2017

PNEUMOCOCCAL CONJUGATE VACCINE 13 COVERAGE IN CHILDREN, HIGH-RISK ADULTS 19-64 YEARS OF AGE, AND ADULTS OVER 65 YEARS OF AGE IN A COMMERCIALLY INSURED U.S. POPULATION

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Digital Object Identifier: https://doi.org/10.13023/ETD.2017.294

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THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science in the
College of Pharmacy
at the University of Kentucky

By

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2017

ABSTRACT OF THESIS

PNEUMOCOCCAL CONJUGATE VACCINE 13 COVERAGE IN CHILDREN, HIGH-RISK ADULTS 19-64 YEARS OF AGE, AND ADULTS OVER 65 YEARS OF AGE IN A COMMERCIALLY INSURED U.S. POPULATION

This thesis aimed to elucidate the demographic characteristics associated with elevated or reduced rates of pneumococcal conjugate 13 (PCV13) vaccination.

A retrospective cohort study was performed using the Truven Health MarketScan® Database. Three cohorts were created corresponding to populations for which the CDC recommends PCV13 vaccination. Cohort 1: children < 36 months of age. Cohort 2: adults 19-64 years of age with high infection risk. Cohort 3: adults > 65 years of age. Odds of having a PCV13 claim were calculated for each cohort.

For Cohort 1, 78% out of a total of 353,214 subjects had a sufficient number of PCV13 doses to meet CDC recommendations. For Cohort 2, 3.7% out of a total of 673,157 subjects had a PCV13 claim. For Cohort 3, 18% of 1,262,531 subjects had a PCV13 claim. Odds of vaccination were generally lower in younger subjects, those with fewer outpatient claims, and those with residence in the Northeast and South regions. In Cohort 2, odds were reduced in subjects with generalized malignancy. Gender and urban residence were poor predictors of vaccination status.

By understanding the demographic factors associated with lower rates of vaccination, clinicians may more effectively direct their efforts to increase pneumococcal vaccination coverage.

KEYWORDS: pneumococcal vaccine coverage, pneumococcal conjugate vaccine 13

Joseph C Vanghelof

26 July 2017

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Acknowledgements

The following thesis, while an individual work, benefitted from the support, insights, and direction of several people.

I would like to thank my family for supporting me in my academic pursuits and providing a safety net in the times when I was not successful. I would also like to thank all of my thesis committee members: Dr. Jeffery Talbert, Dr. Karen Blumenschein, and Dr. Patricia R. Freeman, for their patience and the feedback they provided as I developed this thesis.

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Section One: Introduction

Streptococcus pneumoniae (pneumococcus) is a gram-positive facultative anaerobic bacteria, and is common cause of otitis media, pneumonia, meningitis, osteomyelitis, and bacteremia, with the latter three collectively referred to as invasive pneumococcal disease (IPD).[1-3] Two pneumococcal vaccines are presently recommended for use in the U.S. by the Centers for Disease Control and Prevention (CDC), the pneumococcal polysaccharide 23-valent vaccine (PPSV23) and the pneumococcal polysaccharide conjugate 13-valent vaccine (PCV13).[1] The CDC has developed administration recommendations for each of these vaccines based on patient age and health status.[1] The United States Department of Health and Human Services has incorporated pneumococcal recommendations into their Healthy People 2020 goals.[4] Unfortunately, estimates of pneumococcal vaccination coverage fall below goals.[5-7] This thesis aims to elucidate the demographic characteristics associated with lower and higher rates of PCV13 vaccination, so that populations experiencing lower rates of vaccination can be better addressed.

Pneumococcal Disease

Despite pneumococcal vaccination's significant impact on reducing cases of IPD and pneumonia, pneumococcus remains an important clinical pathogen, and continues to pose an elevated threat to young, elderly, and immunocompromised persons. Pneumococcus causes between 10-36% of pneumonias in the US.[1,3,8] During 2004, approximately 400,000 inpatient pneumococcal pneumonia cases occurred, resulting in approximately 24,000 deaths.[9,10] During 2013, approximately 34,000 cases of IPD were reported in the U.S., with approximately 3,700 resultant deaths. Active Bacterial Core

Surveillance (ABCs) Report Emerging Infections Program Network, Streptococcus pneumoniae, 2013.[11]

Persons with immunocompromising conditions carry greater risk of infection and higher treatment costs compared to their healthy counterparts. Adults aged 19-64 with moderate and high infection risk conditions, defined in Appendix A, respectively, have rates of all-cause pneumonia 4 and 7 times greater than their healthy counterparts.[12] These patients also have 9 and 26 times greater rates of IPD development, respectively, and 1.6 and 3 times greater inpatient treatment costs.[12,13] Additionally, males appear to carry 1.5 to 2 times greater risk of all-cause pneumonia compared to female subjects, with the greatest risk in males ages <2 and 40–64.[11] The cause of this increased incidence in males is unknown, but may be related to hormonal differences and gender related social behaviors.[14]

Pneumococcal Vaccines and CDC Recommendations

The older of the two currently recommended vaccines is PPSV23, brand name Pneumovax 23®, and was approved by the U.S. Food and Drug Administration (FDA) in 1983. The newer of the two currently used vaccines is PCV13, brand name Prevnar 13®, and was approved by the FDA in February 2010. An additional vaccine of historical importance is the pneumococcal polysaccharide conjugate 7-valent vaccine (PCV7), brand name Prevnar®. Introduced in 2000, it is the predecessor to PCV13, and was phased out of use following the introduction of PCV13.

Pathogenic pneumococcus strains are encapsulated by complex polysaccharides. Capsular polysaccharides are antigenic in humans, and are grouped into serotypes. Vaccines against pneumococcus can be created by purifying capsular polysaccharides.

Such vaccines do not provide universal protection against all pneumococcus types, only against the serotypes it contains.[1,2] PPSV23, PCV7, and PCV13 are all polysaccharide containing vaccines, with the numbers 23, 7 and 13 indicating the number of serotypes covered. PCV13 contains 12 serotypes from PPSV23, plus one additional serotype. All of the serotypes in PCV7 are contained in PPSV23 and PCV13. Serotype coverage for all three vaccines is listed in Appendix B.

In contrast to PPSV23, in PCV7 and PCV13 the polysaccharides components are bound to a protein based nontoxic diphtheria toxin; this increases its antigenicity and allows it to be administered at younger ages than PPSV23. In cases where both vaccines are indicated, PCV13 is recommended for administration prior to PPSV23.[1]

PPSV23 is recommended by the CDC for all adults 65 years or older and for those 2 years or older with moderate-high infection risk conditions (Appendix A). At the time of its release, PCV13 was recommended for routine vaccination of children 2-59 months old and children up to 71 months with underlying medical conditions resulting in moderate-high risk for infection, listed in Appendix A).[15,16] The recommended course for children is a series of four PCV13 injections, three prior to 12 months of age, and one after 12 months of age; with recommendations also available for children vaccinated at older ages, detailed in Appendix C. In June 2012, the recommendation was expanded to include adults 19 and over at high risk for infection. In February 2013 it was expanded again to include children 71 months – 18 years of age with high risk for infection.[17,18] Most recently, in September 2014, the CDC again expanded the PCV13 recommendation to include all adults 65 years or older.[17] The cost of PCV13 varies between $135-$170.[19,20]

Pneumococcal Vaccination Impact on Pneumococcal Disease

Prospective epidemiological studies have indicated PCV13, and PCV7, are effective in reducing the number of infections caused by the pneumococcal serotypes they respectively cover. By 2007, the number of IPD infections caused by the serotypes covered by PCV7 were reduced by 97%, and the rate of IPD was reduced by 75% in persons <5 years of age. Persons ≥65 years of age, though never the recipients of PCV7, also benefited for PCV7 with an 84% reduction in infections caused by the serotypes covered by PCV7, and a 35% rate reduction in IPD.[21] As a consequence, IPD caused by serotypes not included in PCV7 has proportionally increased. Similarly, the introduction of PCV13 has resulted in a major reduction of IPD caused by serotypes covered by the vaccine, and a relative increase in the rate of IPD caused by non-covered serotypes.[22] Despite the relative increase in IPD cases caused by non-covered serotypes, the overall rate of IPD has decreased, which may be attributable to the remaining serotypes overall being less virulent (though some, such as serotype 19A, are relatively virulent and resistant to antibiotics).[23,24] Both PCV13 and PPSV23 exhibit greater efficacy in reducing IPD than pneumonia. Among the pediatric population, PCV7 vaccination has also reduced frequency of middle ear infections.[25]

Pneumococcal Vaccination Coverage

Prior to 2012, there had never been a pneumococcal conjugate vaccine recommended for use in adults; subsequently, pneumococcal vaccination estimates did not differentiate between pneumococcal conjugate vaccines and PPSV23, a trend that continued even after PCV13 became recommended for adults.

