SAFETY AND IMMUNOGENICITY OF DTaP–IPV (DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE ADSORBED COMBINED WITH INACTIVATED POLIOVIRUS VACCINE [QUADREC™]) COMPARED TO DAPTACEL® (DIPHTHERIA AND ACELLULAR PERTUSSIS VACCINE ADSORBED) + IPOL® (POLIOVIRUS VACCINE INACTIVATED) AS THE 5TH DOSE IN CHILDREN 4 TO 6 YEARS OF AGE

INTRODUCTION

Vaccination with diphtheria toxoid and pertussis vaccines is recommended for all children in the US, who should receive:

- A 3-dose primary series given at 2, 4, and 6 months of age followed by a booster dose (Dose 4) at 15 to 18 months of age.
- A 5th dose at 4 or 6 years of age

The rationale for giving a 5th dose per US Advisory Committee on Immunization Practices is to:

- Protect beyond the infant and toddler age
- To decrease the risk of disease transmission from school-age children to their not-vaccinated younger siblings
- The potential benefits of DTaP–IPV (Quadracel™, Sanofi Pasteur) as a component of combined vaccines, as a 5th dose for 4–6 year olds

Immunization Practices is:

- To protect children and their not-fully-vaccinated younger siblings
- To decrease the risk of disease transmission from school-age children to their not-vaccinated younger siblings

METHODS

- Multicenter, randomized, controlled, Phase 3 clinical trial comparing DTaP–IPV against control vaccines DTaP–IPV in children 4 to 6 years of age who were primed with Daptacel and DTaP–IPV (Quadracel™, Sanofi Pasteur) at 6 months.

OBJECTIVES

- To compare diphtheria, tetanus, pertussis, and polio antigens elicited booster responses and geometric mean concentrations (GMTs) after DTaP–IPV vaccination (Quad Group) to those from DTaP—IPV vaccination (Quad Group) when administered as a 5th dose

- To determine the proportion of participants who are immune (seroprotected on day 42) to the pertussis, tetanus, and polio antigens elicited in the Quad and OpV Groups.

SAFETY

- Assess the safety profile of those receiving the Quad Group regimen
- Immediate reactions
- Solicited reactions collected 7 days postvaccination

SAFETY RESULTS

- No serious adverse events (SAEs) were reported ≤6-months postvaccination

IMMUNOGENICITY RESULTS

- Geometric mean concentrations/thresholds (GMTs/GeMTs) for each antigen

CONCLUSIONS AND SUMMARY

- In children 4–6 years of age, DTaP–IPV was noninferior to Daptacel® when used as a 5th dose booster for immunogenicity and safety
- Local and systemic reactions to vaccines were comparable among groups
- Availability of DTaP–IPV as a stand-alone 5th dose booster would allow practitioners to complete the recommended 5-dose immunization schedule with 5-component acellular pertussis vaccine technology and fewer overall doses

Table 1. Randomization Scheme

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<th>Group</th>
<th>Randomization</th>
<th>Safety</th>
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<th>N (Dose 2)</th>
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</table>

Figure 1. Immunogenicity: Antipertussis (Pertussis)

Figure 2. Immunogenicity: Antitetanus (Tetanus)

Figure 3. Immunogenicity: Antidiphtheria (Diphtheria)

Figure 4. Noninferiority Comparison of Pts12-Month GMT Ratio and Booster Response Rates for Acellular Pertussis, Tetanus, and Diphtheria Antigens (Pertussis)