**NHS Digital**

**Indicator Supporting Documentation**

**IAP00093 People who have had an acute stroke who receive thrombolysis**

Indicator Assurance Service

**Title:** People who have had an acute stroke who receive thrombolysis

**Set or domain:** CCG OIS 3.6

**IAS Reference Code:** IAP00093

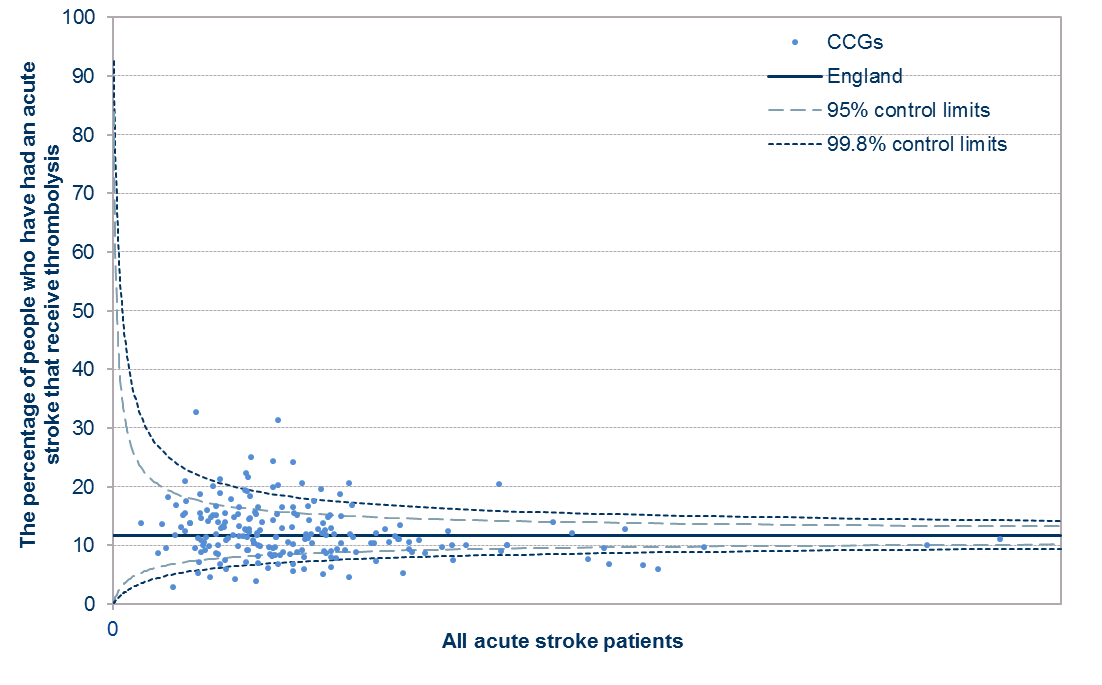
# Application Form

|  |  |
| --- | --- |
| **Title** | People who have had an acute stroke who receive thrombolysis |
| **Set or domain** | CCG Outcomes Indicator Set (OIS) 3.6 |
| **Topic area** | Cardiovascular |
| **Definition** | The percentage of people who have had an acute stroke that receive thrombolysis.  Technical description: Of all acute stroke patients, including those who were already in hospital at the time of new stroke occurrence, the percentage who were given thrombolysis for stroke.  Stroke is defined within this indicator as intracerebral haemorrhage (ICD-10 code: I61), cerebral infarction (I62) and stroke, not specified as haemorrhage or infarction (I64).  The indicator is published annually in December for each CCG in England. It was published for the first time in December 2014 (2013/14 data). |
| **Indicator owner & contact details** | Alison Roe, Senior Service Delivery Manager, HSCIC  [ccgois@hscic.gov.uk](mailto:ccgois@hscic.gov.uk) |
| **Publication status** | Currently in publication |
| **Purpose** | Patients with suspected stroke are admitted directly to a specialist acute stroke unit and assessed for thrombolysis, receiving it if clinically indicated. This indicator provides CCGs with a tool to monitor thrombolysis levels, with the focus being to improve percentages to a more consistent level across CCGs. The percentage must be interpreted in light of other standards, as it is not appropriate to simply have a high percentage due to the procedure carrying significant risk and not being suitable for every patient. |
| **Sponsor** | Richard Owen, Outcomes Strategy Lead, NHS Medical Directorate, NHS England. |
| **Endorsement** | The indicator was constructed following consultation with the following clinical and stroke data experts:   * Professor Anthony Rudd, Chair of the Intercollegiate Stroke Working Party, Associate Director for Stroke, Consultant Stroke Physician * James Campbell, Sentinel Stroke National Audit Programme (SSNAP) Intelligence Programme Manager, Royal College of Physicians (RCP)   Lizz Paley, Acting Stroke Programme Intelligence Manager – Data, RCP |
| **Evidence and Policy base**  Including related national incentives, critical business question, NICE quality standard and set or domain rationale, if appropriate | This indicator supports the NICE Quality Standard for stroke (QS2)¹ which covers care provided to adult stroke patients by healthcare staff during diagnosis and initial management, acute-phase care, rehabilitation and long-term management. It directly supports Quality Statement 3 within the standard, which states: ‘Patients with suspected stoke are admitted directly to a specialist acute stroke unit and assessed for thrombolysis, receiving it if clinically indicated’.  This indicator is aligned to the measure, Thrombolysis rates - England, included in the Department of Health’s Cardiovascular Disease Outcomes Strategy2.  The majority of strokes are due to blockage of an artery in the brain by a blood clot. Prompt treatment with thrombolytic drugs can restore blood flow before major brain damage has occurred. Successful treatment could mean that the patient is more likely to make a good recovery from their stroke3.  Thrombolysis is a clot busting drug which can be a very effective way of treating ischaemic strokes (caused by blood clot). The eligibility criteria for thrombolysis are based on age, type of stroke and time lapse since stroke onset. Based on these criteria, it is expected that between 15 and 20% of patients would be eligible for thrombolysis4.  1.Quality Standard for Stroke (QS2), NICE, June 2010 <https://www.nice.org.uk/guidance/qs2/chapter/Introduction-and-overview>  2. Cardiovascular Disease Outcomes Strategy, Department of Health, Mar 2013 <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/214895/9387-2900853-CVD-Outcomes_web1.pdf>  3. Wardlaw et al, Thrombolysis for acute ischaemic stroke, 2009 <http://www.ncbi.nlm.nih.gov/pubmed/12917889>  4. RCP SSNAP Clinical audit January-March 2015 public report, July 2015 <https://www.strokeaudit.org/Documents/Results/National/JanMar2015/JanMar2015-PublicReport.aspx> |
| **Data source** | RCP SSNAP  The SSNAP is guided by the Intercollegiate Stroke Working Party (ICSWP) and delivered by the Stroke Programme within the Clinical Effectiveness and Evaluation Unit in the RCP. It is centrally funded by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).  <http://www.rcplondon.ac.uk/projects/sentinel-stroke-national-audit-programme> |
| **Justification of source and others considered** | The SSNAP is the single source of data on stroke services, processes of care and outcomes. It provides the data for other statutory reporting mechanisms in England, including the NICE Quality Standard and the five other CCG OIS stroke measures; it is also due to be used for the NHS Outcomes Framework. SSNAP metrics are aligned with those in the Cardiovascular Disease Outcomes Strategy.  Hospital Episode Statistics (HES) was considered as a data source for this indicator; however it does not contain the necessary detail required for this indicator to measure levels of thrombolysis. |
| **Data availability** | CCG OIS indicators are published annually. SSNAP data for the full financial year is available to produce the indicator approximately 8 months after the financial year end; therefore the indicator is published each year in December.  CCG OIS indicators are official statistics and the publication date is pre-announced. There is no gap between the planned and actual publication date.  The RCP make this indicator, along with a number of others, accessible to the public via RCP reporting, including an Easy Access Version aimed at stroke survivors and carers. It is available via Excel spreadsheets and other formats including graphical representation. |
| **Data quality** | The indicator is published in the context of case ascertainment between SSNAP and HES. This is the percentage of patients with primary ICD-10 codes I61, I63 and I64 in HES who are included in SSNAP for the same time period.  The SSNAP is a mandatory collection and overall case ascertainment increased from 72% in Quarter 1 to 95% in Quarter 4, 2013/14 (Quarter 2: 83%, Quarter 3: 90%). It has further improved to 97% by Quarter 4, 2014/15. Case ascertainment is reported alongside the indicator for all CCGs in the published CCG OIS data files. Only five CCGs (2.4%) had their percentages suppressed in the published 2013/14 data due to less than 50% case ascertainment with HES.  Patient records are only included in audit analyses if they include the minimum requirements of completion of mandatory fields. The minimum includes all of the fields required to calculate this indicator. Case ascertainment is reported publicly at hospital level and therefore there is a strong incentive for hospitals to ensure they have submitted all of their patients to the audit and completed the mandatory fields. The data is received via a secure web tool which has strong built-in validation meaning that data is fully complete.  Patients are mapped to a CCG using patient postcode. National level figures are published including patients that could not be mapped to a CCG and therefore the total of the individual CCGs does not match the national level figure. Over 99% of patients are matched to a CCG across each of the CCG OIS stroke indicators. |
| **Quality assurance** | As SSNAP data is subject to strong built-in validation via the secure web tool, it means that it is not possible for providers to enter illogical timings; however, this is double checked during analysis and therefore the accuracy of the indicator is very high. No assumptions are made regarding the arrival and discharge times, apart from when a patient died in hospital.  When submitting SSNAP data, security and confidentiality are maintained through the use of passwords and a person specific registration process. A dedicated helpdesk is in place to answer queries from SSNAP participants, helping to ensure questions are interpreted consistently (which informs updates to FAQs and data set help notes). Users can register for their team on the SSNAP web tool and input data for their team. Once records are complete and correct they can be ‘locked’ at different levels. Records can be ‘locked’ to 72 hours once this information is completed, they can then be locked to discharge once this is applicable. Locking confirms that all data have been clinically signed off and are ready for central analysis. The ‘Lead clinical contact’ role is responsible for ensuring that the overall system of data collection and entry onto the web tool is accurate, robust and functioning. The SSNAP encourage the lead to routinely check data. Only complete and locked to 72 hours records go into data analysis for the 72 hour section and complete and locked to discharge records go into data analysis for the post-72h section.  Eligibility criteria are applied to determine which records can be included in the audit. The criteria are: ICD-10 codes I61, I63, I64, but hospitals have means of checking for eligible patients other than their coding system and participants are encouraged to enter cases prospectively meaning the stroke team have more control over selecting records to be included and can also refer to their stroke register, should they have one. |
| **Quality improvement plan**  If appropriate | N/A |
| **Data linkage** | None. |
| **Quality of data linkage** | N/A |
| **Data fields** | The data fields supplied by the RCP are as follows:  1. Number of records in SSNAP attributed to this CCG according to patient postcode  2. Estimated expected number of patients (from HES)  3. Case ascertainment band  4. Numerator  5. Denominator  6. Percentage of all stroke patients who receive thrombolysis |
| **Data filters** | SSNAP-derived records meeting all of the following requirements are valid for the denominator in this indicator:   * None, all SSNAP stroke patients are included in this indicator.   SSNAP-derived records meeting all of the following requirements are valid for the numerator in this indicator:  Audit Question 2.6 – ‘Was the patient given thrombolysis? (Yes/No/No but)’ is equal to ‘Yes’ |
| **Justifications of inclusions and exclusions**  and how these adhere to standard definitions | Audit Question 2.6 is equal to ‘Yes’ - Identifies whether the patient has been given thrombolysis.  The SSNAP uses the following ICD-10 diagnosis codes to identify stroke patients:   * I61 - Intracerebral haemorrhage * I63 - Cerebral infarction * I64 - Stroke, not specified as haemorrhage or infarction   The coding advice from the Clinical Classifications Service also includes I60 (Subarachnoid haemorrhage) and I62 (Other nontraumatic intracranial haemorrhage), however this advice would not be endorsed by the RCP as subarachnoid haemorrhage and other non-traumatic intracranial haemorrhage have a different care pathway and outcome.  Subarachnoid haemorrhages and other non-traumatic intracranial haemorrhages are routinely and nearly always managed entirely outside of the stroke unit by neurosurgeons or by interventional neuroradiologists, which is what is recommended in national guidelines for these cases. The indicators need to reflect the care given on appropriate clinical pathways, not arbitrary groupings. |
| **Data processing** | The calculated CCG level indicator is provided by the RCP and includes the percentage, numerator, denominator and contextual information. It is provided with any necessary data suppression.  A 95% confidence interval is calculated by Clinical Indicators for each CCG prior to publication. |
| **Numerator** | The number of acute stroke patients who were given thrombolysis for stroke. |
| **Denominator** | All acute stroke patients, including those who were already in hospital at the time of new stroke occurrence. |
| **Computation** | The percentage *p* is given by:  where:  *O* is the numerator and *n* is the denominator. |
| **Risk adjustment or standardisation type and methodology** | The indicator is not standardised or risk adjusted. |
| **Justification of risk adjustment type and variables**  or why risk adjustment is not used | The indicator can be contextualised using the percentage of eligible patients (according to the RCP guideline minimum threshold) thrombolysed, which is a key CCG level indicator in the SSNAP results portal. In addition, the SSNAP reports on several factors which could affect thrombolysis rates such as the haemorrhage rate and onset-to-arrival timings. |
| **Confidence interval / control limit use and methodology** | Confidence Intervals  Confidence intervals are calculated using the Wilson Score method, as specified in “Commonly used public health statistics and their confidence intervals” (Public Health England (PHE), March 2008 <http://www.apho.org.uk/resource/view.aspx?RID=48617>).  The formulae for the 100(1 – α)% confidence interval limits for the proportion p are:  where:  *O* is the observed number of individuals in the sample/population having the specified characteristic (i.e., the numerator);  *n* is the total number of individuals in the sample/population (i.e., the denominator);  *q* = (1 – *p*) is the proportion without the specified characteristic;  *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). |
| **Justification of confidence intervals / control limits used** | The preferred PHE confidence interval method for proportions is the Wilson Score method5 which has been evaluated and recommended by Newcombe and Altman6;7. It can be used with any data values and, unlike some methods, it does not fail to give an interval when the numerator count, and therefore the proportion, is zero8.  5. Wilson EB. Probable inference, the law of succession, and statistical inference. J Am Stat Assoc 1927.  6. Newcombe RG. Two-sided confidence intervals for the single proportion: comparison of seven methods. Stat Med 1998.  7. Newcombe RG, Altman DG. Proportions and their differences. In Altman DG et al. (eds). Statistics with confidence (2nd edn). London: BMJ Books; 2000.  8. Agresti A, Coull BA. Approximate is better than ‘exact’ for interval estimation of binomial proportions. Am Stat 1998 |
| **Presentation of indicator** | The indicator is presented on the HSCIC Indicator Portal in a consistent format to other CCG OIS indicators. It is accompanied by indicator specification and quality statement documents, which provide details of indicator construction, data quality, statistical methods and interpretation considerations [http://indicators.ic.nhs.uk/webview](http://indicators.ic.nhs.uk/webview/index.jsp?v=2&submode=ddi&study=http%3A%2F%2F172.16.9.26%3A80%2Fobj%2FfStudy%2FP01852&mode=documentation&top=yes)  The data is presented with a detailed header including information on the statistic presented, the reporting period, level of coverage, publication date, data source, and any further notes to be aware of. The customer is also able to make use of drop-down filtering. |

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| **Column name** | **Output** |
| Reporting period | Financial year |
| Breakdown | England, CCG |
| Level | CCG Code |
| Level description | CCG Name |
| Percentage | The indicator percentage calculation |
| CI lower | Lower 95% confidence interval |
| CI upper | Upper 95% confidence interval |
| Denominator | All acute stroke patients, including those who were already in hospital at the time of new stroke occurrence. |
| Numerator | The number of acute stroke patients who were given thrombolysis for stroke. |
| Number of records in SSNAP (care delivered within the first 72hrs) | The number of cases in SSNAP for the ‘care delivered within the first 72hrs’ cohort of stroke patients |
| Estimated expected number of patients (from HES) | The number of cases in HES |
| Case ascertainment band | Case ascertainment between SSNAP and HES |

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| **Contextual information provided alongside indicator**  with justification | Alongside the numerator, denominator and percentage, the number of records in SSNAP (care delivered within first 72hrs) is provided for each CCG as contextual information.  The indicator is published in the context of case ascertainment between SSNAP and HES. The ‘Estimated expected number of patients from HES’ figure is the number of patients who have been coded as a primary diagnosis of stroke during their admission in a year’s worth of HES, split by the patient’s CCG recorded in the HES record. Case ascertainment is reported alongside the indicator for all CCGs to highlight audit coverage against HES. MRG requested this further analysis in the original assurance process.  Case ascertainment is reported within the context of the ‘care delivered within the first 72hrs’ cohort of stroke patients for this indicator. The ‘Case ascertainment band’ column in the published output uses the following bandings:   * 90%+ * 80-89% * 70-79% * 50-69% * Less than 50%   The indicator is not reported for any CCGs with lower than 50% case ascertainment or for those with fewer than 20 patients.  The percentage of eligible patients (according to the RCP guideline minimum threshold) given thrombolysis will be included in the indicator as contextual information. This will provide an extra breakdown on the treatment of patients that are eligible for thrombolysis only. See section 5.9 for an example of the output presentation. |
| **Calculation and data source of contextual information** | The contextual information is sourced from the SSNAP and provided by the RCP. |
| **Use of bandings, benchmarks or targets**  with justification | None. NHS England state in their summary of the CCG OIS that ‘The Indicator Set does not in itself set thresholds or levels of ambition for CCGs, it is intended as a tool for CCGs to drive local improvement and set priorities.’ <http://www.england.nhs.uk/resources/resources-for-ccgs/ccg-out-tool/ccg-ois/>.  There is no absolute rate of thrombolysis which is appropriate. This indicator provides CCGs with a tool to monitor thrombolysis levels, with the focus being to improve percentages to a more consistent level across CCGs. |
| **Banding, benchmark or target methodology**  if appropriate | N/A |
| **Interpretation guidelines** | This indicator provides CCGs with a tool to monitor thrombolysis levels, with the focus being to improve percentages to a more consistent level across CCGs. In 2005, only about 1% of people with stroke in the UK received thrombolysis and it was estimated that increasing the proportion to 9% would save £16m each year12. Levels now stand at around 11% across the country and higher in some places.  As it is not appropriate to simply have a high percentage due to the procedure carrying significant risk and not being suitable for every patient, the indicator includes contextual information on the percentage of eligible patients (according to the RCP guideline minimum threshold) thrombolysed. In addition, the SSNAP reports on several factors which could affect thrombolysis rates such as the haemorrhage rate and onset-to-arrival timings.  Thrombolysis is a clot busting drug which can be a very effective way of treating ischaemic strokes (caused by blood clot). The eligibility criteria for thrombolysis are based on age, type of stroke and time lapse since stroke onset. Based on these criteria, it is expected that between 15 and 20% of patients would be eligible for thrombolysis.  There are multiple medical reasons for not providing thrombolysis including (but not limited to) the patient arriving outside the time window for thrombolysis, the stroke being too mild/severe, the patient suffering a haemorrhagic stroke, the patient’s condition improving and the patient having other co-morbidities.  12. RCP SSNAP Annual Report, 2013/14 https://www.strokeaudit.org/Documents/Results/National/Apr2013Mar2014/Apr2013Mar2014-AnnualReport.aspx |
| **Limitations and potential bias** | As it is clinically inappropriate in some cases to give thrombolysis, the maximum achievement percentage for this indicator will vary from CCG to CCG; therefore care must be taken when comparing overall percentages over time or across CCGs. The focus of this indicator is to improve current thrombolysis levels to a more consistent level across CCGs.  The patterns of providing care may vary between organisations in terms of hospital inpatient admission practices and policies.  There may be variation in the prevalence of stroke due to differing levels of deprivation, for other geo-demographic reasons or between patients of different ethnic heritages. |
| **Improvement actions** | It is expected that CCGs will use this indicator to identify improvements in care and how they can be delivered.  Improvements could be made by enhancing aspects of the services CCGs commission for patients. This could come in the form of better recognition and assessment of the symptoms of stroke, particularly for those already in hospital, and an established process for delivering thrombolysis in a timely manner. |
| **Evidence of variability** | The data within this section is taken from the December 2014 CCG OIS publication.  During the financial year 2013/14 there were 70,058 acute stroke patients (including those who were already in hospital at the time of new stroke occurrence). Of these, 8,125 were given thrombolysis.  The data below (at the end of this table) shows the ten CCGs with the lowest and the ten CCGs with the highest percentages in 2013/14. Five CCGs have been suppressed due to insufficient case ascertainment between SSNAP and HES and are not included within the data below. |
| **Similar existing indicators** | This indicator is published in different formats at CCG, trust and stroke team level on the SSNAP results portal <http://www.strokeaudit.org/results/Clinical-audit/National-Results.aspx>  The SSNAP results portal also contains a number of other measures relating to stroke and four further measures that relate specifically to thrombolysis, which could be used as contextual information alongside this indicator. These are:   * Proportion of eligible patients (according to the RCP guideline minimum threshold) given thrombolysis * Proportion of patients who were thrombolysed within 1 hour of clock start * Proportion of applicable patients directly admitted to a stroke unit within 4 hours of clock start AND who either receive thrombolysis or have a pre-specified justifiable reason ('no but') for why it could not be given   Median time between clock start and thrombolysis (hours:mins) |
| **Coherence and comparability** | The methodology and results for this indicator are consistent with the same indicator published on the SSNAP results portal. |
| **Undesired behaviours and/or gaming** | The RCP has wide experience of monitoring the impact of performance indicators, working closely with stroke and cardiac networks, and consider its standard methods to be sufficient to minimise risks of gaming and perverse incentives. |
| **Approach to indicator review** | The Indicator Governance Board (IGB) set a review period of one year when the indicator was originally assured, due to the relative immaturity of the SSNAP data set at that time. The time period for the next review will again be set by IGB.  User feedback and comments on this indicator are welcomed via HSCIC Enquires [enquiries@hscic.gov.uk](mailto:enquiries@hscic.gov.uk) or the CCG OIS mailbox [ccgois@hscic.gov.uk](mailto:ccgois@hscic.gov.uk) |
| **Disclosure control** | Case ascertainment used is the proportion of patients per CCG with primary ICD-10 codes I61, I63 and I64 in HES data who are included in SSNAP for the same time period.  Case ascertainment is reported alongside the indicator for all CCGs. The indicator is not reported for any CCGs with lower than 50% case ascertainment or for those with fewer than 20 patients, instead replacing the percentage with ‘\*’.  Percentages are rounded to one decimal place before publication. |
| **Copyright** | There are no restrictions on the use of these data. Any subsequent use or publishing of these data should reference the RCP SSNAP. |

Table of data showing the ten CCGs with the lowest and the ten CCGs with the highest percentages in 2013/14. Five CCGs have been suppressed due to insufficient case ascertainment between SSNAP and HES and are not included within the data.



Indicator Assurance Report

**Final Assurance Rating from the Indicator Governance Board - 10/02/2016**

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| **Reason for assessment** | Scheduled review (review date reached) |
| **Iteration** | 2nd IGB meeting |

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| **Ratings Against Assessment Criteria** |  | **Overall Rating – not fit for use** |
| Clarity | **Fit for use** |  |
| Rationale | **Fit for use** |  |
| Data | **Fit for use with caveats** |  |
| Construction | **Fit for use with caveats** |  |
| Presentation and Interpretation | **Not fit for use** |  |
| Risks and Usefulness | **Fit for use with caveats** |  |

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| **Outcome** | **This indicator has not been approved for inclusion in the National Library of Quality Assured Indicators** |

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| **Key findings from Assurance** |
| * The indicator was brought back to the group for an assessment of whether it serves as a robust measure in the Library of Quality Assured Indicators based on the purpose set out as a CCG Outcome Indicator Set (OIS) indicator. * IGB members were pointed to the Methodology Review Group (MRG) conclusion that due to the limitations around its interpretation for CCGs it was not suitable, but MRG had also noted that the indicator could have use to a limited audience of “expert” users. * On this basis the Board confirmed that the indicator would not be recommended for inclusion in the Library based on the current stated purpose as a CCGOIS indicator, because the limitations around interpretation of the indicator mean it does not meet the purpose for which the CCGOIS is there for. * Board members however did recognise that the still has value as a quality indicator from an audit perspective as part of the Stroke Care pathway and should not be lost to the system. It was suggested the indicator could go back on the NICE menu and perhaps be used for quality improvement purposes. In terms of assurance this would require a re-purposing of the indicator should it be re-submitted as its utility would be different. |

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| **Approval date** | N/A |
| **Review date** | N/A |

**Final Assurance Rating from the Indicator Governance Board - 14/12/2015**

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| **Reason for assessment** | Scheduled review (review date reached) |
| **Iteration** | 1st IGB meeting |

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| **Ratings Against Assessment Criteria** |  | **Overall Rating - Pending** |
| Clarity |  |  |
| Rationale |  |  |
| Data |  |  |
| Construction |  |  |
| Presentation and Interpretation |  |  |
| Risks and Usefulness |  |  |

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| **Outcome** | **Decision Pending: To return to the Indicator Governance Board** |

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| **Key findings from Assurance** |
| * IGB suggested that the question should be put to the developer (Professor Rudd, RCP) to ask whether it is believed the indicator is suitable for wider use other than the audit. If not the, Library does allow the option to define a particular use case, and as such it could be considered for entry with the clarification that it is for use within the audit, but has limited use beyond that purpose. Should the purpose of the indicator be re-stated to identify its use in support of the audit, rather than any wider purpose, the indicator should be reconsidered in 3 years. |

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| **Approval date** | N/A |
| **Review date** | N/A |

**Details of Methodology Appraisal – 12/11/2015**

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| **Methodology appraisal body** | HSCIC's Indicator & Methodology Assurance Service |
| **Reason for assessment** | Scheduled review (review date reached) |
| **Iteration** | 2nd MRG meeting |

***Suggested Assurance Rating by Methodology Appraisal Body***

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| **Ratings Against Assessment Criteria** |  | **Overall Rating - Not fit for use** |
| Clarity | **Fit for use** |  |
| Rationale | **Fit for use** |  |
| Data | **Fit for use with caveats** |  |
| Construction | **Fit for use with caveats** |  |
| Presentation and Interpretation | **Not fit for use** |  |
| Risks and Usefulness | **Fit for use with caveats** |  |

**Summary Recommendation to Applicant:**

Currently MRG are unable to endorse the indicator for inclusion in the Library due to the issues identified relating to how the indicator should be interpreted and as such its limited user base. MRG have however reflected that the indicator does have value within an informed user base. Additionally MRG members recommend that the indicator is brought back to MRG as and when amendments to the contextual information has been considered.

**Summary Recommendation to IGB:**

The indicator is currently difficult to interpret, as the indicator measures all stroke patients as opposed to only those patients who are eligible for thrombolysis, which is a far smaller subset currently estimated to be approximately 15 – 20%. MRG previously requested that the indicator denominator only be patients who are eligible for thrombolysis, however after this was presented to the group by Professor Tony Rudd, he explained to the group that the way in which eligibility is collected is not reliable and can be gamed. He also explained that although the current methodology including all stroke patients was not ideal, it was useful and the best available.   
  
  
Therefore, MRG conclude that although they do not endorse the indicator for inclusion in the Library of Quality Assured Indicators, they appreciate its value in this field. However the group feel that only informed users would be able to interpret the indicator as it currently stands.

**Please find a detailed description of recommendations and actions in the appraisal log at the end of the document.**

**Details of Methodology Appraisal – 10/09/2015**

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| **Methodology appraisal body** | HSCIC's Indicator & Methodology Assurance Service |
| **Reason for assessment** | Scheduled review (review date reached) |
| **Iteration** | 1st MRG meeting |

***Suggested Assurance Rating by Methodology Appraisal Body***

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| **Ratings Against Assessment Criteria** |  | **Overall Rating - Not fit for use** |
| Clarity | **Fit for use** |  |
| Rationale | **Fit for use** |  |
| Data | **Fit for use with caveats** |  |
| Construction | **Fit for use with caveats** |  |
| Presentation and Interpretation | **Not fit for use** |  |
| Risks and Usefulness | **Fit for use with caveats** |  |

**Summary Recommendation to Applicant:**

MRG noted that the indicator has been previously assured as suitable for inclusion in the Library of Quality Assured Indicators, however this was under an earlier iteration of the assurance process. Members thanked the applicant for the “uplift” in documentation which has allowed the indicator to be assessed against the standard criteria assessment and “levels of assurance”.   
  
Upon review the indicator has been rated as “not fit for purpose” against the ‘Construction’ and “Interpretation” assessment criterion, which in turn mean that the indicator would not at present be suitable for inclusion in the Library. MRG were concerned that the current indicator is hard to interpret, as thrombolysis is not appropriate in most stroke patients and the indicator methodology put forward includes all stroke patients. The applicant needs to reconsider whether only measuring eligible patients would be more appropriate, as currently the indicator is very difficult for users to interpret.  
  
  
  
**Summary Recommendation to IGB:**

The indicator is currently difficult to interpret, as the indicator measures all stroke patients as opposed to only those patients who are eligible for thrombolysis (which is possible). Therefore, MRG strongly recommend the  
indicator returns to the group and currently do not endorse its inclusion in the Library.

**Please find a detailed description of recommendations and actions in the appraisal log at the end of the document.**

**What do the Assurance Ratings mean?**

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| **Rating** | **Description** |
| **Fit for use** | This indicator can be used with confidence that it is constructed in a sound manner that is fit for purpose. |
| **Fit for use with caveats** | The indicator is fit for use, however users should be aware of caveats and/or recommendations for improvement that have been identified during the assurance process. |
| **Use with caution – data quality issue** | The indicator is based on a sound methodology for which the assurance process endorse the use, however issues have been identified with the national data source which have implications for its use as an indicator. |
| **Not fit for use** | Issues have been identified with the indicator which have resulted in the assurance process currently not endorsing its use as a quality indicator. |
| **Not enough information provided** | There has not been enough information supplied to the assurance process to be able to accurately give the indicator a level of assurance. |

**Appraisal Log**

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|  | **Clarity** |  |  |  |  |  |
| ***Rec. no*** | ***Issue or recommendation*** | ***Raised by / Date*** | ***Response or Action taken by applicant*** | ***Response date*** | ***Resolved*** | ***Sign off by / Date*** |
| 1a | MRG recommended that the title of the indicator be reviewed. Should the word ‘acute’ be included when all strokes are included in the denominator? | MRG  6/9/12 | The indicator title remained as *‘People who have had an acute stroke who receive thrombolysis’*.  The indicator denominator was amended to *‘The number of acute stroke patients who were given thrombolysis for stroke (Alteplase)’*. | 13/08/15 | 🗹 | MRG  10/09/15 |

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|  | **Rationale** |  |  |  |  |  |
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| 2a | A sponsor for the indicator needs to be identified. | MRG  10/09/15 | The sponsor of the CCG OIS is Richard Owen, Outcomes Strategy Lead, NHS Medical Directorate, NHS England. | 29/10/15 | 🗹 | MRG  12/11/15 |
| 2b | The definition should be clear as to the types of stroke included in the indicator. | MRG  10/09/15 | A sentence is included in the definition section of the IAS application form and Indicator Quality Statement, stating: Stroke is defined within this indicator as intracerebral haemorrhage (ICD-10 code: I61), cerebral infarction (I62) and stroke, not specified as haemorrhage or infarction (I64). | 29/10/15 | 🗹 | MRG  12/11/15 |

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|  | **Data** |  |  |  |  |  |
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| 3a | Concern was raised around the completeness of the data. As such if these indicators were to be progressed there would need to be a statement of the completeness of the data to provide context to the results. To provide confidence in recording levels there would need to be analysis of the completeness at hospital level, and also at CCG level.  MRG suggested that RCP could be asked to look at a high level cross validation with HES to compare the broad participation numbers by trust. | MRG  27/3/12 | The indicator is published in the context of case ascertainment between SSNAP and HES. This is the percentage of patients with primary ICD-10 codes I61, I63 and I64 in HES who are included in SSNAP for the same time period.  The SSNAP is a mandatory collection and overall case ascertainment increased from 72% in Quarter 1 to 95% in Quarter 4, 2013/14 (Quarter 2: 83%, Quarter 3: 90%). It has further improved to 97% by Quarter 4, 2014/15. Case ascertainment is reported alongside the indicator for all CCGs in the published CCG OIS data files. Only five CCGs (2.4%) had their percentages suppressed in the published 2013/14 data due to less than 50% case ascertainment with HES.  Patient records are only included in audit analyses if they include the minimum requirements of completion of mandatory fields. The minimum includes all of the fields required to calculate this indicator. Case ascertainment is reported publicly at hospital level and therefore there is a strong incentive for hospitals to ensure they have submitted all of their patients to the audit and completed the mandatory fields. The data is received via a secure web tool which has strong built-in validation meaning that data is fully complete. | 13/08/15 | 🗹 | MRG  10/09/15 |
| 3b | Further clarification is sought on how representative the audit data is at CCG level. | MRG  27/3/12 | Only five CCGs were suppressed in the 2013/14 data, due to having insufficient case ascertainment between SSNAP and HES. The audit data is considered to be sufficiently representative to be used at CCG level given the levels of case ascertainment and the suppression rules in place. | 13/08/15 | 🗹 | MRG  10/09/15 |
| 3c | Further clarification is sought on the time periods defined in the indicators, including frequency, collection periods, reporting periods etc. | 27/3/12 | CCG OIS indicator data are reported annually. SSNAP data for the full financial year is available approximately eight months after the financial year end; therefore the indicator is published each year in December. The indicator was published for the first time in December 2014, using 2013/14 for each CCG in England. 2014/15 data is due to be published in December 2015.  CCG OIS indicators are official statistics and the December 2014 publication date was pre-announced. There was no gap between the planned and actual publication date. | 13/08/15 | 🗹 | MRG  10/09/15 |
| 3di | The rationale for selecting the ICD-10 codes used to identify stroke patients should be clearly stated in the documentation for each indicator. | MRG  6/9/12 | The SSNAP uses the following ICD-10 diagnosis codes to identify stroke patients:   * I61 - Intracerebral haemorrhage * I63 - Cerebral infarction * I64 - Stroke, not specified as haemorrhage or infarction   The coding advice from the Clinical Classifications Service also includes I60 (Subarachnoid haemorrhage) and I62 (Other nontraumatic intracranial haemorrhage), however this advice would not be endorsed by the RCP as subarachnoid haemorrhage and other non-traumatic intracranial haemorrhage have a different care pathway and outcome. | During initial assurance | 🗹 | MRG  12/11/15 |
| 3dii | Update:  There is a discrepancy between what SSNAP and the clinical classifications service consider a stroke, therefore further justification for the codes used is required and the definition should be updated (as stated in recommendation 2b). | MRG 10/09/15 | Update:  Subarachnoid haemorrhages and other non-traumatic intracranial haemorrhages are routinely and nearly always managed entirely outside of the stroke unit by neurosurgeons or by interventional neuroradiologists, which is what is recommended in national guidelines for these cases. The indicators need to reflect the care given on appropriate clinical pathways, not arbitrary groupings. |  | 🗹 | MRG  12/11/15 |
| 3e | MRG recommended that investigations into whether case ascertainment is the same for different age and sex breakdowns as selection bias could affect the calculation of the indicators. | MRG  6/9/12 | The age and sex breakdowns were investigated by the RCP in 2012 and found to be comparable with published literature and therefore not felt to represent a selection bias.  The SSNAP annual report provides some overall demographic details of patients included in the SSNAP <https://www.strokeaudit.org/Documents/Newspress/SSNAP-Annual-Report-(April-2013-March-2014).pdf>  Along with a host of other detailed audit information, the quarterly SSNAP public report provides specific details on the casemix breakdowns, including patient numbers, gender, age, co-morbidities, stroke type, Modified Rankin Scales scores, NIHSS and the onset of symptoms (Section 2: Casemix, p48) <https://www.strokeaudit.org/Documents/Results/National/OctDec2014/OctDec2014-PublicReport.aspx> | 13/08/15 | 🗹 | MRG  10/09/15 |
| 3f | The narrative around why SSNAP is being used as opposed to HES should be strengthened. The application states that over-coding occurs in HES, however the results in section 5.9 show that case “ascertainment” against HES is over 100%. | MRG  10/09/15 | The application for this indicator did not state that over-coding occurs in HES. The application stated that HES does not contain the necessary detail required to measure this indicator. | 29/10/15 | 🗹 | MRG  12/11/15 |
| 3g | The applicant should consider how useful it is to provide case ascertainment against HES data, since it is recognised that over-coding occurs in HES, making the figure hard to interpret. If the figure is to be presented, MRG recommend changing the name from “case ascertainment” to “case comparison” and to present bands above 90+%. | MRG  10/09/15 | This contextual case ascertainment information aligns to the information and bandings presented in the RCP SSNAP publication. The RCP view is that it is not case comparison as it is not comparing the same year’s HES with SSNAP. Since the purpose of including case ascertainment is to highlight CCGs with low case ascertainment indicating that hospitals within the CCG have not been entering in all their patients onto SSNAP (and the results may therefore not reflect the care that all the CCGs patients received), having bands above 100% would not be useful. HES is not the ‘gold standard’, but it is a useful indication of case selection.  The HES case ascertainment figure (‘Estimated expected number of patients from HES’) is the number of patients who have been coded as a primary diagnosis of stroke during their admission in a year’s worth of HES, split by the patient’s CCG recorded in the HES record. The indicator is not reported for CCGs with less than 50% case ascertainment. | 29/10/15 | 🗹 | MRG  12/11/15 |

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|  | **Construction** |  |  |  |  |  |
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| 4ai | The denominator for this indicator is all patients with stroke rather than all patients considered suitable for thrombolysis, as there are many clinical reasons for which patients might not be considered suitable which may not be captured by the data. MRG recommended that the accompanying documentation for the indicator should explain why this treatment isn’t suitable for all patients, along with an indication of what might represent good practice. | MRG  6/9/12 |  |  | 🞏 |  |
| 4aii | Update:  MRG recommend that the applicant should reconsider whether including patients who are not eligible for thrombolysis is advantageous. As a minimum, contextual information should be provided alongside the indicator showing the number of eligible patients who receive thrombolysis. | MRG  10/09/15 |  |  | 🞏 |  |
| 4aiii | Update:  MRG were provided with a verbal update from Professor Tony Rudd, who outlined that the way in which eligible patients could be identified in the data was not reliable and may be gamed. Furthermore, as a user of the indicator, he informed the group that indicator that includes all patients is of use, as opposed to the indicator that uses the eligible population, which is not. Therefore MRG agree with decision to not use the eligible patient population in this indicator or its contextual information until the data quality improves. | MRG  12/11/15 | The indicator is to be published in December 2015 in the same way it was published last year. The denominator will remain as the overall stroke patient population. |  | 🞏 |  |
| 4b | It was suggested in the meeting that ineligible patients, those where use of thrombolysis is contraindicated, were evenly distributed and as such there is no need to adjust for case mix or attempt to adjust the denominator to remove these patients. | MRG  6/9/12 | Some initial analysis at PCT level performed in 2012 and presented to MRG (below) suggested that the case mix of stroke admissions is an important factor and is by no means uniform. For example, ICD-10 code I61 which includes a lot of haemorrhagic strokes ranged from 6% in some PCTs to 21% in others.  Graph showing range of the distribution by PCT of HES stroke admissions  In order to contextualise this indicator, the SSNAP also reports on the percentage of eligible patients thrombolysed as a key CCG level indicator. In addition, the SSNAP reports on several factors which could affect thrombolysis rates such as the haemorrhage rate and onset-to-arrival timings.  The Indicator Quality Statement currently advises users to interpret the indicator ‘alongside information from other indicators and sources such as the SSNAP’, however this will be improved to include more detail on which specific measures can be used. |  |  |  |

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|  | **Presentation and Interpretation** |  |  |  |  |  |
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| 5a | MRG recommended that the metadata for the indicator include some indication that there isn’t a variation between CCGs in contraindications such as haemorrhage | MRG  6/9/12 | See section 4b. | 13/08/15 | 🗹 | MRG  10/09/15 |
| 5bi | MRG questioned how useful the indicator is and whether it can be interpreted by users, as it is not clear what “good” would look like. Furthermore, it would not be known whether thrombolysis was being administered to appropriate cases. | MRG  10/09/15 |  |  | 🞏 |  |
| 5bii | It was explained in the meeting by Professor Tony Rudd that although this indicator is hard to interpret, it is of use. However the group feel that only expert users would be able to interpret the indicator as it currently stands. | MRG  12/11/15 |  |  | 🞏 |  |
| 5c | It has been highlighted to MRG that the way in which eligible patients can be identified in the data is not reliable. Therefore the group understand and support the decision to include all stroke patients in the indicator at the present time, and to not present the eligible patients who receive thrombolysis as contextual information. However, the applicant should consider whether as contextual information presenting the proportion of ischaemic stroke cases who receive thrombolysis would add value. | MRG  12/11/15 | The indicator is to be published in December 2015 in the same way it was published last year. The denominator will remain as the overall stroke patient population.  Providing contextual information relating to cases of ischaemic stroke will be investigated with the RCP. |  | 🞏 |  |
| 5d | IGB members have asked for clarification from the developer as to whether the indicator could be reasonably interpreted and understood beyond the purpose of the stroke audit. | IGB – 14/12/15 |  |  | 🞏 |  |

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|  | **Risks and Usefulness** |  |  |  |  |  |
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| 6a | MRG recommended that work on cross-validating the audit data set with HES data should continue, as the credibility of the indicators could be impacted by conflicting sources. MRG recommended including a contextual indicator on the relationship between the audit and HES data as this would also encourage improvements in data quality. | MRG  6/9/12 | The SSNAP is a mandatory collection and overall case ascertainment increased from 72% in Quarter 1 to 95% in Quarter 4, 2013/14 (Quarter 2: 83%, Quarter 3: 90%). It has further improved to 97% by Quarter 4, 2014/15.  The indicator is published in the context of case ascertainment between SSNAP and HES. This is the percentage of patients per CCG with primary ICD-10 codes I61, I63 and I64 in HES who are included in SSNAP for the same time period. Case ascertainment is reported alongside the indicator for all CCGs in the published CCG OIS data files. The indicator is not reported for any CCGs with lower than 50% case ascertainment or for those with fewer than 20 patients. | 13/08/15 | 🗹 | MRG  10/09/15 |
| 6bi | As all patients are included in the indicator (as opposed to only eligible patients), there is a risk that results may be misinterpreted and used to influence future policy or practice. MRG recommend the applicant reconsders whether measuring only eligible patients would be more appropriate. | MRG  10/09/15 |  |  | 🞏 |  |
| 6bii | Update: It was explained that the way in which the eligible population may be identified is unreliable and the group agree with the decision not to base the indicator on this population. However the initial risk highlighted above still stands. | MRG  12/11/15 | The Indicator Quality Statement includes details on the interpretation of this indicator. It also provides a link to the SSNAP reports which include measures on several factors which could affect thrombolysis rates such as the haemorrhage rate and onset-to-arrival timings, as well as other CCG level indicators which may be useful to aid interpretation. |  | 🞏 |  |

**Any complaints or appeals against the decisions made during the assurance process should be made to the Indicator & Methodology Assurance Service (IMAS) Team at HSCIC. Likewise, if you are unclear regarding any of the recommendations in this report, or have any queries about the assurance process in general, please contact the IMAS team.**

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