Conclusion. Findings from observational studies supported PCV13 VE against VT PnPn reported in the RCT. Differences in the study design made the magnitude of PPSV23 effectiveness against PnPn and VT PnPn difficult to assess; however, findings from recent observational studies suggest PPSV23 provides limited protection against VT PnPn.

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

14. Postmarketing Safety Experience With MenACWY-TT

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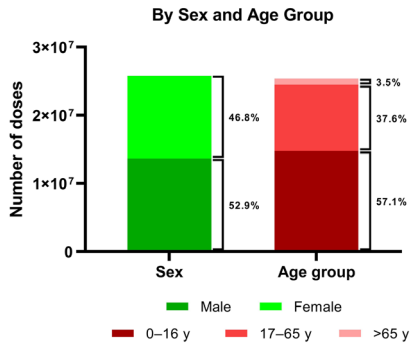
Session: P-02. Adult Vaccines

Background. MenACWY-TT (Nimenrix®), a quadrivalent meningococcal tetanus toxoid conjugate vaccine, was first licensed in 2012 and is available in 82 countries but not in the United States. MenACWY-TT is administered in infants as a 2 + 1 (6 weeks to < 6 months of age) or 1 + 1 (6 to < 12 months of age) schedule with the booster dose at 12 months of age, and from 12 months of age as a single dose. In addition to its widespread use to protect against meningococcal serogroups A, C, W, and Y, MenACWY-TT is a constituent of an investigational pentavalent meningococcal (MenABCWY) vaccine currently undergoing clinical development.

Methods. Using the MenACWY-TT Periodic Safety Update Report (PSUR) with format and content in accordance with Good Pharmacovigilance Practice Module VII and International Council for Harmonisation Guideline E2C, for data up to April 19, 2020, postmarketing safety experience with MenACWY-TT is considered. The PSUR data included herein are spontaneous adverse events (AEs) from the Pfizer safety database. AEs were coded by system organ class (SOC) and preferred term (PT) using MedDRA v.22.1J.

Results. The cumulative estimated exposure of MenACWY-TT was nearly 26 million doses, with the majority administered in 0- to 16-year-olds and in the Western European Union (**Figure 1**). Over the reporting period, 13,301 cumulative AEs occurred. The most common SOCs in the reporting period were general disorders and administration site conditions (n=5169; 39%); nervous system disorders (n=1986; 15%); injury, poisoning and procedural complications (n=1266; 10%); and gastrointestinal disorders (n=1031; 8%) (**Figure 2**). By PT, the most common AEs were pyrexia (n=1613; 12%), headache (n=738; 6%), and vaccination site pain (n=394; 3%) (**Figure 3**). Of the 3299 serious AEs reported, the most common were pyrexia (n=317; 10%) and headache (n=209; 6%).

Figure 1. Cumulative Estimated MenACWY-TT Exposure*

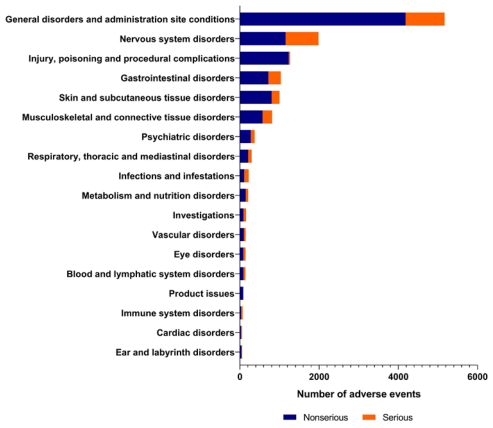


By Region/Country

Region/Country	Doses, %	Total doses
Western European Union	58.7	15,194,888
Latin America	15.9	4,100,149
Africa/Middle East	7.5	1,932,458
Australia/New Zealand	7.1	1,829,817
Central and Eastern Europe	5.8	1,505,066
Asia (excluding Japan)	3.1	800,105
Canada	1.9	502,829

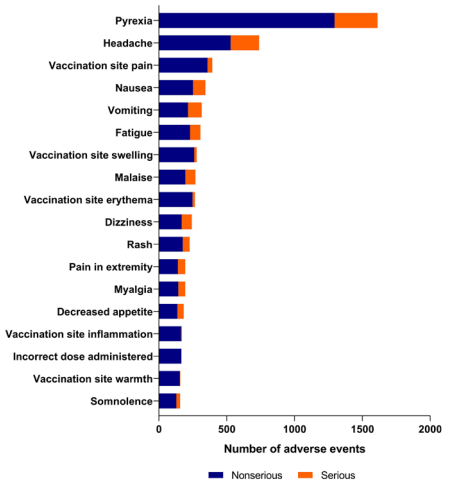
*Due to various dosage regimens and country-specific vaccination schedules, it is not possible to determine with certainty the number of individuals who received Nimenrix vaccine, therefore worldwide distribution information is used to serve as a reasonable indicator of patient exposure

Figure 2. Most Common MenACWY-TT Adverse Events by System Organ Class*



*Includes events reported at a frequency of ≥50.

