Abstract

Purpose

The purpose of this educational initiative was to increase Harlem community pharmacy pneumococcal vaccine delivery, thereby increasing pneumococcal vaccination rates in this predominantly minority low-income NYC neighborhood. Investigation of barriers to greater delivery was included.

Scope

Pneumococcal immunization rates among minorities are consistently below that of whites. In Harlem the rate of invasive pneumococcal disease is twice that of low poverty NYC neighborhoods; rates of particular pneumococcal at risk conditions are notably higher. Project's target audience was supervising pharmacists at the 87 Harlem community pharmacies operating in July 2013.

Methods

A mixed method approach was used. Quantitative data sources included introductory visits, initial and one-year follow up surveys, and corporate vaccination numbers. Qualitative sources included focus groups and pharmacist interviews. Educational intervention included: pneumococcal fact sheet, comprehensive immunization resource manual, pneumococcal vaccine algorithms, and client educational material.

Results

Marked differences in immunization capacity between chains and independents were present. Post intervention, there was a five-fold increase in independents' possession of pneumococcal standing orders, and statistically significant increases in pharmacists' pneumococcal knowledge and vaccine recommendations. Failure to increase number of pneumococcal vaccines administered underscored presence of significant multi-level barriers identified by this project.

Keywords

Community pharmacy, pneumococcal vaccine, pneumococcal immunization, immunization barriers.

Pneumococcal Vaccine Services and Harlem Community Pharmacies

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PURPOSE

In 2013, funded by a grant to explore ways to reduce racial and ethnic disparities in adult pneumococcal immunization rates, we embarked on an initiative to increase vaccination rates among the largely minority low income population in Central and East Harlem. Our strategy was to increase pneumococcal immunization delivery at Harlem community pharmacies through an educational intervention designed to enhance pharmacists' knowledge of pneumococcal disease, at risk conditions, community need, and enhanced reimbursement opportunities so that provision of pneumococcal vaccine would be more viable and remunerative.

Numerous unanticipated barriers encountered during our project led us to expand our goals to include an in depth investigation of barriers to greater community pharmacy pneumococcal vaccine delivery. The elucidation of these barriers was the singular most informative and important contribution the project achieved.

SCOPE

Suboptimal pneumococcal immunization rates

The current national pneumococcal immunization rate of 60.6%¹ for those 65 and older falls far short of the 90% goal set in both Healthy People 2010 and Healthy People 2020.² The problem of low immunization rates is particularly acute among the nation's minorities, including among Medicare beneficiaries.³ In New York City, where pneumococcal immunization levels among those 65 years and older have remained at about 50% for the past decade, there exist notable racial and ethnic disparities, with rates among people of color consistently below those of whites.⁴

¹ National Center for Health Statistics. *Health, United States, 2010: With Special Feature on Death and Dying.* Table 85, p.293. Hyattsville, MD. 2011.

² US Department of Health and Human Services. *Healthy People 2020 objective topic areas*.

http://www.healthypeople.gov/2020/ topicsobjectives2020/pdfs/HP2020objectives.pdf. Updated 2011. Accessed on July 30, 2012.

³ Centers for Disease Control and Prevention. Racial/ethnic disparities in influenza and pneumococcal vaccination levels among persons aged >65 years-United States, 1989-2001. *Morbidity and Mortality Wkly Rep.* 2003; 52(40): 958-962.

⁴ New York City Department of Health and Mental Hygiene. EpiQuery: NYC Interactive Health Data System - Community Health Survey 2012. <u>http://nyc.gov/health/epiquery.</u> Accessed March 24,2015.

Disparities of immunization rates in Central Harlem and East Harlem

For more than a decade influenza and pneumonia have been among the top three leading causes of death in New York City.⁵ In 2011, rates of invasive pneumococcal disease (IPD) in high poverty New York City neighborhoods such as Central and East Harlem were twice as high as rates in low-poverty neighborhoods and almost 50% higher than national rate estimates.⁶ Lower immunization rates coupled with higher rates of at risk conditions, e.g., asthma, diabetes, and HIV infection, were likely important contributing factors.^{7,8}

Racial and ethnic disparities in pneumococcal vaccination rates in New York City, the minority composition of the Central and East Harlem population, high rates of poverty in the area and the high prevalence of at risk conditions, suggest there are tens of thousands of Harlem residents eligible for pneumococcal immunization who would benefit from access to convenient, low cost immunization services in community pharmacies.⁹

Suboptimal immunization levels have been attributed to numerous difficulties, including: access to service; absence of health insurance and primary care providers; patient and provider lack of knowledge, the latter's failure to make recommendations; and lack of effective reminder systems.

Successful efforts have included: patient, provider, and community education; expansion of the provider base to include nurse practitioners and pharmacists; provision of immunization services in alternative community settings such as pharmacies; and availability of standing orders for pharmacists.¹⁰

Pharmacist immunization provision

⁵ New York City Department of Health and Mental Hygiene. *Executive Summary of the Annual Summary of Vital Statistics*. <u>http://www.nyc.gov/html/doh/downloads/pdf/vs/vs-highlights-of-2010summary.pdf</u>

⁶ Dentinger C, Lane K, Cordoba E, Lee E, Wang S. Invasive Pneumococcal Disease Surveillance in New York City. New York City Department of Health and Mental Hygiene. *Epi Data Brief* (7); August 2011.

⁷ New York City Department of Health and Mental Hygiene. EpiQuery: NYC Interactive Health Data

System. Community Health Survey 2010. <u>http://nyc.gov/health/epiquery.</u> Accessed 9/25/2012.

⁸ New York City HIV/AIDS Annual Surveillance Statistics 2010. New York: New York City Department of Health and Mental Hygiene. Accessed 11/14/12 at http://www.nyc.gov/html/doh/html/data/hivtables.shtml.

⁹ *Geevrughese A*. Pneumococcal Vaccination in Commercial Pharmacies. New York City Department of Health and Mental Hygiene Presentation. June 13, 2012.

