

# Interim Results from the PNEUMO Study

*Pneumococcal pNeumonia Epidemiology, Urine serotyping, and Mental Outcomes study*

February 29, 2024

## Study Leadership

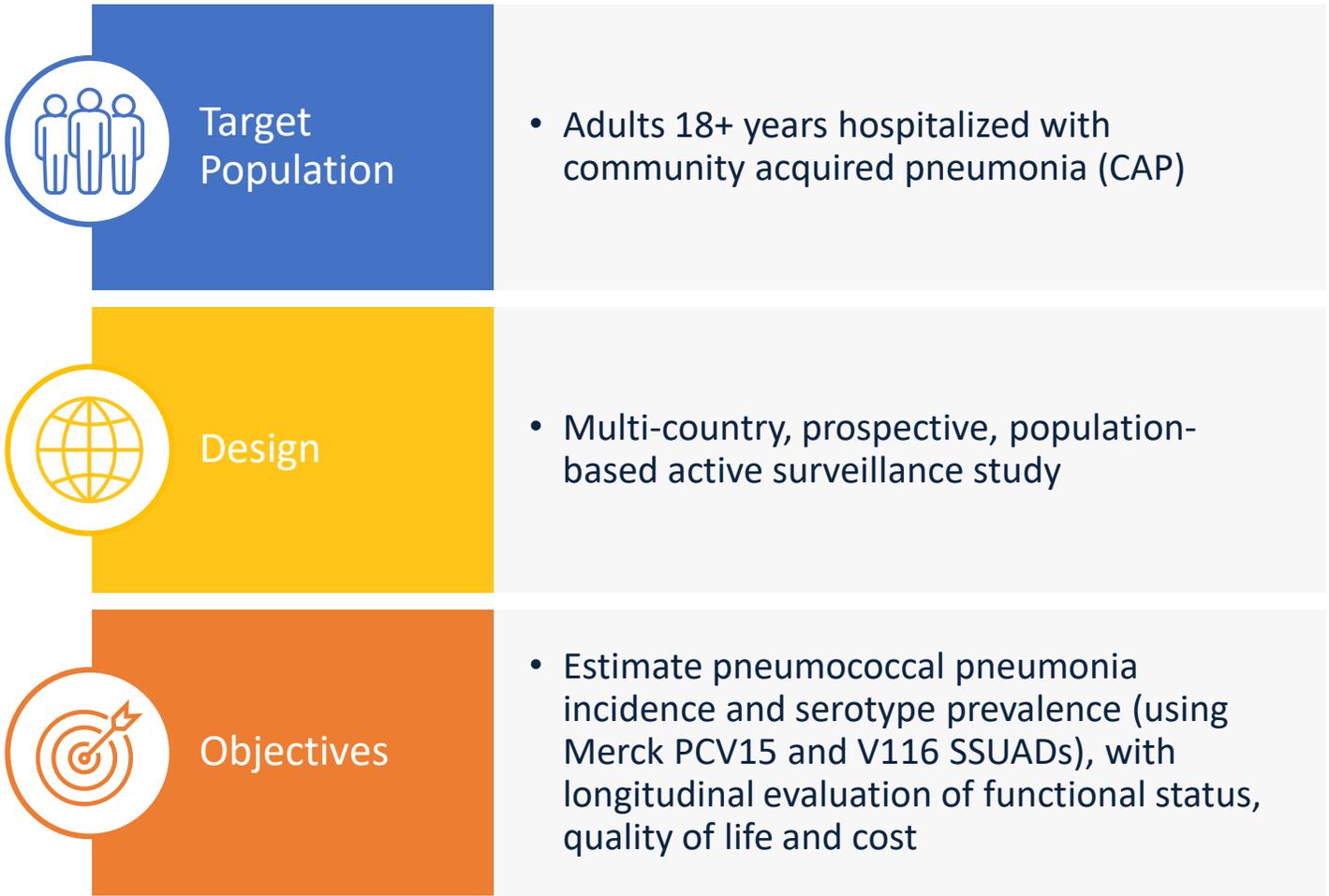
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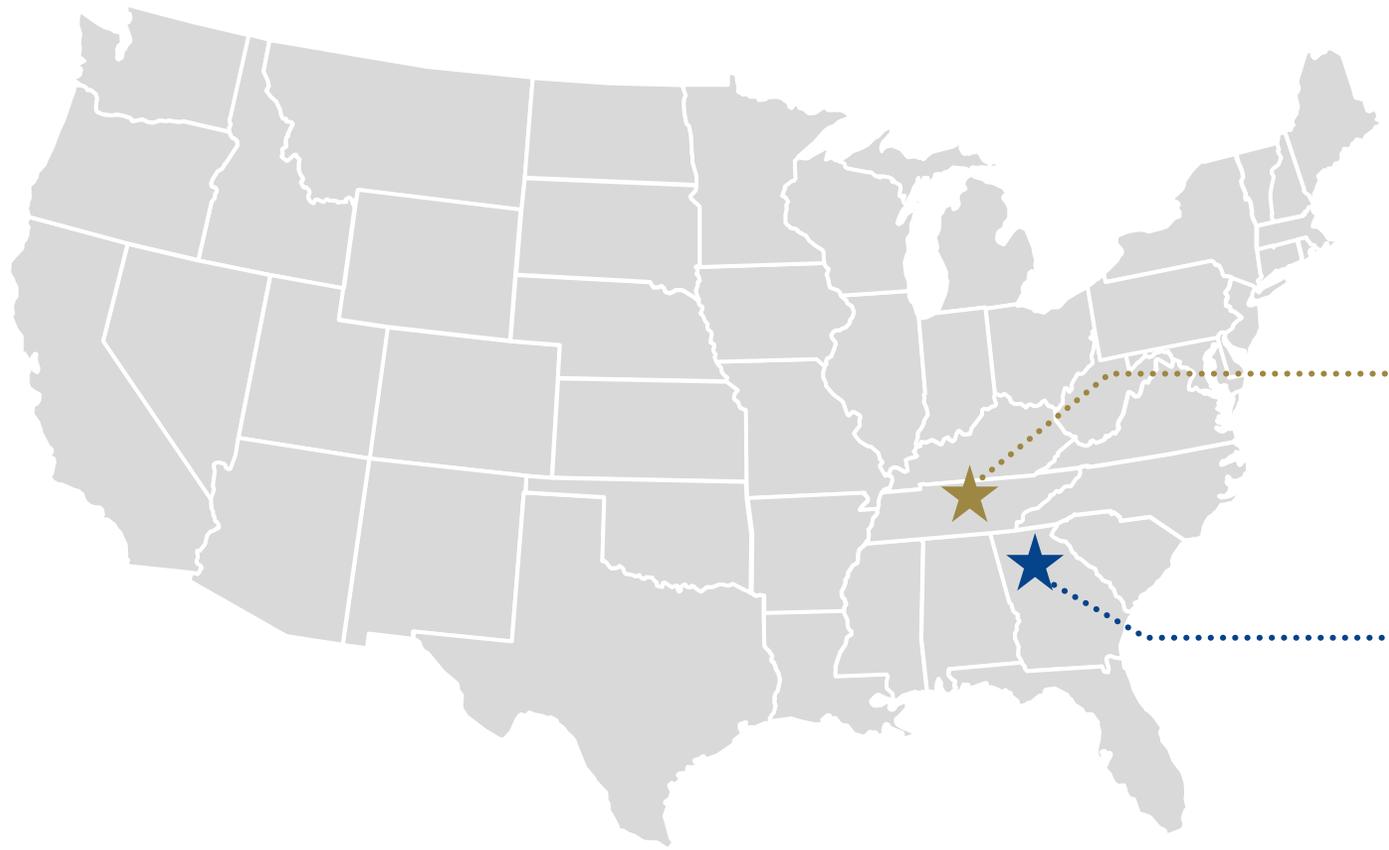
# PNEUMO study overview



