



# Proposed surveillance for the impact of the infant rotavirus immunisation programme in England and Wales

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1.1	01/09/2013	K. Russell	Minor Amendments (see Summary of Changes below)

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## Summary of Changes

1. Changes to the rotavirus vaccine coverage surveillance plan (Section 3.0)
2. Changes to the cover letter requesting NHS hospital virologists to submit rotavirus strains to the national reference laboratory (Appendix 1)
3. Addition of cover letter and questionnaire for follow-up of rotavirus-negative controls (Appendix 2)
4. Minor changes to the surveillance questionnaire (Appendix 2)

### 1.0. Background

A live attenuated oral rotavirus vaccine (Rotarix®) is being introduced into the UK infant immunisation programme on 01 July 2013, as a two dose schedule at 2 and 3 months of age. The programme is being delivered in primary care and it is recommended that the first dose should be administered by 15 weeks and the course should be completed by 24 weeks of age.

Rotaviruses have a segmented, double-stranded ribonucleic acid (RNA) genome. They are non-enveloped viruses. Two key surface proteins, VP7 (G type) and VP4 (P type), are used to characterise and classify strains. 10 G types and 11 P types have been identified in humans.<sup>1</sup> Across the world, the most common types of rotavirus circulating contain one of G1, G2, G3, G4 or G9 proteins in conjunction with P[4] or P[8] proteins. Rotavirus serotypes G1P[8], G2P[4], G3P[8], G4P[8], and G9P[8] account for approximately 82% of the serotypes circulating in the United Kingdom.<sup>2</sup>

Rotavirus causes gastroenteritis which usually lasts between 3 and 8 days.<sup>3</sup> Symptoms include fever, diarrhoea, vomiting, abdominal cramps, and dehydration. The virus is highly contagious and spreads by the faecal-oral route, although respiratory transmission has been documented.<sup>3</sup>

Rotavirus infections are seasonal, usually occurring in winter and spring (January to March). Although individuals of any age can develop rotavirus gastroenteritis, most

illnesses occur in children under 5 years of age. Newborn babies can develop rotavirus gastroenteritis, but protection from maternal antibodies usually results in milder infections.<sup>4,5</sup> Immunity to rotavirus infection is not absolute. The first infection tends to be the most severe and infants and toddlers, who have the highest burden of rotavirus gastroenteritis, may experience multiple episodes of illness by three years of age.<sup>6</sup> This usually results from infection with different rotavirus genotypes, although exposure to a previously-encountered strain can lead to asymptomatic infection. Infections in adults are rarely reported, although they are not uncommon in individuals caring for, or in contact with, children who have rotavirus gastroenteritis, mainly because the disease tends to be mild and, therefore, testing for rotavirus is not usually undertaken. Adults and older children can develop asymptomatic infection, which could play a role in maintaining rotavirus infection in the community.<sup>7</sup>

In England and Wales, rotavirus gastroenteritis is responsible for up to 130,000 annual GP consultations for children under five years, with around 13,000 hospitalisations.<sup>8</sup> These must be considered minimum estimates because the symptoms of rotavirus gastroenteritis are similar to several other viruses and bacteria and most cases of gastroenteritis presenting to the health service do not undergo laboratory-testing to identify the causative pathogen. It is estimated that rotavirus is responsible for around half of all children under five years hospitalised for severe gastroenteritis.<sup>9</sup> In addition, although there has been a downward trend in gastroenteritis caused by bacteria and parasites in young children over the past decade, the proportion of gastroenteritis cases due to viruses, and to rotavirus in particular, has remained stable.<sup>2</sup> In addition, rotavirus gastroenteritis also poses a significant burden of nosocomial illness among hospitalised children.<sup>10</sup> Deaths associated with rotavirus gastroenteritis are extremely rare and it is estimated that there may only be three to four deaths associated with rotavirus each year.<sup>11</sup>

Two vaccines have been licensed by the European Medicines Agency - Rotarix®, manufactured by GlaxoSmithKline, and RotaTeq®, manufactured by Sanofi Pasteur MSD. In the UK, Rotarix® has been selected by the Department of Health for inclusion in the childhood immunisation programme. It is a live attenuated vaccine that is administered orally. A previous rotavirus vaccine, RotaShield®, was withdrawn from the market in the United States in 1999 due to an increased risk of

intussusception in those receiving the vaccine. Research from some countries suggests that Rotarix® may be associated with a very small increased risk of intussusception within seven days of immunisation, possibly two cases per 100,000 first doses given. This risk is significantly less than that previously seen with RotaShield®.

