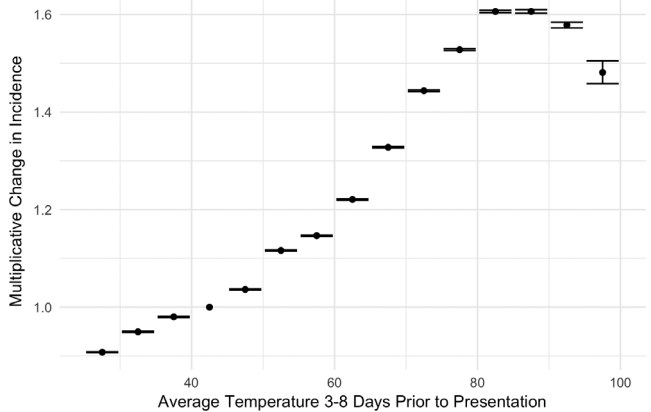


Health MarketScan databases. A total of 192 million person-years of data were included in this dataset and a total of 21,975,244 outpatient claims for UTI were identified by ICD-9 (599.0) and ICD-10 (N39.0) codes. Weather data for each MSA and date were obtained from the National Centers for Environmental Information. We computed the mean temperature during the period 3 to 8 days prior to the service date of the claim. A Poisson generalized linear model was used to estimate the effect of temperature on the count of UTI cases adjusted for MSA size, day-of-week, and week-of-year.

Results. The effect of temperature on UTI risk was significant (likelihood ratio test $P < 0.0001$). Relative to times when the average temperature 3–8 days prior was 40.1–45°F, UTI incidence exhibited a dose–response relationship as shown in the figure.

Conclusion. Incidence of UTIs exhibits a dose–response pattern with temperature during the period 3–8 days prior to presentation. This pattern persists after adjustment for seasonal factors. These results suggest a causal relationship between warm weather, and UTI risk may exist and warrants further investigation.



Disclosures. All authors: No reported disclosures.

128. Sexually Transmitted Infections Among Adolescent Girls in Thika, Kenya

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Session: 33. What's Hot in UTIs and STIs

Thursday, October 4, 2018: 8:45 AM

Background. Globally, the rates of sexually transmitted infections (STIs) are highest among 15- to 24-year-old girls, especially in Sub-Saharan African countries where the adolescent sexual health is poor. Recruiting girls presexual debut could identify risk factors for STI acquisition.

Methods. We recruited a prospective cohort of “low-risk” adolescent girls aged 16–20 in Kenya. To be eligible, girls were HIV and HSV-2 seronegative and reported no history of sexual intercourse or reported having sex with only one partner. Demographic data were collected, and girls had nucleic acid testing of vaginal swabs for *Neisseria gonorrhoea*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*, and vaginal gram stains for bacterial vaginosis (BV).

Results. We enrolled 400 girls, with a median age of 18.6 years. In this cohort, 322 (80.5%) girls reported never having had sex, while 78 (19.5%) reported prior sex with 1 partner. Of those reporting prior sex, only 20 (25.6%) reported contraceptive use in the last 3 months, with 60% using only emergency contraceptive pills. The median age of sexual partners was 22 (IQR 19–25). Of the 373 participants with an STI swab result, 49 participants (13.1%) tested positive for STIs at entry into the study, with 41 chlamydia, 5 gonorrhoea, and 3 trichomonas cases. Of these 49 participants, 33 (67.3%) had denied prior sexual intercourse. Testing positive for STIs was, however, significantly different among those reporting prior sexual intercourse vs. reporting never having had sex, 21.1% vs. 11.1% ($P = 0.02$). BV was rare (5.6%) in the cohort, with 90% of participants with a normal Nugent score of 0–3.

Conclusion. In the initial testing of a sexually inexperienced cohort of girls, we found unexpectedly high numbers of prevalent STIs, especially chlamydia which is not routinely screened for in Kenyan settings. Additionally, lack of sexual activity appeared overreported. BV was rare, with much lower prevalence than in adult women in Africa. Our data suggest that prior to initiation of sexual activity, most girls in this Kenyan cohort have vaginal microflora that is dominated by *Lactobacillus*. Interventions to address STIs, including pre-exposure prophylaxis for HIV, should be targeted at girls at a young age, presexual debut, and in nonmedical settings where girls can be reached who do not self-identify as at risk for STI.