- ▶ Incidence hospitalized pneumococcal CAP
  - ▶ Incidence hospitalized PCV15- and V116- type pneumococcal CAP
  - ▶ Direct medical cost
  - ▶ Work loss
  - ▶ Functional status
  - ▶ Cognitive status
  - ▶ Quality of Life (EQ-5D)
- Up to 6 months post-discharge**

# US PNEUMO sites: enrollment Sept 2018 - present

Pneumonia surveillance with prospective, real-time enrollment of adults hospitalized with CAP (including HCAP)



**VANDERBILT**  **UNIVERSITY**  
**MEDICAL CENTER**  
Nashville, Tennessee

 **EMORY**  
**UNIVERSITY**  
**HOSPITAL**  
(2 hospitals) Atlanta, Georgia

HCAP, healthcare associated pneumonia

# Eligibility criteria

## Inclusion Criteria

1. Age  $\geq$  18 years old
2. Hospitalized
3. Clinical signs and/or symptoms of an acute respiratory illness (e.g., new shortness of breath, cough)
4. Clinical signs and/or symptoms of an acute infection (e.g., fever, leukocytosis)
5. Radiologic evidence of pneumonia interpreted by a radiologist (x-ray or CT)

## Exclusion Criteria

1. Prior enrollment in this study within the past 30 days (to avoid multiple enrollments for same episode of pneumonia).
2. Development of pneumonia  $>72$  hours after hospital admission
3. Inability to obtain consent within 72 hours of hospital admission
4. Inability or unwillingness of the patient to provide a urine sample within 72 hours of hospital admission.
5. Non-pneumonia illness completely explains the patient's acute symptoms.

# Tests for *S. pneumoniae*

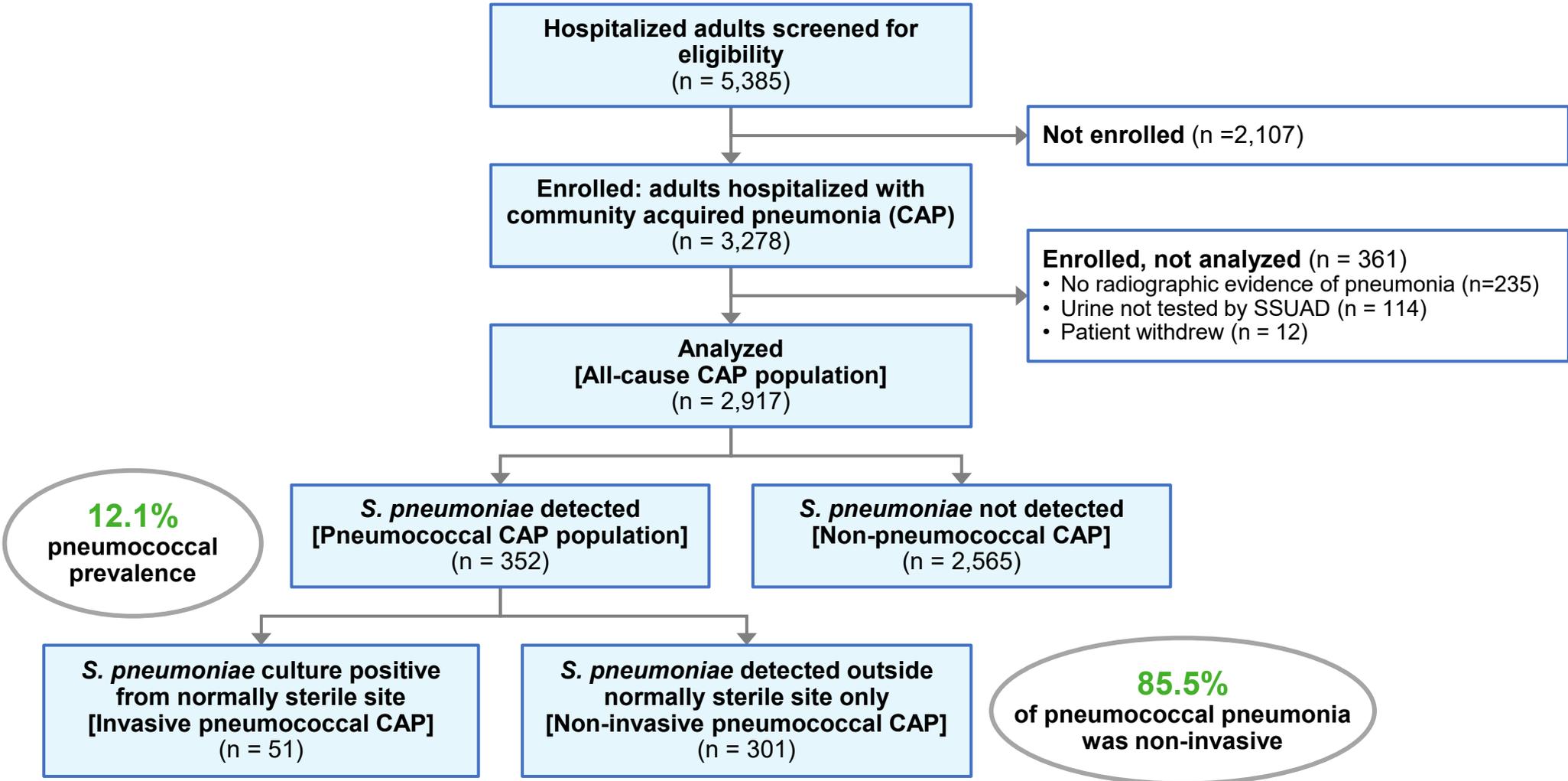
- Urine collection from patients at enrollment
  - (1) BinaxNow pneumococcal urinary antigen test (local testing by research team)
  - (2) Serotype-specific urinary antigen detection (SSUAD) assays:
    - Developed and performed by Merck laboratory
    - 30 serotypes:
      - 1, 3, 4, 5, 6A\*, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15A, 15C#, 16F, 17F, 18C, 19A, 19F, 20A, 22F, 23A, 23B, 23F, 24F, 31, 33F, 35B
        - All serotypes in PCV15, PCV20, and V116 included except 15B
- Results of clinically-obtained bacterial cultures:
  - Sterile sites: blood, pleural fluid, BAL fluid, CSF, synovial fluid
  - Non-sterile sites: high-quality respiratory samples (>25 WBC, <10 epi)
    - sputum, endotracheal aspirate