¹⁰ Vlahov, D., Bond, K.T., Jones, K.C. & Ompad, D.C. (2012). Factors Associated with Differential Uptake of Seasonal Influenza Immunizations Among Underserved Communities During the 2009-2010 Influenza Season. *Journal of Community Health*, 37(2), 282-287, DOI: 10.1007/s10900-011-9443-x

New York State pharmacists were first authorized to provide adult immunizations for influenza and pneumococcal disease in December 3, 2008.¹¹ Pharmacist provision of adult immunizations in New York State requires additional certification beyond licensure, and either the presence of an individual prescription or a standing order from a protocol physician.¹² By June 30, 2011, pharmacists had administered 585,458 doses of seasonal flu vaccine, 68,714 doses of H1N1 influenza vaccine (10/1/09-3/31/10) and 9,621 doses of pneumococcal vaccine.¹³

Although community pharmacists' efficacy and willingness as influenza immunizers have been well documented,¹⁴ their engagement in pneumococcal vaccine administration has been far more limited. Barriers noted to impede greater community pharmacy provision of adult immunization services include variable and inadequate reimbursement; time and space constraints; lack of standing orders; and concerns regarding legal liability.¹⁵

To address the gap between potential and actual pharmacy delivery of influenza and pneumococcal immunizations, in September 2011, the New York City Department of Health and Mental Hygiene (NYCDOH) began to offer influenza and pneumococcal vaccine standing orders to New York City community pharmacies. Participating pharmacists were required to be certified immunizers, and to attend NYCDOH's seminar detailing clinical, retail, and public health aspects of pneumococcal vaccination. More than one year later, the NYCDOH had received only 79 applications from the 1650 eligible New York City pharmacies. Only one application was received from any of the nearly 100 eligible community pharmacies located in Central and East Harlem. By summer 2012, the single pharmacy that had received standing orders had administered only one pneumococcal vaccine.¹⁶

Geographic Location

The New York City neighborhoods of Central and East Harlem, comprised of zip codes 10026, 10027, 10029, 10030, 10035, 10037 and 10039, was the area in which this educational initiative was conducted. Approximately 80% of Central and East Harlem's almost 300,000 residents are

¹¹ http://assembly.state.ny.us/leg/7bn=S8673. ¹² lbid.

¹³ New York State Department of Health Bureau of Immunization. Certified Pharmacist Immunizer Survey Report: 2008-2011 Reporting Period. December 2011. Accessed 10/1/12 at http://www.op.nysed.gov/documents/pharmimmunizerpt.pdf...

¹⁴ Graberstein JD, Guess HA, Gartzema AG. People vaccinated by pharmacists: Descriptive Epidemiology. J. Am. Pharm. Assoc. 2001;(1):46-52.

¹⁵ Taitel M, Cohen E, Duncan I, Pegs C. Pharmacists as providers: targeting pneumococcal vaccinations to high risk populations. Vaccine. 2011; 29:8073-8076. Pace AC, Flowers SK, Hastings, JK. Arkansas Community Pharmacists' Opinions on Providing Immunizations. J. Pharm. Pract.; 2010; 23(5):496-501.

¹⁶ Personal communication. Bureau of Immunization. New York City Department of Health and Mental Hygiene.

black or Hispanic;¹⁷ more than 35% live below the poverty level.¹⁸ Central and East Harlem contains one of three NYCDOH District Public Health Offices, established in 2002 to address the disproportionally higher disease burden and premature mortality in these communities. The other two New York City District Public Health Offices are located in the high need neighborhoods of the South Bronx and North and Central Brooklyn.

Participants

Supervising pharmacists at the 87 Central and East Harlem community pharmacies operating at the project's inception in July 2013, represented the target group for this intervention. Sixtyseven (77%) of these pharmacies were independently owned, and 20 (23%) were part of a pharmacy chain. Participation among supervising pharmacists at chains required corporate approval. At independent pharmacies, participation was most often a personal decision.

METHODS

We adopted a mixed methods approach for this project. Details regarding quantitative and qualitative elements are provided below.

Data Sources

Quantitative Data Sources

Initial Questionnaire and One-Year Follow up Questionnaire Administration

The initial questionnaire was distributed, administered, and retrieved by trained doctoral pharmacy students in fall/winter 2013 and the one-year follow up questionnaire in fall/winter 2014-2015. The development of the questionnaires was informed by an analysis of focus group discussions, and conversations with pharmacists at introductory visits. The initial questionnaire constituted the baseline data regarding pharmacy and pharmacist characteristics, immunization knowledge and practices, and use of coupled services.

¹⁷ New York City Department of Health and Mental Hygiene. EpiQuery: NYC Interactive Health Data System. Census 2010. <u>http://nyc.gov/health/epiquery.</u> Accessed 9/29/12.

¹⁸ Olson EC, Van Wye G, Kerker B, Thorpe L, Frieden TR. Take Care Central Harlem. NYC Community Health Profiles, Second Edition; 2006; 20(42):1-16. and Olson EC, Van Wye G, Kerker B, Thorpe L, Frieden TR. Take Care East Harlem. NYC Community Health Profiles, Second Edition; 2006; 21(42):1-16.

The one-year follow up questionnaire elicited one-year post-intervention immunization practices and was designed for comparison with the initial questionnaire, to serve as a measure of the impact of the intervention.

<u>Corporate Offices</u> of the two participating chains provided data regarding vaccine administration at their Harlem pharmacies.

<u>Pharmacy Management System Vendors</u> provided information regarding contents and capacity of their software systems.

Qualitative Data Sources

<u>Focus Groups</u> were conducted with Touro College of Pharmacy faculty, community pharmacists, and pharmacy doctoral students who participated in the project.

In spring 2013, we conducted two focus groups, one with clinical faculty at the Touro College School of Pharmacy who had community pharmacy experience, and a second with a small number of pharmacists from independent community pharmacies.

The faculty group was convened to elicit perceptions of barriers to and opportunities for reimbursable service delivery such as immunization, smoking cessation, medication management, and syringe exchange; perceptions of clientele and community; and perceptions of roles and potential benefits of immunization.

Our initial attempt to engage community pharmacists in focus group discussions met with some difficulty. Participation by pharmacists at chain pharmacies required approval from supervisors and was limited by constraints on their time. Participation among pharmacists at independent pharmacies were also hindered by time constraints due to long working hours, and by a stated lack of interest in immunization by the pharmacists in follow-up phone calls.

In fall 2013, we conducted two focus groups with doctoral students whose responsibilities included distribution and administration of the initial questionnaire and the follow up questionnaire. They also distributed all educational materials to participants.

Introductory Visits

Having mailed, emailed, and telephoned independent pharmacists in Harlem to invite them to participate in focus groups without success, the first and second authors systematically visited all independent Harlem pharmacies to engage them in the project. The pharmacists expressed greater interest in the project having been addressed in person by two health care professionals and provided essential information about possession of certification, standing orders, and immunization delivery.