Disclosures. All authors: No reported disclosures.

149. Immunogenicity, Safety, and Post-hoc Efficacy Assessment of the Adjuvanted Recombinant Zoster Vaccine in Adults with Hematologic Malignancies: A Phase 3, Randomized Clinical Trial

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Session: 44. Adult and Adolescent Vaccines

Thursday, October 4, 2018: 10:30 AM

Background. Patients with hematologic malignancies treated with anticancer immunosuppressive therapies (ITs) are at increased risk of herpes zoster (HZ). In a previous report of this phase 3, observer-blind, multicenter trial (NCT01767467), the adjuvanted recombinant zoster vaccine (RZV) was shown to be immunogenic and well-tolerated in ≥18 years of age patients with hematologic malignancies who completed or were undergoing anticancer IT.¹ Here we report end-of-study results from the same trial.

Methods. Participants were randomized 1:1 to receive 2 doses of RZV or placebo (PL) 1–2 months apart, either ≥10 days before or after a cancer therapy cycle, or 10 days to 6 months after cancer therapy ended. Humoral and cell-mediated immune (CMI) responses were evaluated at 1 month and 12 months post-dose 2 (month 2 and month 13, respectively). Confirmatory objectives were to evaluate humoral response rate to RZV and to compare humoral immune responses to RZV and PL at month 2 excluding either subjects with chronic lymphocytic leukemia and non-Hodgkin B-cell lymphoma (NHBL), or only those with NHBL. Efficacy against HZ was explored in a post-hoc analysis of confirmed HZ cases. Solicited and unsolicited adverse events (AEs) were recorded for 7 and 30 days after each dose, respectively. Serious AEs (SAEs) and potential immune-mediated diseases (pIMDs) were recorded throughout the study.

Results. Of the 562 (RZV: 283, PL: 279) treated participants, 415 (RZV: 217, PL: 198)/310 (RZV: 168, PL: 142) were included in the according-to-protocol (ATP) cohort for humoral immunogenicity/immune persistence. The ATP sub-cohort for CMI included 132 (RZV: 69, PL: 63) participants at month 2 and 100 (RZV: 54, PL: 46) at month 13. All confirmatory immunogenicity objectives were met (Table 1). RZV efficacy against HZ, assessed post-hoc, was 87.2% (Table 2). RZV was more reactogenic than PL. The occurrence of unsolicited AEs, SAEs, and pIMDs was similar between the study groups (Table 3).

Conclusion. RZV induced robust humoral and cellular immune responses and showed an effect in the reduction of HZ incidence in patients with hematologic malignancies who completed or were undergoing anticancer IT. No safety concerns were identified.

Reference

1. Oostvogels et al. IDWeek2017, abs 1344.

Table 1. Humoral and cell-mediated immunogenicity of the adjuvanted recombinant zoster vaccine

