Is There Any Connection Between a Second Pneumonia Shot and Hospitalization Among Medicare Beneficiaries?

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SYNOPSIS

TO LEARN WHETHER the risk of revaccination in adults should limit its use, the authors investigated whether adverse events requiring hospitalization occurred in a group of Medicare enrollees revaccinated with pneumococcal polysaccharide vaccine.

A prospective cohort analysis and case study of revaccinated people involved five percent of all elderly Medicare enrollees from 1985 through 1988, consisting of 66,256 people receiving one dose of vaccine and 1,099 receiving two doses.

Comparison was made of the hospitalization rate within 30 days after revaccination and rates of singly vaccinated persons using discharge diagnosis for all those hospitalized during the 30 days after revaccination.

No significant difference was found between the hospitalization rate of the revaccinated cohort and comparison group. No adverse reactions attributable to pneumococcal polysaccharide vaccine causing hospitalization were identified among 39 revaccinated persons who were hospitalized within 30 days of revaccination.

Revaccination of elderly Medicare beneficiaries does not cause events serious enough to require hospitalization. Vaccination of persons according to the Public Health Service Immunization Practice Advisory Committee guidelines is recommended when the prior immunization status is unknown.

Pneumonia remains a widespread and deadly disease among the elderly. Persons older than age 60 have an incidence of pneumonia estimated at 25 cases per 1,000 persons per year (*1*). Between 1986 and 1992, the annual rate of hospitalization for pneumonia and influenza as the first-listed diagnosis in Medicare beneficiaries ages 65 and older ranged between 15.1 and 18.2 per 1,000 beneficiaries. The 30-day postadmission mortality rates for the same period varied between 146.0 and 162.3 per 1,000 admissions, according to unpublished data from the Health Care Financing Administration. *Streptococcal pneumoniae* is estimated to be responsible for 30 to 50 percent of all pneumonia cases (*2*).

Pneumococcal vaccine has been available in the United States since 1977. The currently available pneumococcal vaccine contains 23 type-specific capsu-

lar polysaccarides covering strains responsible for 88 percent of bacteremic pneumococcal disease (*3*). Present recommendations by the Immunization Practice Advisory Committee (ACIP) of the Public Health Service include vaccination of all persons ages 65 or older as well as those at high risk. Revaccination should be strongly considered for those who received the 14-valent vaccine (available from 1977 to 1983) if they are at highest risk and for those persons who received the 23-valent vaccine and show a rapid decline in pneumococcal antibody levels (*3*).

Although both of the U.S. manufacturers of the 23-valent pneumococcal vaccine include the ACIP recommendations in their package inserts, the inserts also carry warnings of potential adverse reactions to revaccination. These warnings are based on seven studies in which reactions after revaccination were investigated. They have been summarized by the ACIP (*3*). Four of these showed an increase in local reactions following revaccination, and three showed no increase compared with primary vaccination.

Case reports of persons having "arthus-like" symptoms of temperatures as high as 40.8° Centigrade, chills, and rigors have been reported after primary vaccinations and in revaccinated people (*4–6*). These studies and case reports predominantly involved middle-aged persons or children and investigated the 14-valent vaccine produced prior to 1984.

In this study, we use Medicare claims data to identify beneficiaries ages 65 and older who were vaccinated more than once with 23-valent pneumococcal polyvalent vaccine to determine whether any adverse events requiring hospitalization occurred within 30 days after the second vaccination. We compared the rate of hospitalization in this population and the rate in a group of beneficiaries following receipt of their initial dose of vaccine.

Methods

From Health Care Financing Administration (HCFA) claims data, we derived a five-percent random sample of Medicare Part B claims for the years 1985–88. In this sample, we identified 69,974 claims for persons ages 65 or older who received pneumococcal polysaccharide vaccine (HCFA Common Procedural Terminology codes 90732 and J6065).

Revaccinated cohort. Among the 69,974 claims, we identified 1,644 persons with more than one vaccination claim. Those who had more than two vaccination claims were excluded, leaving 1,450. In addition, we excluded those with a second vaccination claim occurring less than 26 weeks after the first if the second claim reflected vaccination by the same provider. This was done to eliminate possible resubmission of a claim for vaccination with a slightly different date of service from the first claim, which would appear in the administrative data set to be a second vaccination. We also excluded those with claims for vaccinations by different providers occurring less than two weeks apart. After assuring continuity of Medicare enrollment for 30 days after the second vaccination claim, we were left with 1,099 enrollees as the revaccinated cohort.

Comparison group. The comparison group was selected from the original 69,974 vacination claims. After removing those multiply vaccinated and those who did not have 30 days of continuous Medicare enrollment following vaccination, we identified 66,256 persons for the comparison group.