Figure 3. Most Common MenACWY-TT Adverse Events by Preferred Term*



*Includes events reported at a frequency of ≥150.

Conclusion. Based on cumulative safety data in conjunction with existing efficacy and effectiveness data, the benefit-risk profile of MenACWY-TT remains favorable and is consistent with the safety profile of MenACWY-TT established in clinical studies.

Disclosures. **Lidia Serra, MS**, **Pfizer Inc** (Employee, Shareholder) **Susan Mather, MD**, **Pfizer Inc** (Employee, Shareholder) **Cindy Burman, PharmD**, **Pfizer Inc** (Employee, Shareholder) **Chris Webber, MD**, **Pfizer** (Employee, Shareholder)

15. Evaluation of Retained Immunity for *Tetanus-Diphtheria* and *Pneumococcal* Vaccines in Recipients of Cellular Therapies

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Background. Infectious complications in cancer patients (pts) who have received T-cell therapies are similar to those in autologous hematopoietic stem cell transplant (HCT) recipients, who - because they lose prior acquired immunity after undergoing conditioning regimens and transplantation- may be at an increased risk for vaccine-preventable infections. We sought to determine seroprotection rates against pneumococcus and tetanus-diphtheria before and after cellular therapies.

Table 1. Patient's characteristics

Characteristics	No. patients (%), N=38
Age, median (range), years	65 (16-80)
Sex	
Female	11 (29)
Male	27 (71)
Comorbidities	
Hypertension	16 (39)
Diabetes mellitus type 2	6 (16)
Coronary artery disease	1 (3)
Chronic kidney injury stage 3-5	1 (3)
Cancer Diagnosis	
Non-Hodgkin lymphoma	25 (66)
Hodgkin lymphoma	6 (16)
Acute lymphoid leukemia	1 (3)
Chronic lymphocytic leukemia	1 (3)
Multiple myeloma	1 (3)
Solid cancer[1]	4 (11)
History of hematopoietic cell transplantation	5 (13)
Prior pneumococcal vaccine	17 (45)
Prior tetanus/diphtheria/pertussis vaccine	38 (100)
Conditioning therapy	
Fludarabine, cyclophosphamide	2/31 (6)
Fludarabine, bendamustine	11/31 (35)
Fludarabine, cyclophosphamide, mesna	15/31 (48)
Fludarabine, cyclophosphamide, mesna, rituximab	3/31 (9)
Type of CART Cell therapy	
Investigational	17/1 (55)
Standard of care	14/31 (45)
Type of standard of care CAR-T therapy (product name)	
Axicabtagene ciloleucel	8/14 (57)
Brexacabtagene autoleucel	5/14 (35)
Lisocabtagene maraleucel	1/14 (7)
IVIG therapy after CAR-T therapy	3/31 (9)

Abbreviations: CAR-T, chimeric antigen receptor modified T cell; IVIG, intravenous immunoglobulin.

[1]Solid cancer patients included 2 patients with sarcoma, 1 patient with anal cancer, and 1 patient with colon cancer.

Table 2. Patients' laboratory test results and cancer statuses at each timepoint.

Characteristics	History of previous vaccinations N=38 (%)	Before –CART therapy N (%)	1-month after-CART Therapy N (%)[1]	6 months after CART N (%)[1]
Diphtheria antibodies, no. patients (%)	38 (100)	--	--	--
Positive	--	35/37 (95)	20/22 (91)	11/13 (85)
Negative	--	2/37 (5)	2/22 (9)	2/13 (15)
Tetanus antibodies, no. patients (%)	38 (100)	.	--	--
Positive	--	37/37 (100)	22/22 (100)	13/13 (100)
Negative	--	0	0	0
Pneumococcal antibodies, no. patients (%)	17 (45)	--	--	--
Positive	--	8/37 (22)	4/8 (50)	2/3 (67)
Negative	--	29/37 (78)	4/8 (50)	1/3 (33)
CD4 count, median (IQR), cells/μL	--	146 (100-334)	95 (75-102)	99 (46-181)
IgG, median (IQR), mg/dL	--	635 (476-690)	474 (338-576)	495 (375-714)
White blood cell count, median (IQR), K/uL	--	5 (3.5-7.6)	2.2 (1.3-4.7)	4.6 (2.3-6.4)
Absolute neutrophil count, median (IQR), K/uL	--	3.1 (2.2-5.5)	1.2 (0.6-2.6)	2.5 (1.4-4.5)
Absolute lymphocyte count, median (IQR), K/uL	--	0.7 (0.5-1.2)	0.4 (0.2-0.8)	0.7 (0.3-1.3)
Cancer status, , no. patients (%)	--	--	--	--
Remission	--	.	8/22 (36)	5/13 (38)
Partial response	--	.	5/22 (23)	1/13 (8)
Relapse	--	.	9/22 (41)	7/13 (54)