Clinical trials have shown that Rotarix® is effective in protecting against gastroenteritis caused by rotavirus strains G1P[8], G2P[4], G3P[8], G4P[8], and G9P[8]. Although the effectiveness may vary against individual serotypes, studies in high income countries have shown the vaccine to be 85% effective overall at protecting against severe rotavirus gastroenteritis in the first two years of life.<sup>12,13,14, 15,16</sup>

In Finland, RotaTeq® (which is administered as a 3-dose schedule at monthly intervals) was introduced in the national immunisation programme in 2009 and, following high vaccine uptake, a 97% reduction in hospitalisation for rotavirus gastroenteritis was noted,<sup>17</sup> which is in keeping with report from other countries with routine rotavirus immunisation programmes. If a similar decrease occurs in England and Wales, admissions for rotavirus gastroenteritis would decrease from 12,700 to approximately 380 (assuming that two doses of Rotarix® results in comparable vaccine coverage and effectiveness as three doses of RotaTeq®).

## **2.0. Key programme outcome questions**

As with all vaccine-preventable infections, Public Health England (PHE) has initiated enhanced national surveillance for rotavirus gastroenteritis in England and Wales. In order to monitor the impact of the rotavirus immunisation programme, the key outcome questions in children aged < 5 years to be addressed will be:

1. What immunisation coverage is achieved by 6 months of age?
2. What is the impact of the vaccine on hospitalisations for rotavirus-associated, infection-related and all-cause gastroenteritis?

3. What is the impact of the vaccine on laboratory-confirmed rotavirus infections?
4. What is the impact of the vaccine on GP consultations for rotavirus-associated, infection-related and all-cause gastroenteritis?
5. What is the effect of universal vaccine on rotavirus population diversity?
6. What is the effectiveness of the rotavirus vaccine?
7. Does the clinical severity of the disease differ in immunised and unimmunised children before and after routine rotavirus immunisation?
8. How safe is the vaccine?

### **3.0. Enhanced surveillance activities**

In order to answer the above questions, the following enhanced data sources will be used:

- I. Rapid sentinel monthly rotavirus vaccine coverage estimates at 6 months of age collected through automated extracts from GP systems in England via the ImmForm website
- II. Routine quarterly and annual estimates of rotavirus vaccine coverage at the local authority and former PCT levels through COVER programme data, extracted from the Child Health Information Systems (CHISs) in England
- III. Laboratory-confirmed cases will be identified through LabBase2, DataMart and the PHE database of clinical samples submitted to the reference laboratory (MOLIS)
- IV. Immunisation history and severity of illness in vaccine-eligible children with laboratory-confirmed rotavirus infection cases will be obtained using a standardised questionnaire sent to the GP and/or paediatrician.
- V. Trends in hospitalisations and intussusception will be assessed using Hospital Episode Statistics (HES) data.

#### **3.1. Monitoring vaccine coverage**

The rotavirus immunisation programme will be delivered through primary care. There will be two sources of data collection:

- I. *Sentinel collections*: monthly automated surveys from GP systems will run from the start of the programme (1 July 2013) until 31 March 2015. July data (1/7/13 to 31/7/13 inclusive) will be collected in early August 2013 on the ImmForm website. As a GP based collection, there should be little disruption caused by the new organisational structures that formally came into place in April 2013. The automated collection allows the collection of monthly data with minimal or no burden to the NHS and also gives quick and timely coverage estimates. A scope for this temporary ImmForm coverage data collection is detailed in Annex C of the tripartite letter announcing the introduction of the rotavirus programme (<https://www.gov.uk/government/publications/national-immunisation-programme-planned-changes-for-2013-to-2014>)
- II. *Routine childhood population vaccine coverage*: Routine rotavirus vaccine coverage will be evaluated by the UK COVER (Cover of Vaccination Evaluated Rapidly) programme for children who reach their first birthday during each evaluation quarter. COVER data are extracted from Child Health Information Systems (CHISs) on a quarterly and annual basis, and from April 2013 will be collected by both local authority responsible population and PCT responsible population (for historical comparisons of coverage of other vaccines evaluated at same age) The first quarterly evaluation to include rotavirus coverage data will be the April to June 2014 collection

### **3.2. Impact on hospitalisations**

The Hospital Episode Statistics (HES) database provides information for all NHS hospital admissions in England and has been in place for several decades. Although most cases of rotavirus gastroenteritis do not require medical attention, it is recognised that hospitalisation for rotavirus gastroenteritis represents the more severe end of the spectrum of disease and is also responsible for the greatest expense to the healthcare system. Any reduction in hospitalisation as a result of immunisation against rotavirus would, therefore, be testament to the cost-effectiveness of the programme. The ICD-10 code for rotavirus enteritis is A08.0.

During 2011-12, there were 2,648 hospital episodes for rotavirus gastroenteritis in England. It is, however, estimated that rotavirus is also responsible for around half the hospital admissions for gastroenteritis where the pathogen is not recorded, and this is supported by modelling,<sup>9</sup> and vaccine-impact studies in other countries.<sup>17</sup> As such, it will be important to also assess the impact of the rotavirus immunisation programme on all infection-related gastroenteritides (e.g. unspecified viral intestinal infection (A08.4); other gastroenteritis and colitis of infectious and unspecified origin (A09.0), etc.) as well as all-cause gastroenteritis in the different age-groups.

### **3.3. Impact on disease**

Surveillance of laboratory-confirmed rotavirus infections will be undertaken using the electronic reporting database, LabBase2. NHS hospital laboratories routinely report all clinically significant infections on a voluntary basis to PHE through LabBase2. Provisional data for 2012 indicates there were 14,726 laboratory-confirmed rotavirus gastroenteritis episodes, including 5,922 cases reported in < 1 year-olds and 8,078 in 1-4 year-olds. Since LabBase2 has been in place for over two decades, this dataset will enable assessment of the impact of Rotarix® on laboratory-confirmed cases across the age groups.

One concern regarding analysis of vaccine impact using LabBase2 is that it may be affected by changes in frequency of stool testing among children with clinical gastroenteritis. It is possible that following the introduction of the rotavirus vaccine, the incidence may decline to such an extent that clinicians will stop requesting routine testing of stool samples for rotavirus. Alternatively, because of the decline, clinicians may request more stool sample testing in an attempt to identify the causative pathogens. These two scenarios could potentially over-estimate or under-estimate, respectively, the impact of the infant rotavirus immunisation programme because LabBase2 only contains clinically-significant rotavirus-positive reports and no data on the number of clinical specimens tested. Moreover, a recent review of clinical laboratory practices for rotavirus diagnosis in England and Wales highlighted the fact that there is no standard national age policy for rotavirus testing.<sup>18</sup> The majority of laboratories test samples from children under the age of five, but some laboratories may limit testing to those under three years. Experience from the United



States suggests that the infant immunisation programme will lead to an increase in the median age at which children develop rotavirus gastroenteritis. If the testing policy for local laboratories is set at a low age (e.g., under three years), then a significant proportion of severe rotavirus gastroenteritis cases may be missed.

In order to adjust for such differences whilst assessing vaccine impact, PHE is collaborating with a number (~10 sites) of sentinel NHS hospital microbiology laboratories in England to collect disaggregate data on the total number of rotavirus tests performed and the number of samples with a positive result along with minimal demographic data through the DataMart system. DataMart currently serves as an important laboratory surveillance tool for monitoring respiratory viruses circulating in England and uses weekly automatic electronic outputs from a number of hospital laboratories. A de-duplication process is carried out when new data are uploaded into the system by using patients' surname, first name, initial and date of birth. By providing data on all stool samples that are tested, DataMart will provide denominator data to examine trends in sample-testing and proportion positive for rotavirus on a weekly basis before and after the national introduction of the rotavirus immunisation programme.

