

Understanding Black Patients' Refusal of Pneumococcal Vaccination

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Abstract

Objective Racial disparities in rates of pneumococcal vaccine (PPSV23) exist. In one practice, 3.1 % of white patients refused PPSV23 following doctor recommendation, whereas 11.2 % of black patients refused vaccination. Our objective was to understand reasons black patients refused PPSV23.

Methods Mixed-method telephone survey in 2012 of black patients aged ≥ 65 with a documented refusal of PPSV23. The survey assessed beliefs about PPSV23; reasons for non-receipt of PPSV23; receipt of other vaccinations; and comparative perceptions of adult vs. childhood vaccines. Participants responded to items on a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Results Participants' ($N=40$) mean age was 73 years; 95 % were female. Participants recognized pneumonia could be deadly ($M=4.3$, $SD=1.0$), but reported low levels of personal susceptibility ($M=2.8$, $SD=1.4$). Participants perceived childhood vaccines to be safer ($M=4.2$, $SD=1.2$) than adult vaccines ($M=3.4$, $SD=1.4$; $p<0.01$). Qualitative analyses to understand reasons for refusal of vaccine both reinforced identified low perceptions of personal susceptibility as well as identified numerous additional barriers to receipt of PPSV23 (e.g., fear, side effects, and mistrust).

Conclusions Black patients in our sample who refused PPSV23 may not perceive themselves susceptible to the

disease, suggesting that strategies to improve PPSV23 rates among these patients may need to emphasize susceptibility to pneumonia. Further, given the discrepancies in perceptions toward childhood versus adult vaccinations, focusing on vaccination across the lifespan may be a promising vaccine promotion strategy.

Keywords Vaccinations · Disparities · Qualitative research

Introduction

Invasive pneumococcal disease (*Streptococcus pneumoniae*) is one of the leading causes of vaccine-preventable illness and death in the USA [1]. Older adults bear a significant burden of this disease: a third of cases and over half of deaths occurred in people age 65 and older [1]. The USA Advisory Committee on Immunization Practices (ACIP) recommends that adults 65 and older receive the pneumococcal polysaccharide vaccine (PPSV23) [2, 3]. However, in 2013, only 60.2 % of older adults in the USA reported receiving PPSV23, which is far below the 90 % goal set by Healthy People 2020 [4].

Furthermore, racial disparities in PPSV23 rates persist: in 2013 only 48.3 % of non-Hispanic blacks in the USA were vaccinated, as compared to 64.1 % of non-Hispanic whites [4]. A study of Medicare beneficiaries observed a 17 % difference in PPSV23 between blacks and whites, but characteristics of the patients and the health care system explained less than 7 % of the disparity [5]. Santibanez and colleagues found racial disparities in PPSV23 rates do not appear to depend on access to health care; rather physician and patient attitudes may play a more significant role in vaccination decisions [6–9].

Physician recommendation is critically important for increasing PPSV23 rates. Persell and colleagues found that the

