and race/ethnicity was estimated using Cox regression models controlling for age and adjusting for healthcare use, comorbidities and immunocompromise status.

Results. During 2007–2014, 1,355,720 individuals entered the study, including 724,283 (53.4%) females. Among the unvaccinated, the incidence rate of HZ was 7.5 and 10.2 cases per 1,000 person-years (PY) among males and females, respectively. VE was 51.6% [95% CI: 49.2, 53.9] in males and 47.7% [45.8, 49.6] in females. The study included 818,361 (60.4%) Whites, 208,248 (15.4%) Asian/Pacific Islanders, 171,949 (12.7%) Hispanics, 98,914 (7.3%) African Americans, and 58,248 (4.3%) with Other/Unknown race/ethnic group. HZ incidence among the unvaccinated was highest among Hispanics (10.1 per 1,000 PY) and lowest among African Americans (6.7 per 1,000 PY). VE was somewhat higher among Hispanics (57.0% [52.7, 61.0]) compared with Whites (48.1% [46.3, 49.9], Asian/Pacific Islanders (49.7% [46.0, 53.3]), and African Americans (50.5% [42.3, 57.6]).

Conclusion. Overall, VE against HZ was generally similar across sex and race/ethnic groups, except for a somewhat higher VE among Hispanics. This small difference in VE may be due to differences in time since vaccination, since VE tends to wane over time (e.g., average follow-up was 2.2 years for vaccinated Hispanics vs. 2.8 for Whites, resulting in Hispanics having relatively more follow-up closer to vaccination when VE is higher). Longer study follow-up may help to interpret these findings.

Disclosures. **M. A. Marks**, Merck and Co. Inc.: Employee and Shareholder, Salary. **P. Saddier**, Merck and Co. Inc.: Employee and Shareholder, Salary. **N. P. Klein**, Sanofi Pasteur: Investigator, Research grant. Merck: Investigator, Research grant. GSK: Investigator, Research grant. Pfizer: Investigator, Research support. Protein Science: Investigator, Research grant. MedImmune: Investigator, Research grant. Dynavax: Research Contractor, Grant recipient.

2482. Impact of a Recombinant Zoster Vaccine on Quality of Life: Data from a Randomized, Placebo-Controlled, Phase 3 Trial in Adult Hematopoietic Stem Cell Transplant Recipients

Desmond Curran, PhD[1]; Achilles Anagnostopoulos, MD[2]; Ibrahim Barista, MD[3]; Adriana Bastidas, PhD[1]; Pranatharthi Chandrasekar, MD[4]; Michael Dickinson, MBBS FRACP FRCPA DMED SCI[5]; Inmaculada Heras, PhD[6]; Mohamed El Idrissi, MSc[7]; Sean Matthews, MSc[8]; Samuel Milliken, MBBS FRACP FRCPA[9]; Jorge Monserrat Coll, MD[10]; Maria Belen Navarro Matilla, MA, MBBS[11]; Lidia Oostvogels, MD[12]; Dimas Quiel, MD[13]; Scott Rowley, MD[14]; Waleed Sabry, MD MSc Doctorate in Hematology[15]; Dominik Selleslag, MD[16]; Jeff Szer, MB BS FRACP[17]; Koen Theunissen, MD[18]; Zeynep Arzu Yegin, Assoc. Prof.[19]; Su-Peng Yeh, MD[20]; Jo-Anne Young, MD[21]; Francesco Zaja, MD[22] and Beata Piatkowska-Jakubas On Behalf Of The Zoe-Hsct Study Group, MD PhD Assoc. Prof.[23]; [1]GSK, Wavre, Belgium, [2]George Papanikolaou Hospital, Thessaloniki, Greece, [3]Hacettepe University Medical Faculty, Ankara, Turkey, [4]Infectious Diseases, Wayne State University, Detroit, Michigan, [5]Peter MacCallum Cancer Centre, Melbourne, Australia, [6]Hospital General Universitario J.M. Morales Meseguer, Murcia, Spain, [7]GSK, Rixensart, Belgium, [8]Freelance c/o GSK, Wavre, Belgium, [9]St Vincent's Hospital, Sydney, Australia, [10]Hospital Clínico Universitario Virgen de la Arrixaca, Murcia, Spain, [11]Hospital Universitario Puerta de Hierro, Madrid, Spain, [12]CureVac AG, Tübingen, Germany, [13]Complejo Hospitalario Dr. Arnulfo Arias Madrid, Panama, Panama, [14]Hackensack University Medical Center, Hackensack, New Jersey, [15]Saskatoon Cancer Center, Saskatoon, SK, Canada, [16]A.Z. Sint-Jan, Brugge, Belgium, [17]Royal Melbourne Hospital, Melbourne, Australia, [18]Jessa Ziekenhuis - Campus Virga Jesse, Hasselt, Belgium, [19]Gazi University School of Medicine, Ankara, Turkey, [20]China Medical University Hospital, Taichung, Taiwan, [21]University of Minnesota, Minneapolis, Minnesota, [22]Azienda Ospedaliero Universitaria S. Maria Misericordia, Udine, Italy, [23]Jagiellonian University Medical College, Cracow, Poland