Data analysis. Hospitalization data for the revaccinated cohort and comparison group were obtained from the Medicare Provider Analysis and Review (MedPRO). Rates of hospitalization were calculated for the revaccinated cohort for 30 days following their second vaccination and for the comparison group for 30 days after their first vaccination. Demographic information was obtained from the Part B vaccination claims supplemented by the Medicare enrollment files.

We compared the age, sex, and ethnicity of the people in the two groups with Chi-square tests. We also determined

Number of persons receiving a second dose of pneumococcal polysaccharide vaccine from the same or a different provider by the same number of weeks since the first vaccination.

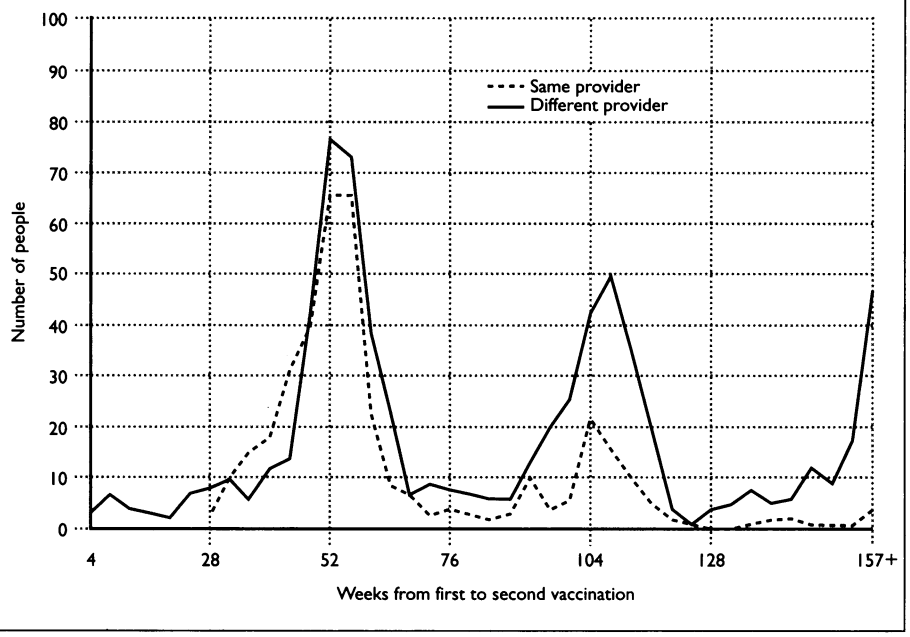

Table 1. Comparison of demographic characteristics of elderly Medicare beneficiaries vaccinated once with pneumococcal polysaccharide vaccine versus revaccinated beneficiaries, 1985–88

Demographic group	Revaccination cohort		Vaccinated once		P value[1]
	Number	Percent	Number	Percent	
Sex:					
Male	485	44.1	26,845	40.5	<.05
Female	614	55.9	39,411	59.5	...
Race:					
White	980	89.2	61,905	93.4	<.001
Black	86	7.8	2,624	4.0	...
Other	23	2.1	1,368	2.1	...
Unknown	10	0.9	425	0.6	...
Age group (years):					
65–74	525	47.8	38,494	58.1	<.001
75 and older	574	52.2	27,761	41.9	...
Totals	1,099		66,255		

[1]Based on chi-square test.

the temporal distribution of second vaccinations in the revaccinated cohort with regard to provider type. Using 30-day hospitalization rates in each group, we calculated relative odds of hospitalization with regard to age, sex, and race using the Wolf method (*7*). Finally, we examined the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes and discharge diagnoses of these people from the revaccinated cohort who had required hospitalization within 30 days of their second vaccination.

Results

The chart illustrates the time between first and second vaccinations in the revaccinated cohort. Revaccination occurred in a pattern, peaking at 52-week intervals, which is consistent with previous evidence of seasonal patterns of vaccination with pneumococcal polysaccharide vaccine (*8*). During the three-year study period, the crude rate of revaccination was 2.3 revaccinations per 100 vaccinated enrollees.

Table 1 presents the demographic characteristics of the revaccinated cohort and the comparison group. Significant differences existed between the two groups with regard to sex, race, and age; the revaccinated cohort was more likely to be male ($P < .05$), black ($P < .001$), and ages 75 and older ($P < .001$).