Abbreviations: CAR-T, chimeric antigen receptor T-cell therapy; IQR, interquartile range; IgG, immunoglobulin G

[1]This is an ongoing study. The denominators represent the number of patients who were tested and had serological test results by the end of May 2021. Some patients have pending serological test results, or they were lost to follow-up.

Methods. In this ongoing prospective observational cohort study, we enrolled pts with any type of cancer who received cellular therapy with chimeric antigen receptor modified T cell (CAR-T), natural killer CAR-T, or T-cell receptor- directed immunotherapies at MD Anderson Cancer Center from January 2020 through May 2021. We performed antibody assays for diphtheria, tetanus, and pneumococcus before, at 1 month, and between 3-6 months after T-cell therapy for each pt regardless of vaccination history.

Results. Of 38 pts enrolled, 27 (71%) were men and 25 (66%) had non-Hodgkin lymphoma (Table 1); 38 (100%) and 17 (45%) had a history of previous diphtheria-tetanus-acellular pertussis (Tdap) and pneumococcal vaccination, respectively (Table 2). Tetanus serologies were positive for all pts tested before, at 1 month and 3-6 months after T cell therapy (37/37 [100%], 22/22 [100%], and 13/13 [100%], respectively). Diphtheria serologies were positive for most pts tested before, at 1 month and 3-6 months after therapy (35/37 [95%], 20/22 [91%], and 11/13 [85%], respectively]. Pneumococcal serologies were positive for 8 out of 37 [22%] pts before therapy, among these 8 pts, 4 had positive serologies 1 month after therapy, and 2 of 3 tested 3-6 months after therapy had positive serologies. One pt received a pneumococcal vaccine 10 months after therapy but had negative serologies post-vaccination.

Conclusion. Most pts who received T-cell therapy retained their immunity for diphtheria and tetanus, but most also lost their immunity for pneumococcus. This suggests that the standard of care for pts receiving T-cell therapy should include more robust strategy for pneumococcal vaccination, but its timing, need for booster dosing, and antibody response needs to be determined in future trials.

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16. An Ambulatory Quality Improvement Initiative to Optimize Influenza Vaccination Amongst Adults Living with HIV During the COVID-19 Pandemic

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Session: P-02. Adult Vaccines

Background. Seasonal influenza vaccination decreases individual and population-level morbidity and mortality, mitigates risk of acquiring influenza-like illness, and prevents healthcare system overburdening. Vaccination is important for people living with HIV (PLWH) who have increased risk for severe disease, hospitalization, and poor outcomes. Moreover, influenza vaccination has been associated with decreased COVID-19 mortality in older patients. Historical annual adult influenza vaccinations rates at the study site were 65%, exceeding local and national benchmarks. Amidst COVID-19, we recognized a need to increase influenza vaccination rates.

Methods. A multifaceted, bundled quality improvement (QI) initiative aimed to achieve ≥ 80% influenza vaccination coverage for the 2020-21 season in PLWH ≥18 years of age at our Wilmington site (N=750). Stakeholders were identified, and a voluntary multidisciplinary team formed to lead the initiative (Fig. 1). Fishbone diagram outlined clear, rapidly implementable, and reproducible levers for change (Fig. 2). Physical and virtual space changes included: diverse clinical displays (visuals, patient materials), phone messaging, and virtual platform use. Staff education and updates were consistently provided by the team. Institutional Review Board exemption was received, and electronic medical record and CareWare data were extracted from 1 Oct 2020 through 31 March 2021. All external vaccinations were confirmed. Overall and eligible in-clinic vaccination rates were updated and displayed weekly.

Figure 1: Multidisciplinary Quality Improvement Team Formation