Session: 253. Vaccines for Herpes Zoster Virus
Saturday, October 6, 2018: 12:30 PM

Background. Herpes zoster (HZ) and its complications can have a substantial impact on patients' quality of life (QoL), particularly in immunocompromised patients. The vaccine efficacy (VE) of an adjuvanted recombinant zoster vaccine (RZV) was studied in a randomized, placebo-controlled, phase 3 study in adult hematopoietic stem cell transplant (HSCT) recipients (NCT01610414). The VE in preventing HZ cases was 68.2% (95% CI: 55.6%–77.5%). Herein we report the impact of the vaccine on patients' quality of life (QoL) associated with HZ episodes.

Methods. HSCT recipients were randomized 1:1 to receive 2 doses of RZV or placebo, given 1–2 months apart and followed for the occurrence of HZ. QoL parameters were measured by the Short-Form health survey (SF-36) and Euro-Quality of Life-5 Dimension (EQ-5D) at baseline, 1 month and 1 year post-dose 2, as well as during suspected HZ episodes in conjunction with the Zoster Brief Pain Inventory (ZBPI). For confirmed HZ cases, QoL scores were compared between the vaccine and placebo groups. The RZV impact in reducing the ZBPI Burden of Illness and Burden of Interference scores was estimated in patients in the modified total vaccinated cohort (mTVC). The 2 scores were calculated from the area under the curve (Days 0 to 182) of the ZBPI Worst Pain and ZBPI Activities of Daily Living scores, respectively, assuming a score of 0 for patients who did not have a confirmed HZ episode.

Results. Both the ZBPI maximum Worst Pain and Average Pain scores were significantly lower in the vaccine than placebo group (Table 1), suggesting less burden in breakthrough HZ cases following RZV. Consequently, the HZ Burden of Illness and Burden of Interference VE estimates were higher than the HZ VE estimate. RZV showed statistically significantly better QoL scores than placebo one week following rash-onset among patients with confirmed HZ, i.e., SF-36 bodily pain, social functioning, role emotional, mental health and mental component scores, and the EQ-5D Utility Score.

Table 1. Analysis of ZBPI questionnaire (mTVC)

	RZV	Placebo
HSCT Recipients	870	851
HZ Confirmed Cases	49	135
HZ ZBPI Evaluable Cases	44	125
Maximum Worst Pain: Mean	5.8	7.1
Wilcoxon Test	P=0.0111	
Maximum Average Pain: Mean	4.7	5.7
Wilcoxon Test	P=0.0183	
HZ Burden of Illness VE	82.5% (95% CI: 73.6%–91.4%)	
HZ Burden of Interference VE	82.8% (95% CI: 73.3%–92.3%)	

RZV, adjuvanted recombinant zoster vaccine; **HZ**, herpes zoster; **ZBPI**, Zoster Brief Pain Inventory; **VE**, vaccine efficacy; **mTVC**, modified total vaccinated cohort: Included HSCT patients who received the second dose of vaccine and did not have a confirmed diagnosis of herpes zoster within 1 month after the second dose. **HZ ZBPI Evaluable Cases:** HZ confirmed cases with an evaluable ZBPI questionnaire within 14 days post-HZ rash onset.

