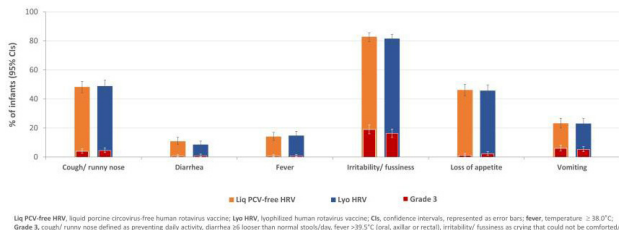


Table 2. Seroprotection/seropositivity rates and geometric mean concentrations/titers for the routine vaccines antigens 1 month post-dose 3 (per-protocol set)

Antibody	Threshold	Liq PCV-free HRV	Lyo HRV	Liq PCV-free HRV	Lyo HRV
		(N=486)	(N=495)	(N=486)	(N=495)
		% (95% CI)	% (95% CI)	GMC/GMT (95% CI)	GMC/GMT (95% CI)
DTaP-HBV-IPV					
Anti-D	≥0.1IU/mL	100 (99.2-100)	100 (99.2-100)	1.85 (1.72-1.98)	1.88 (1.75-2.02)
Anti-T	≥0.1IU/mL	100 (99.2-100)	100 (99.3-100)	1.88 (1.75-2.02)	1.86 (1.74-1.99)
Anti-PT	2.693 IU/mL	99.8 (98.9-100)	100 (99.3-100)	51.0 (47.8-54.5)	54.2 (51.3-57.4)
Anti-FHA	2.046 IU/mL	100 (99.2-100)	100 (99.3-100)	107.3 (101.4-113.5)	107.7 (101.6-114.1)
Anti-PRN	2.187 IU/mL	100 (99.2-100)	100 (99.3-100)	55.0 (50.1-60.4)	56.6 (51.9-61.7)
Anti-HBs	≥10 mIU/mL	99.3 (98.1-99.9)	100 (99.2-100)	2031.3 (1834.6-2249.0)	2168.9 (1977.5-2378.9)
Anti-polio 1		100 (99.2-100)	99.8 (98.9-100)	747.2 (673.5-828.8)	728.2 (656.3-808.0)
Anti-polio 2	≥8 ED ₅₀	99.8 (98.8-100)	99.8 (98.8-100)	659.6 (587.9-740.0)	699.3 (627.7-779.0)
Anti-polio 3		100 (99.2-100)	100 (99.2-100)	1228.7 (1100.3-1372.1)	1291.6 (1159.1-1439.3)
PCV13					
Anti-PnPS 1		98.7 (97.1-99.5)	99.4 (98.1-99.9)	1.95 (1.81-2.1)	1.89 (1.76-2.03)
Anti-PnPS 3		70.8 (66.3-74.9)	69.1 (64.7-73.3)	0.53 (0.49-0.57)	0.53 (0.49-0.57)
Anti-PnPS 4		96.9 (94.8-98.3)	97.2 (95.3-98.5)	1.24 (1.16-1.34)	1.25 (1.18-1.34)
Anti-PnPS 5		92.7 (89.9-95.0)	92.4 (89.6-94.6)	1.28 (1.17-1.39)	1.22 (1.13-1.31)
Anti-PnPS 6A		98.4 (96.8-99.4)	98.9 (97.5-99.7)	2.84 (2.64-3.05)	2.80 (2.61-3.00)
Anti-PnPS 6B		90.8 (87.8-93.4)	91.3 (90.7-92.4)	1.93 (1.72-2.15)	2.00 (1.80-2.22)
Anti-PnPS 7F	≥0.35 µg/mL	100 (99.2-100)	100 (99.2-100)	3.01 (2.83-3.21)	3.04 (2.86-3.22)
Anti-PnPS 9V		96.4 (94.3-97.9)	97.4 (95.5-98.7)	1.68 (1.56-1.81)	1.63 (1.52-1.75)
Anti-PnPS 14		98.4 (96.8-99.4)	97.4 (95.5-98.7)	6.27 (5.74-6.84)	6.26 (5.75-6.82)
Anti-PnPS 18C		97.3 (95.4-98.6)	96.8 (94.7-98.2)	1.81 (1.68-1.95)	1.76 (1.64-1.89)
Anti-PnPS 19A		97.8 (95.9-98.9)	98.3 (96.6-99.3)	1.87 (1.73-2.02)	1.80 (1.68-1.93)
Anti-PnPS 19F		100 (99.2-100)	99.8 (98.8-100)	2.94 (2.76-3.12)	2.85 (2.69-3.03)
Anti-PnPS 23F		91.3 (88.3-93.7)	92.0 (89.1-94.3)	1.14 (1.04-1.24)	1.16 (1.07-1.26)
Hib					
Anti-PRP	≥0.15 µg/mL	97.5 (95.7-98.7)	97.4 (95.5-98.6)	4.41 (3.82-5.09)	4.28 (3.71-4.94)
	≥1 µg/mL	81.2 (77.5-84.6)	82.1 (78.4-85.4)		