Interviews

Following the administration of the one-year follow up surveys, the first and second authors visited several pharmacies and conducted short open-ended interviews with pharmacists to better understand experiences, concerns, and barriers to the delivery of pneumococcal vaccine from the community pharmacist's perspective.

Analysis of Quantitative and Qualitative Data

The questionnaire was administered as an initial and follow up instrument, in order to compare changes in knowledge and behavior from the initial administration to a point in time one year later.

As this project had limited sample size restrictions, we opted for a matched pair design in which initial data obtained were paired (linked or matched) at the individual pharmacy level, to the responses obtained one year later. This approach enhances the statistical power to detect change with smaller sample sizes and is conceptually closer to the question or issue we wished to assess: Were we able to improve the knowledge and behavior of pharmacists with respect to the administration of pneumococcal vaccine? We set the criterion for statistical significance at p<0.05 for two-tailed tests which is the usual level. Microsoft Excel was used to create spreadsheets for data entry and management, and SPSS was used to perform data analysis.

Relative to quantitative data analysis, in the course of on-site observations, we noted substantial differences between the cultures of chain pharmacies and independent pharmacies. These differences included existing immunization capacity, resources available to add services, and the structure of decision-making processes. The chains represent a cluster of franchises around a central authoritative body responsible for policy decisions that affect multiple operating pharmacies.

The independent pharmacies are typically smaller, often offer fewer services, and are privately owned. Policy decisions are made at the individual pharmacies. These differences between chains and independents led us to compare them with respect to immunization capacity and behavior, willingness to participate in the project, and personnel structure related to the administration of immunizations. Following an analysis of these comparisons, we undertook a comparison of reported and perceived barriers and technological resources.

Post-Intervention Assessment of Pharmacy Management Software

At completion of the intervention, based on the results, an audit and assessment of pharmacy management systems software used by Harlem independent pharmacies was undertaken to determine whether the various software systems utilized had the ability to capture information necessary to determine client pneumococcal vaccine candidacy and notify pharmacists; the extent of specific systems' extensibility and technological limitations; software sources, vendors, licensure, terms of use; and to make recommendations for inclusion and development of additional features.

The Intervention

The intervention consisted of the following elements.

Introductory Visits

Prior to distribution of our initial questionnaire all Harlem independent pharmacies were visited to introduce our initiative and encourage participation by supervising pharmacists.

Fact Sheet

A fact sheet detailing community pneumococcal immunization rates and disparities and Harlem community need was distributed at introductory visits.

Notification of Availability of NYCDOH Free Standing Orders

Introductory visits revealed that few independent pharmacists possessed standing orders; therefore, we included the following information in the intervention.

 education regarding availability to certified immunizers of NYCDOH's free standing orders for influenza and pneumococcal vaccines upon completion of their required three-hour class;
notification via email and phone of all independents regarding date and time of each of the three NYCDOH classes offered in summer 2013 and the two offered in summer 2014; and
special arrangements with NYCDOH to allow Harlem pharmacists who were not certified immunizers to attend class and receive their standing orders following receipt of certification.

Administration of the Initial Questionnaire

The initial questionnaire served as an element of the educational intervention, as well as the basis for baseline data and the one-year follow up survey. It was distributed, administered, and retrieved by trained doctoral pharmacy students in fall/winter 2013.

Distribution of Other Educational Materials

The following educational materials were designed by project staff and distributed upon retrieval of the initial questionnaire.

• **Comprehensive Resource Manual**: A Step by Step Guide to Pneumococcal *Immunization* included detailed information regarding pneumococcal disease,

risk and immunization; pneumococcal vaccines and administration schedule; patient vaccine information sheet; information regarding New York State regulations and requirements; means of obtaining certification and standing orders; local area resources, costs and insurance reimbursement; best practices and recommendations for enhanced reimbursement strategies; storage requirements, medical waste disposal, etc.

- **Pneumococcal Immunization Algorithms** (2013 and 2014 revised edition) pocket and wall size materials indicating at risk populations, appropriate pneumococcal vaccine, and vaccine administration schedules.
- Client educational and promotional materials including:
 - Pneumococcal Immunization Poster
 - Pneumococcal Immunization Client Flyers
 - Pharmacist Button: Ask Me About Pneumococcal Vaccine

RESULTS

Pharmacy Participation

All 87 pharmacies, 20 chains and 67 independents located in Central and East Harlem (CEH) were approached for participation in this study. Table 1 below describes pharmacy participation in the initial questionnaire and one year follow up survey. One chain store that participated in the initial questionnaire did not participate in the one-year follow up because it had closed during the intervening time.

Table 1 CEH Pharmacy - Initial and One Year Follow-Up Survey Participation

	All CEH	Independent CEH	Chain CEH
	Pharmacies	Pharmacies	Pharmacies
	(n=87)	(n=67)	(n=20)
Initial Questionnaire	56 (64%*)	44 (66%*)	12 (60%*)
1 Year Follow up Questionnaire	44 (79%**)	33 (75%**)	11 (92%**)

* Percentage of target area pharmacies

** Percentage of those who participated in initial educational questionnaire.

Pharmacy Characteristics

Participating pharmacies varied widely in terms of immunization capacity and activities, prescription volume, pharmacy management software system, nonprescription services offered, staffing, physical facilities, ownership, and hours of business.

Independent and chain pharmacies differed in categorical ways, some potentially significant relative to immunization delivery. At summer 2013 introductory visits, only two of the 44 independent pharmacies that participated in our initiative possessed standing orders for influenza and pneumococcal vaccine, compared to all twelve of the participating chains (p < .000). All 12 of the chains reported having offered influenza and pneumococcal vaccinations in the prior year compared to only five of the independents who had offered influenza vaccine (p<.000) and only three of whom had offered pneumococcal vaccine (p<.000). In addition, all 12 participating chain pharmacies required pharmacists to have immunization certification as a condition of employment compared to only 15 (34%) of independent pharmacies.

Considerable differences between chain and independent pharmacists in vaccine recommendations were also noted. As indicated in Table 2 below chains reported recommending vaccines with significantly greater frequency than independents. All vaccines were reportedly offered on a walk-in basis.

