NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE indicator validity assessment

## Indicator NM206

The percentage of babies who reached 24 weeks old in the preceding 12 months, who have received 2 doses of rotavirus vaccine before the age of 24 weeks.

### Importance

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| **Considerations** | **Assessment** |
| The Department of Health and Social Care (DHSC) published a vaccination strategy in Autumn 2020 with the aim to maintain and develop the UK immunisation programme.  Routine childhood immunisations, including rotavirus vaccination, are part of the general medical services (GMS) contract. | The indicator reflects a specific priority area identified by DHSC. |
| [2019-20 data from NHS Digital and Public Health England](https://digital.nhs.uk/data-and-information/publications/statistical/nhs-immunisation-statistics/england---2019-20) shows 90.1% of children in England were reported to have received two doses of the rotavirus vaccine measured at age 12 months. This increased from 89.7% in 2018-19. Six regions of England achieved coverage of more than 90%. No regions achieved the 95% coverage target for with childhood vaccinations highlighted in the report. There is no data available for coverage at 6 months of age.  [2020-21 data from NHS Digital and Public Health England](https://digital.nhs.uk/data-and-information/publications/statistical/nhs-immunisation-statistics/england---2020-21/coverage-statistics) shows 90.2% of children in England were reported to have received 2 doses of the rotavirus vaccine as measured at 12 months. | The indicator relates to an area where there is performance under the specified 95% national coverage, and variation in practice.  The indicator addresses under-treatment. |
| Rotavirus is highly contagious and causes gastroenteritis that lasts from 3 to 8 days and can lead to dehydration. [The Green Book](https://www.gov.uk/government/publications/rotavirus-the-green-book-chapter-27b) references studies that estimate 130,000 children will visit their GP and approximately 12,700 children will be hospitalised in England and Wales each year due to rotavirus gastroenteritis.  Babies should receive the rotavirus vaccine at 8 and 12 weeks old. | The indicator will lead to a meaningful improvement in patient outcomes. |

### Evidence base

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| **Considerations** | **Assessment** |
| [Immunisations: reducing differences in uptake in under 19s](https://www.nice.org.uk/guidance/ph21) (2009, updated 2017) NICE Public Health guideline PH21, recommendations 1, 2 and 3.  [Immunizations – childhood](https://cks.nice.org.uk/topics/immunizations-childhood/) (2021) NICE clinical knowledge summary. | The indicator is derived from a high-quality evidence base.  The indicator aligns with the evidence base. |

### Specification

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| **Considerations** | **Assessment** |
| Numerator: The number in the denominator who received 2 doses of a rotavirus vaccine before they reached 24 weeks old.  Denominator: The number of babies who reached 24 weeks old in the preceding 12 months.  Exclusions (taken from [the Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)):   * Babies with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine or any component of the vaccine. * Babies with a history of intussusception. * Babies with severe combined immunodeficiency disorder. * Babies who have a malformation of the gastrointestinal tract that could predispose to intussusception. * Babies with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.   [Information from the NHS on rotavirus vaccine FAQs](https://www.nhs.uk/conditions/vaccinations/rotavirus-vaccine-questions-answers/) also detail the following exclusions:   * Babies who are born to mothers who were taking immunosuppressant medicines in pregnancy. * Babies who have been breastfeeding while their mother was taking immunosuppressant medications. | The indicator has defined components necessary to construct the indicator, including numerator, denominator and exclusions.  The rotavirus vaccine should not be given after 24 weeks so the specification reflects this. |
| NICE general practice level indicators are intended for use where there is an average of 20 or more patients per practice. [PHE/NHS Digital experimental GP vaccination coverage statistics 2019-20](https://www.gov.uk/government/publications/cover-of-vaccination-evaluated-rapidly-cover-programme-annual-data) shows a total 12-month denominator of 625,516. This is approximately 93 patients per GP practice (6720 GP practices QOF 2019-10). There is no estimate of number of babies aged 6 months old (24 weeks). | The indicator does outline minimum numbers of patients needed to be confident in the assessment of variation. |