From 2012-2014, the Joint Commission required reporting of pneumococcal immunization measures; but did not differentiate between PCV13 and PPSV23.[26] During the 2012 and 2013, the years for which measures were collected, vaccination rates were 90.6% and 92.5% respectively; however, due to discrepancies in how rates were reported, the Joint Commission has stated these reports may not be accurate, and has retired the pneumococcal immunization measures.[27]

In a 2013 survey of two retirement communities in North Carolina with adults ≥65 total sample size of 210 persons, 183 (87%) reported receiving PPSV23, 34 (16%) reported as immunocompromised, and 1 person (0.4%) reported receiving PCV13.[28] Additional studies in older adults have found disparities in vaccination rates by race and metropolitan type, i.e. rural vs. urban residence.[29,30]

Two major U.S. government sponsored databases are available which contain U.S. pneumococcal vaccines coverage estimates, one from the National Health Interview Survey (NHIS), and one from the Behavioral Risk Factor Surveillance System (BRFSS), though only the former has had coverage estimates published in recent years. The 2015 NHIS estimated the PCV13 vaccination rate at 83% in children under 36 months of age, and combined PPSV23 and PCV13 pneumococcal vaccination at 23% in adults 19–64 years of age with moderate-high infection risk conditions, and 64% in adults ≥65.[6,7] These estimates fall below the Target Healthy People 2020 goals for pneumococcal vaccination coverage, which are 90% in children under 36 months (IID-7.7), 60% in adults 19-64 years of age with moderate-high infection risk conditions (IID-13.2), and 90% in adults over 65 years of age (IID-13.1).[4] In children, this goal refers to vaccination with PCV13, and for adults, refers to vaccination with either PCV13 or PPSV23.

Section Two: Methods

Data Source

A retrospective cohort study was performed using the Truven Health MarketScan® Database, years 2010-2015. This de-identified commercial insurance database contains patient-level enrollment details, and in-patient and outpatient claims. This nationally representative database includes data from commercial insurance companies, Blue Cross and Blue Shield plans, third-party administrators (TPAs), and Medicare Advantage plans. This study was exempt from review by the University of Kentucky Institutional Review Board as it contains only de-identified data that do not meet the Department of Health and Human Services (DHHS) definition of human subjects or the Food & Drug Administration's (FDA) definition of human subjects.

Study Populations

Three cohorts were created corresponding to populations for which the CDC recommends PCV13 vaccination. For all cohorts, gender, region, and urban status, and outpatient days are reported. Urban status was determined by residence in a Core Based Statistical Area as cataloged by the U.S. Office of Management and Budget.[31] Outpatient days reflect the total number of unique days on which an outpatient medical service was claimed by a provider.

Cohort 1: Children < 36 months of age whose coverage began at zero years of age, and had coverage eight out of every twelve months per calendar year up to 2 years of age. Vaccination claims were detected by CPT procedure code '90669' or '90670' (pneumococcal conjugate vaccine administration, for subjects under 5 years of age, and for subjects of any age respectively) prior to 36 months of age, or ICD-9 diagnosis code

‘V0382’ or ‘V066’ (pneumococcal vaccination with and without concurrent influenza vaccination respectively) prior to 24 months of age (in subjects over 24 months of age, these diagnosis codes may indicate administration of PPSV23). For PCV13 claims to be valid, they must have occurred on or after February 10, 2010, the date at which the CDC began recommendation of PCV13 vaccination for all persons 2-59 months of age; additionally, the claim must have occurred a minimum of 10 days following a previous claim. Subjects were categorized based on CDC PCV13 pediatric vaccination recommendations, their total number of PCV13 claims, and their age when the claim occurred. Subjects with three PCV13 claims prior to age one, plus one claim at one year of age, or who met the “catch-up” vaccination criteria listed in Appendix C, were categorized as “vaccination complete.” Subjects with at least one PCV13 vaccination claim, but who did not have a claim for subsequent doses to suggest completion of CDC recommendations by 36 months of age were categorized as “vaccination incomplete.” Subjects without any PCV13 claim were categorized as “No PCV13 Claim.”

Cohort 2: Adults 19-64 years of age with a high infection risk condition, and had coverage eight out of every twelve months per calendar year from 2012-2015. Conditions must have been included in an outpatient claim between 2012 and 2015 via ICD-9 diagnosis or CPT service code as listed in Appendix D. Vaccination claims were determined by the presence of CPT procedure code 90670, and must have occurred on or after June 20, 2012, the date at which the CDC began recommendation of PCV13 vaccination for persons 19 years of age and older with high infection risk conditions. Age was determined on date of vaccination, or for unvaccinated persons, age at the start of

2014. Subjects are included in the count of patients with inpatient claim, if that subject had at least one inpatient claim made after June 20, 2012.

Cohort 3: Adults ≥ 65 years of age, and had coverage eight out of every twelve months per calendar year from 2012-2015. To be counted as a subject with a high infection risk condition, at least one outpatient claim must have been made between 2012 and 2015 for one of the conditions listed in Appendix D. Vaccination claims were determined by the presence of CPT procedure code 90670, and must have occurred on or after June 20, 2012; however, for analysis excluding patients with high infection risk conditions, vaccination must have occurred on or after August 13, 2014, the date at which the CDC began recommendation of PCV13 vaccination for all persons 65 years of age and older.

Statistical Analyses

For each cohort, the odds of receiving PCV13 to completion was determined. For odds ratio analysis, the number of outpatient days was categorized by quartile. For Cohort 2, two analyses were performed, the first includes all qualifying subjects, and the second excludes subjects with an inpatient claim after June 20, 2012. For Cohort 3, two analyses were also performed, the first includes all qualifying subjects, and the second excludes subjects with an inpatient claim after June 20, 2012 or with a high infection risk condition. Subjects with inpatient claims were excluded in the secondary analyses performed for Cohorts 2 and 3, as hospitals may have had standing orders to provide PCV13 to qualifying patients, but are unlikely to submit a PCV13 claim. Statistical analysis was performed using SAS Enterprise Guide software, Version 7.1 of the SAS System for Windows.[32]

Section Three: Results

Cohort 1: Children < 36 months of age

A total of 353,214 subjects were identified, with 78% categorized as "vaccination complete," 13% as "vaccination incomplete," and 9% as "No PCV13 claim" using the categories defined in the Cohort 1 methods.

Table 3.1 provides summary descriptive statistics for the subjects in Cohort 1 and is subdivided by vaccination category. The groups show similar proportions of individuals with "vaccination complete" status when assessed by gender, region, and urban residence. The groups show dissimilar mean number of outpatient days, with subjects reaching vaccination completion having a mean of 57% more outpatient claims.