Always Recommend Vaccine for:	All (n=56)	Independents (n=44)	Chains (n=12)	Significance
Influenza	30 (54%)	18 (41%)	12 (100%)	.000
Pneumococcal	16 (29%)	8 (19%)	8 (67%)	.003
Zoster	13 (23%)	7 (17%)	6 (50%)	.027

Table 2 Pharmacist Vaccine Recommendations on Initial Survey

Medication therapy management, reportedly most often conducted by phone, was the only nonprescription pharmacy service for which most pharmacies reported receiving separate reimbursement. Only one pharmacy reported receiving separate reimbursement for syringe exchange. Additional pharmacy characteristics are described in Table 3 below.

Considerable variation was reported among pharmacies regarding information entered into their pharmacy management software systems relative to identification of pneumococcal disease at risk conditions, e.g., medical diagnosis, smoking status, immunization history, etc. None reported utilizing their systems as a means to do so or to notify pharmacists. No significant difference was noted between chain and independents.

	All	Independents	Chains	D.) (alua
	(n=56)	(n=44)	(n=12)	P value
Pharmacist Owned	33 (59%)	33 (75%)	0 (0%)	.000
Average Hours Open per Week	61	56	80	.000
Average Number of Pharmacists	1.8	2.1	1.7	.020
Average Number of Technicians	2.0	2.7	1.9	.170
Average Weekly Prescription Volume				
<500	14 (25%)	14 (34%)	0(0%)	
500-1000	26 (46%)	18 (44%)	8 (67%)	NS
1000-2000	10 (18%)	6 (15%)	4 (33%)	
> 2000	3 (5%)	3 (7%)	0 (0%)	
% of prescription as refills		(46%)	(34%)	.013
Non-Prescription Services Offered				
Medication Therapy Management	27 (48%)	15 (34%)	12 (100%)	.002
Diabetes Education	36 (64%)	28 (64%)	8 (67%)	NS
Smoking Cessation	12 (21%)	11 (25%)	1(8%)	NS
Syringe Exchange	17 (30%)	12 (30%)	5 (42%)	NS

Table 3 Additional Pharmacy Characteristics

Pharmacy Management Software Systems

An assessment of pharmacy management software systems used at participating independents was undertaken to ascertain if they had the capacity to function as a pneumococcal vaccine notification system. Proprietary software systems at the two participating chains were not available to us.

Forty-two of the 44 (95%) participating independent pharmacies shared information regarding their pharmacy management software systems. Harlem independents utilized five different pharmacy management software systems among the more than 40 such systems currently on the market. Distribution of vendors and software products utilized is provided in Table 4 below.

These vendors were queried regarding whether their software allowed input of information that would enable it to identify pneumococcal vaccine candidates based on at risk factors and if their system had the ability to function as a vaccine notification system for pharmacist and client. Questions and responses are detailed in Table 5 below.

Vendor/Software Product	Pharmacies	Market Share
Micro Merchant Systems/PrimeRx	29	65.9%
Best Computer Systems, Inc./BestRxWin	6	13.6%
Lagniappe Pharmacy Services (LPS)/Opus-ISM InteRx	5	11.4%
Declined to answer	2	4.5%
McKesson Pharmacy Systems/Pharmaserv	1	2.3%
PioneerRx/ <i>PioneerRx</i>	1	2.3%

Table 4 Pharmacy Management Software Vendors Utilized by Independents

Table 5 Pharmacy Management Software System Information and Capacity Relative toPneumococcal Vaccine

Software Product Contains:	PrimeRx	BestRxWin	Opus-ISM InteRx	Pharmaserv	PioneerRx
Smoking Status	Yes	Yes	No	Yes	Yes
Disease Diagnosis Codes	Yes	Yes	Yes	Yes	Yes
Immunization History	No	No	No	No	No
Vaccine recommendation prompts	No	No	No	No	No
Reports that identify vaccine candidates	No	No	No	No	No
Ability for pharmacist to customize reports	No	No	No	No	No
Ability to use report results to make vaccine recommendations via email, text or phone	No	No	No	No	No

Ability to trigger vaccine notification based on					
medication or diagnosis.	No	No	No	No	No

Physical Facilities

In some instances, stark differences in physical facilities between chain and independent pharmacies were commented upon by doctoral students.

In all of the chain pharmacies we went to, I observed that they have nice wide areas for customers to wait, a consultation window, and they all sell most non-prescription drugs.... Some pharmacies also double as supermarkets.... And in the independents, some have no front of the house at all. And also in some, you'd walk in and it would be all glassed inside - a counter and that was it. There were quite a few like that. I'd never seen a pharmacy that looked like that till I did this project.

You'd walk in and the entire place was about a couple of feet not even square yards, just one square yard where the customer could walk in, maybe sit down and then the rest was all behind glass. To me it was very bizarre.

There was Scope or Listerine but it was behind the glass. In a lot of the places, even the candy was behind glass. And there were signs, "We do not carry Oxycodone." You could tell people were taking measures to avoid any kind of violence or theft - which is sad.

Comparison of Initial and One-Year Follow Up Data

Pharmacist Pneumococcal Risk Knowledge

Pneumococcal risk knowledge was assessed in by the initial questionnaire and again in the oneyear follow up survey. Overall average scores on the initial questionnaire were relatively weak with important knowledge gaps of at risk groups particularly relevant to this community. Increases in knowledge regarding at risk conditions with high prevalence in the Harlem community were a prominent part of our educational efforts.

Change in risk knowledge was assessed through two approaches.ⁱ The first approach noted in Table 6 below compared overall average test scores on the initial questionnaire to

those on the one-year follow up survey, compared scores between pharmacists at chain and independent pharmacies, and compared scores between pharmacists with immunization certification and those without. Average test scores in all categories showed a greater than 10% improvement.

	All Mean Score (SD)	Independents (n=40)* Mean Score (SD)	Chains (n=12) Mean Score (SD)	Significance
Risk Test Score at Baseline (n=52)*	63% (18.6)	62% (18.1)	67% (20.5)	NS
Risk Test Score at Follow Up (n=42)	76% (17.4)	74% (18.4)	81% (13.6)	NS
	All Mean Score (SD)	Certified Immunizer (BL n=35) (FU n=26) Mean Score (SD)	Non-Certified Immunizer (BL n=17) (FU n=16) Mean Score (SD)	Significance
Risk Test Score at Baseline (n=52)*	63% (18.6)	66% (18.5)	57% (17.4)	.080
Risk Test Score at Follow Up (n=42)	76% (17.4)	77% (16.7)	73% (18.7)	NS

* 4 independents skipped this item

The second approach, a paired analysis among pharmacists who answered the risk knowledge questions on both the educational questionnaire *and* the follow up survey, showed a significant increase in knowledge at the follow up survey. Table 7 contains the risk knowledge scores at baseline and follow up, and provides a paired analysis of gain in knowledge by paired T-test.

