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Sustained Reduction in 2009 of Pediatric Rotavirus Medical Encounters in a National Medical Claims Database After Introduction of RotaTeq®, Oral Pentavalent Rotavirus Vaccine

T. Christopher Mast PhD, MSc[1], Florence Wang ScD[2], Roberta Glass MS[2] and John Seeger PharmD, DrPH[2,3]

[1]Department of Epidemiology, Merck Research Laboratories, North Wales, PA; [2]i3 Drug Safety, i3, Waltham, MA; [3]Harvard School of Public Health, Boston, MA

Abstract 22838

Abstract

Background: Rotavirus is the leading cause of severe acute gastroenteritis among young children, accounting for an estimated 527,000 deaths among children aged <5 years worldwide every year. To prevent rotavirus gastroenteritis (RGE), a pentavalent rotavirus vaccine (RV5), RotaTeq® (Merck & Co., Inc., Whitehouse Station, New Jersey), was recommended for routine use among US infants in February 2006. Previous reports noted a decline of rotavirus activity during the 2007-08 season after RV5 introduction.

Objectives: In this study, rotavirus-related medical insurance claims were analyzed during the 2007-08 and the most recent 2008-09 seasons to confirm a continued pattern of decreased rotavirus-related health care utilization after RV5 introduction in the US.

Methods: RGE claims [IDC9-CM code 008.61] for hospitalizations, emergency room and outpatient visits for health plan members less than one year of age in the national Ingenix Normative Health Information Database were identified from January 2002 through June 2009. Longitudinal, seasonal rotavirus patterns in the period before and after RV5 introduction were determined by plotting the monthly count of all RGE claims.

Results: From January 1, 2002 through June 30, 2009, 3,363 members of the health plan less than one year of age had claims for RGE. The mean seasonal peak number of rotavirus claims in the database was substantially decreased in both the 2007-08 and 2008-09 seasons since the widespread use of RV5 (276 vs. 75 claims per peak month), representing a 73% reduction of RGE medical claims from the previous six years.

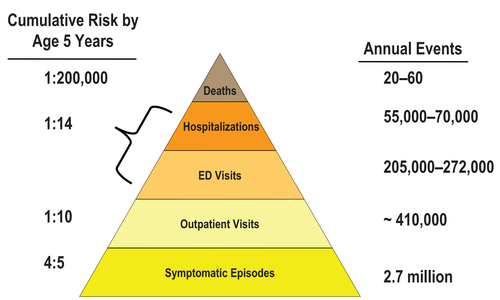
Conclusions: This health insurance database analysis confirms a sustained decrease in the typical longitudinal, seasonal rotavirus pattern after the introduction of RV5 in the US.

Introduction

Historical Rotavirus Disease Burden

- Rotavirus is the leading cause of severe acute gastroenteritis in infants and young children
- Rotavirus caused substantial morbidity in the US every year[1,2]
  - 55,000 – 117,000 hospitalizations
  - 205,000 – 272,000 emergency department visits
  - Over 400,000 physician office visits
  - 20 – 60 deaths
  - Responsible for more than $1 billion US dollars in direct and indirect costs
- Globally, more than 600,000 deaths every year are caused by rotavirus[3]

Pre-Vaccine Era: Estimated Burden of Disease in US Children Less Than 5 Years of Age[4]



Background - RotaTeq™

Pentavalent Rotavirus Vaccine (RV5)

- RotaTeq™, Merck & Co, Inc) [RV5] was efficacious in the Rotavirus Efficacy and Safety Trial (REST)
  - 98% efficacy against severe cases of rotavirus gastroenteritis caused by serotypes G1, G2, G3, and G4 through the first rotavirus season
  - 74% efficacy against all rotavirus gastroenteritis
  - 96% reduction in hospitalizations up to two years following the third dose
  - 94% reduction in emergency room visits
- The safety profile of RotaTeq™ has been established
  - REST demonstrated that RV5 was generally well tolerated and not associated with intussusception
  - Two large post-marketing safety studies confirmed that no elevation in risk was identified for intussusception or any other adverse event[5,6]
- RotaTeq™ was approved by the US FDA on February 3, 2006
  - Merck distributed more than 34 million doses globally of RotaTeq™ through 2009
  - Worldwide RotaTeq™ has been approved in over 90 countries and is available in more than 50 of these countries