### Feasibility

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| **Considerations** | **Assessment** |
| The complete [routine vaccination schedule from June 2020](https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule) details that this vaccine is given at 8 and 12 weeks.  [Cover of vaccination evaluated rapidly (COVER) data](https://www.gov.uk/government/statistics/cover-of-vaccination-evaluated-rapidly-cover-programme-2020-to-2021-quarterly-data) is collected by Public Health England and reported quarterly and annually by NHS Digital and Public Health England including rotavirus by 12 months of age. Data is submitted by the local teams and child health record departments and reported nationally and regionally. From 2019-20 this will include general practice level coverage. | The indicator is repeatable. |
| Existing clinical code clusters as detailed in [NHS Digital’s V&I programmes 2021/22 business rules Rotavirus v11.0](https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/quality-and-outcomes-framework-qof/quality-and-outcome-framework-qof-business-rules/enhanced-services-es-vaccination-and-immunisation-vi-and-core-contract-components-2021-2022):   * ROTAVAC1\_COD rotavirus vaccination 1st dose given codes. * ROTAVAC2\_COD rotavirus vaccination 2nd dose given codes. * ROTAVACEXC\_COD rotavirus vaccination exception reporting codes   Exception reporting codes:  868691000000101 Rotavirus vaccination contraindicated (situation)  868731000000107 No consent for rotavirus vaccination (finding)  882201000000107 First rotavirus vaccination declined (situation)  889571000000106 Adverse reaction to rotavirus vaccine (disorder)  868711000000104 Rotavirus vaccination declined (situation)  870011000000106 Did not attend first rotavirus vaccination (finding)  870041000000107 Did not attend second rotavirus vaccination (finding)  882221000000103 Second rotavirus vaccination declined (situation)  885901000000106 History of rotavirus vaccine allergy (situation) | The indicator is measuring what it is designed to measure.  The indicator uses existing data fields. |

### Acceptability

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| **Considerations** | **Assessment** |
| [The Green book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) recommends that two doses of rotavirus vaccine should be given to infants between 6 and 24 weeks of age to prevent severe gastroenteritis due to rotavirus. Vaccination with rotavirus should not be started for infants aged 15 weeks and 0 days or older. Infants who received their first dose by 15 weeks should receive a second dose at an interval of 4 weeks and by 23 weeks and 6 days.  Administration of the vaccine should be postponed in infants suffering from:   * acute, severe febrile illness * acute diarrhoea and vomiting.   Data is currently collected as part of the vaccination & immunisation core contract 2021/22. [NHS Digital business rules v11.0](https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/quality-and-outcomes-framework-qof/quality-and-outcome-framework-qof-business-rules/enhanced-services-es-vaccination-and-immunisation-vi-and-core-contract-components-2021-2022) detail that payment counts are calculated on a cohort of patients that are 24 weeks of age.  There may be over estimation of denominators and therefore under estimation of coverage for individual practices as children may have moved away but remained on the register.  Some parents choose not to vaccinate their children. | The indicator assesses performance that is attributable to or within the control of the audience.  Data is currently collected on patients who are 24 weeks of age: first dose of rotavirus vaccine between 6 weeks and 14 weeks 6 days in the reporting period and second dose between 10 weeks and 23 weeks and 6 days. This indicator proposes measurement of two doses by 24 weeks of age to reflect that the vaccine cannot be given after 24 weeks of age.  As rotavirus vaccine cannot be started in infants older than 15 weeks, when the vaccination status is unknown and unable to receive before 15 weeks no vaccine should be given.  Patient choice to vaccinate should be considered and personalised care adjustments recorded accordingly. |
| Data is collected by NHS Digital. | The results of the indicator can be used to improve practice. Practices currently submit data to NHS Digital. |

### Risk

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| **Considerations** | **Assessment** |
| The rotavirus vaccination should not be given after 24 weeks of age and this is stated in [The Green book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book). | The indicator has an acceptable risk of unintended consequences. |

### NICE indicator advisory committee recommendation

The NICE indicator advisory committee approved this indicator for publication on the menu.