Liq PCV-free HRV, liquid porcine circovirus-free human rotavirus vaccine; Lyo HRV, lyophilized human rotavirus vaccine; N, maximum number of infants with available results; DTaP-HBV-IPV, diphtheria-tetanus-acellular pertussis, hepatitis B virus and inactivated poliovirus combination vaccine; Hib, monovalent tetanus toxoid-conjugated vaccine against *Haemophilus influenzae* type B; PCV13, 13-valent pneumococcal conjugate vaccine; %, percentage of infants with antibody levels above the threshold; CI, confidence interval; GMC/GMT, geometric mean concentration/titer; D, diphtheria; IU, international units; T, tetanus; ED₅₀, median effective dose; PT, pertussis toxin; FHA, filamentous hemagglutinin; PRN, pertactin; HBs, hepatitis B surface antibody; PRP, polyribosyl-ribitol phosphate; PnPS, pneumococcal capsular polysaccharide.

Figure 2. The incidence of solicited adverse events occurring within 7 days post-vaccination (overall/infant, exposed set)



Conclusion: Routine vaccines (co-)administered with Liq PCV-free HRV showed non-inferior immune responses and similar safety profiles compared to (co-)administration with Lyo HRV.

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1386. Current Estimates of the Impact of Routine Childhood Immunizations in Reducing Vaccine-Preventable Diseases in the United States
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Session: P-63. Pediatric Vaccines

Background. Routine immunizations for children aged 10 years and younger in the United States (US) currently cover 14 diseases. Updated estimates of public health impact are needed, given changes in disease epidemiology, evolving recommendations, and the dynamic nature of compliance with the immunization schedule.

Methods. Pre-vaccine disease incidence was estimated before each routine vaccine was recommended, with average values across multiple years obtained directly from published literature or calculated based on disease surveillance data or annual case estimates from the published literature. Pre-vaccine incidence then was compared to current, post-vaccine incidence, which was generally calculated as average values

over the most recent 5 years of available incidence data. Overall incidence estimates and estimates by age group were calculated. Differences in pre- and post-vaccine disease incidence rates were used to calculate the annual number of cases averted, based on 2019 US population estimates. This analysis did not separately estimate the proportion of disease incidence reduction that may be attributed to adult vaccines or booster doses.

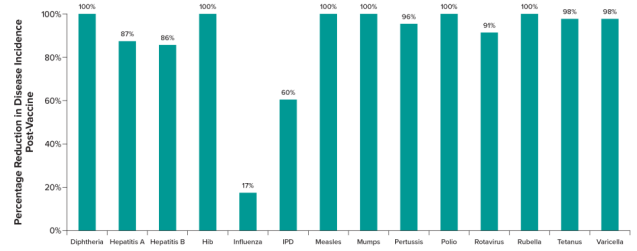
Results. Post-vaccine disease incidence decreased overall and for all age groups across all diseases evaluated (Table 1). Decreases ranged from 17.4% for influenza to 100.0% for polio (Figure 1). Over 90% reduction in incidence was achieved for 10 of the 14 diseases evaluated (including reduction in incidence of rotavirus hospitalizations). Overall post-vaccine disease incidence estimates were highest for influenza, rotavirus, and varicella. Estimated annual cases averted by vaccination in 2019 ranged from 1,269 for tetanus to more than 4.2 million for varicella.