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\* assay for serotype 6A has cross-reactivity with serotype 6C

# assay for serotype 15C has mild cross-reactivity with serotype 15B

# Enrolled Patients



# Patient Characteristics: Demographics

| Characteristic                      | Pneumonia with<br><i>S. pneumoniae</i> detected<br>(n= 352) | Pneumonia without<br><i>S. pneumoniae</i> detected<br>(n= 2565) | P-value |
|-------------------------------------|---|---|---------|
| Age in years, median (IQR)          | 60.3 (50.6, 70.2)   | 60.5 (46.8, 70.2)   | 0.34    |
| Age category, n (%)                 |   |   | 0.01    |
| 18-49 years                         | 85 (24.1%)  | 767/2564 (29.9%)  |         |
| 50-64 years                         | 141 (40.1%)   | 817/2564 (31.9%)  |         |
| ≥65 years                           | 126 (35.8%)   | 980/2564 (38.2%)  |         |
| Female sex assigned at birth, n (%) | 167/350 (47.7%)   | 1147/2558 (44.8%)   |         |
| Race, n (%)                         |   |   | <0.01   |
| White                               | 198 (56.2%)   | 1771 (69.0%)  |         |
| Black                               | 145 (41.2%)   | 703 (27.4%)   |         |
| Asian                               | 1 (0.3%)  | 38 (1.5%)   |         |
| American Indian/Native Alaskan      | 2 (0.6%)  | 14 (0.5%)   |         |
| Native Hawaiian/Pacific Islander    | 2 (0.6%)  | 6 (0.2%)  |         |
| Other                               | 6 (1.7%)  | 54 (2.1%)   |         |
| Ethnicity, n (%)                    |   |   | 0.95    |
| Not Hispanic                        | 328 (93.2%)   | 2394 (93.3%)  |         |
| Hispanic                            | 14 (4.0%)   | 94 (3.7%)   |         |
| Unknown                             | 10 (2.8%)   | 77 (3.0%)   |         |