Opportunity to Assess Evidence for Public Health Impact of RV5 in the US

- For over 2 years after licensure in February 3, 2006, RV5 was the only rotavirus vaccine licensed in the United States
- RV5 was recommended for routine use by ACIP/AAP/AAFP and was therefore widely implemented over time
- Although a different monovalent live oral rotavirus vaccine (Rotarix, GSK) was licensed in April 2008, it had limited commercial availability until 2009
- Therefore, there was opportunity to evaluate the effectiveness of routine RV5 vaccination in the 2007/8 and 2008/9 rotavirus seasons

Previous Evidence for Substantial Impact of RV5 on Rotavirus Disease Burden in the 2007/8 Rotavirus Season in US

- Multiple studies have demonstrated public health benefits in the 2007/8 rotavirus seasons in association with routine vaccination with RV5
  - Controlled vaccine effectiveness studies demonstrated 85 – 100% reduction of rotavirus AGE requiring an ED visit or inpatient admission[7,8]
  - Substantial reduction (85 – 95%) in rotavirus hospitalizations in 2008 compared to previous years[9,10,11]
  - Delayed and diminished rotavirus activity[12]
  - Significant reduction in all-cause and rotavirus gastroenteritis health care costs [8,9]

Objectives

The purpose of this study was to confirm a continued pattern of decreased rotavirus-related health care utilization after RV5 introduction in the US in the 2008/2009 rotavirus season

Methods

Data Source

- Normative Health Information database (NHI)
  - Formerly known as Ingenix Research DataMart
  - Commercial health insurer
  - Diverse geographically
  - Approximately 2% of US population (over time of study)
  - HIPAA compliant
- No active enrollment or active follow-up of children, and no data were directly collected from parents or infants
- Study approved by the Privacy Board of the New England Institutional Review Board

Study Population

- Health plan members <1 year of age
- Subjects identified in database from January 2002 through June 2009
- All subjects had a rotavirus gastroenteritis claim [IDC9-CM code 008.61] associated with a hospitalization, emergency room or outpatient visit

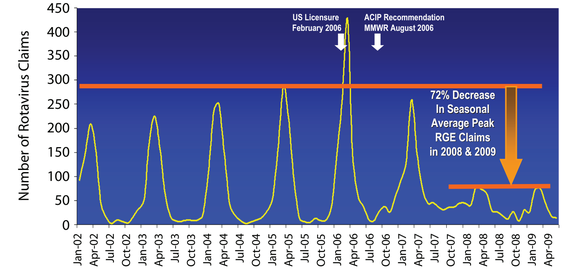
Analysis

- Longitudinal, seasonal rotavirus patterns were determined by plotting the monthly count of all RGE claims in the database from January 1, 2002 – June 30, 2009
- The pattern was divided into the two rotavirus seasonal periods based on whether they could be affected by RV5 introduction
  - Period 1: Rotavirus seasons before RV5 introduction
    - January 1, 2002 – June 30, 2007
    - RV5 coverage in 2006–7 season considered too low to have meaningful impact
  - Period 2: Rotavirus seasons after RV5 introduction
    - July 1, 2007 – June 30, 2009
    - This period corresponds to the 2007–08 and 2008–09 season)
- For each period, the peak (maximum monthly count) was averaged to provide an average peak count for periods before and after RV5 introduction

Results

- From January 1, 2002 through June 30, 2009, 3,363 members of the health plan <1 year of age had claims for RGE
- There was a notable seasonal pattern in the pre-RV5 period
- The mean seasonal peak number of rotavirus claims in the database was substantially decreased in both the 2007–08 and 2008–09 seasons since the widespread use of RV5 (276 vs. 75 claims per peak per month) (See Figure 1).
- The decrease represents a 73% reduction in the average peak number of RGE medical claims from the previous six years in which RV5 was not in widespread use

Figure 1. Continued Decrease in 2009 Number of Seasonal RGE Claims Among Infants <1 Year of Age After RV5 Introduction in a Large Insured US Population (January 1, 2002 – June 30, 2009)



Discussion

- This health insurance database analysis provides evidence that the previously reported decrease in the typical longitudinal, seasonal rotavirus pattern in the 2007/8 season was sustained in the 2008/9 season after the introduction of RV5 in the US
- Similar trends of sustained reduction have been reported by a national surveillance system which concluded that both the 2007–08 and 2008–09 rotavirus seasons were shorter, later, and characterized by substantially fewer positive rotavirus test results, compared with median data for 2000–2006[13]

Conclusions

- RotaTeq® (RV5) had provided sustained reduction in rotavirus disease during more than 3 years of use in US
- RotaTeq® (RV5) remains highly effective in routine use in the US and continues to provide substantial public health benefit

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