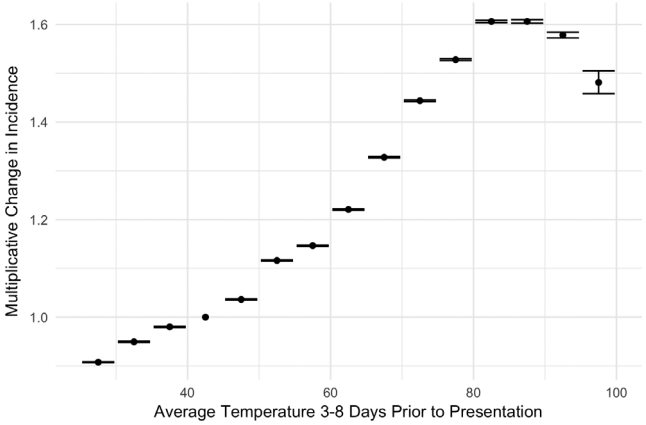
Health MarketScan databases. A total of 192 million person-years of data were included in this dataset and a total of 21,975,244 outpatient claims for UTI were identified by ICD-9 (599.0) and ICD-10 (N39.0) codes. Weather data for each MSA and date were obtained from the National Centers for Environmental 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 gonorrhea*, *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 contraception 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 gonorrhea, 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 selfidentify 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
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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 (NHBCL), or only those with NHBCL. 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 Placebo group	
			N	Value	N	Value
Humoral immunogenicity (adapted ATP cohort for humoral immunogenicity)						
M2	VRR, % (95% CI)	All participants excluding NHBCL & CLL	148	80.4 (73.1[K]–86.5)	130	0.8 (0.0–4.2)
		All participants excluding NHBCL	184	69.0 (61.8[KN]–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)	All participants excluding NHBCL & CLL	148	23132.9 (16642.8–32153.9)	130	777.6 (702.8–860.3)
		All participants excluding NHBCL	184	7722.0 (5355.6–11133.9)	165	856.0 (775.7–944.5)
	Adjusted* GMC ratio (RZV/placebo)	All participants excluding NHBCL & CLL	29.75 (21.09[K]–41.96); p<0.0001			
		All participants excluding NHBCL	9.02 (6.18[KN]–13.17); p<0.0001			
	GMC, mIU/mL (95% CI)	All participants	217	13445.6 (10158.9–17795.6)	198	832.0 (701.1–987.3)
M13	VRR, % (95% CI)	All participants	165	52.1 (44.2–59.9)	140	3.6 (1.2–8.1)
	GMC, mIU/mL (95% CI)	All participants	167	5202.7 (4074.8–6642.8)	142	895.4 (734.5–1091.5)
Cell-mediated immunogenicity (adapted ATP sub-cohort for CMI)						
M2	VRR, % (95% CI)	All participants	43	83.7 (69.3–93.2)	44	6.8 (1.4–18.7)
	Frequency of gE-specific CD4[2+] T cells, Median (IQR)	All participants	53	3081.9 (1766.2–7413.6)	50	99.1 (1.0–268.3)
M13	VRR, % (95% CI)	All participants	33	66.7 (48.2–82.0)	31	6.5 (0.8–21.4)
	Frequency of gE-specific CD4[2+] T cells, Median (IQR)	All participants	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; **NHBCL,** participants with non-Hodgkin B-cell lymphoma; **CLL,** participants with chronic lymphocytic leukemia; **CI,** confidence interval; **IU,** international units; **CD4[2+],** CD4+ T cells producing at least two of the four activation markers assessed (IFN-γ, IL-2, TNF-α, 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 ≥4-fold the cut-off for anti-gE (97 mIU/ml); for initially seropositive participants, antibody concentration at post-vaccination ≥4-fold the pre-vaccination antibody concentration; **VR for CMI,** for participants with pre-vaccination T-cell frequencies below the threshold, ≥2-fold increase as compared to the threshold (320 Positive cells/10^6 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.
[K,N]Co-primary and [KN,KN]secondary immunogenicity objectives met, as: [i] the lower limit [LL] of 95% CI for humoral VRR in the RZV group ≥60%; [ii] LL of 95% CI for adjusted GMC ratio [RZV/Placebo] >3.