National Center for Immunization & Respiratory Diseases



US Adult Pneumococcal Colonization Study: Preliminary Findings

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Pneumococcal Colonization

- Precedes disease
- Pneumococcal colonization in elderly (≥65 years) not well studied
 - 3.4% carriage in US HIV-infected adults (19-66 years) in 2005-2007¹
 - − 9.3% in Native Americans \geq 40 years in 2008²
 - 2.2% in UK adults ≥65 years in 2011 (5 years after PCV7 introduction) ³
- Pneumococcal conjugate vaccine decreases vaccine-type carriage but not pneumococcal colonization
 - HIV-infected adults in Kenya: VT-carriage decreased from 33% to 14% after PCV10 introduction in children (pneumococcal colonization: ~35%)⁴

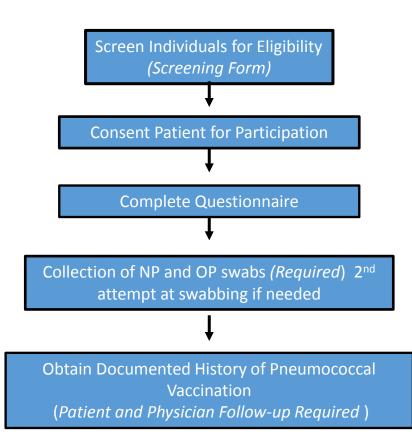
1. Onwubiko. JCM 2008 ; 2. Scott JR JID 2012; 3. Hamaluba Medicine(Baltimore) 2015; 4. Kim. L. 2016 ISPPD poster

Study Objectives

- Define prevalence and serotype distribution of S. *pneumoniae* carriage in seniors
- Assess risk factors for colonization
- Provide baseline data to assess the impact of the new ACIP recommendation on carriage rates through later carriage studies

STUDY SITES	GA	Image: MD	NY	TN
Recruitment Facilities	The Hope Clinic, Senior Centers, Senior Residential Communities	Hopkins Geriatric Research Group + Clinics	Considering UR Geriatric Clinic + Practice based Research Network, Senior residential communities	Vanderbilt Clinical Research Database + Geriatric Clinic, senior residential communities
Enrollment Start Date	June 2015	January 2016	August 2015	September 2015
Enrollment End Date	December 2016	December 2016	September 2016	December 2016

Study Methods



Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
• • •	Age 65 years or older at the time of enrollment Not severely immunocompromised* Signed informed consent from participant or legal representative Both NP and OP swabs obtained English speaker	 Too ill to participate in the study Resident of a nursing home Unsuccessful collection of a NP or OP swab

Target Study Sample Size

Baseline proportion of colonization with VTS*	Reduction associated with PCV13 ^{**} introduction for adults ≥ 65 years	Post-PCV13 proportion of colonization with VTS	for each sample collection round	Sample size needed for each sample collection round with 65% vaccine coverage
0.02 (2%)	50%	0.01 (1%)	2,200	2,970

VT carriage prevalence	Upper/Lower bound	Sample size
0.5%	±0.25%	3,049

Laboratory Methods for NP and OP Specimens: Culture

- NP and OP collected and processed separately
- Culture
 - Optochin and bile solubility
 - Isolates serotyped using Quellung
- Antimicrobial susceptibility (will not be presented today)

Laboratory Methods for NP and OP Specimens: Molecular detection

- NP specimens assessed for quality using RNAseP
- PCR only on NP specimens

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- Targeting lytA for detection of pneumococcal DNA (NP specimens only)
- Multiplex PCR assay for serotype identification of *lytA* positive NP specimens

Non-pneumococcal mitis-group streptococci confound detection of pneumococcal capsular serotype-specific loci in upper respiratory tract

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Results

Adult Carriage Study Enrollment

Study Site	Adults 65+ Enrolled
GA	1,119
MD	549
NY	769
TN	571
Overall	3,008

* Target enrollment: 3,049

Participant Demographics

	All sites N=3008	US population 65 years and older*
Age, years	75.5 median: 74	73.2
Race, n (%)		
White only	2193 (72.9%)	83.5%
Black or African American only	715 (23.8%)	8.9%
Other race	78 (2.6%)	4.8%
More than 1 race	22 (0.7%)	1.0%
Hispanic	50 (1.7%)	7.9%
Female, n (%)	1935 (64.3%)	55.9%
Health insurance, n(%)	2988 (99.3%)	99.2%
Private Ins Only	105 (3.5%)	
Medicare/Medicaid only	433 (14.4%)	
Medicare+Private Insurance	2214 (73.6%)	
Military	236 (7.9)	