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year after implementing performance feedback and electronic health record (EHR) physician reminders to offer PPSV23 that allowed for documentation of medical and patient exceptions (including patient refusals), 89.9 % of eligible patients received PPSV23 or had a documented exception [10]. Despite this high rate of adherence, there was a difference by patient race: 91 % of white patients were vaccinated, compared to only 81 % of black patients [11, 12]. During the same period, only 3.1 % of whites refused PPSV23, whereas 11.2 % of blacks refused PPSV23 [11]. Other research has identified similar patterns: Brownfield and colleagues found, after implementing a similar computer decision support prompt, patient refusal was one of the major reasons for unvaccinated status in a primarily black population [13]. Another large study reported that blacks were more likely to decline PPSV23 than Hispanic and non-Hispanic white patients [14]. It is unclear why patients refused PPSV23 in these studies; these refusals could be the result of a difference due to patient preferences or a disparity. Such disparity may be due to either inadequate communication about the benefits of PPSV23 by the physician, or patient concerns about vaccinations in general. The current study sought to better understand knowledge, attitudes, and perceptions of pneumonia and PPSV23, specifically among black patients who had a documented refusal of PPSV23. Numerous theories, such as the Health Belief Model [15, 16], suggest that individual perceptions of susceptibility toward and severity of an illness are strongly related to intention and behavior. Furthermore, theories such as the Extended Parallel Process Model [17–19] note that in addition to perceptions of susceptibility and severity, one's self-efficacy, or belief in one's own ability to accomplish a behavior (e.g., receipt of PPSV23), as well as response efficacy, or one's perception as to the degree to which the recommended response will avert the threat (i.e., will the PPSV23 vaccine protect against pneumonia and related consequences) influence one's behaviors. Most previous studies have explored participant perceptions of one type of age-appropriate vaccination (e.g., PPSV23, influenza). However, beliefs and attitudes about vaccination may be formed both by beliefs about a specific vaccination, and overall perceptions of the importance and efficacy of vaccinations in general, including perceptions of childhood vaccinations. It is known that principles of commitment and consistency, appealing to one's desire to be consistent and reduce feelings of cognitive dissonance, are persuasive drivers of attitudes and behaviors in other fields [17, 20, 21]. Therefore, data regarding patients' consistency of thoughts and attitudes about vaccinations are needed to determine if their use might be relevant in patient messages about vaccination. Hence, the research team also sought to understand how patients who had refused PPSV23 perceived other adult vaccines and to explore any differences in perceptions of childhood versus adult vaccines.

Methods

Setting and Participants

This study was conducted between January and March 2012 at the Northwestern Medical Faculty Foundation (NMFF) General Internal Medicine clinic, an academic practice in Chicago, IL with 42 physicians providing over 60,000 visits per year. This practice uses a commercial Electronic Health Record (EHR; EpicCare 2010, Epic Systems Corporation, Verona, Wisconsin). Eligible patients were adults age 65 or older, had their race listed in the EHR as black, and had a documented refusal of PPSV23. Patients who had a preferred language other than English and those that did not have a clinic visit within the past year were excluded. Primary care providers were allowed to exclude eligible patients if they felt the recruitment was inappropriate. The Northwestern University Institutional Review Board approved the study and granted a waiver of informed consent to review electronic records to identify eligible patients.

Recruitment

All eligible patients were included in recruitment efforts. Eligible patients were sent a letter that allowed them to opt-out of telephone recruitment. Those that did not opt-out were contacted up to six times by research assistants. For those patients reached, the research assistants confirmed study eligibility, administered the verbal consent, enrolled consenting patients into the study, and proceeded to administer the telephone survey. Patients received a \$25 gift card for completing the survey.

Data Collection

Study authors collaboratively developed the survey, which was informed by previously published studies.(9) The mixed-method survey focused on assessing patient: (1) knowledge and beliefs about pneumonia and pneumococcal vaccination, including perceptions of severity and susceptibility; (2) barriers or reasons for non-receipt of PPSV23, including perceptions of vaccine efficacy; (3) consistency with previous vaccination behavior; and (4) comparative perceptions of adult versus childhood vaccines. Participants responded to nine open-ended items (see Table 1), as well as quantitative items on a Likert scale from 1 (strongly disagree) to 5 (strongly agree). Demographic information was gathered for all interview participants.

The 20-min survey contained 35 items and was programmed with skip patterns. Research assistants audio-recorded interviews and transcribed responses to open-ended

Table 1 Open-ended items

Please tell me what you know about pneumonia. Use as much detail as you want.
How serious do you think pneumonia is?
How likely do you think you are to get pneumonia/pneumonia again?
How can pneumonia be prevented?
How would you describe the difference between pneumonia and influenza (also called flu)?
What were your main reasons for changing your mind and deciding to get the shot? (if relevant)
We're interested in knowing your thoughts about the pneumonia shot. Please tell me why you decided not to get the pneumonia shot?
What is different to you about the pneumonia shot from these other (adult) vaccinations?
We are really trying to understand how best to talk to patients about the pneumonia shot and explain how it can protect their health. What other specific information do you feel you still need to know about the pneumonia vaccine?

items verbatim. Survey data were collected using SNAP software (Snap Survey Software version 9, Snap Surveys Ltd, Bristol, UK).