Table 7 Paired Analysis of Gain in Pharmacist Knowledge

	N	Mean Score	Standard Deviation	Significance
Baseline	39	61.5	19.1	.001
Follow Up	39	74.7	17.5	

The above noted modest but statistically significant increase in overall knowledge regarding pneumococcal risk factors among both chain and independent pharmacists at one year follow up was accompanied by a marked increase in identification of pneumococcal risk conditions particularly relevant to the Harlem community. For example, at one year follow up

62% of pharmacists identified sickle cell disease as a risk factor (versus 31% at baseline), 83% identified congestive heart failure (versus 46% at baseline), and 74% identified diabetes (versus 60% at baseline).

Pharmacist Vaccine Recommendations

Pharmacists' gain in knowledge was accompanied by increased frequency of vaccine recommendation as indicated in Table 8 below. Pharmacists were asked to rate whether they recommended a specific vaccine always, sometimes, rarely and never, with "always" scored as 1 and "never" as 4; lower values indicate more frequent recommendations.

Pharmacy recommends following vaccine:	Means Score o	Significance	
0	Baseline	Baseline Follow Up	
Influenza	1.88	1.72	.001
Pneumococcal	2.24	2.10	.000
Zoster	2.35	2.15	.015

Table 8 Change in Pharmacist Vaccine Recommendations*

*Lower value indicates more frequent recommendations

Possession of Standing Orders

As noted earlier, only two of the 44 independent pharmacies that participated in the project had standing orders for pneumococcal vaccine at the project's inception compared to all twelve of the participating chains (p<.000).

One year later, 11 of the 33 independents who completed the one year follow-up survey reported having standing orders for pneumococcal vaccine, a more than fivefold increase among independents. All 11 had received standing orders from the NYCDOH subsequent to attending the requisite course. All had received multiple notifications from project staff and doctoral students of upcoming classes.

This week we contacted many pharmacists to inform them about the benefits of vaccination and the standing order meeting being held for pharmacists by the New York City Department of Health. In general, the pharmacists appreciated that we informed them about this meeting and sounded eager to attend. Some pharmacists were receptive or even enthusiastic, others were disinterested, and others were confused about the immunization process in general. They did mention that the day of the meeting was not convenient since it was on a Monday. A few pharmacists also mentioned that they had no idea they had to attend this meeting in addition to the certification requirements.

Doctoral student observations

Pneumococcal Vaccines Administered

The increase in immunization capacity among Harlem independent pharmacies and the increase in pharmacists' knowledge and vaccine recommendations did not translate into an increase in the overall number of pneumococcal vaccines administered by participating pharmacies. The 56 pharmacies that participated in our initial survey reported having administered a total of 204 pneumococcal vaccines in the year prior to our intervention. Almost half (98) were administered at one chain pharmacy store. Only two were administered at an independent pharmacy.

The 44 Harlem pharmacies that participated in the one-year follow up survey reported administering a total of 189 pneumococcal vaccines in the prior year. All but five were administered at a chain pharmacy. The one independent that reported having administered pneumococcal vaccine in the initial baseline survey did not participate in the one-year follow up survey. There was a small, but consistent, increase, in the number of pneumococcal vaccines administered among all three stores belonging to one chain. There was also a small but modest increase among most of the stores belonging to the other chain. At the one site in this chain which had been responsible for approximately half the pneumococcal vaccines administered in year prior to our intervention, there was a marked decline. When queried about this decline the supervising pharmacist could offer no apparent explanation.

Students noted, "Different pharmacists had different views regarding the delivery of vaccination. Some of them really want to make changes in Harlem and some think it's too time consuming." Behaviors appear to be influenced by the commitment of individual pharmacists, influences we were not able to explore further given our relatively small sample size.

Perceptions of Barriers and Benefits to Offering Immunization

When queried about possible benefits to pharmacies for offering immunizations, pharmacists at chains were far more likely than independents to consider provision of immunizations as beneficial. Statistically significant differences between pharmacists at chains and independents regarding perception of increases in revenue and service to the community are noted in Table 9 below.

AllIndependentsChains(n=56)(n=44)(n=12)

Table 9 Perceived Benefits of Offering Immunization

Immunization Service is Beneficial to Pharmacy	47 (84%)	35 (84%)	12 (100%)	.152
Ways it is beneficial:				
Increased clientele	38 (69%)	27 (63%)	11 (92%)	.080
Increased revenue	34 (62%)	22 (51%)	12 (100%)	.002
Positive public relations	41 (75%)	30 (70%)	11 (92%)	.156
Service to the community	43 (78%)	31 (72%)	12 (100%)	.050

Barriers

In the one year follow up survey, pharmacists were queried regarding barriers they thought impeded greater pharmacy engagement in immunization delivery. Responses are noted in Table 10 below.

Financial concerns were the leading barriers noted by all pharmacists. Vaccine copayment was the most frequently cited barrier to greater client engagement in pneumococcal immunization. The following barriers were cited with statistically significant greater frequency among independents than among chains: insufficient reimbursement, unknown level of demand, liability, billing procedures, and cost of vaccine. All pharmacists indicated concern about potential opposition from neighborhood physicians on whom they depend for business and therefore did not want to appear to be in competition.

Barriers	All (n=44)	Independents (n=33)	Chains (n=11)	Significance
Client's costs	30 (75%)	20 (75%)	10 (91%)	.233
Low/insufficient reimbursement	25 (63%)	23 (74%)	2 (22%)	.008
Unknown level of demand	24 (60%)	22 (71%)	2 (22%)	.018
Liability	24 (60%)	22 (71%)	2 (22%)	.018
Billing procedures	23 (58%)	21 (68%)	2 (22%)	.023
Prescriber opposition	18 (46%)	15 (50%)	3 (33%)	.464
Cost to purchase vaccine	16 (40%)	16 (52%)	0 (0%)	.006
Vaccine administration space	16 (42%)	13 (43%)	3 (38%)	1.00
Time to prepare and administer	15 (39%)	13 (45%)	2 (20%)	.263
Risk of disease transmission	15 (38%)	14 (45%)	1 (11%)	.067
Vaccine storage	14 (35%)	13 (42%)	1 (11%)	.124
File storage	12 (31%)	9 (30%)	3 (33%)	1.00
Inexperience	12 (31%)	12 (40%)	0 (0%)	.036
Reporting requirements	10 (27%)	10 (35%)	0 (0%)	.079

Table 10 Perceived Barriers to Offering Immunization

DISCUSSION

Immunization Capacity

Despite the project's achievement in the near doubling of Harlem community pharmacies with standing orders and the noted increase in participant knowledge, our effort to increase the number of pneumococcal vaccines administered at Harlem community pharmacies was impeded by the presence of multi-level barriers to greater engagement in immunization in general, and pneumococcal in particular. Although these barriers are identified in the National Vaccine Program Office's 2015 *National Adult Immunization Plan*¹⁹ and elsewhere, an analysis of our project produced a location-specific ecology of factors influencing the introduction of pneumococcal vaccination for disadvantaged Harlem residents.

