

**Table 2.** Efficacy against first or only HZ episode from 30 days post-dose 2 to study end (post-hoc analysis, mTVC)

RZV Adjuvanted recombinant zoster vaccine group N=259			PL Placebo group N=256			Vaccine efficacy % (95% CI)
No. of confirmed HZ cases	Cumulative follow-up (person-years)	Rate of HZ (cases/1000 person-years)	No. of confirmed HZ cases	Cumulative follow-up (person-years)	Rate of HZ (cases/1000 person-years)	
2	236.1	8.5	14	211.6	66.2	87.20 (44.25-98.59) p = 0.0021

HZ, herpes zoster; N, number of participants in the modified total vaccinated cohort (mTVC), which included all participants from the TVC except those who did not receive the second dose or who developed a confirmed HZ case prior to 30 days post-dose two; CI, confidence interval.

**Table 3.** Reactogenicity and safety (total vaccinated cohort)

Specification	RZV Adjuvanted recombinant zoster vaccine group		PL Placebo group	
	n	% (95% CI)	n	% (95% CI)
<b>Within 7 days after each vaccination (overall/subject)</b>	<b>N=278</b>		<b>N=274</b>	
Any solicited local symptom	233	83.8 (78.9-87.9)	48	17.5 (13.2-22.5)
Grade 3 solicited local symptom	37	13.3 (9.5-17.9)	0	0.0 (0.0-1.3)
Any solicited general symptom	206	74.1 (68.5-79.1)	134	48.9 (42.8-55.0)
Grade 3 solicited general symptom	43	15.5 (11.4-20.3)	17	6.2 (3.7-9.7)
<b>Within 30 days after each vaccination (overall/subject)</b>	<b>N=283</b>		<b>N=279</b>	
Any unsolicited adverse event	134	47.3 (41.4-53.3)	128	45.9 (39.9-51.9)
Considered related by investigator	19	6.7 (4.1-10.3)	5	1.8 (0.6-4.1)
Grade 3 unsolicited adverse event	25	8.8 (5.8-12.8)	28	10.0 (6.8-14.2)
Considered related by investigator	5	1.8 (0.6-4.1)	0	0.0 (0.0-1.3)
<b>From first vaccination up to 1 year post-last dose</b>	<b>N=283</b>		<b>N=279</b>	
Any serious adverse event	66	23.3 (18.5-28.7)	82	29.4 (24.1-35.1)
Considered related by investigator	1	0.4 (0.0-2.0)	1	0.4 (0.0-2.0)
Potential immune-mediated disease	3	1.1 (0.2-3.1)	2	0.7 (0.1-2.6)
Fatal adverse events	29	10.2	37	13.3
Considered related by investigator*	1	0.4	0	0.0

N, number of participants with at least one solicited local or general symptom documented as either present or absent; N', number of participants with at least one administered dose; n (%), number (percentage) of participants reporting an event; CI, confidence interval. The total vaccinated cohort included participants who received at least 1 vaccine/placebo dose.

\*Note: One of the fatal serious adverse events in the RZV group was a case of "death neonatal" (preferred term) which was an event in the offspring of a subject which was vaccinated before estimated pregnancy onset and was assessed by the investigator as causally related to vaccination. During the entire study period, there were two pregnancy outcomes in 1 subject who was negative for pregnancy tests at both vaccination Visits 1 and 2 and exposed to the second dose of RZV prior to estimated pregnancy onset. Both pregnancies resulted in live infants with no congenital anomalies.

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### 150. Relative Effectiveness of High-Dose and Standard-Dose Influenza Vaccine Against Influenza-Related Hospitalization Among Older Adults—United States, 2015–2017

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**Session:** 44. Adult and Adolescent Vaccines

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**Background.** Seasonal influenza causes substantial morbidity and mortality, and older adults are disproportionately affected. Newer vaccines have been developed for use in people 65 years and older, including a trivalent inactivated vaccine with a 4-fold higher dose of antigen (IIV-HD). In recent years, the use of IIV-HD has increased sufficiently to evaluate its effectiveness compared with standard-dose inactivated influenza vaccines (IIV-SD).