TP	Population	RZV Adjuvanted recombinant zoster vaccine group		Placebo group	
		N	Value	N	Value
Humoral immunogenicity (adapted ATP cohort for humoral immunogenicity)					
M2	All participants excluding NHBL & CLL	148	80.4 (75.1–86.5)	130	0.8 (0.0–4.2)
	All participants excluding NHBL	184	69.0 (63.8 [†] –75.6)	165	0.6 (0.0–3.3)
	All participants	217	65.4 (58.7–71.7)	198	0.5 (0.0–2.8)
	Adjusted [†] GMC miU/mL (95% CI)	148	2332.9 (1642.9–3215.9)	130	777.6 (702.8–860.3)
	All participants excluding NHBL	184	772.0 (535.6–1133.9)	165	856.0 (775.7–944.5)
	All participants excluding NHBL & CLL		29.75 (21.09 [†] –41.96); p<0.0001		9.02 (6.18 [†] –13.17); p<0.0001
M13	GMC, miU/mL (95% CI)	217	1344.6 (1015.8–1775.6)	198	832.0 (701.1–987.3)
	VRR, % (95% CI)	165	52.1 (44.2–59.9)	140	3.6 (1.2–8.1)
	GMC, miU/mL (95% CI)	167	5202.7 (4074.9–6642.8)	142	895.4 (734.5–1091.5)
Cell-mediated immunogenicity (adapted ATP sub-cohort for CMI)					
M2	VRR, % (95% CI)	43	83.7 (69.3–93.2)	44	6.8 (1.4–18.7)
	Frequency of gE-specific CD4 ⁺ T cells, Median (IQR)	53	3081.9 (1766.2–7413.6)	50	99.1 (1.0–268.3)
	VRR, % (95% CI)	33	66.7 (48.2–82.0)	31	6.5 (0.8–21.4)
M13	Frequency of gE-specific CD4 ⁺ T cells, Median (IQR)	44	1006.7 (416.0–3284.5)	36	66.1 (1.0–161.9)

TP, time point; ATP, according-to-protocol; CMI, cell-mediated immunogenicity; GMC, anti-glycoprotein E (gE) antibody geometric mean concentration; [†] adjusted for baseline values; N, number of participants with available results; %, percentage of participants; NHBL, participants with non-Hodgkin B-cell lymphoma; CLL, participants with chronic lymphocytic leukemia; CI, confidence interval; IU, international units; CD4⁺ CD4⁺ T cells producing at least two of the four activation markers assessed (IFN- γ , IL-2, TNF- γ , and CD40 Ligand) upon in vitro stimulation with the antigen; IQR, interquartile range; VRR, vaccine response rate; VR for humoral, for initially seronegative participants, antibody concentration at post-vaccination 24-fold the cut-off for anti-gE (97 miU/mL); for initially seropositive participants, antibody concentration at post-vaccination 24-fold the pre-vaccination antibody concentration; VR for CMI, for participants with pre-vaccination T-cell frequencies below the threshold, 32-fold increase as compared to the threshold (320 Positive cells/10⁶ CD4⁺ T cells); for participants with pre-vaccination T cell frequencies above the threshold, 2-fold increase as compared to pre-vaccination T-cell frequencies.

[†]Co-primary and ^{††}secondary immunogenicity objectives met. a: [] the lower limit [L] of 95% CI for humoral VRR in the RZV group 265%; [] LL of 95% CI for adjusted GMC ratio (RZV/Placebo) 33.

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)
Within 7 days after each vaccination (overall/subject)	N=278		N=274	
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)
Within 30 days after each vaccination (overall/subject)	N=283		N=279	
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)
From first vaccination up to 1 year post-last dose	N=283		N=279	
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.

Funding. GlaxoSmithKline Biologicals SA.

Disclosures. A. F. Dagnew, GSK: Employee and Shareholder, Salary. J. Murphy, GSK: Investigator, Research support. S. A. McNeil, GSK group of companies: Grant Investigator, Research grant and Research support. B. Salau, GSK group of companies: Employee and Shareholder, Salary. E. Di Paolo, GSK group of companies: Employee, Salary. L. Campora, GSK group of companies: Employee and Shareholder, Salary. M. López-Fauqued, GSK group of companies: Employee, Salary. M. El Idrissi, GSK group of companies: Employee, Salary. A. Schuind, GSK: Employee, Salary. T. C. Heineman, GSK group of companies: Consultant, Employee and Shareholder, Consulting fee and Salary. P. Van Den Steen, GSK: Employee and Shareholder, Restricted shares and Salary. L. Oostvogels, GSK: Employee, Salary and Stock and stock options.

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

Thursday, October 4, 2018: 10:30 AM

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.

Disclosures. H. K. Talbot, sanofi pasteur: Investigator, Research grant. Gilead: Investigator, Research grant. MedImmune: Investigator, Research grant. Vaxinate: Safety Board, none. Seqirus: Safety Board, none.

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

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Session: 44. Adult and Adolescent Vaccines

Thursday, October 4, 2018: 10:30 AM

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