Table 3.1 Children < 36 Months of Age, Descriptive Table

Vaccination Status	No PCV13 Claim	Vaccination Incomplete	Vaccination Complete	All groups (% Complete)
Demographics				
n	30,932	46,604	275,678	353,214 (78.0%)
Male	15,932	24,104	141,811	181,847 (78.0%)
Northeast	6,527	8,886	51,346	66,759 (76.9%)
North Central	5,028	9,048	64,662	78,738 (82.1%)
South	7,439	15,323	95,043	117,805 (80.7%)
West	10,028	12,216	57,745	79,989 (72.2%)
Region Unknown	1,910	1,131	6,882	9,923 (69.4%)
Urban	24,894	39,640	241,401	305,935 (78.9%)
Healthcare Utilization				
Outpatient Days Mean	19	26	30	29
Outpatient Days Standard Deviation	26.75	28.97	32.91	25.10

Table 3.2 provides results from the output of the multiple logistic regression model with "vaccination complete" status as the predicted outcome. All covariates were significant at the 5% level. Subjects who were female, had residence outside the Northeast region, and had urban residence, had greater odds being categorized as

"vaccination complete." Subjects with more outpatient visit days progressively had greater odds of vaccination.

Table 3.2 Children < 36 Months of Age, Odds of Receiving PCV13 to Completion

Effect	Odds Ratio Estimate	95% CI	
Demographics			
Male vs Female	*0.921	0.906	0.936
North Central vs Northeast	*1.640	1.597	1.685
South vs Northeast	*1.342	1.311	1.375
West vs Northeast	*1.034	1.009	1.060
Region Unknown vs Northeast	*1.145	1.085	1.208
Urban vs Rural	*1.464	1.427	1.502
Healthcare Utilization			
Outpatient days 2nd vs 1st quartile†	*2.871	2.809	2.935
Outpatient days 3rd vs 1st quartile†	*3.466	3.386	3.547
Outpatient days 4th vs 1st quartile†	*3.634	3.549	3.721

C-statistic = 0.661
†Quartile breakpoints are <18, 18-24, 25-34, and > 34 days, for quartiles 1-4 respectively
*Denotes significant value

Cohort 2: Adults 19-64 years of age with high risk indication

An initial pool of 8,214,322 subjects 19-64 years of age was identified with continuous enrollment 2012-2015, of these, 673,157 had a high infection risk condition, 3.7% of which had a PCV13 claim.

Table 3.3 provides summary descriptive statistics for the subjects in Cohort 2. The table is subdivided by year of PCV13 claim. PCV13 claim rates appear similar by gender, region, and urban residence. Subjects with a PCV13 claim had a mean 34% greater number of outpatient claim days compared to subjects without a vaccination claim. Subjects over 50 years of age tend to have higher rates of PCV13 claims compared to those in lower age groups. Rate of PCV13 claims varied by diagnosis between 2.2% and 21.4%, with the lowest rates observed in subjects with sickle cell disease or other hemoglobinopathies, and highest rate in subjects who are human immunodeficiency virus (HIV) positive.

Table 3.3 Adults 19-64 Years of Age with High Risk Indication, Descriptive Table

Year of PCV13 Claim	None	2012	2013	2014	2015	All groups (% vaccinated)
Demographics						
n	614,045	557	3,210	5,186	15,410	638,408 (3.8%)
Age Mean	52	51	49	52	56	52
Age Standard Deviation	9.47	9.26	9.40	9.55	8.02	9.45
Age 19-29	18,616	26	114	172	215	19,143 (2.8%)
Age 30-39	50,148	42	353	385	569	51,497 (2.6%)
Age 40-49	119,595	103	862	959	1,700	123,219 (2.9%)
Age 50-59	261,834	304	1,406	2,142	5,834	271,520 (3.6%)
Age 60-64	163,852	82	475	1,528	7,092	173,029 (5.3%)
Male	257,127	296	2,079	2,867	7,419	269,788 (4.7%)
Female	356,918	261	1,131	2,319	7,991	368,620 (3.2%)
Northeast	137,654	117	604	1,095	3,132	142,602 (3.5%)
North Central	118,997	107	582	1,140	3,540	124,366 (4.3%)
South	268,962	248	1,502	2,058	6,078	278,848 (3.5%)
West	87,009	85	514	882	2,649	91,139 (4.5%)
Region Unknown	1,423	-	8	11	11	1,453 (2.1%)
Urban	542,841	500	2,941	4,692	13,695	564,669 (3.9%)
Rural	70,286	57	269	494	1,704	72,810 (3.5%)
Healthcare Utilization						
Outpatient Days Mean	71	93	82	94	98	71
Outpatient Days Standard Deviation	67.32	73.91	81.30	83.14	85.50	68.20
# of Patients with Inpatient Claim	183,003	169	969	1,919	6,057	192,117 (4.7%)
Diagnosis						
Cochlear Implant	1,245	1	59	56	96	1,457 (14.6%)
Cerebrospinal Fluid Leak	3,228	3	6	18	52	3,307 (2.4%)
Asplenia	1,342	5	53	74	169	1,643 (18.3%)
Sickle Cell Disease or Other Hemoglobinopathy	19,594	11	28	89	304	20,026 (2.2%)
Chronic Kidney Disease	156,970	127	628	1,361	4,886	163,972 (4.3%)
Other Immune System Diseases	85,432	153	588	1,107	2,829	90,109 (5.2%)
Generalized Malignancy	343,872	188	719	1,629	6,722	353,130 (2.6%)
HIV	18,644	152	1,663	1,527	1,741	23,727 (21.4%)
Hodgkin's Disease	6,732	15	76	93	255	7,171 (6.1%)
Radiation Therapy	72,598	78	362	665	2,149	75,852 (4.3%)
Leukemia	13,761	46	134	281	710	14,932 (7.8%)

Lymphoma	24,444	42	189	325	938	25,938 (5.8%)
Multiple Myeloma	5,926	37	117	184	410	6,674 (11.2%)
Nephrotic Syndrome	4,354	5	23	54	153	4,589 (5.1%)
Solid Organ Transplant	7,114	43	150	250	575	8,132 (12.5%)

Table 3.4 provides results from the output of the multiple logistic regression model with having a PCV13 claim as the predicted outcome. All covariates except age 30-39 vs 19-29, urban residence, CSF leak, were significant at the 5% level. Subjects who were male, had residence outside of the Northeast and unknown regions, or had an inpatient stay had greater odds of having a PCV13 claim. Subjects of increasing age and increasing number of outpatient visits were more likely to have a claim. Odds were reduced when subjects had sickle cell disease or other hemoglobinopathy, or generalized malignancy. Odds were increased in subjects with a cochlear implant, asplenia, chronic kidney disease (CKD), other immune system diseases, HIV, Hodgkin's disease, radiation therapy, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, or solid organ transplant.

Table 3.4 Adults 19-64 Years of Age with High Risk Indication, Odds of Having a PCV13 Claim

Effect	Odds Ratio Estimate	95% CI	
Demographics			
Age 30-39 vs 19-29	1.108	0.997	1.231
Age 40-49 vs 19-29	*1.413	1.284	1.556
Age 50-59 vs 19-29	*2.049	1.867	2.249
Age 60-64 vs 19-29	*3.486	3.173	3.831
Male vs Female	*1.215	1.182	1.249
North Central vs Northeast	*1.386	1.33	1.444
South vs Northeast	*1.058	1.02	1.097
West vs Northeast	*1.424	1.363	1.488
Region unknown vs Northeast	*0.598	0.41	0.872
Urban vs Rural	1.011	0.968	1.056
Healthcare Utilization			
Outpatient days 2nd vs 1st quartile†	*1.386	1.326	1.449
Outpatient days 3rd vs 1st quartile†	*1.860	1.780	1.942
Outpatient days 4th vs 1st quartile†	*2.601	2.488	2.719