# Patient Characteristics: Social History

| Characteristic   | Pneumonia with<br><i>S. pneumoniae</i> detected<br>(n= 352) | Pneumonia without<br><i>S. pneumoniae</i> detected<br>(n= 2565) | P-value |
|--|---|---|---------|
| Type of home before illness, n (%)                                 |   |   | 0.27    |
| Community dwelling   | 320 (90.9%)   | 2382 (92.9%)  |         |
| Nursing Home   | 6 (1.7%)  | 43 (1.7%)   |         |
| Assisted Living  | 6 (1.7%)  | 33 (1.3%)   |         |
| Rehabilitation hospital  | 1 (0.3%)  | 13 (0.5%)   |         |
| School housing   | 0 (0.0%)  | 0 (0.0%)  |         |
| Homeless/shelter   | 12 (3.4%)   | 40 (1.6%)   |         |
| Other  | 3 (0.9%)  | 33 (1.3%)   |         |
| Unknown  | 4 (1.1%)  | 21 (0.8%)   |         |
| Ever regularly smoked tobacco, n (%)                               | 205/349 (58.7%)   | 1232/2554 (48.2%)   | <0.01   |
| Alcohol use >3 days/week, n (%)                                    | 30/348 (8.6%)   | 145/2543 (5.7%)   | 0.03    |
| Use of opioids at least weekly, n (%)                              | 68/339 (20.1%)  | 438/2462 (17.8%)  | 0.31    |
| Interacts with child <5 years old at<br>least once per week, n (%) | 122/340 (35.9%)   | 682/2468 (27.6%)  | <0.01   |
| Lives with children, n (%)   | 83/346 (24.0%)  | 517/2534 (20.4%)  |         |