Study authors ran an EHR query to abstract clinical data about the consented participants, collecting past immunization history and receipt of other clinical preventive services (i.e., colorectal, breast, cervical, or prostate cancer screenings, diabetes, and cholesterol screening).

Analysis

Descriptive statistics were used to describe study participants and to report summary measures for quantitative items. Study authors ran paired *t* tests to compare the means of responses to items on adult versus childhood vaccines. For qualitative analysis, responses to all open-ended questions were transcribed. Three authors (KAC, TB, and SNG) reviewed all responses independently and then collaboratively to gain a sense of content as a whole. Coding was conducted by searching the data for both a priori categories, based on our theoretical models (e.g., susceptibility to and severity of pneumonia), as well as in vivo categories, where we allowed additional categories to emerge. This coding process resulted in the identification of both larger overarching categories as well as some nested sub-categories of responses. Two authors then independently coded a sample of responses and, after reconciling discrepancies by discussion, believed the identified categories to be sufficiently comprehensive. For the final analysis, each response was reviewed independently by two coders (TB, SG). When necessary, coding disagreements were discussed and reconciled [22, 23].

Results

Of the 107 eligible patients, 40 completed the survey, a response rate of 39.6 % (Fig. 1) [24]. Participants' mean age was 73.5 years (SD = 4.9), 95 % were female, 72 % had attended at least some college, and 35 % self-reported receiving other adult vaccinations (Table 2). Additionally, 80 % of participants had completed at least one cancer screening. Research assistants asked all participants if they had subsequently received PPSV23 after refusing it at the study clinic. One participant reported receipt of PPSV23; the remaining 39 reported no PPSV23 receipt by the time of survey completion. Eight overarching categories emerged; sub-categories were identified in six of them (see Table 3). When qualitative responses overlapped with topics assessed in quantitative items (e.g., severity, susceptibility), we have presented the results in tandem. Unique categories of qualitative responses are presented separately.

Description of Pneumonia

When asked to describe pneumonia, responses ranged from general to specific, with some participants discussing symptoms or comparing pneumonia to other illnesses. General comments included identification of pneumonia as a virus or bacteria, for example: "Pneumonia is a virus that you get in your lungs." More specific comments described symptoms "Oh well I know one thing, it's a lot of cold inside your lungs I would assume. You know in your chest and lungs. It's tight at