At the onset of our educational initiative, the striking disparity in capacity between Harlem independent and chain pharmacies became evident. Among independents (who constitute 77% of Harlem community pharmacies), only 5% possessed standing orders and only 34% required certification of staff pharmacists. In contrast, all participating chain pharmacists possessed standing orders and required immunization certification as a condition of employment.

In the year following inception, the more than five-fold increase in possession of standing orders among the independents suggested a growing awareness and interest in providing immunizations, a relatively new role for New York State pharmacists who were only authorized to do so in late 2008.

The NYCDOH provision of free standing orders to certified immunizers who attended their course was essential to this increase in capacity. Participation of Harlem pharmacists in NYCDOH's program was strenuously supported through our educational activities which included introductory visits, notification of all independents of each standing order class, and special arrangements with NYCDOH that allowed Harlem pharmacists who were not certified immunizers to attend class with receipt of standing orders dependent upon certification completion. This policy was later adopted citywide.

Reimbursement

The barrier most frequently identified by independent pharmacists was low or insufficient reimbursement. Given that independents are small businesses with over 90% of revenue derived from prescriptions,²⁰ their greater concern with the financial aspects and viability of immunization delivery is not surprising. One independent pharmacist commented:

¹⁹ National Vaccine Program Office. Draft National Adult Immunization Plan. Accessed on 11/25/15 at www.hhs.gov/nvpo/about/adults/2015nat-adult-immunization-plan.pdf.

²⁰ National Community Pharmacists Association. The Impact of Recent Medicare and Medicaid Cuts on Patients' Access to Independent Community Pharmacies. <u>http://www.ncpanet.org/pdf/leg/oct11/pharmacycutsfinal.pdf</u>. Accessed 11/15/15.

The barrier is money; the reimbursement is not there. For a pharmacy, I think the number one thing would be getting the reimbursements for getting these patients to come into the pharmacy for the inoculations.

In some instances, no reimbursement was available at all. At winter 2014/2015 interviews, pharmacists commented that several insurance companies would not reimburse for Prevnar13, despite the August 2014 recommendations of the Advisory Committee on Immunization Practices that adults 65 years and older now receive *Prevnar13* in addition to *Pneumovax23*.²¹ Moreover, in winter 2015, Medicare would still only pay for one pneumococcal vaccine per older adult. Coverage for a second shot was not expected until 2016.²² Pharmacists at both chains and independents were also confused about whether *Prevnar13* could be administered solely with a standing order or required an individual prescription, as *Pneumovax23* was the only pneumococcal vaccine covered under the standing order.

We had expected to address the problem of low reimbursement through promotion of coupled reimbursement strategies, for example, the administration of pneumococcal vaccine concurrent with provision of another reimbursed service such as medication therapy management or influenza immunization. However, coupled reimbursed strategies could not be implemented because other services were often not provided, (e.g., syringe exchange programs), or if provided were not reimbursed (e.g., diabetes education), or were provided in a manner that made coupling with pneumococcal vaccine untenable (e.g., medication therapy management via the telephone.)

The unexpected paucity of reimbursed services to which pneumococcal vaccine might have profitably been joined limited adoption of our recommended strategies to the concurrent administration of pneumococcal and influenza vaccines. All participating chain pharmacists reported promoting this strategy; however, in interviews, chain pharmacists noted that these recommendations were often met with client's unwillingness. This resistance was variously attributed to disinclination for a second injection, reluctance in the absence of their physician's recommendation, and lack of knowledge of need.

Independents' perception of barriers was dominated by other financial considerations, which were far less frequently cited by chains. These included high vaccine costs, unknown levels of demand, liability, and billing procedures.

Cost

²¹ Tomczyk S, Bennett NM, Stoecker C, Gierke R, Moore MR, Whitney CG, et al. <u>Use of PCV-13 and PPSV-23 vaccine</u> among adults aged 65 and older: recommendations of the ACIP. *MMWR*. 2014;63(37);822-825.

²² Loftus P. Wall Street Journal 9/1/14 (New Advice for Vaccine to Stave Off Pneumonia.)

The considerably higher cost of pneumococcal vaccines (*Pneumovax23* and *Prevnar13*) as compared to influenza vaccine further discouraged greater engagement by independent pharmacies. For independents, the most cost efficient means of purchasing pneumococcal vaccine would be in ten-pack containers. Administration of between eight and nine pneumococcal vaccines would be required to at least cover capital investment; a minimum of 10 would be required to achieve a return on investment. While this number may seem quite small, only seven of the 11 chains achieved it in the year following our intervention. The cost of *Prevnar13*, at more than double that of *Pneumovax23*,²³ will only intensify the financial barriers, particularly among small independent pharmacies.

For chains, with greater buying power due to collective volume, vaccine costs are usually lower, and product can be shared between multiple sites, thus lowering financial risk and enhancing profit.

Vaccine copayment

The overwhelming majority of independent pharmacists and chain staff identified vaccine copayment as a significant barrier to greater client engagement in pneumococcal immunization, particularly in low-income communities like Harlem. Participants noted the absence of requisite copayment for influenza vaccine and thought the same should obtain for pneumococcal vaccine. Copayments were seen as discouraging client engagement and contributing to a marked paucity of demand.

Low and Uncertain Demand

Low and uncertain demand was another factor cited by independent pharmacists as discouraging greater pharmacy interest in and provision of pneumococcal vaccine services. Low demand, apparent in the low numbers of pneumococcal vaccines administered at participating pharmacies, is further underscored by the fact that the number of zoster vaccines administered exceeded that of pneumococcal vaccine despite similar indications, copayments, and zoster's additional requirement of an individual prescription. The paucity of patient demand speaks to the need for a greater commitment to educating providers, the general public, and at risk individuals regarding pneumococcal vaccine.