# Patient Characteristics: Chronic Medical Conditions

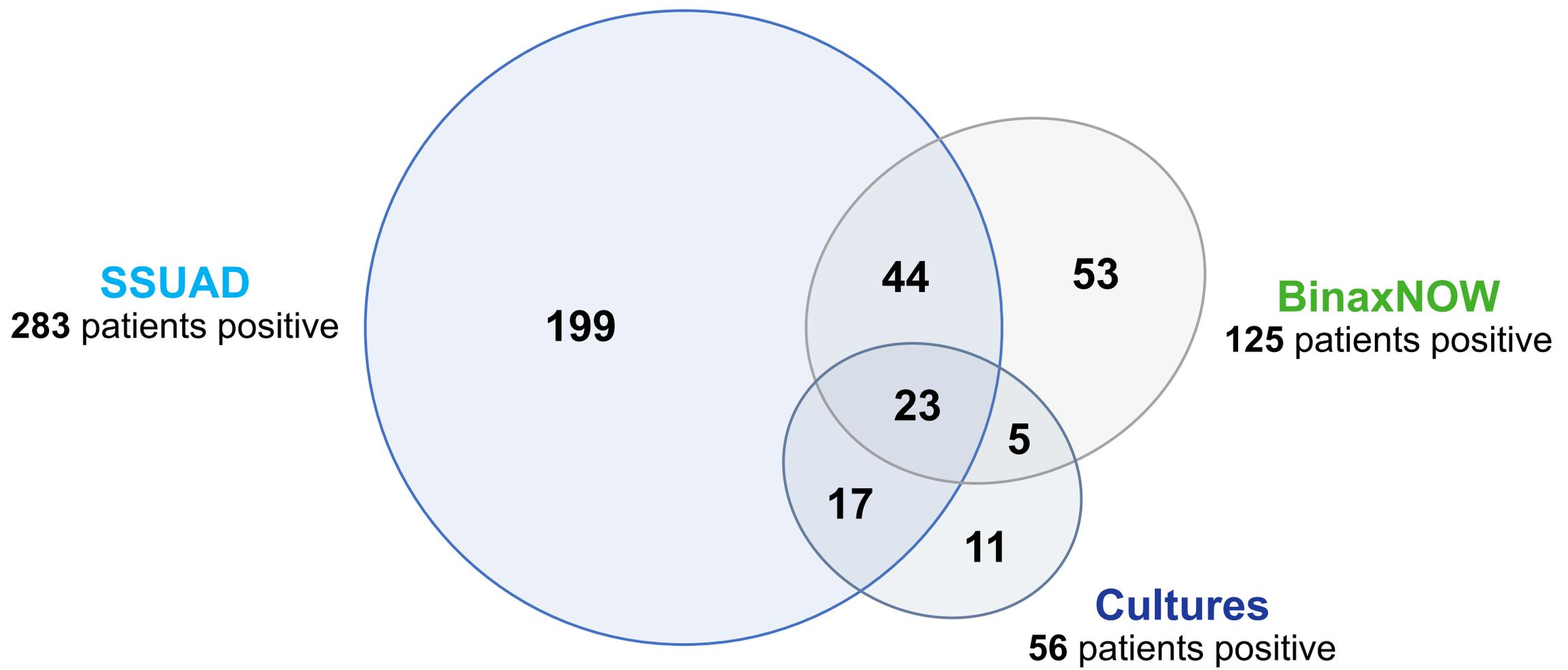
| Characteristic  | Pneumonia with<br><i>S. pneumoniae</i> detected<br>(n= 352) | Pneumonia without<br><i>S. pneumoniae</i> detected<br>(n= 2565) | P-value |
|---|---|---|---------|
| Chronic medical conditions, n (%)                           |   |   |         |
| Dementia  | 11/349 (3.2%)   | 65/2528 (2.6%)  | 0.362   |
| COPD  | 97/346 (28.0%)  | 487/2510 (19.4%)  | <0.001  |
| Asthma  | 72/346 (20.8%)  | 474/2518 (18.8%)  | 0.413   |
| Heart failure   | 61/340 (17.9%)  | 446/2509 (17.8%)  | 0.824   |
| Prior MI  | 37/344 (10.8%)  | 231/2525 (9.1%)   | 0.359   |
| Prior stroke  | 38/347 (11.0%)  | 255/2516 (10.1%)  | 0.651   |
| End stage kidney disease with<br>chronic kidney replacement | 14/342 (4.1%)   | 125/2515 (5.0%)   | 0.424   |
| Diabetes mellitus   | 82/348 (23.6%)  | 684/2525 (27.1%)  | 0.159   |
| Chronic liver disease                                       | 30/343 (8.7%)   | 173/2508 (6.9%)   | 0.254   |
| Immunosuppression   | 72/343 (21.0%)  | 529/2499 (21.2%)  | 0.983   |
| Solid organ cancer  | 80/348 (23.0%)  | 589/2501 (23.6%)  | 0.981   |
| Hematologic cancer  | 30/346 (8.7%)   | 193/2511 (7.7%)   | 0.598   |
| Solid organ transplant                                      | 25/347 (7.2%)   | 205/2528 (8.1%)   | 0.545   |
| Pregnant  | 0/348 (0.0%)  | 22/2533 (0.9%)  | 0.081   |
| Obesity with body mass index<br>>30 kg/m <sup>2</sup>       | 89/355 (25.9%)  | 1009/2479 (40.7%)   | <0.001  |

# Patient Characteristics: Acute Illness

| Characteristic   | Pneumonia with<br><i>S. pneumoniae</i> detected<br>(n= 352) | Pneumonia without<br><i>S. pneumoniae</i> detected<br>(n= 2565) | P-value |
|--|---|---|---------|
| Received antibiotics for current illness before hospitalization, n (%)     | 71/328 (21.6%)  | 613/2297 (26.7%)  | 0.05    |
| Duration of acute illness prior to hospital admission [days], median (IQR) | 2.6 (1.3, 5.0)  | 2.7 (1.1, 5.7)  | 0.36    |
| CURB-65* score at hospital admission, n (%)                                |   |   | 0.17    |
| 0 (low risk)   | 123/345 (35.7%)   | 943/2523 (37.4%)  |         |
| 1 (low risk)   | 126/345 (36.5%)   | 869/2523 (34.4%)  |         |
| 2 (moderate risk)  | 60/345 (17.4%)  | 547/2523 (21.7%)  |         |
| 3 (high risk)  | 31/345 (9.0%)   | 150/2523 (5.9%)   |         |
| 4 (high risk)  | 5/345 (1.4%)  | 14/2523 (0.6%)  |         |
| 5 (high risk)  | 0/345 (0.0%)  | 0/2523 (0.0%)   |         |
| Timing of Enrollment   |   |   | <0.01   |
| Before COVID-19 in US (October 2018 – February 2020)                       | 231/345 (67.0%)   | 1249/2519 (49.6%)   |         |
| After COVID-19 in US (March 2020 – October 2022)                           | 114/345 (33.0%)   | 1270/2519 (50.4%)   |         |