Conclusion. In addition to reducing the risk of HZ and HZ complications, RZV significantly reduces the impact of HZ on patient's QoL in those who develop breakthrough disease.

Funding: GlaxoSmithKline Biologicals SA.

Disclosures. **D. Curran**, GlaxoSmithKline: Employee, GSK Shares and Salary. **A. Bastidas**, GSK: Employee, Salary. **M. El Idrissi**, GSK: Employee and Shareholder, Salary. **S. Matthews**, GSK group of companies: Consultant, Consulting fee. **L. Oostvogels**, GSK group of companies: Employee, Salary and stock and stock option. **J. A. Young**, GSK: Investigator, The University of Minnesota is reimbursed for contract costs associated with conducting clinical trials of vaccine. I receive no personal financial benefit.

2483. Twelve-Month Immunogenicity and Safety of an Adjuvanted Recombinant Zoster Vaccine in Immunosuppressed Adults Post Renal Transplant: a Phase III Randomized Clinical Trial

Peter Vink, MD[1]; Josep Maria Ramon Torrell, PhD, MD[2]; Ana I. Sanchez-Fructuoso, PhD[3]; Sung-Joo Kim, MD, PhD[4]; Sang Il Kim, MD[5]; Jeffrey Zaltzman, MD, FRCP (C)[6]; Fernanda Ortiz, MD, PhD[7]; Josep Maria Campistol Plana, MD[8]; Ana Maria Fernandez Rodriguez, MD, PhD[9]; Henar Rebollo Rodrigo, MD, PhD[10]; Magda Campins Marti, MD, PhD[11]; Rafael Perez, MD[12]; Francisco Manuel González-Roncero, MD[13]; Deepali Kumar, MD Msc[14]; Yang-Jen Chiang, MD[15]; Karen Doucette, MD, MSc, FRCPC[16]; Lissa Pipeleers, MD[17]; Maria Luisa Agüera Morales, MD[18]; Maria Luisa Rodriguez Ferrero, MD[19]; Antonio Secchi, MD[20]; Shelly A McNeil, MD, FIDSA[21]; Laura Campora, MD[22]; Emmanuel Di Paolo, MSc[23]; Mohamed El Idrissi, MSc[23]; Marta López-Fauqued, PhD[22]; Bruno Salaun, PhD[23]; Thomas Heineman, MD, PhD[24,25] and Lidia Oostvogels, MD[1] and On Behalf Of The Zoe-50/70 Study Group[22,26]; [1]GSK, Rockville, Maryland, [2]Bellvitge University Hospital, Barcelona, Spain, [3]Hospital Clínico San Carlos, Madrid, Spain, [4]Sungkyunkwan University, Seoul, Korea, Republic of (South), [5]Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea, Republic of (South), [6]St. Michael's University of Toronto, Toronto, ON, Canada, [7]Helsinki University Hospital, Helsinki, Finland, [8]Hospital Clínic de Barcelona, Barcelona, Spain, [9]Hospital Ramón y Cajal, Madrid, Spain, [10]University Hospital Valdecilla, Santander, Spain, [11]Hospital Universitario Vall d'Hebron, Barcelona, Spain, [12]Social Security of Panama, Panama, Panama, [13]Hospital Universitario Virgen Rocio, Sevilla, Spain, [14]Transplant Infectious Diseases, University Health Network, Toronto, ON, Canada, [15]Chang Gung Memorial Hospital, Taoyuan, Taiwan, [16]University of Alberta, Edmonton, AB, Canada, [17]UZ Brussel, Brussels, Belgium, [18]Hospital Universitario Reina Sofia, Córdoba, Spain, [19]Hospital General Universitario Gregorio Marañón, Madrid, Spain, [20]Scientific Institute San Raffaele, Milan, Italy, [21]Canadian Center for Vaccinology, IWK Health Centre and Nova Scotia Health Authority, Dalhousie University, Halifax, NS, Canada, [22]GSK, Wavre, Belgium, [23]GSK, Rixensart, Belgium, [24]GSK, King of Prussia, Pennsylvania, [25]GSK, King of Prussia, PA, Current affiliation: Halozyme Therapeutics, San Diego, California, [26]CureVac AG, Tübingen, Germany