Inpatient Claim	*1.096	1.064	1.130
Diagnosis or Condition			
Chronic Kidney Disease	*1.115	1.072	1.159
Other Immune System Diseases	*1.427	1.373	1.484
Generalized Malignancy	*0.724	0.698	0.752
HIV	*12.893	12.327	13.485
Hodgkin's Disease	*1.646	1.476	1.834
Radiation Therapy	*1.048	1.003	1.096
Leukemia	*1.742	1.627	1.865
Lymphoma	*1.208	1.135	1.286
Multiple Myeloma	*2.271	2.089	2.467
Nephrotic Syndrome	*1.247	1.087	1.432
Solid Organ Transplant	*2.425	2.252	2.610

C-statistic = 0.764
†Quartile breakpoints are <31, 31-54, 55-92, and >92 days, for quartiles 1-4 respectively
*Denotes significant value
For diagnosis or condition based covariates, the reference group is not having the diagnosis or condition

Table 3.5 provides summary descriptive statistics for the subjects in Cohort 2, excluding individuals with inpatient claims between 2012 and 2015. The overall PCV13 claim rate was 3.3%, slightly lower than the overall vaccination rate when including subjects with inpatient claims. PCV13 claim rates are similar compared to analysis not excluding subjects with inpatient claims with the following exceptions, subjects over 50 years of age, or those with multiple myeloma, or solid organ transplants; these groups were less likely to receive vaccination. Outpatient stays are a mean 20% less compared to the analysis including subjects with inpatient claims.

Table 3.5 Adults 19-64 Years of Age with High Risk Indication, Excluding Individuals with Inpatient Claims, Descriptive Table

Year of PCV13 Claim	None	2012	2013	2014	2015	All groups** (% vaccinated)
Demographics						
n	431,042	388	2,241	3,267	9,353	446,291 (3.4%)
Age Mean	52	50	49	52	56	52
Age Standard Deviation	9.34	9.26	9.27	9.68	8.02	9.33
Age 19-29	12,829	18	79	114	122	13,162 (2.5%)
Age 30-39	33,043	30	262	262	349	33,946 (2.7%)

Age 40-49	87,905	79	677	659	1,089	90,409 (2.8%)
Age 50-59	186,095	208	940	1,319	3,517	192,079 (3.1%)
Age 60-64	111,170	53	283	913	4,276	116,695 (4.7%)
Male	179,071	218	1,543	1,916	4,538	187,286 (4.4%)
Female	251,971	170	698	1,351	4,815	259,005 (2.7%)
Northeast	98,519	78	411	673	1,895	101,576 (3.0%)
North Central	81,015	67	369	666	2,038	84,155 (3.7%)
South	187,191	176	1,093	1,360	3,707	193,527 (3.3%)
West	63,306	67	363	561	1,703	66,000 (4.1%)
Region Unknown	1,011	-	5	7	10	1,033 (2.1%)
Urban	382,607	348	2,093	2,980	8,346	396,374 (3.5%)
Rural	47,793	40	148	287	997	49,265 (3.0%)
Healthcare Utilization						
Outpatient Days Mean	57	73	59	67	73	57
Outpatient Days Standard Deviation	49.24	50.83	52.28	52.96	55.58	49.49
# of Patients with Inpatient Claim	-	-	-	-	-	0 (0%)
Diagnosis						
Cochlear Implant	1,021	1	49	46	76	1,193 (14.4%)
Cerebrospinal Fluid Leak	1,450	2	1	9	21	1,483 (2.2%)
Asplenia	861	4	36	55	103	1,059 (18.7%)
Sickle Cell Disease or Other Hemoglobinopathy	14,648	6	17	46	189	14,906 (1.7%)
Chronic Kidney Disease	101,954	79	337	697	2,548	105,615 (3.5%)
Other Immune System Diseases	57,112	89	286	536	1,460	59,483 (4.0%)
Generalized Malignancy	237,279	115	388	839	3,816	242,437 (2.1%)
HIV	14,555	127	1,378	1,249	1,394	18,703 (22.2%)
Hodgkin's Disease	4,727	8	35	40	141	4,951 (4.5%)
Radiation Therapy	37,922	42	127	213	890	39,194 (3.2%)
Leukemia	9,132	28	54	120	362	9,696 (5.8%)
Lymphoma	16,411	24	87	147	502	17,171 (4.4%)
Multiple Myeloma	3,349	16	28	40	131	3,564 (6.0%)
Nephrotic Syndrome	2,502	4	8	20	68	2,602 (3.8%)
Solid Organ Transplant	2,611	19	32	48	122	2,832 (7.8%)

Table 3.6 provides results from the output of the multiple logistic regression model with having a PCV13 claim as the predicted outcome, excluding individuals with inpatient claims between 2012 and 2015. All covariates except Region Unknown vs. Northeast, urban residence, CSF leak, and radiation therapy, were significant at the 5% level. Odds ratios were similar to the analysis excluding outpatient stays.

Table 3.6 Adults 19-64 Years of Age with High Risk Indication, Excluding Individuals with Inpatient Claims, Odds of Having a PCV13 Claim

Effect	Odds Ratio Estimate	95% CI	
Demographics			
Age 30-39 vs 19-29	*1.226	1.074	1.399
Age 40-49 vs 19-29	*1.523	1.350	1.718
Age 50-59 vs 19-29	*2.193	1.950	2.466
Age 60-64 vs 19-29	*4.065	3.609	4.580
Male vs Female	*1.269	1.224	1.315
North Central vs Northeast	*1.473	1.397	1.553
South vs Northeast	*1.140	1.089	1.194
West vs Northeast	*1.474	1.395	1.558
Region Unknown vs Northeast	0.717	0.461	1.116
Urban vs Rural	1.009	0.954	1.068
Healthcare Utilization			
Outpatient days 2nd vs 1st quartile†	*1.425	1.358	1.496
Outpatient days 3rd vs 1st quartile†	*1.922	1.830	2.019
Outpatient days 4th vs 1st quartile†	*2.548	2.418	2.684
Diagnosis			
Asplenia	*10.158	8.611	11.982
Sickle Cell Disease or Other Hemoglobinopathy	*0.781	0.685	0.890
Chronic Kidney Disease	*1.109	1.051	1.171
Other Immune System Diseases	*1.369	1.296	1.447
Generalized Malignancy	*0.689	0.654	0.726
HIV	*15.287	14.434	16.19
Hodgkin's Disease	*1.568	1.353	1.816
Radiation Therapy	1.064	0.997	1.134
Leukemia	*1.792	1.631	1.968
Lymphoma	*1.211	1.113	1.318
Multiple Myeloma	*1.584	1.370	1.830
Nephrotic Syndrome	*1.316	1.071	1.616
Solid Organ Transplant	*2.209	1.914	2.550

C-statistic=0.777

†Quartile breakpoints are <31, 31-54, 55-92, and >92 days, for quartiles 1-4 respectively

*Denotes significant value
For diagnosis or condition based covariates, the reference group is not having the diagnosis or condition

Cohort 3: Adults ≥ 65 years of age

A total of 1,262,531 subjects were identified, 18% of which had a PCV13 claim.

Table 3.7 provides summary descriptive statistics for the subjects in Cohort 3. The table is subdivided by year of PCV13 claim. Subjects with a PCV13 claim have a mean 14% greater number of outpatient claim days compared to subjects without a PCV13 claim. Rate of having a PCV13 was highest at ages 70-79.