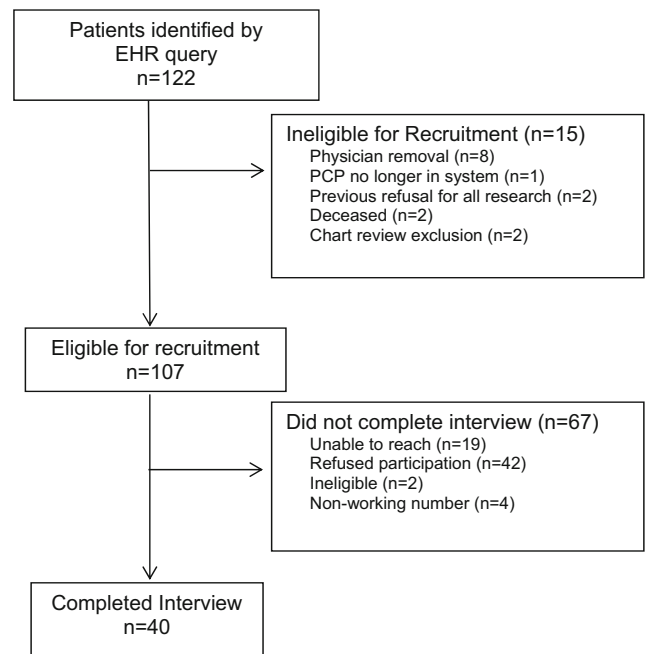


Fig. 1 Participant flow diagram

Table 2 Participant characteristics

Characteristic	<i>N</i> = 40
Age, mean (SD)	73.5 (4.9)
Female, %	95.0
Education, %	
Less than high school	10.0
High school graduate/GED	17.5
Some college or college graduate	72.5
Received prior adult vaccinations, %	35.0
Received cancer screenings, %	80.0

first you can't really recognize it" or recognition of multiple types or strains: "...and also the different types of pneumonia. It's a general term that means a whole lot of different types and how you can get it according to the type that it is." Some participants indicated they were unable to describe or define pneumonia, whereas others related to other, more common diseases: "... a lot of people have thought they had colds, and all of sudden they were diagnosed with pneumonia. So it must be pretty much similar to a cold."

Medical History

When describing pneumonia, or responding to other open-ended questions regarding perception of severity or susceptibility, some participants referenced past personal history of pneumonia or referenced individuals they knew who had had pneumonia. Many reflections of personal history of pneumonia also overlapped with descriptions of the symptoms of pneumonia: "Well, I don't know anything too much about pneumonia. I had it years ago. I know that you can hardly breathe, that's the only thing" or with perceptions of severity: "Can be very serious, in fact you can die from it if not treated. Raises havoc with the respiratory system. Whatever I was taking at the time was not helping and how I wound up in hospital."

Perceived Severity of Pneumonia

Overall, participants recognized that pneumonia could be deadly ($M = 4.3$, $SD = 1.0$) (Table 4). Qualitative responses were consistent with this finding: "[it is] truly serious because pneumonia can kill and that's as serious

Table 3 Qualitative coding categories and sub-categories

Category	Sub-category
Description of Pneumonia	General
	Symptoms (including duration)
	Types/strains
	Unknown/unable to describe
	Comparison to flu or other disease
Medical history (referencing personal or others' history of pneumonia)	
	Severity of pneumonia
Susceptibility	General
	Deadly/life threatening
	Specified population
	Population/general
	Low/medium/none (in reference to self)
Treatment	High
	Unknown
	Exception or rationale as to why not susceptible
Pneumococcal vaccination	Awareness of vaccine or effectiveness of vaccine
	Comparison to other vaccines
Barriers and reasons for non-receipt or refusal of pneumococcal vaccine	Fear of vaccination
	Refusal of all vaccinations
	Concern about side effects/previous bad reactions to vaccination
	Mistrust of vaccines/medical system
	Lack of perceived susceptibility as related to necessity of pneumococcal vaccine
Prevention	Non-vaccination related activities and/or behaviors
	Unknown/lack of awareness of how to prevent

Table 4 Participant perceptions of pneumonia and pneumococcal vaccination

Survey item	Mean (SD)*
Beliefs about pneumonia and pneumococcal vaccination	
Pneumonia can kill me.	4.3 (1.0)
I am at risk for getting pneumonia.	2.8 (1.4)
The pneumonia shot works well to prevent pneumonia.	3.0 (1.2)
Getting a pneumonia shot is a wise thing to do.	3.1 (1.2)
Beliefs about barriers to pneumococcal vaccination	
Getting a pneumonia shot is more trouble than it is worth.	2.9 (1.3)
I worry about the side effects from the pneumonia shot.	4.1(1.3)
I am scared of shots.	2.5 (1.6)
The pneumonia shot does not work well.	2.8 (1.0)
The pneumonia shot can cause pneumonia.	3.3 (1.3)
I don't like getting shots.	3.1 (1.7)