Session: 253. Vaccines for Herpes Zoster Virus
Saturday, October 6, 2018: 12:30 PM

Background. The efficacy of the non-live adjuvanted recombinant zoster vaccine (RZV, containing a truncated form of varicella-zoster glycoprotein E [gE] and Adjuvant System $AS01_B$) is >90% in adults ≥50 years of age (YOA) (ZOE-50/70) and >68% in hematopoietic stem cell transplant recipients ≥18 YOA (ZOE-HSCT).[1] This study (NCT02058589) evaluated immunogenicity and safety of RZV in renal transplant recipients ≥18 YOA receiving immunosuppressive therapy. Previously unreported reactogenicity and 12-month post-last dose safety and immune persistence data are presented.

Methods. In this phase III, 1:1 randomized, observer-blind, multicenter trial, patients received 2 doses of RZV or placebo. gE-specific immune responses were assessed at 1 (M2) and 12 (M13) months post-dose 2: humoral immunity by vaccine response rate (VRR) and geometric mean antibody concentration (GMC), and cell-mediated immunity (CMI) by VRR and $CD4^+$ T-cell frequency. Solicited general and unsolicited adverse events (AEs) were collected 7 days pre-dose 1 as a within-participant control. Solicited and unsolicited AEs were also recorded for 7 and 30 days after each dose, respectively. Serious AEs (SAE) and potential immune-mediated diseases (pIMDs) were recorded up to study end (M13).

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

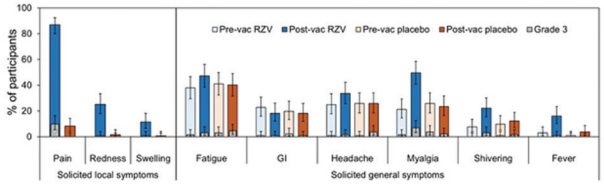
Month 2 & 13 (1 & 12 month[s] after last vaccination); N, number of participants with available results; CI, confidence interval; IU, international units. **Bolded values** indicate that success criteria were met for primary immunogenicity objective (lower limit of 95% CI ≥60% for humoral VRR) and secondary 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

Eric Fela, PharmD[1]; Kaitlyn Rivard, PharmD[2]; Andrea Pallotta, PharmD[3]; Michael Spinner, MA, PharmD[3]; Maryjoy Lepak, PharmD[4] and Blanca E Gonzalez, MD[5]; [1]Cleveland Clinic, Cleveland, Ohio, [2]Department of Pharmacy, Cleveland Clinic, Cleveland, Ohio, [3]Pharmacy, Cleveland Clinic, Cleveland, Ohio, [4]Nemours Children's Hospital, Orlando, Florida, [5]Pediatrics, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio

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

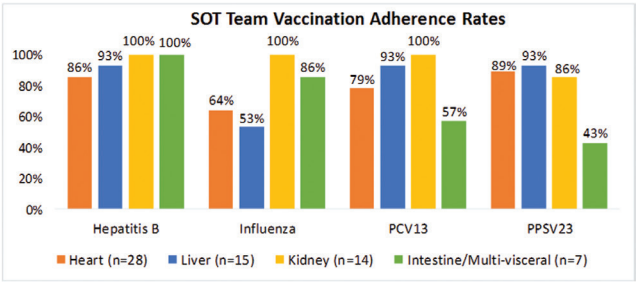
Background. Adherence rates for recommended pre-transplant (pre-txp) vaccinations in pediatric solid-organ transplant (SOT) patients are variable and practice-dependent. Cleveland Clinic Children's Hospital (CCCH) pre-txp adherence rates for select vaccines have not been described. The purpose of this 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

Nicole Le Corre, MD/PhD[1,2]; Constanza Martinez-Valdebenito, MS[1,2]; Francisco Barriga, MD[3]; Marcela Contreras, Nurse[3]; Marcela Vidal, Nurse[3];