Table 1. Pre- and Post-Vaccine Disease Incidence Estimates, Annual Cases, and 2019 Cases Averted, by Disease

Age Group and Disease	Pre-Vaccine		Post-Vaccine		2019 Cases Averted
	Disease Incidence per 100,000*	Annual Cases*	Disease Incidence per 100,000*	Annual Cases*	
Age < 5 years (n = 19,576,683)					
<i>Haemophilus influenzae</i> type b	92.3	18,063	0.2	29	18,034
Rotavirus [†]					
Hospitalizations		66,561	291	5,705	60,856
ED visits	1,072	209,862	420	83,366	127,676
Outpatient visits	2,228	436,668	1,222	239,246	198,923
Non-medically attended cases	11,364	2,224,694	6,233	1,220,282	1,004,412
Age < 10 years (n = 43,833,518)					
Diphtheria	89.3	39,944	0.0	0 [‡]	39,944
Influenza	16,232	7,015,206	13,412	5,879,003	1,236,202
Age < 40 years (n = 170,936,198)					
Measles	2,129	3,638,861	0.1	253	3,638,609
Mumps	1,312	2,242,785	17	2,983	2,239,803
Rubella	1,124	1,921,317	0.002	3	1,921,314
All ages (n = 328,239,523)					
Hepatitis A	16.9	55,533	2.1	7,000	48,533
Hepatitis B	45.6	149,535	6.6	21,506	128,029
Pertussis	5.1	1,678,851	22.0	72,209	1,606,641
Invasive pneumococcal disease	24.1	79,106	9.6	31,445	47,660 [‡]
Polio	21.4	70,212	0.0	0	70,212
Tetanus	0.4	1,298	0.009	29	1,269
Varicella	1,328	4,359,207	29.7	97,438	4,261,769

* Incidence estimates are adjusted by underreporting factors of 1.7 for hepatitis A, 6.5 for hepatitis B, 3.3 for pertussis, 2.1 for polio pre-vaccine (to capture paralytic and nonparalytic cases), 2.2 for varicella pre-vaccine, and 2.4 for varicella post-vaccine (with all other diseases assumed fully reported and/or already adjusted to account for underreporting from the source data).
[†] Pre- and post-vaccine case estimates are based on 2019 US population estimates. For *Haemophilus influenzae* type b, rotavirus, diphtheria, influenza, measles, mumps, and rubella, disease incidence and case estimates are based on age-defined population subsets, as outlined in the table, to account for disease epidemiology, available data, and/or focus on the effects of the childhood vaccination program.
[‡] Rotavirus results are shown separately by health care resource use based on the available disease incidence data.
[§] Although zero post-vaccine cases of diphtheria are shown, this estimate is based on rounded disease incidence values from the NNDSS data, which reported one case of diphtheria in individuals aged < 10 years over the 5-year period between 2004-2008.
[¶] Some proportion of cases averted may be attributable to the adult vaccine.

Figure 1. Percentage Reduction in Disease Incidence Post-Vaccine, by Disease



Hib = *Haemophilus influenzae* type B; IPD = Invasive pneumococcal disease.
 Note: For rotavirus, the percentage reduction refers to hospitalizations. Percentage reductions in disease incidence rounded up to 100% for several diseases, although there are still some post-vaccine cases (as shown in Table 1).

Conclusion. Routine childhood immunization in the US continues to result in high, sustained reduction in disease across all vaccines and for all age groups evaluated.

Disclosures. Elizabeth M. La, PhD, RTI Health Solutions (Employee) Justin Carrico, BS, GlaxoSmithKline (Consultant) Sandra E. Talbird, MSPH, RTI Health Solutions (Employee) Ya-Ting Chen, PhD, Merck & Co., Inc. (Employee, Shareholder) Mawuli K. Nyaku, DrPh, Merck & Co. Inc. (Employee, Shareholder) Cristina Carrias, PhD, Merck (Employee, Shareholder) Gary S. Marshall, MD, GlaxoSmithKline (Consultant, Scientific Research Study Investigator) Merck (Consultant, Scientific Research Study Investigator) Pfizer (Consultant, Scientific Research Study Investigator) Sanofi Pasteur (Consultant, Grant/Research Support, Scientific Research Study Investigator, Honorarium for conference lecture) Seqirus (Consultant, Scientific Research Study Investigator) Craig S. Roberts, PharmD, MPA, MBA, Merck & Co., Inc (Employee, Shareholder)

1387. Current practices in the diagnosis and treatment of varicella infections in the United States
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Session: P-63. Pediatric Vaccines

Background. The Advisory Committee on Immunization Practices recommended a 1 dose varicella immunization program in 1996, expanding this to include 2 doses in 2006. As a result, more than 3.5 million cases of varicella, 9,000 hospitalizations, and 100 deaths are prevented annually in the United States. Since varicella infections have become uncommon, the response of health care providers (HCPs) to

patients presenting with varicella symptoms may result in misdiagnosis and/ mistreatment. This study investigated the diagnostic and treatment strategies used by HCPs for managing varicella infections in US children.

