A live, oral, human rotavirus vaccine (RV1) was launched in the United States (US) in August 2008. Pre-licensure clinical trial data did not suggest an increased intussusception (IS) or mortality risk following RV1 vaccination. Recent post-marketing data suggests a small increase in IS risk within 7 days of vaccination.

Background and Objective

- A live, oral, human rotavirus vaccine (RV1) was launched in the United States (US) in August 2008. Pre-licensure clinical trial data did not suggest an increased intussusception (IS) or mortality risk following RV1 vaccination. Recent post-marketing data suggests a small increase in IS risk within 7 days of vaccination.

Methods: Using administrative claims data from large US health insurers, infants receiving RV1 and IPV were identified during the first 5 years of RV1 availability. IPV recipients were identified by claims with a code for vaccination, gender, calendar quarter and year of vaccination. Potential IS cases were identified by claims with an International Classification of Diseases, Ninth Revision (ICD-9) or International Classification of Diseases, Tenth Revision (ICD-10) code for IS (571.80). Deaths were identified in claims and via external links to the National Death Index. Outcomes were assessed in predefined risk windows (vaccination to day 7) following any dose of 2 vaccines. Incidence rates (IRs) were calculated per 1,000 person-months.

Results: A total of 371,931 infants in the RV1 cohort were identified and matched to 173,344 infants in the concurrent IPV cohort and 159,344 infants in the historical IPV cohort. The IR of medical record-confirmed IS during the 60 days following any dose was 0.021 (95% CI: 0.006 – 0.055) in the RV1 cohort and 0.022 (0.012 – 0.037) in the concurrent IPV cohort and 0.021 (0.010 – 0.037) in the historical IPV cohort. No cases of medical-record-confirmed IS were identified within 7 days following RV1 vaccination. The IR of all-cause mortality following any dose was 0.048 (0.022 – 0.029) in the RV1 cohort and 0.010 (0.003 – 0.037) in the historical IPV cohort.

Conclusion: No meaningful increase in risk of medical-record-confirmed IS and all-cause mortality was observed with RV1 vaccination.

Data Sources

- Optum Research Database (ORD): Database that contains eligibility, pharmacy and medical claims for large US health insurers in 18 individual health plans that represents ~4% of the US population.
- HealthCore Integrated Research DatabaseSM (HIRD): Database that includes a broad, clinically rich and geographically diverse spectrum of longitudinal claims data from 14 health plans distributed throughout the US and represents ~4% of the US population.
- National Death Index (NDI): Database: Computed index of death record information on file in state vital statistics offices with the US, with a 12-18 month lag in data availability.

References