Results. Humoral and CMI in the RZV group persisted through M13 appearing higher in the RZV group vs. placebo (Table 1). The frequency of solicited local AEs and of general AEs myalgia and fever was higher in the RZV group vs. placebo and balanced between study groups for the other general AEs, pIMDs and SAEs (including allograft rejections) (Table 2, Figure 1). No concerns regarding renal function were reported. Suspected HZ cases were recorded among 2 RZV and 6 placebo recipients. In the RZV group, within-participant pre- and post-vaccination solicited general AEs were reported at similar rates for fatigue, gastrointestinal symptoms and headache, and higher rates post-vaccination for myalgia, shivering, and fever (Figure 1).

Conclusion. RZV was highly immunogenic, eliciting robust humoral and CMI that persisted up to 12 months in adult renal transplant recipients. No safety concerns were identified over a 1-year follow-up.

Reference

1. de la Serna, BMT Tandem Meeting 2018, abs LBA2.

Funding: GlaxoSmithKline Biologicals SA

Table 1. Humoral and cellular immune responses at M2 and M13 (according-to-protocol cohort)

	RZV		Placebo		Adjusted ratio RZV:placebo
	N	Value	N	Value	
Humoral immune response (anti-gE antibody geometric mean concentration), mIU/mL (95% CI)					
Pre-vaccination	121	1354.4 (1118.3–1640.4)	119	1495.7 (1202.3–1860.8)	
Month 2	121	19163.8 (15041.5–24416.0)	119	1489.4 (1215.8–1824.7)	–
Month 13	111	8545.1 (6753.7–10811.5)	111	1572.7 (1269.6–1948.1)	–
Humoral vaccine response rate#, % (95% CI)					
Month 2	121	80.2 (**71.9**–86.9)	119	4.2 (1.4–9.5)	–
Month 13	111	66.7 (57.1–75.3)	109	6.4 (2.6–12.8)	–
Cell-mediated immune response (mean CD4⁺T-cell frequencies) (±SD)					
Pre-vaccination	31	110.9 (±182.1)	30	165.8 (±242.9)	–
Month 2	32	2433.1 (±2102.3)	31	157.0 (±274.8)	
Month 13	33	1320.9 (±1823.6)	31	129.4 (±197.9)	–
Cell-mediated immune vaccine response rate#, % (95% CI)*					
Month 2	28	71.4 (**51.3**–86.8)	28	0.0 (0.0–12.3)	–
Month 13	30	56.7 (37.4–74.5)	27	0.0 (0.0–12.8)	–
Adjusted humoral immune response (anti-gE antibody geometric mean concentration), mIU/ml (95% CI)**					
Month 2	121	19983.3 (15779.7–25306.7)	119	1427.3 (1310.0–1555.2)	14.0 (**10.9**–18.0) p <0.0001
Adjusted cell-mediated immune response (CD4⁺T-cell frequencies geometric mean), (95% CI)**					
Month 2	28	1440.5 (1044.4–1959.6)	28	83.5 (8.6–181.5)	17.3 (**5.9**–50.4) p <0.0001

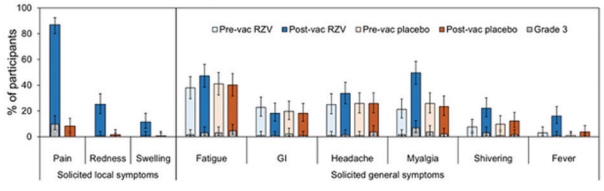
Month 2 & 13 (1 & 12 month[s] after last vaccination); N, number of participants with available results; CI, confidence interval; IU, international units. **Bolded values** indicate that success criteria were met for primary immunogenicity objective (lower limit of 95% CI ≥60% for humoral VRR) and secondary immunogenicity objectives (lower limit of 95% CI ≥50% for cell-mediated VRR, >3 for humoral GM ratio, and >1 for cell-mediated GM ratio).
*for the inferential analysis, the frequency of CD4⁺ T cells producing ≥2 activation markers from among IFN-γ, IL2, TNFα, and CD40 Ligand per 10^6 CD4⁺ T cells; **adjusted for baseline values. #Vaccine responses: (i) for humoral immune response: (a) in initially seronegative participants, a post-vaccination antibody concentrations ≥4-fold the cut-off for anti-glycoprotein E (gE) (4x97 mIU/ml); (b) in initially seropositive participants, a post-vaccination antibody concentration ≥4-fold the pre-vaccination antibody concentration; (ii) for cell-mediated immune response: (a) in participants with initial pre-vaccination T-cell frequencies below the cut-off ($320/10^6$ CD4⁺ T cells), a post-vaccination T-cell frequencies ≥2-fold the cut-off ($2x320/10^6$ CD4⁺ T cells); (b) in participants with initial pre-vaccination T-cell frequencies above the cut-off, a post-vaccination T-cell frequencies ≥2-fold the pre-vaccination T-cell frequencies.

Table 2. Incidence of unsolicited AEs, SAEs, pIMDs and suspected HZ cases (TVC, overall/participant)

AEs			n (%) RZV N=132	n (%) Placebo N=132	Reporting period
Unsolicited AEs	All	Any grade	9 (6.8%)	7 (5.3%)	7 days before first vaccination
		Grade 3	0 (0.0%)	0 (0.0%)	
	All	Any grade	51 (38.6%)	44 (33.3%)	30 days after each vaccination
		Grade 3	7 (5.3%)	5 (3.8%)	
	Related	Any grade	7 (5.3%)	3 (2.3%)	
		Grade 3	1 (0.8%)	0 (0.0%)	
	With medically attended visits		34 (25.8%)	29 (22.0%)	
SAEs	All		26 (19.7%)	33 (25.0%)	First vaccination up to study end
	Related		0 (0.0%)	1 (0.8%)	
	Fatal		1 (0.8%)	1 (0.8%)	
	Biopsy-confirmed allograft rejections		4 (3.0%)	7 (5.3%)	
pIMDs	All		4 (3.0%)	2 (1.5%)	
Suspected HZ cases	All (post 1 or 2 doses)		3 (2.3%)	7 (5.3%)	
	In participants post 2 doses		2 (1.5%)	6 (4.5%)	Second vaccination up to study end

TVC, total vaccinated cohort; AE, adverse event; n (%), number (percentage) of participants with at least one AE; SAE, serious AE; pIMD, potential immune-mediated disease; HZ, herpes zoster; N, number of participants with ≥1 one administered dose; grade 3, preventing normal activity; related, causally related to vaccination per investigator assessment.