*Strongly disagree = 1, slightly disagree = 2, neutral = 3, slightly agree = 4, strongly agree = 5

as you can get,” and “On a scale of 1 to 10, I would think it must be a 9.” Some participants noted the severity of pneumonia, yet explicitly coupled that recognition with their refusal to be vaccinated. One participant stated, “I believe it is pretty serious, my doctor has explained it to me and he ask(s) me every time I go in am I ready to take the pneumonia shot, but I always refuse.” Some participants referenced their own experiences when assessing their perception of severity, such as, “It’s very serious. I didn’t know I had it, and I almost died.” Others voiced their beliefs that pneumonia could be more severe for certain populations, saying, “[it is] serious for people who health isn’t really good, especially elderly people. [It] can be serious if not treated,” and “I think that would depend on the individual. I think that with some people it can be serious and some it could just be mild.”

Perceived Susceptibility to Pneumonia

The majority of participants believed that they were not at risk of contracting pneumonia, reporting low perceived personal susceptibility to the disease (Table 4). Some participants felt that never having pneumonia in the past was indicative of lower risk for acquiring it in the future, for example: “I haven’t had it, and I’m 69 so I would say it’s fairly unlikely.” Others noted their beliefs that they could take specific actions, aside from getting vaccinated, to lower their risk of acquiring pneumonia, illustrated by the participant who said, “[I] probably wouldn’t get it. I take good care of myself, so I don’t think I would get pneumonia.” In addition, several participants voiced their opinions that pneumonia was something that happened to people who were sicker or older than themselves:

“Read about someone ill and old [who] came down with pneumonia.”

Knowledge and Beliefs about Treatment and Prevention of Pneumonia

The majority of participants described prevention behaviors aside from vaccination that they believed could be effective in preventing pneumonia. For example, when asked an open-ended question on how to prevent pneumonia, only two of the forty participants referenced PPSV23 or vaccination against pneumonia. Most participants described preventive behaviors they could do to avoid contracting pneumonia, primarily encompassing general wellness (e.g., “I guess just like most health preventions. Take good care of yourself, eat the right foods, get proper rest and doctor check-ups. That’s the preventive measures I would take”), good hygiene, (e.g., “That’s a hard one. I would say taking preventive measures as much as you can toward catching a cold. Washing your hands and not exposing yourself to crowds of people that are sneezing and coughing or whatever”), and proper precautions against cold weather (e.g., “Careful dressing, proper clothing when it’s cold and everything. Don’t just expose yourself. A lot of people go out there half dressed. You can catch germs from other people. But I believe with pneumonia its overexposing yourself in the cold”). A number of participants felt protected by diet and supplements. For example one woman stated, “[I am] only going by what I’ve done in my lifetime. I eat certain foods and vitamins that should keep me away from a bunch of things that are out here.” Few participants discussed treatment of pneumonia, and when they did they provided very general statements: “You need medication, and it takes a while to get rid of once it’s cured.”

Barriers and Reasons for Non-Receipt or Refusal of PPSV23

With respect to barriers to receiving PPSV23, participants expressed a strong fear of side effects ($M=4.1$, $SD=1.3$), but felt neutral toward shots in general ($M=3.1$, $SD=1.7$) and the idea that PPSV23 could cause pneumonia ($M=3.3$, $SD=1.3$). More specifically, 42.9 % of participants slightly or strongly agreed that PPSV23 could cause pneumonia and 37.1 % were neutral. Qualitative responses from participants discussing barriers to or reasons for refusing PPSV23 were numerous and are summarized with illustrative quotes in Table 5. Often, participants cited multiple reasons for refusing PPSV23, for example both a fear of side effects or a negative reaction and low perceived susceptibility to pneumonia. Participant refusal of all adult vaccinations, influenza vaccination in particular, was common (Table 2). Participants also reported refusing vaccination due to fear of putting *something* in their bodies or distrust of medicine in general or vaccines in particular (see Table 4).