Methods. An online cross-sectional survey of licensed HCPs was conducted, after an Institution review board approval and HCP consent. 8 clinical vignettes with information on patients with varying varicella symptoms (representing uncomplicated and complicated cases) were presented. For each vignette, HCPs selected a diagnosis and appropriate intervention(s) from pre-determined lists. Descriptive analyses were performed.

Results. A total of 153 HCPs (50 nurses, 103 doctors) completed the survey. Mean age was 44 years, 62% were female, and 82% were licensed after 1995. Varicella infection was correctly diagnosed 79% of the time. HCPs were able to recognize uncomplicated cases of varicella 85% of the time and complicated cases 61% of the time. HCPs recommended the correct intervention 43% of the time for uncomplicated cases and 25% of the time for complicated cases. For example, HCPs recommended antibiotics 17% of the time and/or antivirals 18% of the time (Table 1), of which 25% and 69% (respectively) were not appropriate per the American Academy of Pediatrics guidelines respectively. Antibiotics were incorrectly recommended 6% of the time for uncomplicated cases of varicella.

Table 1. Additional Diagnosis & Treatment Results

Table 1. Additional Diagnosis & Treatment Results		
	Total Diagnoses	Correct Diagnoses
Diagnosis		
Correct diagnosis as varicella (8 vignettes)	1,224	970 (79%)
Correct diagnosis as varicella - uncomplicated cases (6 vignettes)	918	784 (85%)
Correct diagnosis as varicella - complicated cases (2 vignettes)	306	186 (61%)
Correct assignment as complicated versus uncomplicated varicella	1,224	841 (69%)
Treatment	Antibiotics	Antivirals
Total antibiotic or antiviral recommendations	204 (17%)	218 (18%)
Correct antibiotic or antiviral treatment recommendation	127 (62%)	61 (28%)
Incorrect antibiotic or antiviral treatment recommendation	77 (38%)	157 (72%)

Conclusion: Given the low incidence of varicella infections in the US, complicated cases of varicella may be under-recognized or inappropriately treated by some HCPs. Additional training may help HCPs better recognize/ treat cases of varicella. Further, ensuring high rates of varicella vaccination is important to avoid vaccine preventable conditions and to minimize unnecessary exposure to antimicrobial and antiviral therapies.

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1388. DTaP-containing combination vaccines use and adherence to the recommended infant-toddler vaccination series among privately insured children in the US

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Session: P-63. Pediatric Vaccines

Background. Despite universal recommendation of the 3 + 1 diphtheria, tetanus, and pertussis (DTaP) vaccine series in infants and toddlers, adherence (i.e. coverage and timeliness) remain suboptimal in the US. DTaP-containing combination vaccines are presumed to improve vaccine coverage rates and timeliness, but research on this topic is limited. The purpose of this study was to compare adherence to the recommended infant-toddler vaccination series between recipients of DTaP-containing combination vaccines (i.e. quadrivalent/pentavalent) and stand-alone vaccines (i.e. trivalent).

Methods. We used the Optum de-identified Clinformatics Data Mart database to create a cohort of children born between 2009 and 2016 with > 24 months of continuous enrollment from birth, and records of > 1 DTaP vaccine receipt. Patients were classified by DTaP-containing vaccine receipt: combination vaccines only, stand-alone vaccines only, or a mixture of both. The primary adherence outcome was completion of the 4-dose series within 20 months of life. We adjusted outcomes for gender, birth year, race, and socioeconomic status via a logistic regression model.

Results. The cohort contained 200,568 female (48.6%) and 211,882 male (51.4%) children. Of these children, 167,091 received combination vaccines only (40.5%), 61,342 received stand-alone vaccines only (14.9%), and 184,017 received a mixture of both (44.6%). Completion of the 4-dose series was highest among children who received combination vaccines only (75.5%), followed by those who received a mixture of vaccines (72.7%) and those who received stand-alone vaccines only (54.5%). Relative to those who received stand-alone vaccines only, adjusted odds of completion were approximately 2.9 times higher among combination vaccine recipients (odds ratio, OR = 2.93 [95% CI: 2.87, 2.98]) and 2.5 times higher among those who received a mixture of vaccines (OR = 2.54 [2.49, 2.59]).