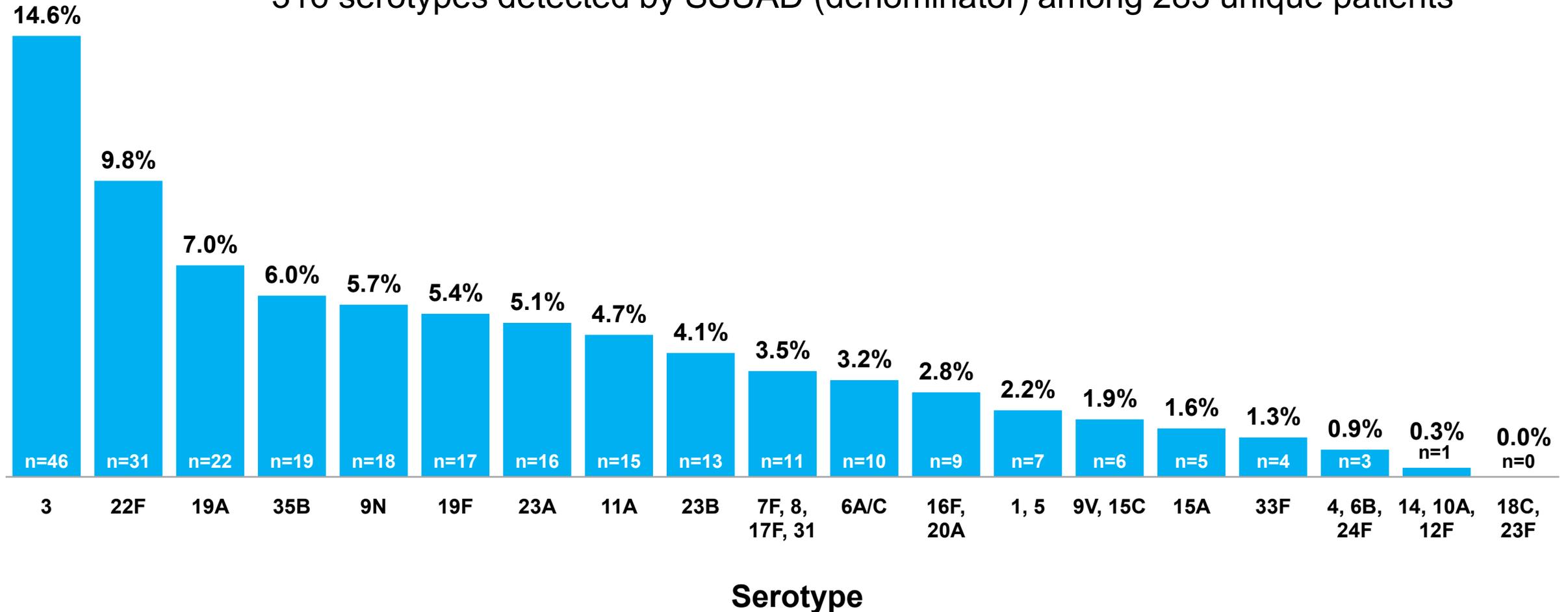
\* CURB-65: pneumonia severity scoring system, consisting of the following variables: confusion, uremia, respiratory rate, blood pressure, age >65

