



# A population based study comparing changes in rotavirus burden on the Island of Ireland between a highly vaccinated population and an unvaccinated population



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## ARTICLE INFO

### Article history:

Received 25 April 2016

Received in revised form 29 July 2016

Accepted 1 August 2016

Available online 12 August 2016

### Keywords:

Rotavirus  
Immunisation  
Vaccination

## ABSTRACT

**Background:** Rotavirus infection is a leading cause of gastroenteritis in infants and children globally. Reductions in rotavirus activity have been observed following introduction of rotavirus vaccination programmes, however a reductions have also been reported in some unvaccinated countries.

The Island of Ireland incorporates the two jurisdictions Northern Ireland (NI) and the Republic of Ireland (IE). Both have similarities in climate, demography, morbidity and mortality but distinct health administrations and vaccination policies. Rotarix was added to the childhood immunisation programme in NI on the 1 July 2013. IE have not introduced routine rotavirus vaccination to date.

The aim of this population based ecological study was to evaluate the impact of the rotavirus vaccine on burden of rotavirus disease in NI, and to compare with IE as an unvaccinated control population. This will help determine if the changes seen were due to the rotavirus vaccine, or due to confounding factors.

**Methods:** A number of population based measures of disease burden were compared in both jurisdictions pre-vaccine (six years; 2007/08–2012/13) and post-vaccine (two years; 2013/14–2014/15). The data sources included national rotavirus surveillance data based on laboratory reports/notifications; hospital admission data; and notifications of gastroenteritis in under 2 year olds.

**Results:** In the post-vaccination period, rotavirus incidence in NI dropped by 54% while in IE it increased by 19% compared to the pre-vaccine period. Notifications of gastroenteritis in under 2 s in NI declined by 53% and hospital admissions in under 5 year olds in NI declined by 40% in the post vaccine period.

**Conclusions:** This natural experiment demonstrated a significant reduction in rotavirus disease activity post-vaccine introduction in NI with associated reductions in healthcare utilisation, with a concurrent increase in rotavirus disease activity in the non-vaccinated population in IE. These findings support rotavirus vaccination as an effective measure to reduce childhood morbidity.

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## 1. Introduction

Rotavirus infection is a leading cause of gastroenteritis in infants and children globally [1]. In the UK deaths from rotavirus infection are rare, but it remains a common cause of childhood morbidity [2]. Rotavirus infections cause around half of all gastroenteritis in children aged under five years [2]. This is a significant burden to the health care system; the cost to the health service in England and Wales was estimated to be £14.2 m per

annum in 2007 [3]. Rotavirus vaccination was introduced to the UK childhood immunisation programme on the 1st of July 2013 [4]. The vaccine selected was Rotarix<sup>®</sup>, a monovalent (RIX4414) live attenuated vaccine strain given in two doses at 2 and 3 months of age. Clinical trials have shown Rotarix<sup>®</sup> has an efficacy of 91.8% (CI 84–96%) against rotavirus gastroenteritis requiring medical attention in the first year of life [5].

A number of studies have demonstrated a decline in rotavirus activity since rotavirus childhood vaccination programmes have been introduced. In the USA rotavirus related hospital admissions for young children reduced by more than two-thirds post rotavirus vaccination; in England and Wales laboratory confirmed

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rotavirus infections declined by 77%, and all-cause acute gastroenteritis hospitalisations by 26% in 2013–14 [6,7]. However, decline in rotavirus disease activity was reported in some unvaccinated countries in 2013 [8]. Potential contributing factors may include a mild winter, high rotavirus season in the previous year, low birth rate and rotavirus vaccination in neighbouring countries [8].

The Island of Ireland, which incorporates the two jurisdictions Northern Ireland (NI) and the Republic of Ireland (IE), is a unique setting to study the impact of population level interventions such as national vaccination programmes. NI and IE share many close similarities in terms of climate, demography, morbidity and mortality, but have distinct health administrations and vaccination policies. NI records vaccination rates that are above the UK average, and amongst the highest globally, with vaccination coverage consistently over 95% for the childhood immunisation programme for under one year olds [9]. NI tends to follow recommendations from the UK Joint Committee on Vaccination and Immunisation (JCVI) and vaccination policy is implemented universally across NI. Rotarix was added to the NI immunisation programme on the 1 July 2013 in line with the UK. Routine childhood rotavirus immunisation has not been introduced in IE to date.

This situation presents a unique natural experiment, and provides an opportunity to examine the impact of Rotarix® in two similar populations within the Island of Ireland: a vaccinated NI population compared to a quasi-control unvaccinated IE population in a neighbouring country.