The overall rates of hospitalization in various categories of beneficiaries, as well as the relative odds of the revaccinated cohort versus the comparison group, were similar (table 2). The overall rate of hospitalization during the 30-

Table 2. Hospitalization rates per 100 elderly Medicare beneficiaries vaccinated once with pneumococcal polysaccharide vaccine versus revaccinated beneficiaries by sex, race and age group, 1985–88

Demographic group	Revaccination cohort		Comparison group		Relative odds	95 percent confidence interval
	Number	Rate	Number	Rate		
Sex:						
Male	19	3.92	1,159	4.32	0.91	0.58, 1.42
Female	21	3.42	1,335	3.39	1.01	0.66, 1.54
Race:						
White	36	3.67	2,328	3.78	0.98	0.71, 1.35
Black	4	4.65	109	4.15	1.12	0.42, 2.97
Other	0	0.00	39	2.85	...	...
Unknown	0	0.00	25	5.88	...	...
Age group (years):						
65–74	15	2.86	1,267	3.29	0.87	0.53, 1.43
75 and older	25	4.36	1,227	4.42	0.99	0.67, 1.45
Totals	40	3.64	2,494	3.76	0.97	0.71, 1.31

day interval after vaccination, 3.6 per 100 enrollees in the revaccinated cohort, was similar to that in the comparison group, 3.8 per 100 enrollees. Relative odds for hospitalization occurring 30 days after vaccination in various strata indicated no significant difference between the revaccinated cohort and the comparison group.

Table 3 lists the 39 revaccinated enrollees requiring hospitalization within 30 days after the second vaccination with their demographics, first-listed diagnosis, and time period between vaccinations. The interval between vaccination in this group ranged from six to 36.1 months. Review of all diagnoses listed in the MedPAR record revealed that no admissions occurred with a ICD-9-CM E-code (externally caused injury) that would indicate adverse reactions to

Table 3. Hospitalization among elderly Medicare beneficiaries occuring within 30 days after revaccination with pneumococcal polysaccharide vaccine

Case number	Sex	Age	Days from vaccination to hospital	Months between vaccinations	ICD-9-CM code	Principal diagnoses
1	F	83	1	24.0	428.0	Congestive heart failure
2	F	85	4	24.6	733.1	Pathological fracture
3	F	72	4	15.3	627.1	Postmenopausal bleedlng
4	F	73	5	23.2	433.3	Occlusion and stenosis of precerebral artery (multiple and bilateral)
5	F	72	6	21.3	434.9	Cerebral artery occlusion, unspecified
6	M	82	7	10.1	550.01	Inguinal hernia with gangrene (unilateral or unspecified, recurrent)
7	F	67	7	14.3	428.0	Congestive heart failure
8	M	68	9	14.3	558.9	Other and unspecified noninfectious gastroenteritis and colitis
9	F	78	10	10.2	788.2	Retention of urine
10	M	69	10	6.0	453.8	Venous embolism and thrombosis of other unspecificd veins
11[1]	F	80	10	36.1	411.8	Other acute and subacute forms of ischemic heart disease
12	M	77	12	13.6	998.5	Postoperative infection
13	M	67	12	25.1	185	Prostate cancer
14	F	73	12	10.3	431	Intercerebral hemorrhage
15	M	68	12	23.9	519.1	Other diseases of trachea and bronchus, NEC
16	M	89	13	11.8	593.4	Other utereric obstructions
17	M	73	15	24.3	431	Intercerebral hemorrhage
18	M	73	16	15.5	008.0	Intestinal infection from escheria coli
19	M	70	16	16.2	434.9	Cerebral artery occlusion, uuspecified
20	M	77	17	9.5	427.69	Other premature ventricular beats, contractions, or systoles
21	F	79	17	21.6	306.1	Respiratory malfunction from mental factors
22	F	73	18	33.5	411.1	Intermediate coronary syndrome
23	F	68	18	33.8	562.11	Diverticulitis of colon, no hemorrhage
24	F	90	18	33.8	411.1	Intermediate coronary syndrome
25[1]	F	80	18	36.1	574.30	Calculus of bile duct with acute cholecystitis, no obstruction
26	M	90	20	9.8	188.9	Malignant neoplasm of bladder, part unspecified
27	F	77	20	14.8	427.89	Other specified cardiac dysrhythmias
28	M	91	20	27.4	481	Pneumococcal pneumonia
29	F	73	21	24.3	V71.8	Observation for other specified suspected conditions
30	M	84	21	15.5	410.2	Acute myocardial infarction, of infolateral wall
31	M	82	21	12.6	366.12	Incipient cataract
32	F	78	24	15.1	410.1	Acute myocardial infarction, of other anterior wall
33	M	87	24	11.5	600	Hyperplasia of prostate
34	F	76	24	23.9	428.0	Congestive heart failure
35	F	90	26	10.2	972.1	Poisoning by cardiotonic glycosides and drugs of similar action
36	M	75	28	10.7	414.9	Chronic ischemic heart disease, unspecified
37	M	69	28	10.7	492.8	Other emphysema
38	F	92	29	13.7	428.0	Congestive heart failure
39	M	83	29	24.5	331.0	Alzheimer's disease
40	F	77	30	12.7	428.0	Congestive heart failure

[1]Same person.

pneumococcal polysaccharide vaccine. (Data for diagnosis positions two through five are available from Dr. Richard Snow)

Comments

This analysis of Medicare claims data revealed that no adverse events serious enough to require hospitalization could be identified following immunization with a second dose of pneumococcal vaccine. The odds of being hospitalized within 30 days of revaccination were the same in the revaccinated cohort and comparison group as well as in the subgroups selected according to age, sex, and ethnicity. Using discharge diagnoses, we found that people vaccinated twice were hospitalized for reasons other than adverse reactions to pneumococcal vaccine.