Table 3.7 Adults ≥65 Years of Age, Descriptive Table

Year of PCV13 Claim	None	2012	2013	2014	2015	All groups** (% vaccinated)
Demographics						
n	1,069,894	1,212	3,644	20,148	167,633	1,262,531 (18.0%)
Age Mean	76	72	74	76	77	76
Age Standard Deviation	7.71	7.39	7.33	6.96	6.80	7.59
Age 65-69	168,627	422	909	3,291	21,634	194,883 (15.6%)
Age 70-79	507,455	506	1,680	10,202	88,983	608,826 (20.0%)
Age 80-89	300,323	223	832	5,623	48,217	355,218 (18.3%)
Age 90-99	63,733	25	101	846	8,024	72,729 (14.1%)
Age 100+	906	-	2	6	48	962 (6.2%)
Male	478,276	541	1,669	9,094	74,100	563,680 (17.9%)
Female	591,618	671	1,975	11,054	93,533	698,851 (18.1%)
Northeast	249,358	372	993	5,241	34,342	290,306 (16.4%)
North Central	368,569	329	1,239	6,740	68,147	445,024 (20.7%)
South	341,588	432	1,164	4,407	44,320	391,911 (14.7%)
West	108,043	79	248	3,748	20,762	132,880 (23.0%)
Region Unknown	2,336	-	-	12	62	2,410 (3.2%)
Urban	899,255	1,059	3,145	17,796	144,126	1,065,381 (18.5%)
Rural	168,867	153	499	2,340	23,455	195,314 (15.7%)
Healthcare Utilization						
Mean Outpatient Days	70	93	94	88	80	72
Outpatient Days Standard Deviation	66.17	68.01	77.80	67.33	62.69	65.91
# of Patients with Inpatient Claim	232,294	281	890	4,504	33,476	271,445 (16.9%)

# Patients with High Infection Risk	365,616	506	1,557	842	61,874	430,395 (17.7%)

Table 3.8 provides results from the output of the multiple logistic regression model with having a PCV13 claim as the predicted outcome. All covariates except gender were significant at the 5% level. Subjects 70-79 or 80-89 years of age, who had residence in the North Central or West regions, no high infection risk conditions, or no inpatient stays, had greater odds of having a PCV13 claim. Subjects with increasing number of outpatient visits were more likely to have a claim.

Table 3.8 Adults ≥65 Years of Age, Odds of Having a PCV13 Claim

Effect	Odds Ratio Estimate	95% CI	
Demographics			
Age 70-79 vs Age 65-69	*1.229	1.211	1.248
Age 80-89 vs Age 65-69	*1.086	1.068	1.103
Age 90-99 vs Age 65-69	*0.841	0.820	0.863
Age 100+ vs Age 65-69	*0.394	0.301	0.517
Male vs Female	1.003	0.993	1.013
North Central vs Northeast	*1.339	1.321	1.356
South vs Northeast	*0.927	0.914	0.940
West vs Northeast	*1.447	1.422	1.473
Region Unknown vs Northeast	*0.270	0.214	0.341
Urban vs Rural	*1.177	1.160	1.194
High Infection Risk Condition	*0.987	0.976	0.997
Healthcare Utilization			
Outpatient days 2nd vs 1st quartile†	*1.841	1.813	1.868
Outpatient days 3rd vs 1st quartile†	*2.104	2.071	2.137
Outpatient days 4th vs 1st quartile†	*2.355	2.317	2.393
Inpatient Claim vs no inpatient claim	*0.761	0.751	0.770

C-statistic=0.603

†Quartile breakpoints are <30, 30-60, 61-97, and >97 days, for quartiles 1-4 respectively

*Denotes significant value

Table 3.9 provides summary descriptive statistics for the subjects in Cohort 3, excluding individuals with inpatient claims or high infection risk conditions between

2012 and 2015. The overall PCV13 claim rate was 14.3%, compared to 18% when including subjects with inpatient claims or high infection risk conditions. PCV13 claim rates were correspondingly lower in all groups, with no groups exhibiting a higher rate.

Table 3.9 Adults ≥65 Years of Age, Excluding Individuals with Inpatient Claims and Individuals with High Risk Conditions, Descriptive Table

Year of PCV13 Claim	None	2014	2015	All groups** (% vaccinated)
Demographics				
n	589,227	9,072	89,056	687 (14.3%)
Age Mean	75	75	75	75
Age Standard Deviation	7.48	6.59	6.49	7.35
Age 65-69	111,617	1,735	13,839	127 (12.2%)
Age 70-79	293,722	4,890	50,224	349 (15.8%)
Age 80-89	138,943	2,124	21,522	163 (14.5%)
Age 90-99	26,826	275	3,098	30 (11.2%)
Age 100+	494	1	16	0.5 (3.3%)
Male	246,809	3,763	36,472	287 (14.0%)
Female	342,418	5,309	52,584	400 (14.5%)
Northeast	138,761	2,324	18,253	159 (12.9%)
North Central	199,239	2,984	36,050	238 (16.4%)
South	189,105	1,957	23,488	215 (11.9%)
West	60,446	1,802	11,232	73 (17.7%)
Region Unknown	1,676	5	33	1.7 (2.2%)
Urban	490,754	8,029	76,091	575 (14.6%)
Rural	97,182	1,038	12,935	111 (12.6%)
Healthcare Utilization				
Mean Outpatient Days	50	67	62	52
Outpatient Days Standard Deviation	45.66	48.87	46.34	46.05
# Patients with Inpatient Stays	0	0	0	0 (0.0%)
# Patients with High Risk	0	0	0	0 (0.0%)

Table 3.10 provides results from the output of the multiple logistic regression model with having a PCV13 claim as the predicted outcome, excluding individuals with inpatient claims or high infection risk conditions between 2012 and 2015. All covariates except gender were significant at the 5% level. Odds ratios were similar to the analysis excluding outpatient stays.

Table 3.10 Adults ≥65 Years of Age, and Individuals with High Risk Conditions, Odds of Having a PCV13 Claim

Effect	Odds Ratio Estimate	95% CI	
Age 70-79 vs Age 65-69	*1.268	1.249	1.288
Age 80-89 vs Age 65-69	*1.104	1.086	1.122
Age 90-99 vs Age 65-69	*0.844	0.822	0.867
Age 100+ vs Age 65-69	*0.384	0.291	0.507
Male vs Female	0.994	0.984	1.004
North Central vs Northeast	*1.342	1.324	1.360
South vs Northeast	*0.923	0.910	0.936
West vs Northeast	*1.480	1.454	1.507
Region Unknown vs Northeast	*0.269	0.212	0.341
Urban vs Rural	*1.178	1.161	1.195
Outpatient days 2nd vs 1st quartile†	*1.788	1.761	1.815
Outpatient days 3rd vs 1st quartile†	*1.977	1.947	2.008
Outpatient days 4th vs 1st quartile†	*2.097	2.065	2.129

C-statistic=0.598

†Quartile breakpoints are <30, 30-60, 61-97, and >97 days, for quartiles 1-4 respectively

*Denotes significant value

Section Four: Discussion

Across all cohorts, the most consistent supportive covariate for vaccination was having a greater number of outpatient visits. Residence in North Central and West regions were generally supportive of vaccination. Urban residence was supportive in all cohorts, but not significantly so in Cohort 2. Gender inconsistently predicted vaccination, at times being protective against vaccination, supportive for vaccination, and non-significantly affecting vaccination. Similarly, having an inpatient stay was supportive for vaccination and protective against and vaccination in Cohorts 2 and 3 respectively. Further discussion of each cohort follows.

Cohort 1: Children < 36 months of age

The overall measured rate of completed PCV13 vaccination in children under 36 months of age was 78%, comparable to the approximately 83% pneumococcal vaccination rate reported for children under 36 months of age between 2010-2015.[7] This provides evidence to suggest good capture of vaccinations.

Cohort 2: Adults 19-64 years of age with high risk indication

The overall measured rate of PCV13 vaccination in adults 19-64 years of age with high infection risk conditions was 3.8%. This is a lower coverage rate than the 23% estimated by the NHIS.[6] This is expected as the NHIS estimate includes vaccination with both PCV13 and the much older PPSV23; additionally, the NHIS estimate includes adults with moderate-high infection risk conditions, and it is unclear how this effects the reported percent covered. Subjects were progressively more likely to have a claim for PCV13 in older age groups. Subjects who had more outpatient visits were progressively

more likely to have a claim for PCV13; however, this trend was not observed for HIV and sickle cell or other hemoglobinopathies; instead, individuals with these diagnoses were equally likely to have a PCV13 claim regardless of how frequently they had outpatient visits. This suggests that subjects and their physicians have a greater awareness of the need for proactively preventing infectious diseases.