Conclusion. DTaP-containing combination vaccine use was associated with significantly greater adherence. Although these results warrant further investigation to better understand the determinants of infant vaccination adherence, such evidence may further support preferential recommendations for combination vaccine use.

Disclosures. Matthew M. Loiacono, MSc, Sanofi Pasteur (Employee) Vitali Pool, MD, Sanofi Pasteur (Employee) Robertus Van Aalst, MSc, Sanofi Pasteur (Employee)

1389. Economic Evaluation of Universal Varicella Vaccination in Mexico

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Session: P-63. Pediatric Vaccines

Background. Universal varicella vaccination (UVV) has proven to be cost-effective in countries where implemented. However, this has not yet been evaluated for Mexico. We assessed the cost-effectiveness of UVV in the Mexican Immunization Program from both healthcare and societal perspectives.

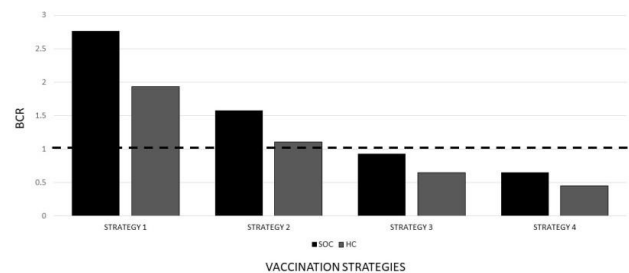
Methods. The annual disease burden (varicella cases/deaths, outpatient visits, and hospitalizations) were derived from Mexican seroprevalence-published data adjusted to the 2020 country's population. The annual economic burden was calculated by combining disease with Mexican published unit cost data. Four different vaccination strategies were evaluated: 1. One dose of a single varicella vaccine at 1 year old; 2. Two doses of single varicella vaccine at 1 and 6 years; 3. One dose of a single varicella vaccine at 1 year, and quadrivalent measles-mumps-rubella-varicella vaccine (MMRV) at 6 years; 4. Two doses of MMRV at 1 and 6 years.

We developed an economic model for each vaccination strategy where 20 consecutive birth cohorts were simulated. The impact of vaccination (number of avoided cases/deaths) was evaluated for a 20 years follow-up period based on vaccine effectiveness (87% and 97.4%), and assuming a 95% coverage. Subsequently, we estimated net vaccination costs, benefit-cost ratio (BCR), annual costs saved, cost-effectiveness ratio.

Results. From annual disease burden estimation, avoided cases with one dose, and two doses were of 20,570,722 and 23,029,751, respectively. From the 20 years cohort, the yearly number of varicella cases was estimated at 2,041,296, and total costs at \$115,565,315 (USD) (healthcare perspective) and \$165,372,061 (healthcare and societal perspectives). Strategies 1 and 2 were found to be cost-saving (BCR >1) (Figure 1), and strategy 3 to be cost-effective (CE) (\$1539 per Life Year Gained). Strategy 4 was not CE. Strategies 1 and 2 would allow saving annually \$53.16 million and \$34.41 million, respectively, to the Mexican society.

FIGURE 1

FIGURE 1
BENEFIT-COST RATIO (BCR) PER VACCINATION STRATEGY: SOCIETY (DIRECT AND INDIRECT COSTS) AND HEALTHCARE (ONLY DIRECT COSTS) PERSPECTIVES. (95% VACCINATION COVERAGE)



Conclusion: 1. The disease and economic burden of varicella in Mexico are high. 2. UVV with four different vaccination strategies results in a high reduction of cases. 3. From healthcare and societal perspectives, UVV was shown to be cost-effective (with strategy 3), and cost-saving (with strategies using one dose or two doses separately).

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1390. Effectiveness of M-M-R⁺ II in outbreaks - a systematic literature review of real-world observational studies

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Session: P-63. Pediatric Vaccines

Background. M-M-R⁺ II was approved in the US in 1978 and has been used globally for over 40 years. Widespread use of M-M-R⁺ II has resulted in important declines in incidence, morbidity, and mortality of measles, mumps, and rubella in the US and other countries. While vaccine immunogenicity and efficacy were established in multiple placebo-controlled trials of each vaccine component, there are limited studies on vaccine effectiveness (VE) of M-M-R⁺ II. This systematic literature review was conducted to summarize the VE of M-M-R⁺ II from real-world observational studies.

Methods. The literature search was conducted in Medline and Embase (through May 2019), and grey literature sources (through July 2019). All publications and findings in English language were screened by two independent reviewers. The study characteristics and VE results were extracted for each study.