If revaccination exacerbated an underlying disease, leading to hospitalization, we would expect a grouping of hospitalizations to occur shortly after the revaccination. Examining the hospitalizations during the first seven days after revaccination reveals an admission rate of one beneficiary per day compared with a rate of 1.4 beneficiaries per day for days eight through 30 (table 3).

This study has several strengths. First, since fewer than one percent of vaccinated persons receive a second vaccination in any given year, the large sample allowed us to identify 1,099 cases of revaccination. Second, the conservative method of case selection helps to eliminate the potential error of classifying a person as revaccinated if the second claim was a resubmission of the original claim. Third, calculating the odds ratio of hospitalization and investigating the diagnoses of those persons in the revaccinated cohort provided us with two techniques to detect risk for adverse events causing hospitalization.

One potential weakness of this study arises from the fact that the data used are secondary data collected for administrative purposes. The potential problem of duplicate billing, which necessitated the conservative method of case selection, may lend bias to the odds ratios calculated. Another potential weakness is the outcome measure. By choosing hospitalization as an outcome measure, we do not measure adverse events occurring after revaccination that responded to outpatient treatment. The finding that revaccinated people were not hospitalized more frequently indicates that severe reactions did not occur in this cohort.

We have not attempted any multivariate analysis of the outcome. If one cohort were inherently sicker, this could cause a confounding effect in this study. However, it is more likely that the cohort that was revaccinated was sicker. In that case, one would expect a higher unadjusted rate of hospitalization in the revaccinated cohort. Such findings were not observed.

Finally, in this study we examined reactions to revaccination in people who were identified by Medicare claims data as receiving pneumococcal vaccine. The population not billing for this vaccine, primarily members of managed care plans, is not represented. However, we have no reason to believe this population would be any different with regard to adverse events after revaccination.

Reactions to revaccination have been summarized previously for children, middle-aged adults, and persons with sickle cell disease (*3*). The reactions in that report were all local with the exception of four reported severe reactions, consisting of temperatures of more than 100 degrees Fahrenheit occurring in people with sickel cell disease.

Pneumonia remains a common disease in the elderly, with a substantial portion caused by *Streptococcus pneumoniae*. Polyvalent pneumococcal vaccine has been shown to be efficacious in the prevention of invasive pneumococcal infections in a number of studies (*9–12*). Although the rate of mild revaccination reactions has not been defined in the elderly, it is likely that the warnings used in the package inserts may keep health care providers from using the vaccine when the previous vaccination status of the patient is unknown (*13*).

The information presented in this paper should encourage health care providers to administer pneumococcal vaccine in cases in which the vaccination status is unclear without fear of severe reactions requiring hospitalization. The estimate from the 1993 National Health Interview Survey was that only 28.2 percent of persons older than age 65 have received one dose of pneumococcal polysaccharide vaccine *(14)*. Thus, improved strategies will be necessary to increase vaccination to the 60-percent level, the goal of the Department of Health and Human Services Healthy People 2000 program. Our findings support the use of the pneumococcal vaccine in people whose vaccination status is unknown.

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SCIENTIFIC CONTRIBUTION

Strategic Questions for Consumer-Based Health Communications

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SYNOPSIS

USING THE CONSUMER-oriented approach of social and commercial marketers, this article presents a process for crafting messages designed to improve people's health behaviors. The process, termed consumer-based health communications (CHC), transforms scientific recommendations into message strategies that are relevant to the consumer.

The core of CHC is consumer research conducted to understand the consumer's reality, and thereby allowing six strategic questions to be answered. The immediate result of the CHC process is a strategy statement—a few pages that lay out who the target consumer is, what action should be taken, what to promise and how to make the promise credible, how and when to reach him or her, and what image to convey.

The strategy statement then guides the execution of all communication efforts, be they public relations, mass media, direct marketing, media advocacy, or interpersonal influence. It identifies the most important "levers" for contact with the consumer. Everyone from creative specialists through management and program personnel can use the strategy statement as a touchstone to guide and judge the effectiveness of their efforts. The article provides a step by step illustration of the CHC process using the 5 A Day campaign as an example.