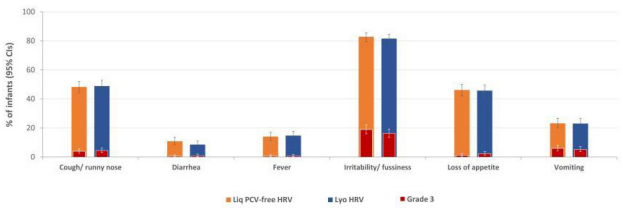
Table 2. Seroprotection/seropositivity rates and geometric mean concentrations/titers for the routine vaccines antigens 1 month post-dose 3 (per-protocol set)

| Antibody | Threshold | Liq PCV-free HRV (N=486) % (95% CI) | Lyo HRV (N=495) % (95% CI) | Liq PCV-fee HRV (N=486) GMC/GMT (95% CI) | Lyo HRV (N=495) 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) | 93.3 (90.7–95.4) | 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<br>≥1 µg/mL | 97.5 (95.7–98.7)<br>81.2 (77.5–84.6) | 97.4 (95.5–98.6)<br>82.1 (78.4–85.4) | 4.41 (3.82–5.09) | 4.28 (3.71–4.94) |

**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; $ED_{50}$, median effective dose; **PT**, pertussis toxoid; **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)




**Liq PCV-free HRV**, liquid porcine circovirus-free human rotavirus vaccine; **Lyo HRV**, lyophilized human rotavirus vaccine; **CIs**, confidence intervals, represented as error bars; **fever**, temperature ≥ 38.0°C; **Grade 3**, cough/ runny nose defined as preventing daily activity, diarrhea ≥6 looser than normal stools/day, fever >39.5°C (oral, axillar or rectal), irritability/ fussiness as crying that could not be comforted/ preventing normal activity, loss of appetite as did not eat at all, vomiting ≥3 episodes of vomiting/day.

***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.

***Funding.*** GlaxoSmithKline Biologicals SA

***Disclosures.*** Remon Abu-Elyazeed, MD, PhD, GSK group of companies (Employee) Nicola P. Klein, MD, PhD, GSK group of companies (Research Grant or Support)Merck (Grant/Research Support)Pfizer (Grant/Research Support)Protein Science (now SP) (Grant/Research Support)Sanofi Pasteur (Grant/Research Support) Leentje Moerman, PhD, GSK group of companies (Employee) Michael Povey, MSc, GSK group of companies (Employee) Shelly Senders, MD, Pfizer (Grant/Research Support) Dan Bi, MD, MPH, GSK group of companies (Employee)

## 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: Disease Incidence per 100,000[a] | Pre-Vaccine: Annual Cases[b] | Post-Vaccine: Disease Incidence per 100,000[a] | Post-Vaccine: Annual Cases[b] | 2019 Cases Averted |
|---|---|---|---|---|---|
| **Age < 5 years (n = 19,576,683)** | | | | | |
| *Haemophilus influenzae* type b | 92.3 | 18,063 | 0.2 | 29 | 18,034 |
| Rotavirus[c] | | | | | |
| Hospitalizations | 340 | 66,561 | 29.1 | 5,705 | 60,856 |
| ED visits | 1,072 | 209,862 | 420 | 82,186 | 127,676 |
| Outpatient visits | 2,228 | 436,168 | 1,222 | 239,246 | 196,923 |
| 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 | 39,144 | 0.0 | 0[d] | 39,144 |
| Influenza | 16,232 | 7,115,206 | 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 | 1.7 | 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 | 511 | 1,678,851 | 22.0 | 72,209 | 1,606,641 |
| Invasive pneumococcal disease | 24.1 | 79,106 | 9.6 | 31,445 | 47,660[e] |
| 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 |

[a] 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), 22.2 for varicella pre-vaccine, and 10.4 for varicella post-vaccine (with all other diseases assumed fully reported and/or already adjusted to account for underreporting from the source data).

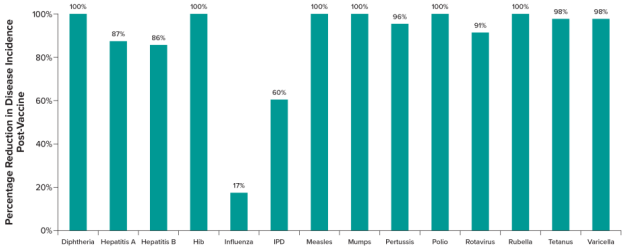
[b] Pre- and post-vaccine case estimates are based on 2019 US population estimates. For *Haemophilus influenzae* type b, rotavirus, diphtheria, influenza, measles, mumps, and rubella, disease incidence and case estimates are based on age-defined population subsets, as outlined in the table, to account for disease epidemiology, available data, and/or focus on the effects of the childhood vaccination program.

[c] Rotavirus results are shown separately by health care resource use based on the available disease incidence data.

[d] 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 2014-2018.

[e] 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 round 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 Carias, 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