Cohort 3: Adults ≥ 65 years of age

The overall measured rate of PCV13 vaccination in adults over 65 years of age was 18%. As with Cohort 2, this is lower than NHIS reported rate of 64%.[5] This is an expected result as the NHIS estimate includes both PPSV23 and PCV13 vaccination. Females, persons over 75 years of age, and persons residing in a rural area, or the Midwest or West region have higher reported rates of pneumococcal vaccination.[6] As with Cohort 2, individuals were progressively more likely to be vaccinated than younger individuals; however, this trend reversed in the age groups containing subjects aged 80 and older. With the exception of urban residence, these same factors were found to have higher rates of PCV13 vaccination in table 3.7; although gender was found to be non-significant when correcting for all other covariates in table 3.8.

Limitations

Insurance claims data are collected for billing purposes rather than tracking patient health status. This leads to multiple consequences which hamper the utility of datasets based on claims data, such as the Truven Health MarketScan® databases used in this analysis. One such consequence is that patient details such as income, race, and physician and lab reported values are not available. Another consequence is that diagnosis and service codes may not be specific to a condition of interest. In the case of

pneumococcal vaccination, multiple diagnosis and service codes may validly be used to file a claim for PCV13 vaccination, some of which may also be used for PPSV vaccination. This study followed a conservative approach, including only service codes specific to PCV13. Even so, providers may mistakenly use the wrong billing code when submitting a claim; such unintentional misreporting is not possible to distinguish from genuinely provided services.

In the outpatient setting, a maximum of four diagnoses may be reported for an outpatient claim, leading physicians to only report diagnoses pertinent to services provided, thus limiting the ability to determine high infection risk conditions in Cohort 2.

In the inpatient setting, claims are typically made via a prospective payment system, wherein claims are made for an overall service provided, not specific procedures such as PCV13 administration. This is of particular concern, because from 2012 to 2014, the Joint Commission included pneumococcal vaccination as a performance measurement, encouraging hospitals provide PCV13 to qualifying patients.[26] In recognition of this practice, separate analyses were performed for Cohorts 2 and 3, which excluded subjects with inpatient claims. In addition, for Cohort 3, this secondary analysis also excluded subjects with high infection risk conditions, as this group qualified for vaccination at earlier dates than subjects without high infection risk conditions.

To assess the accuracy of measured prevalence of high infection risk diseases in Cohort 2, national rates of high infection risk diseases were reviewed, and are reported in Appendix F. Measured rates were overall similar to national rates, with some exceptions. Conditions in which measured rates were low compared to national averages include asplenia and solid organ transplant, both of which may be attributable to infrequent

claims being made which include pertinent diagnoses codes. Chronic kidney disease was also measured at rates lower than national averages, and this may be attributable to such persons becoming eligible for Medicare prior to 65 years of age. Sickle cell disease was measured at rates above national averages, this may be due to misreporting of sickle cell trait as sickle cell disease. Prevalence of CSF leak, radiation therapy, nephrotic syndrome, and other immune system diseases in the U.S. are not well defined, and therefore were not assessed in comparison to measured rates.

Last, because the Truven MarketScan® databases contain subjects whose insurance coverage is provided by their employer, this analysis may not be generalizable to all persons residing in the U.S, particularly those with lower incomes who may rely on Medicaid for health insurance. Subjects may also have used an alternate insurance for vaccination, or may have paid for vaccination in cash, either of which would lead to undocumented vaccination.

The sum of the limitations and methods used in this study indicate that measured vaccination prevalence rates are more likely to underestimate than overestimate.

Conclusions

At the time of writing, there is no assessment of PCV13 coverage in high infection risk adults in the U.S. Insurance claims records are primarily kept for billing purposes, rather than as a means to record patient health status. Subsequently, it is difficult to determine the health status of individuals contained in datasets derived from these records. Methods for assessing the prevalence of PCV13 vaccination that have not been reported in literature include analysis of hospital electronic health records to determine true inpatient rates of PCV13 administration. The Medical Expenditure Panel

Survey (MEPS), which unifies detailed surveys provided to individuals with their health records may offer deeper insight into vaccination rates. Published survey questions include “Have you ever had a pneumonia shot? A pneumonia shot or pneumococcal vaccine is usually only given once or twice in a person's lifetime,” which precludes the possibility of differentiating between PPSV23 and PCV13.[33] Overall there is an unmet need to track vaccination status. A potential solution to the difficulty in assessing vaccination prevalence would be the creation of a national vaccine registry, to which all providers must report administered vaccines; however, for such a registry to be maximally useful for research purposes, it would require patient diagnostic information, or ability to link to other datasets.

National estimates of pneumococcal vaccination indicate rates below Healthy People 2020 goals. This study builds upon these studies by revealing the specific characteristics of patients who are less likely to be vaccinated. By identifying these individuals, providers and insurers may more effectively try to reach these patients and make a recommendation for pneumococcal vaccination.

Appendix A: Medical conditions at moderate and high risk for infection

Medical indication	Moderate risk medical condition	High risk medical condition
Immunocompetent persons	Alcoholism	Cochlear implant
	Chronic heart disease [a]	Cerebrospinal fluid leak
	Chronic liver disease	
	Chronic lung disease [b]	
	Cigarette smoking	
	Diabetes mellitus	
Persons with functional or anatomic asplenia		Congenital or acquired asplenia
		Sickle cell disease / other hemoglobinopathies
Immunocompromised persons		Chronic renal failure
		Congenital or acquired immunodeficiencies [c]
		Generalized malignancy
		HIV infection
		Hodgkin disease
		Iatrogenic immunosuppression [d]
		Leukemia
		Lymphoma
		Multiple myeloma
		Nephrotic syndrome
		Solid organ transplant

a. Including congestive heart failure and cardiomyopathies, and in children cyanotic congenital heart disease and cardiac failure.

b. Including chronic obstructive pulmonary disease, emphysema, and asthma

c. Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

d. Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

Adapted from [34]

Appendix B: Streptococcus pneumoniae vaccine serotype coverage

Streptococcus pneumoniae serotype	Vaccine		
	PPSV23	PCV7	PCV13
1	✓		✓
2	✓		
3	✓		✓
4	✓	✓	✓
5	✓		✓
6A			✓
6B	✓	✓	✓
7F	✓		✓
8	✓		
9N	✓		
9V	✓	✓	✓
10A	✓		
11A	✓		
12F	✓		
14	✓	✓	✓
15B	✓		
17F	✓		
18C	✓	✓	✓
19A	✓		✓
19F	✓	✓	✓
20	✓		
22F	✓		
23F	✓	✓	✓
33F	✓		

As of 2011, 92 Pneumococcal serotypes have been documented.[1]

Additional Sources: Vaccine package inserts for PCV7, PCV13, and PPSV23. [35-37]