# 352 Patients with $\geq 1$ Positive Pneumococcal Test

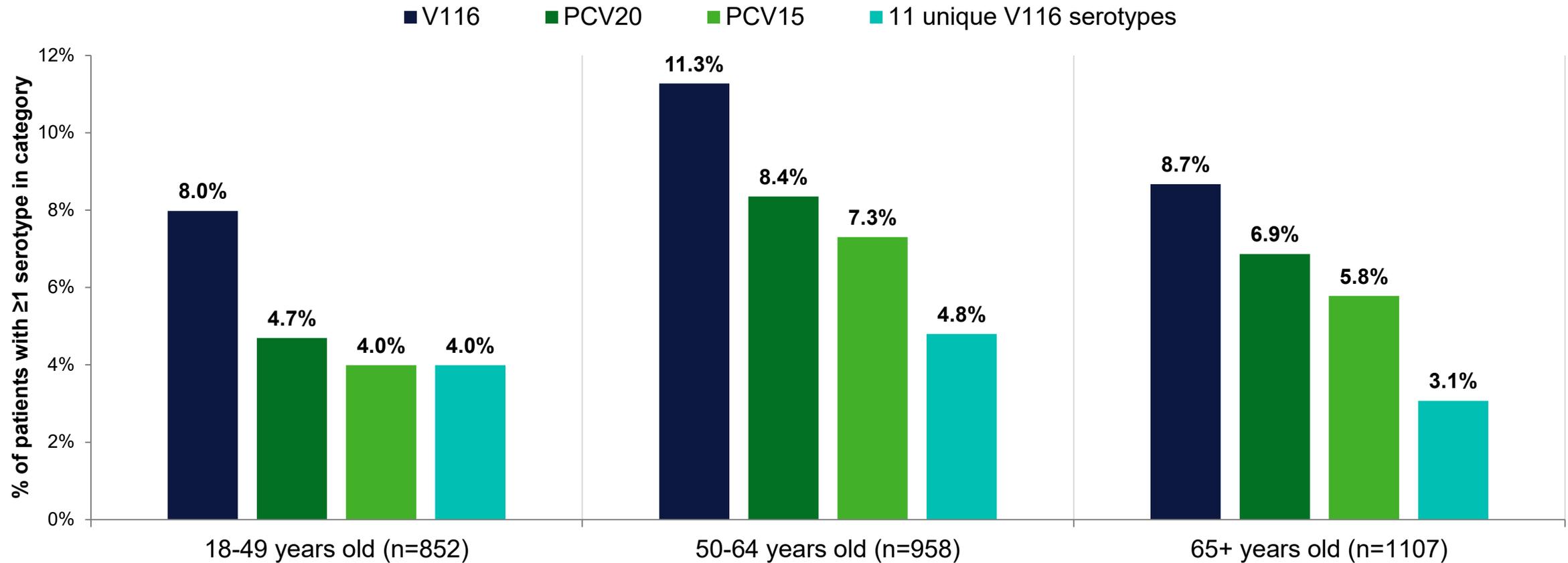


# Percentage of Pneumococcal Serotype Detections

316 serotypes detected by SSUAD (denominator) among 283 unique patients



# Percentage of Pneumococcal Serotype by Vaccine in Adults Hospitalized with CAP



| Vaccine Category                                     | Pneumococcal serotypes  | % of serotypes in adults hospitalized with CAP (n=2917) |
|--|---|---|
| <b>V116</b> (21 serotypes)                           | 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, 35B | <b>9.3%</b>   |
| <b>PCV20</b> (19 serotypes; serotype 15B not tested) | 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 18C, 19A, 19F, 22F, 23F, 33F                  | <b>6.7%</b>   |
| <b>PCV15</b> (15 serotypes)                          | 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F                                    | <b>5.8%</b>   |
| <b>V116 and not PCV15 or PCV20</b> (11 serotypes)    | 9N, 15A, 15C, 16F, 17F, 20A, 23A, 23B, 24F, 31, 35B   | <b>4.1%</b>   |

# Conclusions

- Pneumococcal CAP remains a major cause of adult hospitalizations
- SSUAD assays greatly increase *S. pneumoniae* detection over traditional testing
- Among adults hospitalized with CAP:
  - 12.1% with *S. pneumoniae* detected
  - 9.3% with a pneumococcal serotype in V116
  - 4.1% with a serotype unique to V116 (not PCV15 or PCV20)
    - Most commonly detected serotypes unique to V116: 35B, 9N, 23A, 23B