#### ***3.4. Impact on hospital-acquired rotavirus gastroenteritis***

It is recognised that a significant proportion of laboratory-confirmed rotavirus gastroenteritis cases are acquired in hospital. In order to assess the contribution of hospital-acquired rotavirus gastroenteritis to the overall burden of rotavirus gastroenteritis in children, cases reported through LabBase2 will be linked to HES before and after vaccine introduction. By linking dates of laboratory confirmation in LabBase2 with dates of hospital admission and discharge in HES, it should be possible to estimate the proportion of laboratory-confirmed rotavirus gastroenteritis that are hospital-acquired and, also, any impact of the rotavirus immunisation programme on hospital-acquired rotavirus gastroenteritis. Matching variables would include NHS number, date of birth, first name, last name, gender, hospital and postcode. The ICD-10 codes to be used for the search and linkage will include:

A080            Rotaviral enteritis

A084	Viral intestinal infection, unspecified
A049	Bacterial intestinal infection, unspecified
A090	Other gastroenteritis and colitis of infectious and unspecified origin
K528	Other specified non-infective gastroenteritis and colitis
K529	Non-infective gastroenteritis and colitis, unspecified

A pilot is currently underway to link LabBase2 with HES for a one-year period prior to the rotavirus vaccine being implemented. If the linkage is successful and able to provide robust and reproducible data, then the same methodology will be used after vaccine introduction.

### ***3.5. Impact on GP consultations***

The Royal College of General Practitioners (RCGP) has an established network of 100 sentinel GP practices that regularly report on specific clinical conditions from a patient population of ~900,000 individuals. GP-based diagnoses are presented as incident rates per 100,000 and reported twice weekly. The weekly returns service has been running for 45 years and is co-ordinated by the RCGP Research and Surveillance Centre. This information could be used to compare rates of consultations for infectious intestinal disease (IID) in children under five years before and after the introduction of the vaccine. Although this analysis will be based on clinical assessment and may not always have laboratory test results to confirm a diagnosis, it is estimated that approximately half of all gastroenteritis in the community in children under five is caused by rotavirus so the immunisation programme should result in a significant reduction in the numbers of GP consultations for IID.

Another potential source of information is the Clinical Practice Research Datalink (CPRD; <http://www.cprd.com/home/>), a computerised database of anonymised patient data including demographics, medical diagnoses, prescription information, referral and treatment outcomes. CPRD currently collects data on about 3 million patients, equivalent to 5% of the UK population, but is continually expanding to cover a larger proportion of the English population.

### ***3.6. Laboratory confirmation of cases in primary care.***

In addition to data on consultations for IID, the Royal College of General Practitioners (RCGP) scheme can also integrate microbiological testing into the surveillance system and therefore could be used to collect samples from cases of IID seen in primary care. At present, there is no intention to undertake molecular surveillance of gastroenteritis presenting in primary care but this could potentially be performed – if indicated – following rotavirus vaccine introduction.

### ***3.7. Molecular surveillance of rotavirus in sentinel hospitals***

PHE Virus Reference Department (VRD) has provided a national service for molecular typing of rotavirus strains submitted by NHS laboratories for 10 years. These data are collected passively through voluntary submission of rotavirus-positive samples by NHS laboratories. In anticipation of the introduction of infant rotavirus immunisation, sentinel NHS hospital microbiology laboratory sites in England are collaborating with PHE VRD to conduct more comprehensive molecular surveillance of rotavirus and have been submitting all positive rotavirus samples in children aged under 5 years to PHE VRD for molecular typing since 01 January 2013. These sentinel laboratories have been identified in LabBase2 as 'high volume laboratories' that process and report the highest number of rotavirus samples, and will be encouraged to continue submitting samples during subsequent rotavirus seasons. The data from these sites will provide a pre-vaccine baseline for monitoring rotavirus strains in the coming years. It is anticipated that PHE will characterise approximately 1,000 strains in 2013, but this number will decline as disease burden declines following routine immunisation. As part of the enhanced surveillance, PHE will also request all NHS laboratories to submit rotavirus-positive samples isolated from the cohort eligible for immunisation to be submitted to PHE VRD for strain characterisation.