Consistency with Previous Vaccination Behavior

Regarding vaccinations across the lifespan (e.g., beginning in childhood and continuing throughout adulthood), participants felt childhood vaccines were safer ($M=4.2$, $SD=1.2$) than adult vaccines ($M=3.4$, $SD=1.4$; $p<0.01$). Similarly, participants believed childhood vaccines were important ($M=4.2$, $SD=1.3$), yet were neutral about the importance of adult booster vaccinations ($M=3.2$, $SD=1.5$; $p<0.01$). A majority of participants (65 %) reported refusing all adult vaccinations.

Discussion

This sample of primarily female, well-educated black patients provided information regarding perceptions toward PPSV23 among patients who have previously refused the vaccine. Most recognized the severity of pneumonia, yet did not perceive themselves to be susceptible to the disease. Most participants felt that their existing wellness behaviors served as sufficient protection against *catching* pneumonia. While some mentioned specific aspects of PPSV23 that influenced their decision to decline vaccination (e.g., fear, concern of side effects), the majority of participants reported an overall refusal of adult vaccinations. These data are consistent with previous studies showing that patients who receive influenza vaccination are more likely to receive PPSV23 [8, 9, 25].

However, a striking inconsistency emerged regarding acceptance and perceptions of safety of childhood vaccines compared to adult vaccines. Identification of this inconsistency is important, as it may suggest an alternate avenue via which to discuss the importance of adult vaccination, or

“vaccination across the lifespan.” What these data suggest is that childhood vaccinations are perceived more positively (and are perceived to be more efficacious) than adult vaccines. It is possible that such a perception arises from a belief that some adult vaccines, such as PPSV23, are newer and have not been around as long as the childhood vaccines, which have become more acceptable. Alternately, as childhood vaccinations are often required for matriculation to school for young children, it is possible that the persuasive effects of consistency are in play here, in that as the children are required to be vaccinated, then individuals may shift their attitudes to be more accepting of childhood vaccinations. Identifying how best to frame the continued protective effects of vaccination through adulthood may benefit providers and health officials in their attempts to reach Healthy People 2020’s goals, and to reduce existing disparities in adult vaccination.

The finding that low perceived susceptibility to pneumonia was an important factor in non-vaccinated status is similar to other studies conducted with black patients. One qualitative study found that many black patients who were unvaccinated believed vaccines to be irrelevant to their health [26]. It is possible that participants in this study also felt PPSV23 was irrelevant to them, as, in general, they did not perceive pneumonia to be a threat to their health. Zimmerman et al. found that among unvaccinated patients, 47 % felt they were not likely to get pneumonia [9]. Similarly, Santibanez and colleagues reported that among unvaccinated patients, 22 % reported that an important reason they had never gotten the pneumonia shot was due to the belief they were not likely to contract pneumonia [7]. As noted, many theories, including the Health Belief Model and Extended Parallel Process Model, identify perceived susceptibility as an important predictor of behavior [15–18]. Messages to ensure individuals understand both their risk of contracting pneumonia as well as their likelihood of experiencing consequences, such as invasive pneumococcal disease (bacteremia or meningitis), and increased fatality rates of these diseases due to their age are needed. Our data of vaccine refusers reporting low perceived susceptibility, and thus a decreased likelihood to see the need for PPSV23, are consistent with these behavioral models, and suggest that attention to the need to convey the risk of pneumonia and its consequences should be included in vaccine recommendations.