Figure 1. Solicited local and general AEs reported within 7 days pre-vaccination and post each dose (TVC, overall/participant)



TVC, total vaccinated cohort; pre-vac, pre-vaccination adverse events (AEs); post-vac, post-vaccination AEs; GI, gastrointestinal symptoms (nausea, vomiting, diarrhea and/or abdominal pain); grade 3, preventing normal activity (for fatigue, GI, headache, myalgia, shivering), significant pain at rest and preventing normal everyday activities (for pain), having a surface diameter >100 mm (for injection site redness and swelling); for fever, oral temperature >39.0 °C was represented.

Disclosures. **P. Vink**, GSK group of companies: Employee and Shareholder, Salary and stock shares. **S. J. Kim**, GSK group of companies: Investigator, Research grant and Research support. **M. Campins Marti**, GSK group of companies: Consultant, Investigator, Scientific Advisor and Speaker's Bureau, Consulting fee, Research grant and Speaker honorarium. **D. Kumar**, GSK group of companies: Scientific Advisor, Consulting fee. **K. Doucette**, GSK group of companies: Investigator, Research support. **S. A. McNeil**, GSK group of companies: Grant Investigator, Research grant and Research support. **L. Campora**, GSK group of companies: Employee and Shareholder, Salary. **E. Di Paolo**, GSK group of companies: Employee, Salary. **M. El Idrissi**, GSK group of companies: Employee, Salary. **M. López-Fauqued**, GSK group of companies: Employee, Salary. **B. Salaun**, GSK group of companies: Employee and Shareholder, Salary. **T. Heineman**, GSK group of companies: Consultant, Employee and Shareholder, Consulting fee and Salary. **L. Oostvogels**, GSK group of companies: Employee, Salary and stock and stock option.

2484. Pre-Transplant Vaccination Adherence in Pediatric Solid Organ Transplant Patients at a Large Academic Medical Center

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Session: 254. Vaccines for the Elderly and Immune Compromised
Saturday, October 6, 2018: 12:30 PM

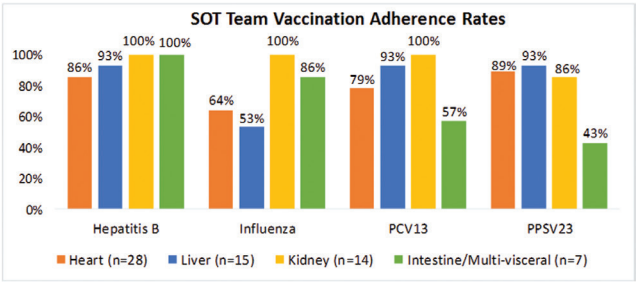
Background. Adherence rates for recommended pre-transplant (pre-txp) vaccinations in pediatric solid-organ transplant (SOT) patients are variable and practice-dependent. Cleveland Clinic Children's Hospital (CCCH) pre-txp adherence rates for select vaccines have not been described. The purpose of this study was to evaluate pre-txp adherence rates for the following vaccines: hepatitis B, influenza, pneumococcal conjugate (PCV13), pneumococcal polysaccharide (PPSV23), and hepatitis A (if at-risk).

Methods. This retrospective cohort study included patients undergoing initial pediatric heart, kidney, liver, or intestine/multi-visceral transplant at CCCH between 1/1/14 and 7/31/17. Data collected from the electronic medical record and Ohio Department of Health Statewide Immunization Information System included demographics, transplant-related data, immunization administration history, and quantitative/qualitative values for titer/serology. The primary objective of vaccination adherence rate was defined as the aggregate of patients who had completed the vaccine series, had positive titer/serology data, or were ineligible to receive the vaccine due to age or administration restrictions. Data are descriptive in nature and reported as number (percent) or median (interquartile range), as appropriate.

Results. 64 pediatric SOT recipients met inclusion criteria. Median age was 7.9 (2.1, 15.8) years. Majority of patients were American (73%) and male (63%). Most common organ was heart (41%), followed by liver (25%), kidney (21%), and intestine/multi-visceral (13%). Sixty-three (98%) patients underwent ID pre-txp evaluation. CCCH adherence rates were highest for hepatitis B at 92%, followed by PCV13 and PPSV23 at 84%, and influenza at 72%. Thirty-two (50%) patients were indicated to receive the hepatitis A vaccine and the respective adherence rate was 91%. Vaccination adherence by SOT team is described in Figure 1.

Conclusion. CCCH pre-txp vaccination adherence rates are higher than previously reported. Opportunities for improvement include influenza vaccination adherence across all SOT teams and PCV13/PPSV23 vaccination adherence in intestine/multi-visceral transplant patients.

Figure 1: CCCH SOT team vaccination adherence rates.



Disclosures. **All authors:** No reported disclosures.

2485. Circulating T Follicular Helper Cells and Immune Response Induced by Influenza Vaccine in Children With Acute Lymphoblastic Leukemia During Maintenance Therapy

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