Microbiology laboratories are, therefore, requested to submit all rotavirus-positive samples from **children born since 01 May 2013 and diagnosed since 01 July**

**2013** to PHE VRD for molecular analysis. This service is offered free of charge when submitted with the sample referral form in the Appendix section of this document.

## **4.0. Monitoring vaccine effectiveness**

### ***4.1. Vaccine effectiveness against laboratory-confirmed infections***

Vaccine effectiveness will be calculated by obtaining immunisation histories for all cases in the vaccine-eligible cohort diagnosed since 01 July 2013. Cases will be identified on a weekly basis from integrated rotavirus surveillance database and immunisation status will be requested from the infant's GP by post or, if required, by telephone. A number of controls will be used to assess vaccine effectiveness, including:

- I. population-based rotavirus immunisation coverage estimated from any of the three sources: COVER, RCGP data and ImmForm (the screening method)
- II. rotavirus test-negative cases reported through DataMart (case-control method).

### ***4.2. Rotavirus strain-specific vaccine effectiveness***

In addition to the rotavirus strains submitted by sentinel laboratories, all NHS hospital microbiology laboratories will be contacted to submit rotavirus-positive samples from children in the vaccine-eligible cohort to PHE VRD for molecular characterisation. By obtaining immunisation histories for these children, it will also be possible to calculate strain-specific vaccine effectiveness using this information.

## **5.0. Clinical severity of rotavirus disease**

In addition to providing details on the immunisation history, GPs will be asked to provide details of hospitalisations and to complete a Vesikari Scoring scheme,<sup>19</sup> for assessing the severity of illness (Table 1). This score includes information on episodes and duration of vomiting and diarrhoea, fever, hydration status and treatment required. A score of <7 suggests mild disease, 7-10 suggests moderate

disease and  $\geq 11$  suggests severe disease, with a maximum possible score of 20. Such a scoring system will allow assessment of severity following routine immunisation and determine differences in disease severity among vaccinated, partially-vaccinated and unvaccinated children.

Parameter	SCORE		
	1	2	3
Diarrhoea			
Maximum stool episodes per day	1-3	4-5	>5
Diarrhoea duration (days)	1-4	5	>5
Vomiting			
Maximum vomiting episodes per day	1	2-4	>4
Vomiting Duration (number of days)	1	2	>2
Temperature	37.1-38.4	38.5-38.9	$\geq 39$
Dehydration	No/mild	Moderate (1-5%)	Severe (>5%)
Treatment	Not hospitalised	Hospitalised	-

**Table 1:** Vesikari Clinical Severity Scoring System Parameters and Scores

## 6.0. Monitoring vaccine safety

Due to concerns regarding the increased incidence of intussusception following the introduction of RotaShield in the past, a comprehensive safety assessment programme will be place in collaboration between the Medicines and Healthcare products Regulatory Agency (MHRA) and Public Health England. Particular emphasis will be placed on estimating any increased risk in Rotarix®-associated intussusception using HES data and immunisation histories obtained through record linkage with child health databases or by contacting GPs directly. The ICD-10 code for intussusception is K56.1.