This study has several limitations, including limited generalizability due to a small sample of primarily well-educated females recruited from a single site. Our study response rate was less than 50 % and we have no data about non-respondents. Additional research in other settings is necessary to be able to describe valid and reliable reasons for older black patients’ refusal of vaccinations. The study authors are also unable to make comparisons between other race/ethnicities as the interviews only occurred with black patients. However, despite these limitations the study contributes insights into

Table 5 Qualitative barriers and reasons for non-receipt or refusal of pneumococcal vaccination

Sub-category	Illustrative quotes
Fear of vaccination	<i>I think the shot is as dangerous as the disease itself Well, I don't like putting a virus into me that I don't have in order to keep me from getting it.</i>
Refusal of all vaccinations	<i>Not keen on injections period, pneumonia or any of that, if I can avoid it and not absolutely necessary then just don't want them. Never gotten them and I don't want them</i>
Concern about side effects/previous bad reactions to vaccination	<i>I just feel like with the pneumonia shot it's like with anything else, taking medicine when you're not sick is really sick. You know to me. That's the only reason why I would not take the pneumonia shot. I had a flu shot many, many years ago and I was so sick... Just feel that it would make me sick, no use in getting it and then turn around and be sick. Two people I've known that had the shot said they got the shot and they felt like they had the pneumonia</i>
Mistrust of vaccines/medical system	<i>Don't feel it's necessary. It's just like... people or doctors feel that it is necessary to get the flu shot and I don't agree with that. To me it's pharmaceutical and another form of pharmacies making money. Don't care for vaccines and such (no problems with children getting them, hadn't read anywhere where it was detrimental to health but beneficial) Being a part of the African/African American culture, can't get out of mind about the Tuskegee Airman/project. Really opened eyes to some of the devious things that go on in this country and that are still going on. Very apprehensive about injecting ANYTHING into my body such as a vaccine for some type of preventative measures</i>
Lack of perceived susceptibility as related to necessity of pneumococcal vaccine	<i>I decided because I'm not exposed a lot. I'm in the house most of the time. My immune system is pretty good. I don't get respiratory issues, respiratory diseases like cold or flu, that kind of thing. I have a cold or respiratory condition maybe not even every year. Basically, I decided because I have, I think I have a good immune system as far as respiratory problems are concerned. Oh, and everything h as side effects. One reason is because, in my family history, nobody has ever had pneumonia, and I feel like that I would probably never have it either.</i>

patients' thoughts and concerns regarding PPSV23 and is one of the first to describe differences in patient attitudes between childhood and adulthood vaccines, in particular among patients with a documented refusal for an adult vaccination. These data can help inform the design of patient messages about PPSV23 by providing rationales that incorporate patients' own words while also addressing salient concerns and encouraging the critical need for vaccination across the lifespan.

The results provide critical information on multiple elements that may be effective when communicating the importance of pneumococcal vaccination to black seniors. As participants reported low levels of susceptibility to pneumonia,

even while recognizing the potential severity of the disease, PPSV23 patient education messages and provider recommendations may need to include a specific focus on personal susceptibility, as often advised by multiple behavioral theories [15–18]. Additionally, as participants indicated more favorable perceptions of childhood than adult vaccinations, use of the persuasive principles of commitment and consistency in health messages should be explored, for example, by highlighting the importance of vaccination across the lifespan [20]. Reminding patients of vaccines they might have received as a child or highlighting the safety and importance of childhood vaccines could encourage associating these more positive beliefs with adult vaccines (not just PPSV23) which may

lead to adults retaining a consistently more positive attitude toward vaccines. Participants endorsed many health behaviors they undertake to protect their health. Explicit recognition of these behaviors, paired with the presentation of vaccination as another relevant health behavior, also could be leveraged using principles of commitment and consistency to encourage vaccination. Specifically, placing vaccination in the context of other preventive wellness behaviors that individuals may already be undertaking, such as healthy eating and cancer screenings, could serve to frame vaccination as just another way that people consistently maximize health.

Compliance with Ethical Standards We confirm that all patient/personal identifiers have been removed so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Conflict of Interest Dr. Persell receives grant support from Pfizer, Inc. All other authors report no conflicts of interest. The study sponsor had no role in the study design; collection, analysis or interpretation of data; writing the report; or the decision to submit this report for publication.

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