The Introduction of Community Pharmacy Delivered Immunizations

Our findings suggest that for independents, engagement in immunization delivery is a process that likely begins with provision of influenza vaccine, which is far less costly than pneumococcal vaccines and in much greater demand. It may be that only with the introduction of a well-

²³ The cost of *Prevnar13 is* \$152 per dose purchased as 10 pack versus \$72 per dose of *Pneumovax23* purchased as 10 pack. Accessed on 4/6/15 at cdc.gov/adult immunization costs.

established first line with sufficient demand and profit margins (e.g., influenza), would a second more costly and financially risky line (pneumococcal) be considered feasible.

From an independent pharmacy's perspective, provision of pneumococcal vaccine differs from that of influenza in several important ways. The significantly higher vaccine cost coupled with mandatory copayment, smaller potential recipient pool, absence of provider recommendations, and lack of public demand renders provision of pneumococcal vaccine a risky business endeavor. Independents, which operate as small businesses, have fewer financial resources, less buying power, and less frontend business to augment income.

Among pharmacists at participating chains the reported increase in pneumococcal vaccine *recommendations* did not result in an increase in number of pneumococcal vaccine *administrations*. The failure to increase vaccine administration at chains cannot be attributed to a lack of financial considerations, which constituted significant barrier among independents, and strongly points to other potentially remedial factors impeding greater pneumococcal vaccine vaccine delivery.

Absence of Pneumococcal Vaccine Notification System

One important impediment common to participating chains and independents is the absence of an efficient means to identify at risk clientele or a pneumococcal vaccine reminder system. None of the participating Harlem pharmacies reported using their pharmacy management software system to identify at risk clients or to notify pharmacist or client of pneumococcal vaccine candidacy.

Current iterations of pharmacy management system software used at Harlem independent pharmacies do not contain the necessary clinical data, e.g., disease diagnosis, or the functional capacity that would permit them to serve as a pneumococcal vaccine notification system. None provides preprogrammed reports that identify pneumococcal vaccine candidates, would allow pharmacists to independently create or customize reports, possessed the capacity to trigger vaccine notifications based on medication profile or diagnosis, or to use the report to make vaccine recommendations via email, text or phone.

Limitations of content and capacity among the pharmacy management systems software are not unique to Harlem independents or their vendors. Purposed to serve the needs of pharmacists when their activities were confined to medication dispensing and counseling, pharmacy software systems have traditionally served as a workflow tool designed to accept incoming prescriptions, manage billing, reimbursement, inventory, and handle dispensing medication. Under this circumstance the only necessary clinical data was that directly related to medications, e.g., patient allergies. The present process of expansion of pharmacists' role into the realm of clinical services requires enhancement of pharmacy infrastructure and tools, including health information technology that supports and integrates pharmacists in health care service delivery.

The Pharmacy e-Health Information Technology Collaborative was founded in 2010 by nine professional pharmacy associations to address the need for alignment of pharmacy management software systems with the standards for electronic health records articulated by the Office of the National Coordinator for Health Information Technology. The Collaborative has developed a guide specific to an electronic health record for a community pharmacy practice setting with specific, technical criteria and standards, as a measure against which to certify a Pharmacist/Provider Electronic Health Record (PP-EHR).²⁴ This new class of tool in the pharmacy setting ensures access to the kind of clinical data that can be used to better identify individuals for whom pneumococcal vaccine is appropriate, as well as other clinical activities, and has the ability to recommend required immunizations; and manage and document immunization related details.²⁵

Educating pharmacists and other providers within the health care system, including software vendors, regarding the value of pharmacists' adoption of the PP-EHR functionality in their practice management software systems is imperative and was clearly recognized in the Collaborative's *Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care: 2014 to 2017 Update.*²⁶

When queried regarding familiarity with the Pharmacy e-Health Information Technology Collaborative's efforts, one participating pharmacy management systems software vendor said he'd come across them a few months ago while reading about efforts to give pharmacists the authority to prescribe. When asked whether he had any plans to have his product certified as a PP-EHR, he said not unless there is sufficient demand from his pharmacy customers.

Community pharmacists demand for PP-EHR will likely depend on their perception of its utility relative to their activities and its financial impact. Economic changes within the community pharmacy environment including lower reimbursement for maintenance medications, management of high dollar medications by specialty pharmacies, mail order options offered by insurance companies, and Centers for Medicare and Medicaid Services (CMS) Star Ratings score for pharmacy reimbursement will likely motivate independent pharmacies to become more service centered rather than dispensing centered. As community pharmacies become more clinically and service oriented PP-EHR will increasingly be necessary to support their success. Incentives, such as the inclusion of PP-EHR as a quality assurance measure when evaluating retail pharmacies, could expedite adoption.

Improved pharmacy management software systems with the capacity to identify vaccine candidates would also allow pharmacists to accurately estimate potential demand, financial

²⁴ Pharmacy Health Information Technology Collaborative. *HL7 EHR-System for a Pharmacist/Pharmacy Electronic Health Record Implementation Guide for Community Practice*. Accessed on 10/5/15 at

http://www.hl7.org/documentcenter/public/standards/informative/13-294_HITSbook_HL7_Web.pdf ²⁵ Ibid

²⁶ http://www.pharmacyhit.org/pdfs/RoadmapUpdate 2015.pdf

feasibility and profitability, and encourage greater engagement. In addition PP-EHR could further support pharmacy specific quality assurance measures, as well national quality initiatives enabled by health information technology.

Lack of Quality Assurance Measures

More effective immunization quality assurance measures and meaningful incentives would encourage greater community pharmacy pneumococcal vaccine delivery.

The vaccine quality assurance measures that exist at the two participating chains appear to be ineffectual relative to pneumococcal vaccine. At one chain, which had quotas for specific vaccines, vaccine numbers were reported in two categories: influenza and non-influenza, with purportedly little or no follow-up for non-influenza quotas.²⁷

At chains where pharmacist's productivity is measured by number of prescriptions filled per day and rewarded by increases in staffing, the perception by some pharmacists that pneumococcal vaccine activities are more time consuming than medication dispensing, may discourage engagement. The introduction of incentives for pneumococcal vaccine administration would support more strenuous efforts in this direction.