**As with all new vaccines, all health professionals will be reminded to report all suspected adverse reactions associated with the rotavirus vaccine through the Yellow Card scheme.**

## 7.0. Dissemination of information and outputs

Successful implementation of the national surveillance programme relies on collaboration with RCGP, consultants in communicable disease control, local health

protection teams, immunisation leads, virologists, hospital paediatricians and GPs. Information on the surveillance scheme will be made available on the PHE website. In addition, regular reports on the rotavirus programme outcome will be made to the following:

- Regular reports to the Joint Committee on Vaccination and Immunisation (JCVI)
- Rotavirus COVER data will be available on the PHE and NHS immunisation websites.
- Peer reviewed publications

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[http://www.path.org/publications/files/VAD\\_vesikari\\_scoring\\_manual.pdf](http://www.path.org/publications/files/VAD_vesikari_scoring_manual.pdf)



Public Health  
England

**APPENDIX 1:**  
**Letter for Microbiology Laboratories**





Consultant Virologist

Lab Address 1

Lab Address 2

Lab Address 3

Lab Postcode

Date

Dear Colleague,

## Enhanced surveillance for rotavirus gastroenteritis

Re : Patient Name	PRN	Date of Sample
DOB	NHS No	SPEC NUMBER
HOSP NUMBER		

A childhood vaccination programme against rotavirus infection has been introduced in England and Wales from 01 July 2013. As with all vaccine-preventable diseases, Public Health England (PHE) has enhanced surveillance in place for rotavirus gastroenteritis.

In order to monitor vaccine effectiveness and changes in the molecular epidemiology of rotavirus following routine infant immunisation, we are requesting all NHS laboratories to submit positive rotavirus samples from vaccine eligible infants (i.e. born since 01 May 2013 and diagnosed since 01 July 2013) to PHE Virus Reference Department (VRD). This service is provided free of charge when using the referral form provided.

According to our records, the above-named child had laboratory-confirmed rotavirus infection recently. We would be grateful if you could refer any residual sample to PHE as above. Laboratories are requested to use the attached form to ensure that they will not be charged. PCR amplification and sequencing of rotavirus will be undertaken on all samples to determine rotavirus genotype. For your records, results of the molecular analysis will be sent to you within 4 weeks of receipt of the sample at Colindale. Please ignore the request if you have already referred a sample to Colindale for this patient.

Yours Sincerely,

Dr Shamez Ladhani  
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Professor David Brown  
Director, Virus Reference Department  
E-mail: [david.brown@phe.gov.uk](mailto:david.brown@phe.gov.uk)



**PATIENT DETAILS**

Patient First Name: \_\_\_\_\_

Patient Surname: \_\_\_\_\_

DOB (dd/mm/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_ Sex: M/F

NHS No: \_\_\_\_\_ Hospital no: \_\_\_\_\_

GP Name : \_\_\_\_\_ Tel No: \_\_\_\_\_

Practice Address: \_\_\_\_\_

\_\_\_\_\_

PostCode: \_\_\_\_\_

**REFERRING LABORATORY**

Laboratory/Hospital Name: \_\_\_\_\_

Laboratory Sample Number: \_\_\_\_\_

Sample Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Lab Contact Name: \_\_\_\_\_

Lab Tel No: \_\_\_\_\_

Symptom Onset Date (dd/mm/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

**Available Rotavirus Laboratory Results** (Please state platform used)

TEST	Status (Pos/Neg/UNK)	Quantity	Units/OD/OD ratio
_____	_____	_____	_____
_____	_____	_____	_____

Please send in aliquot of the FIRST sample which led to a report of Rotavirus infection  
Please include this form with the sample when dispatching

**APPENDIX 2:**  
**Letters for General Practitioners**



GP Practice Name  
Address 1  
Address 2  
Address3  
Postcode  
Date

**Enhanced surveillance for  
rotavirus gastroenteritis**

Dear Colleague,

Re : Patient Name                      PRN  
          DOB                                NHS No

Public Health England is evaluating the effectiveness of the oral rotavirus vaccination programme that was introduced into the national infant immunisation programme on 01 July 2013. The above-named child was reported to us as having laboratory-confirmed rotavirus infection on <<date\_of\_sample>>.

In order to monitor vaccine effectiveness and clinical severity of infection, we would be most grateful if you would **complete the enclosed questionnaire** and return it to us in the stamped, addressed envelope provided. You may wish to contact with the child's parents to obtain some of the requested information (e.g. episodes and duration of vomiting, diarrhoea, etc.).

We would also be grateful if you would kindly provide a copy of the hospital and/or paediatric/neonatal intensive care **discharge summary** if available. If you were not aware that this child had rotavirus infection before receiving this letter, please let us know before you contact the parents so that we can verify our details.

