POST-HOC ANALYSIS OF THE 13-VALENT POLYSACCHARIDE CONJUGATE VACCINE EFFICACY AGAINST VACCINE-SEROTYPE PNEUMOCOCCAL COMMUNITY ACQUIRED PNEUMONIA IN AT-RISE OLDER ADULTS

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Background and Aim
- The Community Acquired Pneumonia Immunization Trial in Adults (CAPiTA) was a randomized, double-blind, placebo-controlled clinical trial with 84,496 subjects randomized.
- CAPiTA demonstrated that vaccination of adults ≥65 years of age with 13-valent pneumococcal polysaccharide conjugate vaccine (PCV13) was efficacious in preventing vaccine-type (VT) Streptococcus pneumoniae community-acquired pneumonia (VT-CAP) and VT invasive pneumococcal disease.\(^1\)
- Public health authorities such as the U.S. Advisory Committee on Immunization Practices have been interested in knowing the performance of PCV13 in populations known to have higher risk of CAP (at-risk).
- The current study is a post-hoc exploratory analysis of PCV13 vaccine efficacy (VE) performed by stratifying participants in CAPiTA by their at-risk status.

Methods
- All participants were asked to complete a questionnaire with a screening list of medical conditions before they received the study vaccine: heart disease, lung disease, asthma, diabetes with insulin use, diabetes without insulin use, liver disease, smoking, and history of splenectomy.
- Self-identified medical conditions were not verified by medical record review.
- Subjects were excluded from this analysis if they self-identified with a history of splenectomy or if participants did not respond to any of the questions in the screening list of the medical conditions form.
- "At-risk" classification was based on at least one of the other self-identified medical conditions.
- Participants without any at-risk condition were classified as "without known-risk."
- Outcomes of interest included PCV13 VE against VT-CAP and against Streptococcus pneumoniae CAP (Sp-CAP) in at-risk and without-known-risk groups.
- The same case definitions (for VT-CAP, Sp-CAP), analyses (per-protocol of first episode), and statistical methods (calculation for VE and confidence interval [CI]) were applied as in the original CAPiTA publication.\(^1\)

Results
- Of the 84,496 participants in the original efficacy analysis, 75 were excluded from the post-hoc analysis. (Table 1)
- Of those included in the current analysis, 41,590 were at-risk and 42,831 were without-known risk. Each group was distributed evenly between PCV13 and placebo groups. (Table 1)
- The prevalence of each self-identified medical condition was: heart disease, 25.4%; diabetes, 12.5%; smoking, 12.3%; lung disease, 10.2%; asthma, 4.9%; liver disease, 0.5%, with similar prevalence in PCV13 and placebo groups.
- VT-CAP was identified in 115 at-risk participants (43 and 72 in the PCV13 and placebo groups, respectively). PCV13 VE: 40.3% (95.2% CI: 11.4%, 60.2%). (Table 3)
- Sp-CAP was identified in 197 at-risk participants (81 and 116 in the PCV13 and placebo groups). PCV13 VE: 30.2% (95%CI: 6.5%, 48.1%). (Table 3)
- VT-CAP was identified in 24 participants without-known-risk (6 and 18 in the PCV13 and placebo groups, respectively). PCV13 VE: 66.7%; (95.2% CI: 11.7%, 89.3%). (Table 3)
- Sp-CAP was identified in 47 participants without-known-risk (19 and 28 in the PCV13 and placebo groups, respectively). PCV13 VE: 32.1% (95%CI:-25.9%,64.2%). (Table 3)

Conflicts of interest:
All authors except MB and HvW were Pfizer employees at the time of this post-hoc analysis and poster development.

References:

Results (cont.)

Table 1. Population Attribution and At-Risk Classification in Post-hoc Analysis of PCV13 Vaccine Efficacy in Adults

<table>
<thead>
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<th></th>
<th>PCV13</th>
<th>Placebo</th>
<th>Total</th>
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<tbody>
<tr>
<td>Participants</td>
<td>42,440</td>
<td>42,256</td>
<td>84,696</td>
</tr>
<tr>
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<td>49.6%</td>
<td>48.8%</td>
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Table 2. Baseline Characteristics of Participants in Post-hoc Analysis of PCV13 Vaccine Efficacy in Adults

Table 3. Post-hoc Analysis of PCV13 Vaccine Efficacy in Adults

Discussion
- In this post-hoc exploratory analysis, there were statistically significant estimates of PCV13 efficacy against VT-CAP and Sp-CAP in participants at-risk, that were overall similar to those estimates for the entire study participants.\(^1\)
- In participants without-known risk, the point estimate of PCV13 efficacy against VT-CAP was higher than in participants at-risk: PCV13 VE: 67.7%; (95.2% CI: 11.7%, 89.3%) vs. 40.3% (95.2% CI: 11.4%, 60.2%).
- PCV13 efficacy against Sp-CAP in participants at-risk was similar to participants without-known risk. However, no statistical significance was observed among the participants without-known risk.

Limitations
- Because of the nature of post-hoc analysis (unplanned up front), results should be seen as exploratory and hypothesis generating.
- Medical conditions were self-reported and lacked medical record verification.
- Medical conditions were not mutually exclusive.
- Study was not designed or powered to estimate VE in sub-populations.

References: