NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE indicator validity assessment

### Indicator NM197

The percentage of babies who reached 8 months old in the preceding 12 months, who have received at least 3 doses of a diphtheria, tetanus and pertussis containing vaccine before the age of 8 months.

### Importance

|  |  |
| --- | --- |
| **Considerations** | **Assessment** |
| The Department of Health and Social Care (DHSC) will publish a vaccination strategy in Autumn 2020 to maintain and develop the UK immunisation programme.  Babies receive the hexavalent (6-in-1) vaccine at 8, 12 and 16 weeks old. This vaccine is for immunisation to diphtheria, tetanus and pertussis (DTaP) as well as hepatitis B, haemophilus influenzae type B (Hib) and poliomyelitis (IPV).  Routine childhood immunisations are part of the general medical services (GMS) contract. | The indicator reflects a specific priority area identified by the DHSC. |
| Coverage of DTaP/IPV/Hib at a national level has declined following a peak in 2012-13. 2018-19 data from [NHS Digital and Public Health England](https://digital.nhs.uk/data-and-information/publications/statistical/nhs-immunisation-statistics/england-2018-19) shows 92.1% coverage at 12 months of age for this vaccine. Regional coverage reported by local authority ranged from 87.4% (London) to 95.4% (North East). Note the misalignment in measurement with that in the proposed indicator. | The indicator relates to an area where there is performance under the WHO recommended target of 95% national coverage, and variation in practice.  The indicator addresses under-treatment. |
| Diphtheria is an acute infectious disease affecting the upper respiratory tract resulting in membranous pharyngitis. The toxin can affect the myocardium, nervous and adrenal tissues and can cause paralysis and cardiac failure.  Tetanus is an acute disease caused by the action of tetanus toxin following infection by the bacterium Clostridium tetani. The disease is characterised by generalised rigidity and spasms of skeletal muscles.  Pertussis (whooping cough) is an acute infectious disease with an initial catarrhal stage followed by an irritating cough that becomes paroxysmal within one to two weeks. This is followed by a characteristic ‘whoop’ or vomiting. In young infants there may be periods of apnoea. It may be complicated by bronchopneumonia and cerebral hypoxia. | The indicator will lead to a meaningful improvement in patient outcomes. |

### Evidence base

|  |  |
| --- | --- |
| **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/immunizations-childhood) (2020) NICE clinical knowledge summary | The indicator is derived from a high-quality evidence base.  The indicator measures receipt of the 3 doses of the vaccine by 8 months of age although the immunisation schedule states this is due at 8, 12 and 16 weeks of age. Measurement by 8 months old allows for delays, for example due to fever and allows for bimonthly reminders. |

### Specification

|  |  |
| --- | --- |
| **Considerations** | **Assessment** |
| Numerator: The number in the denominator who have received 3 doses of a diphtheria, tetanus and pertussis containing vaccine before they reached 8 months old.  Denominator: The number of babies who reached 8 months old in the preceding 12 months.  Exclusions: Babies with a confirmed anaphylactic reaction to a previous dose of the vaccine or any component of the vaccine. | The indicator has defined components necessary to construct the indicator, including numerator, denominator and exclusions.  At consultation, this indicator measured the percentage of babies who received 3 doses of a diphtheria, tetanus and pertussis containing vaccine before 6 months of age. This was amended following discussion at the Indicator Advisory Committee in August 2020. |
| This indicator would be reported at general practice level for practices with more than 20 eligible patients. | The indicator outlines minimum numbers of patients needed to be confident in the assessment of variation. |

### Feasibility

|  |  |
| --- | --- |
| **Considerations** | **Assessment** |
| The childhood vaccination schedule details that this vaccine is given at 8, 12 and 16 weeks of age.  [Cover of vaccination evaluated rapidly (COVER)](https://www.gov.uk/government/statistics/cover-of-vaccination-evaluated-rapidly-cover-programme-2018-to-2019-quarterly-data) data is collected by [Public Health England](https://www.gov.uk/government/statistics/cover-of-vaccination-evaluated-rapidly-cover-programme-2018-to-2019-quarterly-data) and reported quarterly and annually by NHS Digital and Public Health England including 12-month DTaP/IPV/HiB. 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 Childhood Immunisation Scheme is part of the GP contract in England. Data for this is extracted quarterly. | Data at the age of 8 months is not currently collected by PHE or NHS Digital. The vaccinations are scheduled to be given before 8 months of age, so it should be possible to extract the data from GP systems.  The indicator is repeatable. |
| There are codes available for this vaccine and contraindication to the vaccine on SNOMED-CT. | The proposed indicator is measuring what it is designed to measure.  The indicator uses existing data fields. |

### Acceptability

|  |  |
| --- | --- |
| **Considerations** | **Assessment** |
| Interrupted courses or doses should be resumed but not repeated, allowing an interval of 4 weeks. Missed doses should be given as soon as possible.  The hexavalent vaccine should not be given to infants with a confirmed anaphylactic reaction to a previous dose of the vaccine or a component of the vaccine. Data quoted in the Green Book suggests rates of 0.65 to 3 anaphylaxis events per million doses of vaccines given ([Public Health England](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book), 2013).  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.  Parents may choose not to vaccinate their children. | The indicator assesses performance that is attributable to or within the control of the audience. There are few exclusions or exceptions. Patient choice to vaccinate should be considered and personalised care adjustments recorded accordingly.  The indicator was amended after discussion at the Indicator Advisory Committee as measurement of achievement before 6 months was considered too short a timescale (last dose is due to be given at around 4 months of age). A short timescale may not allow for the four-week interval required for interrupted or missed doses. Measurement before 8 months of age gives allowance for delay due to illness and allows for bimonthly reminders to be sent. |
| Data for the GP additional services contract is collected quarterly by NHS Digital. | Practices currently submit data to NHS Digital. The results of the indicator can be used to improve practice. |

### Risk

|  |  |
| --- | --- |
| **Considerations** | **Assessment** |
| Parents may choose not to vaccinate their children.  Some data quality issues have been reported as part of the COVER collection, including missing data, late immunisations and systems in transition. | The indicator has an acceptable risk of unintended consequences. Care should be taken to respect patient choice and record personalised care adjustments accordingly. |

### NICE indicator advisory committee recommendation

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