Yours sincerely

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Public Health England has approval under PIAG Section 60 of the Health and Social Care Act 2001 (now subsumed into the National Information Governance Board for Health and Social Care with Section 60, now Section 251 of the NHS Act 2006) to process confidential patient information for the purpose of monitoring the efficacy and safety of vaccination programmes (see <http://www.legislation.hmsso.gov.uk/si/si2002/20021438.htm>)



**Clinical Questionnaire (rotavirus-positive cases)**

Patient Name:

PRN:

Patient DOB:

NHS Number:

Date of diagnosis:

**1. Was the child immunised against rotavirus with Rotarix®? Y / N**

If yes, (i) date of first dose of Rotarix®: \_\_\_ / \_\_\_ / \_\_\_ Batch Number: \_\_\_\_\_

(ii) date of second dose of Rotarix®: \_\_\_ / \_\_\_ / \_\_\_ Batch Number: \_\_\_\_\_

**2. Date of onset of symptoms: \_\_\_ / \_\_\_ / \_\_\_**

*Please circle the appropriate number for each of the parameters below from the day the child became unwell. You may wish to liaise with the child's parents to answer some of these questions*

(i) Method of feeding the time of illness? – Exclusively breastfed / Exclusively bottle-fed / Both

(ii) Did the child have diarrhoea at any time during the illness? - Y / N

If yes, maximum diarrhoea episodes per day (circle): **1-3 / 4-5 / more than 5** episodes

If yes, number of days with diarrhoea (circle): **1-3 / 4-5 / more than 5** days

(iii) Did the child have vomiting at any time during the illness? - Y / N

If yes, maximum vomiting episodes per day (circle): **1 / 2-4 / more than 4** episodes

If yes, number of days with vomiting (circle): **1 / 2 / more than 2** days

(iv) Did the child have fever at any time during the illness? - Y / N

If yes, highest temp. in °C (circle): **37.1-38.4 (low-grade) / 38.5-38.9 (moderate) / ≥39.0 (high)**

(v) Was the child dehydrated at any time during the illness? - Y / N

If yes, how dehydrated (circle): **moderate (1-5%) / severe (more than 5%)**

***Please turn over.....***

3. Did the child **visit a hospital A&E department** during the illness? - **Y / N**

If yes, was the child **admitted to hospital?** - **Y / N**

If yes, date of hospital admission: \_\_\_ / \_\_\_ / \_\_\_ and number of days admitted \_\_\_\_\_

4. Was the child admitted to **intensive care?** - **Y / N**

If yes, date of intensive care admission: \_\_\_ / \_\_\_ / \_\_\_ and number of days admitted \_\_\_\_\_

5. Any other comments: \_\_\_\_\_

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**Thank you for taking the time to complete the questionnaire**

Person completing questionnaire (name): \_\_\_\_\_ Designation: \_\_\_\_\_

***If you would like us to contact the child's parent for completion of some of the questions, please provide the following information:***

Name of parent: \_\_\_\_\_ Telephone: \_\_\_\_\_

***Please return completed form with copy of hospital discharge letter (if available) in envelope provided to:  
Rotavirus Surveillance, Immunisation Department, Public Health England, 61 Colindale Avenue, London NW9 5EQ***



Public Health  
England

Immunisation, Hepatitis and Blood Safety Department T +44 (0)20 8200 4400  
Public Health England  
61 Colindale Avenue  
London  
NW9 5EQ  
[www.gov.uk/phe](http://www.gov.uk/phe)

GP Practice Name  
Address 1  
Address 2  
Address3  
Postcode  
Date

## Enhanced surveillance for rotavirus gastroenteritis

Dear Colleague,

Re : Patient Name                      PRN  
          DOB                                NHS No

Public Health England is evaluating the effectiveness of the oral rotavirus vaccination programme that was introduced into the national infant immunisation programme on 01 July 2013. The above-named child recently had a stool sample submitted to your local hospital microbiology laboratory on <<date\_of\_sample>>, **which was negative for rotavirus infection.**

In order monitor the impact of the rotavirus vaccination programme, we need to compare rotavirus vaccination status and clinical severity of disease in children with and without laboratory-confirmed rotavirus infection. We would, therefore, be most grateful if you would **complete the enclosed questionnaire** and return it to us in the stamped, addressed envelope provided. You may wish to contact with the child's parents to obtain some of the requested information (e.g. episodes and duration of vomiting, diarrhoea, etc.).