Participant Characteristics

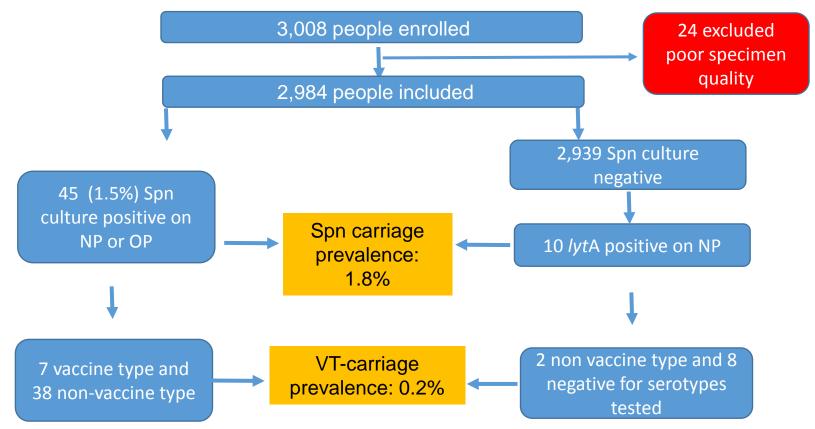
	All sites
	N=3008
# People live in house; mean	
(median)	1.6 (median: 1)
Smoker, n(%)	203 (6.8%)
Live with smoker, n(%)	115 (3.8%)
Any Chronic conditions, n(%)	1196 (39.8%)
Asthma	294 (9.8%)
Cardiovascular disease	582 (19.4%)
Stroke	266 (8.8%)
Diabetes	632 (21.0%)
COPD	219 (7.3%)
Heart failure	155 (5.2%)
Chronic kidney disease (not on	
dialysis)	90 (3.0%)
Illness symptoms, n(%)	
Cough prior 2 weeks, n(%)	641 (21.3%)
Any antibiotics prior 2 weeks, n(%)	128 (4.3%)

Vaccination History

	GA	MD	NY	TN	All sites
	N=1041	N=521	N=760	N=517	N=2839
DC(12 m(0/))	436	285	410	230	1361
PCV13, n(%)	(41.9%)	(54.7%)	(53.9%)	(44.5%)	(47.9%)
PPSV, n(%)*	608	239	552	252	1651
	(58.4%)	(45.9%)	(72.6%)	(48.7%)	(58.2%)

*PPSV coverage likely underestimated

Laboratory Results



Serotypes Detected

Vaccine-type serotype	n
3	1
19A	2
19F	4

Non-vaccine type serotype	n
11A	6
23A	4
23B	4
33F/33A/37	4
9N	3
15A/15F	3
15C	3
7C	2
16F	2
6C	1
10A	1
21	1
28A	1
29	1
31	1
34	1
35B	1
37	1
Negative for serotypes tested	8 16

Carriage by Vaccination Status

	Vaccinated N= 1353	Non-Vaccinated N=1464
Pneumococcal carriage, n(%)*	24 (1.8%)	23 (1.6%)
VT-Pneumococcal carriage, n(%) [‡]	3 (0.2%)	2 (0.1%)

* 8 excluded due to unknown vaccination status * 2 excluded due to unknown vaccination status

Summary

- Pneumococcal carriage prevalence was 1.8%
 - Similar to what was found in UK (2.2%) pre-PCV13 introduction
- PCV13-type pneumococcal carriage was 0.2%
 - PCV13-type carriage in UK prior to PCV13 introduction: 0.5%

Study Implications for 2018 ACIP Policy Review

- Carriage of pneumococcus is rare in adults \geq 65 years of age
- PCV13 types account for only 13% of the pneumococcus detected and 0.2% VT carriage rate regardless of vaccination status
- Low VT-carriage rates:
 - > Herd effects from PCV13 introduction in children
 - Difficult to distinguish between direct vs. indirect of PCV13 on adult carriage

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Thanks!

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