Appendix C: PCV13 catch-up guidance for children 4 months - 18 years of age

If current age is	AND # of previous doses is	AND		THEN	NEXT DOSE
4 - 6 Months	0 or unknown	→	→	Give Dose 1 today	Give Dose 2 at least 4 weeks after Dose 1
	1	→	It has been at least 4 weeks since Dose 1	Give Dose 2 today	Give Dose 3 at least 4 weeks after Dose 2
		→	It has not been at least 4 weeks since Dose 1	No Dose today	Give Dose 2 at least 4 weeks after Dose 1
	2	→	It has been at least 4 weeks since Dose 2	Give Dose 3 today	Give Dose 4 (Final Dose) at 12 months of age or older
		→	It has not been at least 4 weeks since Dose 2	No Dose today	Give Dose 3 at least 4 weeks after Dose 2
7-11 Months	0	→	→	Give Dose 1 Today	Give Dose 2 at least 4 weeks after Dose 1
	1	Dose 1 was given before 7 months of age	It has been at least 4 weeks since Dose 1	Give Dose 2 today	Give Dose 3 at least 8 weeks after Dose 2 and at 12 months of age or older (Final Dose)
			It has not been 4 weeks since Dose 1	No Dose today	Give Dose 2 at least 4 weeks after Dose 1
		Dose 1 was given at 7 months or older	It has been at least 4 weeks since Dose 1	Give Dose 2 today	Give Dose 3 at least 8 weeks after Dose 2 and at 12 months of age or older (Final Dose)
			It has not been 4 weeks since Dose 1	No Dose today	Give Dose 2 at least 4 weeks after Dose 1
	2	Dose 2 was given	It has been at least 4 weeks	Give Dose 3 today	Give Dose 4 at least 8 weeks after

		before 7 months of age	since Dose 2		Dose 3 and at 12 months of age or older (Final Dose)
			It has not been 4 weeks since Dose 2	No Dose today	Give Dose 3 at least 4 weeks after Dose 2
		Dose 2 was given at 7 months or older	→	No Dose today	Give Dose 3 at least 8 weeks after Dose 2 and at 12 months of age or older (Final Dose)
12-23 Months	0	→	→	Give Dose 1 today	Give Dose 2 at least 8 weeks after Dose 1 (Final Dose)
	1	Dose 1 was given before 12 months of age	It has been at least 4 weeks since Dose 1	Give Dose 2 today	Give Dose 3 at least 8 weeks after Dose 2 (Final Dose)
			It has not been at least 4 weeks since Dose 1	No Dose today	Give Dose 2 at least 4 weeks after Dose 1
		Dose 1 was given at 12 months of age or older	It has been at least 8 weeks since Dose 1	Give Dose 2 today (Final Dose)	No additional doses needed
			It has not been at least 48 weeks since Dose 1	No Dose today	Give Dose 2 at least 8 weeks after dose 1 (Final Dose)
	2	Both doses were given before 12 months of age	It has been at least 8 weeks since Dose 2	Give Dose 3 today (Final Dose)	No additional doses needed
			It has not been 8 weeks since Dose 2	No Dose today	Give Dose 3 at least 8 weeks after Dose 2 (Final Dose)
		At least one dose was given at 12 months of age or older	It has been at least 8 weeks since Dose 2	Give Dose 3 today (Final Dose)	No additional doses needed
			It has not been 8 weeks since Dose 2	No Dose today	Give Dose 3 at least 8 weeks after Dose 2 (Final Dose)
	3	All doses were given before 12	It has been at least 8 weeks since Dose 3	Give Dose 4 today (Final Dose)	No additional doses needed

		months of age	It has not been at least 8 weeks since Dose 3	No Dose today	Give Dose 4 at least 8 weeks after Dose 3 (Final Dose)
		1 or more doses was given at 12 months of age or older	→	No Dose today	No additional doses needed
24-59 Months	0	→	→	Give Dose 1 today	No additional doses needed
	1	Dose 1 was given before 24 months of age	It has been at least 8 weeks since the first dose	Give Dose 2 today (Final Dose)	no additional doses needed
			It has not been at least 8 weeks since the first dose	No Dose today	Give Dose 2 (Final Dose) at least 8 weeks after Dose 1
		Dose was given at 24 months or older	→	No Dose today	No additional doses needed
	2	Dose 2 was given before 24 months of age	It has been at least 8 weeks since Dose 2	Give Dose 3 today (Final Dose)	No additional doses needed
			It has not been 8 weeks since Dose 2	No Dose today	Give dose 3 (Final Dose) at least 8 weeks after Dose 2
		Dose 2 was given at 24 months of age or older	→	No Dose today	No additional doses needed
	3	All 3 doses were given before 12 months of age	→	Give Dose 4 today (Final Dose)	No additional doses needed

As listed in [38]

Appendix D: ICD-9 diagnosis codes

Condition	ICD-9 diagnosis code
Cochlear implant	procedure code: V5273, 69930, 92601-92604, L8614-L8619, L8621-L8624, L8627-L8629,
Cerebrospinal fluid leak	34981, 38861, V452
Congenital or acquired asplenia	7590 or procedure code: 38100, 38102, 28120
Sickle cell disease or other hemoglobinopathy	282.4x, 282.6x, 282.7
Chronic kidney disease	V420, V451, V56.x, 403.x, 404.x, 582.x, 583.x, 585.x, 7530, 7925
Congenital or acquired immunodeficiency	2790.x, 2791.1, 2791.2, 2791.3, 2792, 2793, 2794.x, 2798, 2799
Generalized malignancy	185, 140.x-165.x, 170.x-172.x, 174.x-176.x, 179.x-184.x, 186.x, 199.x, 202.x, 203.8x 208.x
HIV infection	V08, 042.x, 043.x, 044.x, 27910, 27919, 7953, 7958, 79571
Hodgkin's disease	201.x
Radiation therapy	V580, V581.x, V661, V662, V671, V672
Leukemia	202.4, 203.1x, 204.x-208.x
Lymphoma	200.x, 202.0x-202.2x, 202.7x, 202.8x, 202.9x
Multiple myeloma	203.0x
Nephrotic syndrome	581.x
Solid Organ Transplant	2795.x, 9968.x

Appendix E: Correlation Matrices

Cohort 1 Pearson Correlation Coefficient Correlation Matrix				
	Gender	Urban Residence	Region	Outpatient Quartile
Gender	1	-0.0018	0.00019	0.08182*
Region	0.00019	-0.14368*	1	-0.13717*
Urban Residence	-0.0018	1	-0.14368*	0.01797*
Outpatient Quartile	0.08182*	0.01797*	-0.13717*	1

Cohort 2 Pearson Correlation Coefficient Correlation Matrix																			
	Age Category	Gender	Region	Urban Residence	Cochlear Implant	Cerebrospinal Fluid Leak	Asplenia	Sickle Cell Disease or Other	Chronic Kidney Disease	Other Immune System Diseases	Generalized Malignancy	HIV	Hodgkin's Disease	Radiation Therapy	Leukemia	Lymphoma	Multiple Myeloma	Nephrotic Syndrome	Solid Organ Transplant	Outpatient Quartile	Inpatient Stay
Age Category	1	0.05491*	-0.00333*	-0.04220*	-0.01644*	-0.05511*	-0.01966*	-0.09823*	0.07817*	-0.10756*	0.14883*	-0.12512*	-0.05056*	0.03348*	-0.00179	-0.00673*	0.02354*	-0.02663*	-0.02185*	0.12219*	0.01269*
Gender	0.05491*	1	0.00163	0.00022	0.00115	-0.00448*	-0.00158	-0.00627*	0.14913*	-0.09736*	-0.11303*	0.11617*	0.01022*	-0.08007*	0.02870*	0.02982*	0.00725*	0.01275*	0.03556*	-0.14610*	0.00909*
Region	-0.00333*	0.00163	1	-0.04157*	0.00467*	0.00764*	0.00415*	0.00691*	0.05564*	-0.00668*	-0.03659*	0.00245	-0.00980*	0.01850*	-0.01222*	-0.02035*	-0.01687*	-0.00020	0.00157	-0.03695*	-0.00456*
Urban Residence	-0.04220*	0.00022	-0.04157*	1	-0.00192	-0.00485*	-0.00331*	0.01681*	-0.02185*	0.01668*	-0.01258*	0.04299*	0.00062	-0.02156*	-0.00095	0.00201	-0.00049	-0.00209	0.00207	0.01313*	-0.01743*
Cochlear Implant	-0.01644*	0.00115	0.00467*	-0.00192	1	0.00066	-0.00178	-0.00804*	-0.02368*	0.01515*	-0.04549*	-0.00836*	-0.00447*	-0.01462*	-0.00588*	-0.00868*	-0.00427*	-0.00368*	-0.00280*	-0.00861*	-0.01249*
CSF Leak	-0.05511*	-0.00448*	0.00764*	-0.00485*	0.00066	1	-0.00237	-0.01236*	-0.03353*	-0.02261*	-0.05992*	-0.01210*	-0.00666*	-0.01766*	-0.00886*	-0.01054*	-0.00634*	-0.00459*	-0.00625*	0.01432*	0.03943*