We would also be grateful if you would kindly provide a copy of the hospital and/or paediatric/neonatal intensive care **discharge summary** if available. If you were not aware that the child was unwell, please let us know before you contact the parents so that we can verify our details.

Yours sincerely

Dr Shamez Ladhani  
Paediatric Infectious Diseases Consultant  
E-mail: [shamez.ladhani@phe.gov.uk](mailto:shamez.ladhani@phe.gov.uk)

Public Health England has approval under PIAG Section 60 of the Health and Social Care Act 2001 (now subsumed into the National Information Governance Board for Health and Social Care with Section 60, now Section 251 of the NHS Act 2006) to process confidential patient information for the purpose of monitoring the efficacy and safety of vaccination programmes (see <http://www.legislation.hms.gov.uk/si/si2002/20021438.htm>)



**Clinical Questionnaire (rotavirus-negative cases)**

Patient Name:

PRN:

Patient DOB:

NHS Number:

Date of diagnosis:

**1. Was the child immunised against rotavirus with Rotarix®? Y / N**

If yes, (i) date of first dose of Rotarix®: \_\_\_ / \_\_\_ / \_\_\_ Batch Number: \_\_\_\_\_

(ii) date of second dose of Rotarix®: \_\_\_ / \_\_\_ / \_\_\_ Batch Number: \_\_\_\_\_

**2. Date of onset of symptoms: \_\_\_ / \_\_\_ / \_\_\_**

*Please circle the appropriate number for each of the parameters below from the day the child became unwell. You may wish to liaise with the child's parents to answer some of these questions*

(i) Method of feeding the time of illness? – Exclusively breastfed / Exclusively bottle-fed / Both

(ii) Did the child have diarrhoea at any time during the illness? - Y / N

If yes, maximum diarrhoea episodes per day (circle): **1-3 / 4-5 / more than 5** episodes

If yes, number of days with diarrhoea (circle): **1-3 / 4-5 / more than 5** days

(iii) Did the child have vomiting at any time during the illness? - Y / N

If yes, maximum vomiting episodes per day (circle): **1 / 2-4 / more than 4** episodes

If yes, number of days with vomiting (circle): **1 / 2 / more than 2** days

(iv) Did the child have fever at any time during the illness? - Y / N

If yes, highest temp. in °C (circle): **37.1-38.4 (low-grade) / 38.5-38.9 (moderate) / ≥39.0 (high)**

(v) Was the child dehydrated at any time during the illness? - Y / N

If yes, how dehydrated (circle): **moderate (1-5%) / severe (more than 5%)**

***Please turn over.....***



3. Did the child **visit a hospital A&E department** during the illness? - **Y / N**

If yes, was the child **admitted to hospital?** - **Y / N**

If yes, date of hospital admission: \_\_\_ / \_\_\_ / \_\_\_ and number of days admitted \_\_\_\_\_

4. Was the child admitted to **intensive care?** - **Y / N**

If yes, date of intensive care admission: \_\_\_ / \_\_\_ / \_\_\_ and number of days admitted \_\_\_\_\_

5. Any other comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Thank you for taking the time to complete the questionnaire**

Person completing questionnaire (name): \_\_\_\_\_ Designation: \_\_\_\_\_

***If you would like us to contact the child's parent for completion of some of the questions, please provide the following information:***

Name of parent: \_\_\_\_\_ Telephone: \_\_\_\_\_

***Please return completed form with copy of hospital discharge letter (if available) in envelope provided to:  
Rotavirus Surveillance, Immunisation Department, Public Health England, 61 Colindale Avenue, London NW9 5EQ***