**Methods.** Hospitalized patients with acute respiratory illness were enrolled in an observational vaccine effectiveness study at 8 hospitals in 4 states participating in the United States Hospitalized Adult Influenza Vaccine Effectiveness Network during the 2015–2016 and 2016–2017 influenza seasons. Predominant influenza A virus subtypes were H1N1 and H3N2, respectively, during these seasons. All enrolled patients were tested for influenza virus with polymerase chain reaction. Receipt and type of influenza vaccine was determined from electronic records and chart review. Odds of laboratory-confirmed influenza were compared among vaccinated and unvaccinated patients. Relative odds of laboratory-confirmed influenza were determined for patients who received IIV-HD or IIV-SD, and adjusted for potential confounding variables via logistic regression.

**Results.** Among 1,744 enrolled patients aged ≥ 65 years, 1,105 (63%) were vaccinated; among those vaccinated, 621 (56%) received IIV-HD and 484 (44%) received IIV-SD. Overall, 315 (18%) tested positive for influenza, including 97 (6%) who received IIV-HD, 86 (5%) who received IIV-SD, and 132 (8%) who were unvaccinated. Controlling for age, race, sex, enrollment site, date of illness, index of comorbidity, and influenza season, the adjusted odds of influenza among patients vaccinated with IIV-HD vs. IIV-SD were 0.72 ( $P = 0.06$ , 95% CI: 0.52 to 1.01).

**Conclusion.** Comparison of high-dose vs. standard-dose vaccine effectiveness during 2 recent influenza seasons (1 H1N1 and 1 H3N2-predominant) suggested relative benefit (nonsignificant) of high-dose influenza vaccine in protecting against influenza-associated hospitalization among persons aged 65 years and older; additional years of data are needed to confirm this finding.

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### 151. Evaluation of Pneumococcal Vaccine Effectiveness Against Invasive Pneumococcal Disease Among US Medicare Beneficiaries ≥65 Years Old

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**Background.** Pneumococcal conjugate vaccine (PCV13) was recommended in series with PPSV23 for all US adults ≥65 years in late 2014. We evaluated effectiveness of PCV13 against invasive pneumococcal disease (IPD) among Medicare beneficiaries ≥65 years old to assess this new policy.

**Methods.** We linked records for IPD cases (pneumococcus isolated from sterile sites) in persons ≥65 years old identified through Active Bacterial Core surveillance with those of Medicare beneficiaries. Isolates were serotyped and classified as PCV13 (with or without cross-reacting type 6C), and nonvaccine types. We selected Medicare beneficiaries with no record of IPD or pneumonia as controls, and matched to cases on age, residence census tract, and length of Medicare enrollment; we included all eligible controls. Vaccination and medical histories were obtained through Medicare. We estimated vaccine effectiveness (VE) as 1 minus the IPD odds ratio for vaccinated (PCV13) vs. unvaccinated (no PCV13 or PPSV23) persons using conditional logistic regression, adjusted for sex and underlying conditions.

**Results.** From 2,246 IPD cases identified in 2015–2016, 1,017 (45%) were matched to Medicare beneficiaries. After excluding cases in persons residing in long-term care facilities or with <1 year of Medicare enrollment, we included 699 eligible cases and 10,152 controls in our analysis. PCV13-types (+6C) accounted for 164 (23%) cases, and serotype 3 was the most common PCV13-type. Case patients were more likely than controls to have one or more chronic (88% vs. 58%) or immunocompromising (54% vs. 32%) conditions present. Fourteen percent, 22%, and 8% of case patients, and 18%, 21%, and 8% of controls received PCV13 only, PPSV23 only, or both vaccines, respectively. PCV13-only VE against PCV13-types was 36% (95% CI –18, 65%). When we included type 6C with PCV13-types, VE was 67% (95% CI 11, 88%). PCV13 showed similar effectiveness against PCV13 type (+6C) IPD among adults >75 years