Asplenia	-0.02663*	0.02354*	-0.00673*	-0.00179	0.03348*	-0.05056*	-0.12512*	0.14883*	-0.10756*	0.07817*	-0.09823*	-0.01966*
Sickle Cell Disease	0.01275*	0.00725*	0.02982*	0.02870*	-0.08007*	0.01022*	0.11617*	-0.11303*	-0.09736*	0.14913*	-0.00627*	-0.00158
Chron. Kidney Disease	-0.00020	-0.01687*	-0.02035*	-0.01222*	0.01850*	-0.00980*	-0.00245	-0.03659*	-0.00668*	0.05564*	0.00691*	0.00415*
Other Immune System Diseases	-0.00209	-0.00049	0.00201	-0.00095	-0.02156*	0.00062	0.04299*	-0.01258*	0.01668*	-0.02185*	0.01681*	-0.00331*
General--ized Mal--ignancy	-0.00368*	-0.00427*	-0.00868*	-0.00588*	-0.01462*	-0.00447*	-0.00836*	-0.04549*	-0.01515*	-0.02368*	-0.00804*	-0.00178
HIV	-0.00459*	-0.00634*	-0.01054*	-0.00886*	-0.01766*	-0.00666*	-0.01210*	-0.05992*	-0.02261*	-0.03353*	-0.01236*	-0.00237
Hodgkin Disease	-0.00286*	-0.00370*	0.00035	-0.00254*	-0.00891*	0.00661*	-0.00867*	-0.04265*	-0.01207*	-0.02293*	-0.00347*	1
Rad. Therapy	-0.01244*	-0.01108*	-0.02884*	-0.02012*	-0.05344*	-0.01483*	-0.02999*	-0.17468*	-0.05747*	-0.08486*	1	-0.00347*
Leukemia	0.09080*	-0.01393*	-0.08928*	-0.06085*	-0.16197*	-0.04960*	-0.08288*	-0.52187*	-0.15446*	1	-0.08486*	-0.02293*
Lymph--oma	-0.01341*	0.03623*	0.02409*	0.02490*	0.09356*	0.00055	-0.04324*	-0.25684*	1	-0.15446*	-0.05747*	-0.01207*
Multiple Myeloma	-0.07729*	-0.04605*	-0.11387*	-0.11731*	0.20024*	-0.06988*	-0.19056*	1	-0.25684*	-0.52187*	-0.17468*	-0.04265*
Nephrotic Syndrome	-0.01211*	-0.01384*	-0.02445*	-0.02284*	-0.06150*	-0.01277*	1	-0.19056*	-0.04324*	-0.08288*	-0.02999*	-0.00867*
	-0.00590*	0.00790*	0.24254*	0.02215*	0.05664*	1	-0.01277*	-0.06988*	0.00055	-0.04960*	-0.01483*	0.00661*
	-0.01640*	0.07839*	0.12641*	0.05285*	1	0.05664*	-0.06150*	0.20024*	0.09356*	-0.16197*	-0.05344*	-0.00891*
	-0.00618*	0.05766*	0.13178*	1	0.05285*	0.02215*	-0.02284*	-0.11731*	0.02490*	-0.06085*	-0.02012*	-0.00254*
	-0.01047*	0.05311*	1	0.13178*	0.12641*	0.24254*	-0.02445*	-0.11387*	0.02409*	-0.08928*	-0.02884*	0.00035
	0.01058*	1	0.05311*	0.05766*	0.07839*	0.00790*	-0.01384*	-0.04605*	0.03623*	-0.01393*	-0.01108*	-0.00370*
	1	0.01058*	-0.01047*	-0.00618*	-0.01640*	-0.00590*	-0.01211*	-0.07729*	-0.01341*	0.09080*	-0.01244*	-0.00286*
	0.01762*	0.02746*	0.01653*	0.06301*	-0.00165	0.00711*	-0.01213*	-0.08620*	0.07427*	0.10289*	-0.01595*	-0.00384*
	0.02494*	0.06185*	0.04754*	0.03137*	0.25551*	0.00495*	-0.07712*	0.04363*	0.13504*	0.04109*	-0.05957*	-0.00196
	0.02450*	0.03699*	0.01663*	0.01678*	0.14599*	0.00201	-0.03820*	0.03040*	0.03442*	0.07045*	-0.01776*	0.00604*

Solid Organ Transplant	-0.02185*	0.03556*	0.00157	0.00207	-0.00280*	-0.00625*	-0.00384*	-0.01595*	0.10289*	0.07427*	-0.08620*	-0.01213*	0.00711*	-0.00165	0.06301*	0.01653*	0.02746*	0.01762*	1	0.08688*
Out--patient Quartile	0.12219*	-0.14610*	-0.03695*	0.01313*	-0.00861*	0.01432*	-0.00196	-0.05957*	0.04109*	0.13504*	0.04363*	-0.07712*	0.00495*	0.25551*	0.03137*	0.04754*	0.06185*	0.02494*	0.08613*	1
In--patient	0.01269*	0.00909*	-0.00456*	-0.01743*	-0.01249*	0.03943*	0.00604*	-0.01776*	0.07045*	0.03442*	0.03040*	-0.03820*	0.00201	0.14599*	0.01678*	0.01663*	0.03699*	0.02450*	0.08688*	0.33670*

Cohort 3 Pearson Correlation Coefficient Correlation Matrix								
	Age Category	Gender	Region	Urban Residence	High Infection Risk Condition	Outpatient Quartile	Inpatient Stay	
Age Category	1	-0.07247*	0.05583*	0.01956*	0.10405*	0.10797*	0.13729*	0.00867*
Gender	-0.07247*	1	-0.00235*	-0.02406*	0.08677*	-0.02247*	0.00867*	0.00921*
Region	0.05583*	-0.00235*	1	-0.00453*	0.00473*	-0.04121*	-0.00921*	0.00441*
Urban Residence	0.01956*	-0.02406*	-0.00453*	1	0.02501*	0.04493*	0.00441*	0.16374*
High Infection Risk Condition	0.10405*	0.08677*	0.00473*	0.02501*	1	0.30741*	0.16374*	0.31523*
Outpatient Quartile	0.10797*	-0.02247*	-0.04121*	0.04493*	0.30741*	1	0.31523*	1
Inpatient Stay	0.13729*	0.00867*	-0.00921*	0.00441*	0.16374*	0.31523*	1	

*Denotes significant value

Appendix F: Rates of High Infection Risk Disease in the U.S.

	Reported in Literature		Measured	
	n	% total	n	% total
Total Population, 19-64 Years of Age	194,296,087[39]	100.00%	8,214,322	100.00%
Cochlear Implant	41,000[40]	0.02%	1,457	0.02%
Asplenia	272,015[41]	0.14%	1,643	0.02%
Sickle Cell Disease	62,931[42]	0.03%	20,026	0.24%
Chronic Kidney Disease	15,306,381[43,44]	7.88%	163,972	2.00%
Generalized Malignancy	6,343,720[45]	3.26%	353,130	4.30%
HIV	895,940[46,47]	0.46%	23,727	0.29%
Hodgkin's Disease	142,641[48]	0.07%	7,171	0.09%
Leukemia	387,728[49]	0.20%	14,932	0.18%
Lymphoma	282,672[50]	0.15%	25,938	0.32%
Multiple Myeloma	44,452[51]	0.02%	6,674	0.08%
Solid Organ Transplant	534,249[52]	0.27%	8,132	0.10%
Cerebrospinal fluid leak, radiation therapy, nephrotic syndrome, and other Immune system diseases U.S. prevalence not well defined				

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