referent	Referent	Referent	Referent	Referent
No. of people who store vaccines						
1	Referent	Referent	Referent	Referent	Referent	Referent
2+	2.0 (1.1–3.4)	1.1 (0.7–1.6)	1.4 (0.9–2.0)	1.0 (0.6–1.8)	0.8 (0.5–1.4)	1.2 (0.7–2.0)
Type of PCPs						
Pediatrics	5.2 (1.9–14.3)	0.7 (0.3–1.4)	5.1 (2.5–10.4)	4.5 (1.4–14.1)	2.3 (0.8–6.7)	5.6 (1.9–16.7)
Family practice	3.8 (2.0–7.1)	0.9 (0.5–1.6)	2.2 (1.3–3.7)	2.0 (0.7–5.5)	1.3 (0.5–3.5)	1.5 (0.6–4.2)
Internal medicine	Referent	Referent	Referent	Referent	Referent	Referent
Multispecialty	1.6 (0.6–14.3)	0.7 (0.3–1.4)	5.1 (2.5–10.4)	4.5 (1.4–14.1)	2.3 (0.8–6.7)	5.6 (1.9–16.7)
Practice size						
1	Referent	Referent	Referent	Referent	Referent	Referent
2	2.0 (0.9–4.1)	1.0 (0.6–1.7)	1.2 (0.7–1.9)	2.3 (1.0–5.0)	1.6 (0.7–3.4)	2.0 (1.0–4.0)
3	1.2 (0.4–3.1)	1.1 (0.5–2.3)	1.5 (0.7–3.0)	1.4 (0.5–3.6)	1.6 (0.6–4.2)	1.2 (0.5–2.8)
4+	1.9 (0.8–4.5)	1.3 (0.7–2.5)	2.9 (1.5–5.6)	2.3 (1.0–5.4)	1.0 (0.5–2.1)	2.2 (1.0–4.5)
Participation in program						
0	Referent	Referent	Referent	Referent	Referent	Referent
1	1.5 (0.8–2.8)	0.7 (0.4–1.2)	1.8 (1.1–3.0)	3.0 (1.4–6.5)	1.5 (0.7–3.1)	2.4 (1.2–4.9)
2+	2.1 (0.9–5.0)	0.5 (0.3–1.0)	1.7 (1.0–2.9)	2.7 (1.3–5.9)	2.1 (0.9–4.5)	2.1 (1.0–4.3)
Use of guidelines						
0	Referent	Referent	Referent	Referent	Referent	Referent
1	1.1 (0.6–2.1)	1.1 (0.6–1.8)	2.1 (1.3–3.4)	3.0 (1.3–6.5)	2.1 (1.0–4.6)	3.0 (1.4–6.4)
2+	1.7 (0.8–3.8)	2.5 (1.3–4.7)	3.0 (1.7–5.3)	2.6 (1.2–5.6)	1.9 (0.9–4.0)	2.4 (1.2–4.9)

App, appropriate; CDC, Centers for Disease Control and Prevention; CI, confidence interval; log, temperature log; OR, odds ratio; PCP, primary care physician; temp, temperature.

minus column C. The following is an example using the guideline "refrigerator temperature appropriate" (Table 5, row 2): Eleven percent of offices had an out-of-range refrigerator temperature during the pre-intervention assessment and an appropriate temperature at the post-intervention assessment (column B), while 8% of offices had an appropriate refrigerator temperature during the pre-intervention assessment and out-of-range temperature during the post-intervention assessment (column C), resulting in a +3% net change (column E) for this measurement.

Measurements that showed significant improvement ($p < 0.01$) following the QI activity included temperature log posted (19% improvement in refrigerator, 16% improvement in freezer); no vaccine stored in the refrigerator door (14% improvement); and thermometer present (12% improvement in freezer, 10% improvement in refrigerator).

During the post-intervention assessment, 89% of out-of-range refrigerator temperatures were too cold (<2°C), and 11% were too warm (>8°C). Of the refrigerators that were too cold, 70% were at or below freezing (<0°C). All out-of-range freezer temperatures were too warm, as freezer temperatures must be kept at ≤15°C, and no freezer temperature is considered "too cold."

In response to questions assessing the usefulness of the QI activity, 47% of offices reported that they found the CDC guidelines to provide helpful information, 39% found the temperature log to be helpful, and 33% found the feedback sheet to be helpful.

Discussion

Overall, compliance was high, at >80% for most recommended vaccine storage guidelines in the PCP offices that participated in this study. These rates were dramatically higher than what has been reported in other studies.[14–25] Our higher rates may reflect the larger scale of this study, which is likely to be representative of PCP offices in the United States or the attention in the United States given to vaccine storage practices and the possible impact of immunization campaigns.

Overall, it appeared that pediatricians' offices had the highest compliance rates. This may reflect that they likely administer more vaccines than other types of providers. Moreover, the consistent differences between study locations suggest that there may be important geographic influences that we were not able to examine. For example, the study location in the Midwest had consistently higher compliance rates than the

Table 5. Adherence to CDC vaccine storage guidelines pre- and post-intervention, by study location

Vaccine storage	A OK pre and post (%)	B Not OK pre OK post (%)	C OK pre Not OK post (%)	D Not OK pre and post (%)	E[a] Net change (%)	F[b] Total adherence after intervention (%)
Refrigerator						
Thermometer present*	641/721 (89)	74/721 (10)	0/721 (0)	6/721 (1)	74/721 (+10)	715/721 (99)
Appropriate temperature	495/641 (77)	71/641 (11)	52/641 (8)	22/641 (3)	19/641 (+3)	566/641 (88)
Log posted*	523/715 (73)	143/715 (20)	8/715 (1)	41/715 (6)	135/715 (+19)	666/715 (93)
Frequency of log recording[c]	465/523 (89)	33/523 (6)	16/523 (3)	9/523 (2)	17/523 (+3)	498/523 (95)
No vaccines stored in door*	548/721 (76)	128/721 (18)	27/721 (4)	18/721 (3)	101/721 (+14)	676/721 (94)
Freezer						
Thermometer present*	375/438 (86)	53/438 (12)	0/438 (0)	10/438 (2)	53/438 (+12)	428/438 (98)
Appropriate temperature	287/374 (77)	40/374 (11)	27/374 (7)	20/374 (5)	13/374 (+4)	327/374 (87)
Log posted*	339/428 (79)	72/428 (17)	4/428 (1)	13/428 (3)	68/428 (+16)	411/428 (96)
Frequency of log recording[c]	300/339 (89)	20/339 (6)	15/339 (4)	4/339 (1)	5/339 (+1)	320/339 (94)
No vaccines stored in door	417/438 (95)	12/438 (3)	8/438 (2)	1/438 (<1)	4/438 (+1)	429/438 (98)

*$p < 0.01$, McNemar test comparing difference between pre- and post-intervention adherence.
[a]E = B − C; includes both offices that improved and offices that decreased in adherence between pre- and post-intervention.
[b]F = A + B.
[c]Less than once a day "not OK"; once or more per day "OK."
CDC, Centers for Disease Control and Prevention; OK, meets CDC guidelines.

other locations. Perhaps those differences could be due to a greater emphasis on vaccinations. Finally, it seemed that being involved in other vaccine programs and using other guidelines was related to higher compliance rates. Perhaps regular monitoring associated with programs such as VFC may increase awareness of guidelines as well as vigilance in adhering to them, or that offices emphasizing involvement in vaccine programs and the use of guidelines are inherently more compliant in nature.

Following the QI activity, all measurements showed improvement. However, the most substantial improvements were observed for temperature log posted, no vaccine stored in the refrigerator door, and thermometer present. There was little improvement in frequency of freezer temperature log recording and no vaccine stored in freezer door, and this slight improvement may have been due to chance variation rather than the intervention.

We saw little improvement in appropriate temperatures, arguably the most important of the guidelines. Reasons for lack of improvement are unclear, although this is likely the hardest measure to affect because it requires more time and effort on the part of office staff. A possible addendum to future interventions would be to distribute a "tip sheet" with suggestions that offices could follow if temperatures are out of range (e.g., adjust internal controls, check and clean refrigerator coils as necessary, use a minimum-maximum thermometer to better understand temperature fluctuations).

Most out-of-range refrigerator temperatures were too cold rather than too warm, and 70% were at or below freezing temperatures. While more attention is focused on ensuring that vaccines are not stored at warm temperatures, freezing vaccines (other than varicella vaccine) can be equally harmful.[16,27] If vaccine vials are frozen, hairline fractures can develop upon defrosting and may allow bacterial contamination.[21] Manufacturers recommend that vaccines stored at <0°C be discarded.[16]

Our study is one of the largest of PCP offices, representing the most common healthcare providers that administer vaccines to insured populations in the United States. In addition, the study took place within an existing framework, which enabled data collection to be completed in a relatively inexpensive, timely manner by personnel who were well known to PCP office staff. Using personnel who were familiar with and accepted in the offices probably resulted in our very high participation rate. Finally, in addition to simply providing educational materials and thermometers, PSCs gave office staff direct feedback on adherence to guidelines at their particular site. The feedback sheets enabled office staff to compare changes (if any) in adherence between the pre- and post-intervention assessment.

Despite the strengths of this study, there were at least four limitations. First, given the size of this study and multiple study locations, we did not conduct continuous monitoring (e.g., 48 hours) of the storage unit

temperatures, which would have assessed the stability of the temperatures more accurately than our measurement method. Moreover, we did not calibrate the clinics' thermometers against our study thermometers. Second, additional research is needed to determine if not meeting guidelines results in reduced vaccine efficacy. Certain guidelines have stronger implications than others if they are not met (e.g., not storing vaccines at the appropriate temperature or beyond the expiration date may pose a higher risk of vaccine failure than storing food in the refrigerator with vaccines). Third, office staffs were aware that PSCs would be returning to assess vaccine storage practices, and we were not able to measure whether this knowledge made an impact on behavior. Finally, because baseline adherence to vaccine storage guidelines was considerably higher in our study than in previous reports of vaccine storage practices, our results may have been influenced by a "ceiling effect" and may not indicate the true impact of a QI activity.

The opportunity to improve vaccine storage practices on a national level addresses a vital patient safety issue. In-person assessment, education, and feedback are potentially costly and time consuming, and may be difficult to maintain over long periods of time or in a large number of physician offices. Further research is needed to determine the possible benefits of tailoring interventions to a particular provider type (e.g., internists). In our study, PCP offices made improvements after participating in the QI activity, demonstrating that education and feedback may be an effective way to improve vaccine storage practices. As new vaccines continue to be introduced in the United States, it is important to be aware of recommendations and update guidelines appropriately. A managed care plan could provide valuable patient safety information in its routine interactions with participating PCP offices.

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