**NHS Digital**

**Indicator Supporting Documentation**

**IAP00397 Neonatal mortality and Stillbirths (ONS mortality)**

Application Form

Indicator and Methodology Assurance Service

**Title: Neonatal mortality and stillbirths**

**Set or domain: CCG Outcomes Indicator Set**

**IAS Reference Code: IAP00397**

**Version History**

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Changed By | Change |
| V0.1 | 17/06/2017 | Andy Besch | Uplift of previous form uplift commenced |
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# Application Form

Section 1 Introduction / Overview

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| --- | --- |
| **1.1 Title** | Neonatal mortality and stillbirths |
| **1.2 Set or domain** | Clinical Commissioning Group Outcomes Indicator Set (CCG OIS) |
| **1.3 Topic area** | Maternity |
| **1.4 Definition** | This indicator measures the proportion of live and stillbirths which were stillborn or died within 28 days, per 1,000 live and stillbirths that occur in a calendar year. The indicator will be reported at the national level, disaggregated by CCG of residence.  This indicator uses an extract of data held by Office for National Statistics, where birth registration and death registration data have been linked. This data is used by the ONS to produce the Childhood, Infant, and Perinatal Mortality in England and Wales statistical bulletin.  This indicator will use the same definitions as used in the ONS publication. The ONS defines a stillbirth as “born after 24 or more weeks completed gestation and which did not, at any time, breathe or show signs of life”; neonatal mortality is defined as “deaths under 28 days”.  CCG level data will be aggregated from the Lower Super Output Area (LSOA) of the mother’s home postcode. This will result in the distribution of activity being aggregated based on the resident population of the CCG, as opposed to the usual convention in the CCG OIS of using the registered population, which is based on GP Practice. |
| **1.5 Indicator owner & contact details** |  |
| **1.6 Publication status** | Currently in publication |

Section 2 Rationale

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| **2.1 Purpose** | The number of stillbirths and neonatal deaths is influenced by a number of maternal health factors, including obesity, smoking and a range of chronic diseases. The treatment/support for many of these fall within CCG commissioning responsibilities. Even where the relevant service is not commissioned by a CCG - for example, smoking cessation - the identification and referral of women with a need for such support falls within the role of maternity services commissioned by CCGs. The number is also influenced by effective support during the birth process and the postnatal period in services mainly commissioned by CCGs. Where the number of local stillbirths and neonatal deaths is disproportionately high, CCGs should consider the reasons for this and take appropriate action.  This indicator is currently published at national level and lower tier local authority level within the NHS Outcomes Framework (NHS OF) indicator 1.6.ii, Neonatal mortality and stillbirths, however, has not been disaggregated at CCG level. |
| **2.2 Sponsor** |  |
| **2.3 Endorsement** |  |
| **2.4 Evidence and Policy base**  Including related national incentives, critical business question, NICE quality standard and set or domain rationale, if appropriate | Adverse outcomes of pregnancy, such as stillbirth or neonatal mortality, are sometimes unpredictable events. These events can be associated with a number of risk factors; these include, but are not limited to fetal growth restriction, preterm birth and birth weight, the age of the mother, ethnicity and region of residence. Maternal health factors such as obesity, smoking status, as well as underlying conditions such as diabetes are also risk factors in stillbirth and neonatal mortality[[1]](#footnote-1)[[2]](#footnote-2).  Infant mortality rates have fallen dramatically in the last decade; however the number of stillbirths has remained stable. The UK compares poorly with other countries with similar populations who have managed to reduce their still birth rates by as much as 50% in the last 20 years[[3]](#footnote-3).  It has been suggested that the number of stillbirths and neonatal mortalities can be reduced through better care, availability of midwives, and screening of pregnant mothers in order to better determine any complications, as routine checks can often find no indication of an issue3.  Problems during pregnancy (such as miscarriage, foetal growth restriction and preterm birth) remain common and stillbirth rates have not changed significantly in recent years. This indicator will monitor neonatal mortality and stillbirth rates to help inform care to help reduce these in the future.  This indicator aims to reflect the provision of high quality care as set out in the NICE Quality Standard for Antenatal care (QS22)[[4]](#footnote-4) and the NICE Quality Standard for Caesarean section (QS32)[[5]](#footnote-5).  An infant mortality indicator has been included in the Department of Health Business Plan[[6]](#footnote-6).  The CCG OIS is an integral part of the NHS England’s systematic approach to quality improvement. It is intended to provide clear, comparative information for CCGs, patients and the public about the quality of health services commissioned by CCGs and the associated health outcomes. All of the CCG outcome indicators have been chosen on the basis that they contribute to the overarching aims of the five domains in the NHS Outcomes Framework and it is intended as a tool for CCGs to drive local improvement and set priorities <http://www.england.nhs.uk/ccg-ois/>  This indicator fits within Domain 1 of the CCG OIS: Preventing people from dying prematurely. |

Section 3 Data

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| **3.1 Data source** | ONS. <http://www.ons.gov.uk/>  The data is taken from an extract of data held by ONS, where birth registration and death registration data have been linked. This data is used by ONS to publish live birth, stillbirth, and neonatal mortality figures as part of the Childhood, Infant and Perinatal Mortality in England and Wales statistical bulletin. |
| **3.2 Justification of source and others considered** | ONS is the official source for birth and death statistics in England and Wales. This data is derived from birth and death registrations.  The ONS publication Childhood, Infant and Perinatal Mortality in England and Wales contains information on the number of live births, stillbirths, and neonatal deaths. This data source is also used by NHS OF indicator 1.6.ii Neonatal mortality and stillbirths.  No other data sources were considered for this indicator. |
| **3.3 Data availability** | The underlying record level data is not publicly available. The statistical bulletin and aggregated tables for a given calendar year are published annually about 14 months after the end of the reference year at the following link: <http://www.ons.gov.uk/ons/rel/vsob1/child-mortality-statistics--childhood--infant-and-perinatal/index.html>.  Special extracts and tabulations of child mortality data for England and Wales are available to order (subject to legal frameworks, disclosure control, resources and agreements of costs, where appropriate). Such enquiries should be made to:  Vital Statistics Outputs Branch  Office for National Statistics  Segensworth Road  Titchfield  Fareham  Hants PO15 5RR  Telephone: 01329 444110  email: [vsob@ons.gsi.gov.uk](mailto:vsob@ons.gsi.gov.uk)  ONS have confirmed that CCG level data can be provided for this indicator. However, CCG level data will be aggregated from the LSOA of the mother’s home postcode. This will result in the distribution of activity being aggregated based on the resident population of the CCG, as opposed to the usual convention in the CCG OIS of using the registered population, which is based on GP Practice.  CCG level data for 2013 can be requested from ONS from March 2015 using the above extract process. This indicator is due to be included as part of the 2015-16 CCG OIS. |
| **3.4 Data quality** | **i) What data quality checks are relevant to this indicator?**  **Coverage**  **Completeness**  **Validity**  **Default**  **Integrity**  **Timeliness**  **Other**  **If you included ‘Other’ as a data quality check, please describe the check, how it will be measured, and its reason for use below:**    **ii) What are the current values for the data quality checks selected?** The period of data the current values are calculated from should be stated. Current values should be recorded as a percentage and calculated as described below.  **Period of data:**  **Coverage:**  **Calculation:**  **Completeness:**  **Calculation:**  **Validity:**  **Calculation:**  **Default:**  **Calculation:**  **Integrity:**  **Calculation:**  **Timeliness:**  **Calculation:**  **Other:**  **Calculation:**  **iii) What are the thresholds for the data quality checks selected?**  **Coverage:**  **Completeness:**  **Validity:**  **Default:**  **Integrity:**  **Timeliness:**  **Other:**  **iv) What is the rationale for the selection of the data quality checks and thresholds selected above?**    **v) Describe how you would plan to improve data quality should it not meet, or subsequently fall below, the thresholds required for this indicator.**    **vi) Who will own the data quality risks and issues for this indicator?**  **Name:**  **Job Title:**  **Role:**  **Email:**  **Telephone:**  **vii) Describe how the data quality risks and issues will be managed for this indicator, including the escalation process.**    **viii) Describe any assumptions you have made about data quality for this indicator.**    **ix) Describe any data quality constraints you are aware of for this indicator.**    **x) Additional data quality information:** |
| **3.5 Quality assurance** | When birth registrations are received by ONS, a number of checks are carried out on records to ensure that they are valid. Checks are more frequent on those records with extreme values for key variables (such as age of mother and age of father) as these have a greater impact on published tables. For example, when looking at multiple births, checks are carried out to ensure that the number of triplets is divisible by three and that there is one maternity recorded for each set of triplets. Any birth records which appear questionable are raised with the GRO on a monthly basis for further investigation.  Births Metadata, <http://www.ons.gov.uk/ons/guide-method/user-guidance/health-and-life-events/births-metadata.pdf>, provides detailed information on the registration, collection and quality of births data in England and Wales.  Mortality data passes through a number of processes before becoming usable for analysis. Simple validations include examination of dates or employment status to ensure that they are likely. More complicated validations include checks for consistency between dates of birth, death and registration, or between age and marital status.  More information on the process is available here: <http://www.ons.gov.uk/ons/guide-method/user-guidance/health-and-life-events/mortality-metadata.pdf>  As part of the production process for this indicator, the national figures reported will be checked against published figures from ONS. In addition, as further years of data are published they will be checked to determine whether the change is in line with changes seen previously. Investigation into the source of any issues will be conducted where necessary |
| **3.6 Data linkage** | Birth registration and death registration data is linked and aggregated to LSOA level by ONS before the extract is provided to NHS Digital. The denominator for this indicator is taken from the births data, whilst the numerator is taken from the deaths data. |
| **3.7 Quality of data linkage** | Linking infant death records to their corresponding birth registration has been conducted since 1975. This allows information on social and biological factors of the parents and baby collected at the birth registration to be obtained. This information includes birth weight; mother’s age; mother’s country of birth; father’s socio-economic status; number of previous children.  In 2012, 98% of infant deaths in England and Wales were successfully linked to the corresponding birth registration record; the linkage rate for infant deaths has remained consistent since the beginning of the linkage exercise. The main reasons for the linkage to fail are that the birth registration cannot be found, or the birth was registered outside of England and Wales. |
| **3.8 Data fields** | ONS will provide pre-calculated denominator and numerator volumes at CCG of Residence level from the birth and birth notifications data. The following fields will be provided to NHS Digital:  CCG of Residence code  CCG of Residence name  Denominator - The number of live births and stillbirths that occur during a calendar year  Numerator - Of the denominator, the number of stillbirths and neonatal deaths. |
| **3.9 Data filters** | The data included in this indicator is the number of live births and stillbirths that occurred in the reference year plus any late birth registrations from the previous year. Mortality figures are based on deaths that occurred in the reference year. Only births that occurred in an English LSOA will be included. As such, this data will be aggregated to the patients CCG of Residence.  This data will be extracted by ONS in accordance with their usual process.  This indicator will use the same definitions as used in the ONS publication. The ONS defines a stillbirth as “born after 24 or more weeks completed gestation and which did not, at any time, breathe or show signs of life”; neonatal mortality is defined as “deaths under 28 days”. |
| **3.10 Justifications of inclusions and exclusions**  and how these adhere to standard definitions | Babies aged under 28 days is a standard definition of neonatal. This definition is used by ONS7, NICE8, and the World Health Organisation (WHO)9, amongst others.  The definition used for stillbirths is also standard; this is taken from the Still-Birth (Definition) Act 199210, which revised the definition of a stillborn baby from 28 weeks to 24 weeks. This definition is used by a range of organisations, including NHS Choices11, and ONS7.  These definitions are used by the NOF indicator on which this indicator is based.   1. Statistical bulletin: Deaths Registered in England and Wales, 2015, ONS, July 2016, <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregistrationsummarytables/2015> 2. Quality Standard 57: Neonatal Jaundice, NICE, March 2014, <http://www.nice.org.uk/guidance/QS57/chapter/introduction> 3. Health Topics: Infant, newborn, WHO, 2014, <http://www.who.int/topics/infant_newborn/en/> 4. Still-Birth (Definition) Act 1992, The National Archives, March 1992, <http://www.legislation.gov.uk/ukpga/1992/29/pdfs/ukpga_19920029_en.pdf> 5. Stillbirth, NHS Choices, February 2012, <http://www.nhs.uk/conditions/Stillbirth/Pages/Definition.aspx> |
| **3.11 Data processing** | The numerator and denominator data at CCG level is provided to NHS Digital by ONS. The rate for each CCG is calculated by NHS Digital using the calculation presented in section 4.3. |

Section 4 Construction

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| **4.1 Numerator** | Of the denominator, the number of stillbirths and neonatal deaths. |
| **4. 1Denominator** | The number of live births and stillbirths that occur during a calendar year, by CCG of Residence. |
| **4.3 Computation** |  |
| **4.4 Risk adjustment or standardisation type and methodology** | **None**  *Variables and methodology:* |
| **4.5 Justification of risk adjustment type and variables**  or why risk adjustment is not used | It is proposed to not risk adjust or standardised this indicator.  This indicator is commonly reported without risk adjustment by ONS (the data source) and in the NOF indicator on which this is based. Data will be provided to NHS Digital in an aggregated form, risk adjustment for this indicator would require patient level data which will be subject to a Data Sharing Agreement,  It is accepted that there could be value in standardising this indicator, as there are various non-modifiable factors that could influence the proportion of neonatal mortality and stillbirths. It would be technically possible to standardise this indicator, but difficult due to data access issues. It has been decided on balance, in order to maintain consistency with convention, to not standardise this indicator. |
| **4.6 Confidence interval / control limit use and methodology** | Confidence Intervals  *Methodology:*  Using the Wilson Score method12,13, the 100(1– *α*)% confidence limits are given by:  where:  *q* is 1–*p*;  *z* is the 100(1– *α* /2)th percentile value from the Standard Normal distribution.  For example, for a 95% confidence interval, *α* = 0.05 and *z* = 1.96 (i.e. the 97.5th percentile value from the Standard Normal distribution)14.  Reference   1. Wilson EB. Probable inference, the law of succession, and statistical inference. J Am Stat Assoc 1927; 22: 209–12. 2. Newcombe RG, Altman DG. Proportions and their differences. In Altman DG et al. (eds). Statistics with confidence (2nd edn). London: BMJ Books; 2000: 46–8.   Eayres D. Technical Briefing 3: Commonly used public health statistics and their confidence intervals. York: APHO; 2008. Available at <http://www.apho.org.uk/resource/item.aspx?RID=48457> |
| **4.7 Justification of confidence intervals / control limits used** |  |

Section 5 Presentation and Interpretation

Presentation

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| **5.1 Presentation of indicator** |  |
| **5.2 Contextual information provided alongside indicator**  with justification | NHS OF indicator 1.6.ii, Neonatal mortality and still births, can be used as contextual information. This could be included as a link in the indicator metadata.  NHS OF indicator 1.6.ii presents the same information contained in this indicator at different breakdowns, but not at CCG level. The breakdowns cover gender, age, deprivation quintile, geographic region, and lower tier local authority level. This information can be used to provide context to the CCG level indicator. |
| **5.3 Calculation and data source of contextual information** | N/A |
| **5.4 Use of bandings, benchmarks or targets**  with justification | None |
| **5.5 Banding, benchmark or target methodology**  if appropriate |  |

Interpretation

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| **5.6 Interpretation guidelines** | A low proportion of stillbirths and deaths under 28 days is desirable.  This indicator requires careful interpretation and should not be viewed in isolation, but instead be considered alongside information from other indicators and alternative sources. When evaluated together, these will help to provide a holistic view of CCG outcomes and provide a more complete overview of the impact of the CCGs processes on outcomes.  Examples of other indicators include: NHS OF indicator 1.6.ii and publications from ONS such as the Childhood, Infant and Perinatal Mortality in England and Wales statistics. |
| **5.7 Limitations and potential bias** | When the extract of data occurs, not all deaths may have been registered; therefore there is the chance that this indicator may omit a small proportion of activity.  A number of factors can influence neonatal mortality and the number of stillbirths; these include ethnicity and socio economic status. These factors are not taken into account as part of this indicator, meaning that the rates observed in CCGs may be due in part to the differing makeups of these factors.  The neonatal mortality and stillbirth rate may be influenced by the number of multiple births. However, overall, in England and Wales in 2011, there were 22,796 multiple births, compared to 696,828 singleton births. . Of the 2,116 neonatal deaths in England and Wales in 2011, 1,761 (83.2%) were singleton births, and 355 (16.8%) were multiple births. Data on multiplicity of births and stillbirths is not available without an extract. As the number of multiple births is only a small proportion of the total, it is recommended to retain these cases in the indicator. This will allow for consistency with the source publication and the NHS OF indicator on which this is based.  These limitations will be included in the indicator metadata. |
| **5.8 Improvement actions** | This indicator requires careful interpretation and should not be viewed in isolation, but instead be considered alongside information from other indicators and alternative sources. CCGs can use this indicator in context to identify if improvements are needed in their delivery of service, further investigation will be required in order to determine what, where and how these services should improve, leading to the desirable outcome of a reduction in stillbirths and deaths under 28 days.  If a CCG would like to reduce the amount of neonatal mortality and stillbirths it may consider commissioning additional services that are in accordance with NICE Quality Standards 22 and 32. |
| **5.9 Evidence of variability** | The below figures are taken from the NHS OF 1.6.ii Neonatal mortality and still births publication. CCG level data for 2013 can be requested from ONS from January 2015. |

At the national level, there were 694,241 live births, 3,357 stillbirths, and 1,933 neonatal deaths in England in 2012. When this is broken down into the 324 lower tier local authorities of residence (Isles of Scilly local authority has been merged with Cornwall and City of London local authority has been merged with Hackney due to small numbers), the number of live births ranges from 289 to 17,766, the number of stillbirths ranges from 0 to 87, and the number of neonatal deaths ranges from 0 to 85.

Although figures at CCG of Residence level are not currently available, it can be inferred from this data that the numbers will generally be of a larger volume, due to the increase in area coverage.

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|  | **Level description** | **Indicator value** | **Lower CI** | **Upper CI** | **Live births** | **Stillbirths** | **Neonatal deaths** |
| LA1 | Christchurch | 0 | 0 | 0 | 418 | 0 | 0 |
| LA2 | West Dorset | 1.2 | 0.2 | 1.4 | 827 | 1 | 0 |
| LA3 | South Bucks | 1.3 | 0.2 | 1.5 | 753 | 1 | 0 |
| LA4 | Oadby and Wigston | 1.6 | 0.3 | 1.8 | 616 | 1 | 0 |
| LA5 | Maldon | 1.8 | 0.3 | 2 | 559 | 0 | 1 |
| LA6 | Richmondshire | 1.8 | 0.3 | 2.1 | 543 | 1 | 0 |
| LA7 | Warwick | 1.9 | 0.6 | 2 | 1,619 | 0 | 3 |
| LA8 | Ribble Valley | 2.1 | 0.4 | 2.4 | 475 | 1 | 0 |
| LA9 | Bolsover | 2.1 | 0.6 | 2.3 | 940 | 1 | 1 |
| LA10 | Bromsgrove | 2.2 | 0.6 | 2.3 | 929 | 1 | 1 |

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| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Level description** | **Indicator value** | **Lower CI** | **Upper CI** | **Live births** | **Stillbirths** | **Neonatal deaths** |
| LA315 | Aylesbury Vale | 12.1 | 8.4 | 12.4 | 2,299 | 19 | 9 |
| LA316 | Blackpool | 12.3 | 8.1 | 12.6 | 1,770 | 17 | 5 |
| LA317 | Tendring | 12.4 | 7.8 | 12.8 | 1,365 | 7 | 10 |
| LA318 | Oxford | 12.4 | 8.4 | 12.7 | 2,006 | 10 | 15 |
| LA319 | Lewes | 13 | 7.6 | 13.5 | 987 | 10 | 3 |
| LA320 | Leicester | 13.2 | 10.4 | 13.4 | 5,273 | 43 | 27 |
| LA321 | Sandwell | 13.5 | 10.7 | 13.7 | 5,151 | 37 | 33 |
| LA322 | Taunton Deane | 14.1 | 9 | 14.5 | 1,260 | 14 | 4 |
| LA323 | Rutland | 14.8 | 6.4 | 15.6 | 333 | 4 | 1 |
| LA324 | Corby | 17.5 | 10.9 | 18 | 959 | 14 | 3 |

It would be expected that 95% of data points would be within 2 standard deviations of the England figure (denoted by Average on the chart above). Of the 324 lower tier local authorities, 47 (14.5%) are outside the 2 standard deviations limit. This is slightly higher than what might be expected, and could be reduced through standardisation of the data; however this would go against convention.

Section 6 Risks

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| **6.1 Similar existing indicators** | This indicator is currently published at national, geographic region, and lower tier local authority level within the NHS OF indicator 1.6.ii Neonatal mortality and stillbirths.  The methodology of this indicator and 1.6.ii, mentioned above, is the same. This indicator will allow for comparisons on the numbers of live births, stillbirths, and neonatal mortality between CCGs.  This indicator is linked to the ‘low birth weight’ and ‘admission of full-term babies to neonatal care’ indicators that have also been proposed for inclusion into the CCG OIS for 2015/16. These indicators also use ONS birth data. |
| **6.2 Coherence and comparability** | The methodology should remain consistent with that of NHS OF 1.6.ii. Both indicators are taken from the same source.  The difference between the NOF indicator and the CCG OIS indicator is the level of reporting. The NOF indicator has the geographic breakdowns lower tier local authority, region, and national, whereas the CCG OIS indicator will be presented at CCG of Residence and national (Resident in England) level.  National level figures will be checked with the source ONS publication and the NOF indicator to ensure that they are consistent. |
| **6.3 Undesired behaviours and/or gaming** |  |
| **6.4 Approach to indicator review** | The time period for when the indicator is to be reviewed will be set by the Indicator Governance Board (IGB). This indicator will be reviewed by NHS Digital Clinical Indicators team in accordance with this timeframe.  User feedback and comments on this indicator are welcomed via NHS Digital Enquires [enquiries@hscic.gov.uk](mailto:enquiries@hscic.gov.uk) or the HSCIC CCG OIS mailbox [ccgois@nhs.net](mailto:ccgois@nhs.net) |
| **6.5 Disclosure control** | Guidance on disclosure control of birth and death registration data’ published by ONS states that disclosure control for the year 2013 onwards is only applicable to populations below 5,000, where values of 0, 1, and 2 are suppressed. Populations of 5,000 and over are not subject to disclosure control. The population in this case refers to the denominator of Live Births and Still Births.  Data will be received from ONS with the suppression in place. |
| **6.6 Copyright** | Users reproducing ONS content should include a source accreditation to ONS – Source: Office for National Statistics licensed under the Open Government Licence v1.0. |

**Indicator Assurance Extension Cover Sheet**

**Lapsed Date** **07/05/2016**

**Criteria Check List**

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| 1 | There is evidence that IGB assured the indicator to a period ending 1st January 2016 or after | Yes |
| 2 | Are there any outstanding caveats? List them here:   Indicator to be reviewed alongside:  IAP00398 Low birth weight of term babies | Yes |
| 3 | Are there any changes to …   1. Policy 2. Data source 3. Sponsoring organisation   Methodology | No  No  No  No |
| 4 | Are there any issues with data quality? | No |
| 5 | Has the indicator been superseded by another indicator? If yes, what is the new indicator’s reference number and title? | No |
| 6 | Has the indicator been withdrawn by the sponsoring organisation? | No |
| 7 | Are there any patient safety implications? | No |
| 8 | Have there been any complaints of risk associated with this indicator? | No |
| 9 | Primary category | Pregnancy and neonates |
| 10 | Publication reference |  |

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| **Recommendation** | Fit for extension |
| **Prepared by** | Sue Slade |
| **IGB decision** | Fit for use |
| **Accreditation period** | Two years |
| **IGB approval date** | 13/09/2018 |
| **Review date** | 07/05/2018 |

Indicator Assurance

**Appraisal Summary**

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| Ref | IAP00397 |
| Title | **Neonatal mortality and stillbirths** |
| Set / Framework | CCG Indicator Outcomes Set |

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| **Definition** | This indicator measures the number of stillbirths and neonatal deaths, per 1,000 live births and stillbirths, reported for England at CCG level for the calendar year.  Stillbirth is defined as born after 24 or more weeks, completing gestation, which did not show signs of life. Neonatal is defined as under 28 days from birth.  Data from Office for National Statistics (ONS) Childhood, Infant and Perinatal Mortality in England and Wales is used to determine the number of births, stillbirths and neonatal deaths that occurred in the reference period. CCG level data will be aggregated from the Lower Super Output Area (LSOA) of the mother’s home postcode, i.e. the resident population, as opposed to the usual convention of using the registered population, based on GP practice. |
| **Purpose** | The number of stillbirths and neonatal deaths is influenced by a number of maternal health factors, including obesity, smoking and a range of chronic diseases. The treatment/support for many of these fall within CCG commissioning responsibilities. Even where the relevant service is not commissioned by a CCG - for example, smoking cessation - the identification and referral of women with a need for such support falls within the role of maternity services commissioned by CCGs. The number is also influenced by effective support during the birth process and the postnatal period in services mainly commissioned by CCGs. Where the number of local stillbirths and neonatal deaths is disproportionately high, CCGs should consider the reasons for this and take appropriate action.  This indicator is currently published at national level and lower tier local authority level within the NHS Outcomes Framework (NHS OF) indicator 1.6.ii, Neonatal mortality and stillbirths, however has not been disaggregated at CCG level. |

**Assurance Details:**

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| **Reviewing Body** | **HSCIC Indicator Assurance Service** |
| **Application Date** | 05/01/2015 |

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| **Peer Review** |
| Reviewers: |
| *No peer review undertaken at present* |

**Methodological Review**

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| Review Group | HSCIC Methodology Review Group (MRG) |
| Discussion Dates | 15/01/2015, |
| Minutes Available | **Yes** |

Appraisers:

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| --- | --- | --- |
| **Chris Roebuck (Chair)** | HSCIC | Director, Benefits and Utilisation |
| **Chris Dew** | HSCIC | Programme Manager, Clinical Indicators |
| **Paul Fryers** | PHE | Deputy Director, East Midlands Knowledge and Intelligence Team |
| **Jonathan Hope** | HSCIC | Section Head, Statistical Response Unit |
| **Paul Iggulden** | HSCIC | Interim Head of Clinical Analysis, Research & Development |
| **John Sharp\*** | HSCIC | Head of Data Quality |
| **Julie Stroud (chair)** | HSCIC | Interim Head of Profession (Statistics) |

Conflicts of interest: None Declared

**Indicator Governance Board**

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| Discussion Dates | 24/03/15 |
| Minutes Available | **Yes** |

**Indicator Governance Board**

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| --- | --- |
| Discussion Dates | 07/05/15 |
| Minutes Available | **Yes** |

**Summary of Assurance Discussions**

**Methodology Review:**

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| Statement of Recommendation | 15/01/15 – MRG felt that this was a good indicator, and would recommend it for inclusion in the Library on the condition that evidence of significant variability is supplied and minor changes to the application form are made.  27/02/15 – MRG pre-meet update: Chair of MRG was satisfied with the changes made to the application and felt there was enough variation for the indicator to be of use. |

**Indicator Governance Board:**

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| Review Period Set | It was agreed the indicator be assured for a period of 1 year |
| Rationale | The applicant should review the effect of excluding multiple births on the results as CCG level data becomes available. These results should be included as part of the review consideration. As the indicator follows the methodology used in the NHS Outcomes Framework indicator, both indicators should be reviewed together. |

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| **Level of Assurance**  [determined at meeting] | Assured |
| **Basis of Decision** | Members agreed that, with the exception of seeing sample CCG level data, the questions posed at the previous IGB meeting (24/03/15) had been adequately responded to. The lack of sample data shouldn’t prevent the assurance of the indicator but will mean a shorter review date is required. |
| Sign-off Date | 07/05/15 |

Appraisal Log

**Criterion: CLARITY**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 1a | It would be desirable to make clear throughout the documentation, but specifically in the numerator and denominator, that the resident population is being used for this indicator, as opposed to the registered population that is usually used in the CCG OIS. | MRG 15/01/15 | Recommended | Updated references to CCG to CCG of Residence and updated references to National to National (Resident in England), where applicable. | 17/02/15 |  | MRG Chair  27/02/15 |
| 1b | The wording of the definition would benefit from improvement to make it easier to read. Some typos were identified which would be forwarded to the applicant. | MRG 15/01/15 | **Required** | The definition has been reworded. A number of slight ammendments have been made throughout the document based on comments received. | 17/02/15 |  | MRG Chair  27/02/15 |

**Criterion: RATIONALE**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 2a | An updated evidence base (as referred to during the meeting by the applicant) needs to be supplied to the Indicator Assurance Service team. | IAS  15/01/15 | **Required** | This has been supplied as part of the updated documentation. | 17/02/15 |  | MRG Chair  27/02/15 |

**Criterion: DATA**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 3a | The first paragraph of Section 3.3 (Data availability) should be more clear regarding why the data is not available and where the data is published. | MRG  15/01/15 | Recommended | Added a reference to state that the underlying data is not available as it would be inappropriate to release record level birth and death data to the public. A link to the report on the ONS website has been added. | 17/02/15 |  | MRG Chair  27/02/15 |
| 3b | Section 3.9 (Data fields) should state the numerator and denominator. | MRG  15/01/15 | Recommended | These have been added. | 17/02/15 |  | MRG Chair  27/02/15 |
| 3c | Section 3.10 (and any other reference to completed gestation) should be changed, as this indicator measures any baby born after 24 weeks, not necessarily reaching full gestation. | MRG  15/01/15 | **Required** | This section has been updated to use the direct quote from the ONS publication. The reference to completed gestation is intended to mean that 24 or more weeks of gestation have been completed, not a gestation length of 24 or more weeks, who completed gestation. | 17/02/15 |  | MRG Chair  27/02/15 |

**Criterion: CONSTRUCTION**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 4a | The numerator should read “of the denominator, the number of stillbirths and deaths under twenty-eight days”, i.e. “occurring during a calendar year” should be deleted. | MRG  15/01/15 | **Required** | This has been amended. | 17/02/15 |  | MRG Chair  27/02/15 |
| 4b | The appropriate confidence interval methodology for the indicator should be Wilson Score Method as the indicator is a proportion. | MRG  15/01/15 | **Required** | This methodology has been updated. | 17/02/15 |  | MRG Chair  27/02/15 |
| 4c | It was noted that the indicator does include multiple births prompting IGB members to ask why, in light of the decision to exclude them from the low birth weight indicator.  IGB members felt that in order to determine the suitability of including or excluding multiple births they would need a clearer understanding of the purpose of the indicator. It was suggested that useful information to feed into the rationale may be found in the underlying evidence base. As this indicator has an equivalent in the NHS Outcomes Framework, this might be a useful place to find information on the evidence base, noting however that the NHSOF indicator is for a different purpose (and audience). | IGB  24/03/15 | **Required** | The rationale used in the application is provided by Jeff Featherstone (Programme Lead; Commissioning Outcomes and Incentives, NHS England)  The indicator is to provide information to CCGs on their rates of stillbirths and neonatal mortality so they can determine whether they need to amend their commissioning practices.  The rationale for the equivalent NHS OF indicator on which this indicator has been based aims to reflect care in pre-pregnancy, pregnancy, and the perinatal period, explaining that differences in rates are down to the quality of care.  This ambition to monitor the provision of high-quality care is also included in the NICE rationale for this CCG OIS indicator. | 15/04/15 |  |  |

**Criterion: INTERPRETATION**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 5a | The tables of figures provided in section 5.7 (Evidence of variability) and Section 7 do not appear to add up, as for example the number of still births for Corby in a 3 year period are less than in a 1 year period. | MRG  15/01/15 | **Required** | This section has been removed in accordance to 5b. | 17/02/15 |  | MRG Chair  27/02/15 |
| 5b | MRG noted the information provided by the applicant as evidence of variability (form section 5.7), however felt it did not sufficiently demonstrate **significant** variability in the indicator. It was appreciated by the Group that the current paperwork does not make it explicity clear that this is the intent of the form and apologised to the applicant.  It was put forward that it is likely there is significant variance however this needed to be evidenced. It was identified that this should be through the provision of a funnel plot. If variability is not identified, the indicator will require further consideration at a future MRG meeting.  If significant variability is identified, MRG are content that the indicator would not require further discussion on this point by the group.  In addition the information provided in section 7 of the form should be deleted to avoid cinfusion. | MRG | **Required** | Confidence intervals have been added to the table, and a funnel plot has been added. | 17/02/15 |  | MRG Chair  27/02/15 |
| 5c | It was suggested that the results being presented (in section 5.7 of the application form) appear to represent a non-normal distribution. Members asked whether MRG had determined whether other statistical process that may present a more “normal” distribution had been considered in the development process. Members noted that similar issues had been raised as part of the assessment of the Summary level Hospital Mortality Indicator (SHMI), e.g. in terms of how the developers approached over dispersion, and suggested the outcomes of those discussion may provide learning in this instance. | IGB  24/03/15 | Recommended | The inclusion of a funnel plot in the application was provided with the purpose of demonstrating variability in the indicator. It is not the intention to publish the funnel plot as part of the final product. | 15/04/15 |  |  |

**Criterion: RISKS AND USEFULNESS**

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| **No** | **Issue or recommendation** | **Raised By/Date** | **Action Status\* Assigned** | **Response / Action taken (if appropriate)** | **Response date** | **Resolved** | **Checked by / Date** |
| 6a | IGB members determined it would be useful to see sample data showing results both including and excluding multiple births, as with the low birth weight indicator, for the purpose of consistency (noting that this could potentially put it out of kilter with the equivalent NHSOF indicator). However the appropriateness of the decision to include or exclude ultimately depends on the purpose of the indicator | IGB  24/03/15 | Required | CCG level figures are not currently available for analysis and would require an extract from ONS  National level data currently available shows:   * In England and Wales in 2011, multiple births accounted for 3.2% of total births (696,828 singleton births, compared to 22,796 multiple births). * Neonatal deaths occurring in multiple births accounted for 16.8% of the total neonatal deaths (1,761 neonatal deaths in singleton births, 355 in multiple births). * Data on multiplicity of births and stillbirths is not available without an extract.   However the rationale for the indicator is aligned to the equivalent NHSOF indicator which sets out to measure the quality of care in in pre-pregnancy, pregnancy, and the perinatal period (as opposed to being a measure relating to lifestyle). The decision to include the indicator in the CCGOIS is to provide this information at CCG level in order that they can determine whether they need to amend their commissioning practices.  As a measure of care it would seem appropriate that all neonatal mortality and stillbirths are included in the indicator regardless of whether it is in singleton or multiple births. This allows the indicator to remain consistent with the NHS OF indicator on which is has been based. | 15/04/15 |  |  |

\*The description of the states given to each recommendation are as follows:

**Action required**: The group concerned is of the opinion that the indicator is not ready to go into the library of Quality Assured Indicators, based on the point raised.

**Action recommended:** The group concerned recommend action is undertaken in the particular area in order to increase the quality and rating of the indicator, however do not feel this would prevent its inclusion in the Library of Quality Assured Indicators.

See our [accessibility statement](https://www.nice.org.uk/accessibility#what-to-do) if you’re having problems with this document.

1. Maternal and fetal risk factors for stillbirth: population based study, Cardosi, J. et al, January 2013, <http://www.ncbi.nlm.nih.gov/pubmed/23349424> [↑](#footnote-ref-1)
2. Born Too Soon: Accelerating actions for prevention and care of 15 million newborns born too soon, Lawn JE et al, November 2013, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3828574/> [↑](#footnote-ref-2)
3. Preventing Babies Deaths, SANDS, January 2012, <http://www.uk-sands.org/sites/default/files/PREVENTING_BABIES_DEATHS_REPORT_2012LR02.pdf> [↑](#footnote-ref-3)
4. Quality standard for antenatal care, NICE, September 2012, <http://www.nice.org.uk/guidance/QS22> [↑](#footnote-ref-4)
5. Quality standard for caesarean section, NICE, June 2013, <http://www.nice.org.uk/guidance/qs32> [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)