The aim of this study was to determine the impact of the rotavirus vaccination in NI on burden of rotavirus disease, to compare this to equivalent measures in the control population of IE, and to add to the evidence base in determining if the decline in rotavirus activity is due to natural variation, or due to introduction of a routine vaccination programme.

## 2. Methods

### 2.1. Data sources

#### 2.1.1. Cover of vaccination evaluated rapidly (COVER) statistics

Vaccination uptake in NI was determined from vaccination coverage statistics for completed primary immunisations by 12 months [9].

#### 2.1.2. National rotavirus surveillance data

The study population included individuals living in NI and IE over an eight year period (2007/08–2014/15). The start and duration of the annual rotavirus season (i.e. the expected annual period of heightened rotavirus activity) were determined by retrospective assessment of rotavirus activity in both jurisdictions during 2004–2013. A study year was therefore defined as week 29 of one year to week 28 of the following year. A universal vaccination programme was introduced in NI in the summer of 2013, therefore the time period for comparison was pre-vaccination period (six years; 2007/08 to 2012/13) compared to post-vaccination period (two years; 2013/14 to 2014/15).

The Public Health Agency (PHA) collected reports of laboratory confirmed rotavirus infections on a weekly basis from all laboratories in NI that test for rotavirus. A week was defined as Monday to Sunday inclusive. Data collected included sex and age; for a small number of cases this information was not available (<1%). Data were de-duplicated based on an episode length of 2 weeks; any positive result occurring >2 weeks after a previous positive result for rotavirus was considered a new case. Additionally, information on non-specific gastroenteritis in children aged <2 years was collected from notifications of infectious disease (NOIDs) reports to the PHA by clinicians.

Surveillance of rotavirus in IE was based on clinical and laboratory notifications to the Health Protection Surveillance Centre (HPSC). Rotavirus has been a notifiable disease within Acute Infectious Gastroenteritis since 2004, and became notifiable as a disease in its own right under the Infectious Diseases (Amendment) Regulations 2011 (S.I. No. 452 of 2011) [10]. A total of 98% of notifications were laboratory confirmed. Gastroenteritis in under 2 year olds is not notifiable in IE.

Weekly counts of the number of laboratory reports/notifications from each jurisdiction were extracted for all ages and individuals under 5 years old. Disease burden was measured using incidence proportions which were calculated for NI and IE for each study year. We estimated the impact of the vaccination programme by calculating the overall disease reduction, i.e. disease burden in the pre-vaccination period (six years; 2007/08 to 2012/13) compared to disease burden in the post-vaccination period (two years; 2013/14 to 2014/15) for each population.

#### 2.1.3. Hospital episode statistics

Hospital admissions data were obtained from national sources of hospital episode statistics. In NI the Patient Administration System (PAS) records all inpatient admissions to National Health Service (NHS) hospitals. In IE Hospital In-Patient Enquiry (HIPE) collects demographic, clinical and administrative data on discharges from acute public hospitals nationally. All admissions are coded using the tenth revision of International Classification of Disease (ICD-10) in both jurisdictions. Admissions with a primary diagnosis of rotavirus enteritis (A08.0) and/or acute unspecified viral intestinal infection (A08.4) in under 5 year olds were extracted for a pre-vaccine period (three years; 2010/11 to 2012/13) and post-vaccine period (two years in NI; 2013/14 to 2014/15 and one year in IE; 2013/14). A08.4 was included as rotavirus causes approximately 50% of gastroenteritis in this age group, but it may not be recorded as such due to lack of laboratory confirmation and coding practices [11]. Delays in coding for 2014/15 in IE meant that coding coverage was not deemed adequate at the time of writing for analysis. Rates of admission per 100,000 population with A08.0 or A08.5 were calculated for the pre-vaccination period and compared to the post vaccination period for under five year olds, and by single age year. Reduction in admissions was calculated with 95% confidence intervals.

NI denominators were obtained from the mid-year population estimates provided by the Northern Ireland Statistics and Research Agency (NISRA). IE denominators were obtained from the estimated population in April of each year provided by the Central Statistics Office.

We plotted the weekly incidence of each indicator in each jurisdiction stratified by age to illustrate the changes following the introduction of the rotavirus vaccination programme. Disease reduction was calculated with 95% confidence intervals based on binomial distribution. Data were analysed using Microsoft Excel and STATA 12.0 (Statacorp. College Station, TX, USA).

## 3. Results

Mean uptake of two doses of Rotarix® by 12 months of age in NI from July 2014 to 2015 was 94.7%.

### 3.1. National rotavirus surveillance data

#### 3.1.1. Trends and incidence over time

Figs. 1 and 2 show the weekly incidence of rotavirus laboratory confirmed cases for all ages and <5 years in NI, notifications of rotavirus for all ages and <5 years in IE between 2007/08 and 2014/15. The weekly incidence was consistently higher in IE

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