The absence of adequate vaccine quality assurance measures in chain or independent community pharmacies is not unrelated to their absence in rating systems promulgated by government agencies and adopted by health insurance plans. While administration of influenza vaccine is included as an outcome measure in the CMS 2016 Star Ratings for Medicare Advantage Plans and Prescription Drug Plans, pneumococcal vaccine is not included, though this would certainly seem an important and appropriate recommendation for virtually all Medicare recipients.²⁸

Under CMS 2016 Star Ratings system health insurers will be rated on the pharmacy services delivered under their plan and subject to a quality based payment structure based on these ratings. One such rating measure is medication adherence rates for patients on maintenance medication for particular chronic diseases. Inclusion of pneumococcal vaccine activities as a measure of treatment adherence in medication therapy management protocols for at risk conditions would strongly encourage pharmacist recommendation and administration of pneumococcal vaccine. Incorporation of immunization histories and recommendations into standards for pharmacist annual comprehensive medication reviews would further reinforce these efforts.

²⁷ Personal communication, former district manager at one chain.

²⁸ <u>http://go.cms.gov/partcanddstarratings</u>. Accessed on 10/15/15

Many options exist for health insurance companies to play a more active role in driving vaccination rates. One such possibility would be for pharmacies to receive an annual incentive bonus if they vaccinated a certain proportion of a health plan's at risk patients. This additional reimbursement could be used to compensate pharmacists and technicians and encourage them to focus on vaccine initiatives.

Development of stronger quality assurance protocols related to immunization in general would contribute to greater immunization engagement on the part of community pharmacists.

Limitations of the Project

Limitations of this initiative include its small sample size which limited analysis of effects of various pharmacy and pharmacist characteristics, e.g., prescription volume, age, ethnicity, etc. In addition, because only 56 of 87 of Harlem community pharmacies participated in this educational intervention and only 44 in the one year follow up, our sample may not reflect Harlem pharmacies in general. A possible selection bias may have had an unknown impact on results.

Moreover, had we been aware of the unexpectedly large differences between independent and chain pharmacies at the project inception, we might have developed different strategies for each. For example, the one year follow up period may have been insufficient for most independent pharmacies to develop sufficient capacity (including immunization certification and standing orders) and vaccination experience to engage in pneumococcal immunization.

Conclusion

As our project evolved, the proposed educational intervention targeting community pharmacists appeared inadequate to achieving the goal of increasing the number of Harlem residents who would receive pneumococcal vaccinations. It became apparent that educational activities alone, even when preceded by the required acquisition of standing orders and certification, might not be sufficient to ensure timely proposed implementation of vaccinations among the broad swath of community pharmacies, many of whom function with only the limited resources available to small independent business owners.

The identification of barriers to our goal eventually contributed to our conception of the constituents of a multilevel ecology of pharmacy-based immunization services. These constituents include the pharmacies, health care providers, health insurers, vaccine manufactures, software venders, governmental and quality assurance entities, and last but not least, the clients themselves, who are presumably the ultimate recipients of a successful system of community pharmacy-based immunization services.

Based on our data, changes required to achieve the goal of increased pneumococcal vaccinations call for a consideration of pharmacy finances; the role of payers and health plans; the introduction of quality assurance measures; relevant software development; enhanced patient education; and communications with other health care providers. These interactive components contribute various weights of impact at different points in the process, as well as differing opportunities to enact changes that optimize rates of vaccinated patients as the desired end point.

The identification of barriers and a process of change called for a point of entry, an actionable opportunity which would set in motion a path of a realistic means to achieve the goal of increased pneumococcal vaccinations which would benefit not only the economic interests of the components, but ultimately the health of the patients. We suggest the development of additional quality assurance measures, improved health information technology, and reduction of financial barriers for providers and consumers, as advantage first steps to stimulate pharmacy-based immunization services.

The development and application of stronger quality assurance protocols inclusive of immunization standards in rating systems promulgated by government agencies and adopted by private health insurance plans, and an incentive and rewards system related to immunization in general and pneumococcal vaccine in particular would contribute to greater immunization engagement on the part of community pharmacists.

The incorporation of immunization histories into protocols for comprehensive medication reviews and medication therapy management, and the adoption of pneumococcal vaccine activities as a measure of treatment adherence for high-risk individuals would serve to educate patients and encourage provider immunization efforts.

Advanced pharmacy management software systems would encourage greater pharmacy immunization engagement through its ability to evaluate client vaccine needs, notify pharmacists of clients' candidacy, streamline provision and documentation of vaccination activities, support quality assurance measures at individual pharmacies and within the broader health care system, and most importantly, increase the number of appropriately vaccinated Harlem residents.

Clearly the challenge will be to get community pharmacy and pharmacy software vendors to adopt these guidelines and include these new features and functionalities.

Changes in financial components are also called for. Many options exist for health insurance companies to play a more active role in driving vaccinations. These include elimination of patient copayment, increase in pharmacy reimbursement, and incentives for pharmacies meeting defined immunization goals.

Addressing the multiple functionally connected barriers identified in this project through broader practice and policy changes would support greater community pharmacy adoption of

immunization delivery in general and pneumococcal vaccine in particular. With multiple locations, extensive hours, ease of access, and low cost immunizations community pharmacies are in a position to significantly expand the health care system's capacity for vaccine administration. Greater engagement in pneumococcal vaccine delivery by independent pharmacies, which are disproportionately present in poorer underserved urban and rural areas, would increase the pneumococcal immunization rate among at risk individuals in lowincome minority neighborhoods and contribute to the elimination of racial, ethnic and economic disparities in immunization.

NOTES

ⁱ In the educational questionnaire, one item listed 14 conditions (3 of which are not considered high risk for pneumococcal disease) in which respondents were asked to check a box for each condition, if they thought it put someone at high risk for pneumococcal disease. All unchecked boxes were assumed to be a 'no' response and therefore a correct answer for the 3 not at risk conditions. A 'test' score for the baseline was calculated by identifying all the correct answers, (including the 3 assumed 'no answers'), and dividing by the total number of items (n=14) and multiplied by 100 for a percent score on a scale of 0 - 100%.

In the post-test we modified this question slightly by asking, for each condition whether, yes or no, it was a risk factor for pneumococcal disease. This change had minor implications for calculation of the "knowledge score". We opted scoring the "test" by assigning correct responses out of all questions asked. This lumped wrong answers and non-responses together as incorrect. This was biased in favor of the null. This was our analytic approach although we analyzed the data using several systems and found it made no difference.