



**Royal College  
of Physicians**  
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# **GREAT BRITAIN AND IRELAND CAROTID ENDARTERECTOMY AUDIT**

## **PUBLIC REPORT**

### **CLINICAL AUDIT REPORT – ROUND 1**

(December 2005 - December 2007)

Prepared on behalf of  
The Steering Group  
by

Clinical Effectiveness and Evaluation Unit  
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Royal College of Physicians of London

**2008**

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## Glossary

<b>angiography</b>	This is an investigation of the arteries usually performed with x-rays taken following injection of a contrast liquid into the blood stream. Similar images can now be obtained with duplex, CT and MR scanning (see below)
<b>ABCD<sup>2</sup></b>	Prognostic scores to identify people at high risk of stroke after a transient ischaemic attack. It is calculated based on: <b>A</b> – age ( ≥60 years, 1 point) <b>B</b> – blood pressure at presentation (≥ 140/90 mm Hg, 1 point) <b>C</b> – clinical features (unilateral weakness, 2 points or speech disturbance without weakness, 1 point) <b>D</b> – Duration of symptoms (≥ 60 minutes 2 points or 10 – 59 minutes, 1 point) <b>D</b> – presence of diabetes (1 point)  Total scores range from 0 (low risk) to 7 (high risk).
<b>amaurosis fugax</b>	Temporary visual loss in one eye
<b>anaesthetic (general or local)</b>	Agent used to block sensation including pain
<b>anaesthetist</b>	Doctor specialising in the administration of anaesthetics
<b>angina</b>	Chest pain due to impaired blood supply to the muscle of the heart
<b>anticoagulants</b>	A group of drugs used to reduce the risk of clots forming by thinning the blood.
<b>antiplatelets</b>	A group of drugs used to prevent the formation of clots by stopping platelets in the blood sticking together.
<b>antithrombotic drugs</b>	Drugs with a variety of different mechanisms of action designed to prevent blood clotting
<b>arrhythmia</b>	Irregular heart beat
<b>asymptomatic carotid disease</b>	There is narrowing of the carotid artery but this has not caused any symptoms such as a stroke or TIA .
<b>beta blockers</b>	A type of drug which controls the heart rate
<b>cardiac embolism</b>	Blood clot arising from the heart which can pass to other parts of the circulation
<b>cardiac failure</b>	A condition in which there is a problem with the <i>structure</i> or <i>function</i> of the <u>heart</u> that impairs its ability to supply sufficient <u>blood</u> flow to meet the body's needs
<b>cardiology</b>	Medical speciality dealing with disease of the heart
<b>cardiovascular</b>	Related to the heart or circulation
<b>cardiovascular disease</b>	Disease of the heart or circulation
<b>carotid artery</b>	There are two carotid arteries that supply the brain with blood. Disease of a carotid artery is a common cause of stroke
<b>Carotid duplex scanning</b>	Ultrasound imaging to assess the carotid arteries
<b>carotid endarterectomy (CEA)</b>	The surgical removal of plaque from a blocked carotid artery to restore blood flow
<b>carotid stenosis</b>	The narrowing of the carotid arteries in the neck.
<b>case selection criteria</b>	The factors for an individual patient which predict the most appropriate cases (patients) to benefit from surgery
<b>case mix</b>	Pre-existing demography and health of individual patients that may influence the outcome of healthcare
<b>cases</b>	Carotid endarterectomy operations
<b>CCST</b>	Certificate of Completion of Specialist Training

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<b>cholesterol</b>	A fatty substance that, if present in excess, can be deposited in the wall of the artery to produce <i>atheroma</i>
<b>clinical audit</b>	An examination or review that establishes the extent to which a condition, process, or performance conforms to predetermined clinical standards or criteria
<b>Cochrane review</b>	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
<b>co-morbidities</b>	Other medical conditions which may present in addition to the primary disease being treated
<b>complications</b>	Conditions which occur following treatment which may adversely affect the outcome
<b>computed tomography (CT)</b>	The X-ray technique most commonly used to examine the brain
<b>confidence interval (CI)</b>	The probability of the observed data (or data showing a departure more extreme from the null hypothesis) when the null hypothesis is accepted.
<b>consultant</b>	A doctor trained in a specialist field, normally working in hospital
<b>contralateral</b>	On the opposite side
<b>coronary artery bypass surgery</b>	An operation on the blood vessels (arteries) supplying the heart muscles to bypass blockages in these arteries
<b>coronary heart disease</b>	Disease of the arteries supplying the heart muscle
<b>cost-effectiveness analysis</b>	An economic study design in which consequences of different interventions are measured using a single outcome, usually in natural units (for example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
<b>cranial nerve injury</b>	Damage to one of the nerves supplying the head and neck
<b>diabetes</b>	A medical condition characterised by high blood sugar levels
<b>disability</b>	Physical, mental, cognitive, intellectual or sensory impairment
<b>evacuation</b>	Removal of
<b>evidence base/consensus</b>	Evidence which exists for a particular treatment or the opinion of a significant group of healthcare professionals
<b>follow-up</b>	Seeing a patient again after treatment to assess outcomes
<b>GALA trial</b>	General anaesthetic versus local anaesthetic for carotid surgery – to compare the risk of stroke, myocardial infarction and death as a result of CEA under either general or local anaesthetic
<b>haemorrhage</b>	Bleeding caused by blood escaping into the tissues.
<b>haemostasis</b>	Stopping bleeding
<b>High Dependency Unit (HDU)</b>	An area for patients who require more intensive observation, treatment and nursing care than are usually provided on a general ward. It is a standard of care between the general ward and full intensive care
<b>histology</b>	Examination of tissues at microscopic level in order to determine pathology
<b>hospital episode statistics (HES)</b>	Routine national statistics collected on reasons for admission to hospital and procedures undertaken. In this report the number of CEAs reported to central statistics, is used to describe the total number of CEAs being undertaken in the country and will be referred to throughout this report as

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	<i>Hospital Episodes Statistics (HES)</i> . The source of this information is different for each region: <a href="http://www.dh.gov.uk">www.dh.gov.uk</a> (England), <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> (Wales), <a href="http://www.dhsspsni.gov.uk">www.dhsspsni.gov.uk</a> (Northern Ireland) <a href="http://www.isdscotland.org">www.isdscotland.org</a> (Scotland).
<b>Hyperperfusion syndrome</b>	A condition which occurs rarely after carotid endarterectomy which can include severe frontal headache, seizures, and bleeding into the brain
<b>hypertension</b>	High blood pressure
<b>infarct/infarction</b>	An area of cell death (e.g. part of the brain) as a result of being deprived of its blood supply
<b>inpatient death</b>	Death of a patient in hospital
<b>international normalised ratio (INR)</b>	A measure of the clotting ability of blood, usually following use of anticoagulant drugs. It is calculated as the ratio of the length of time it takes blood to clot over the time it would take the blood of a normal subject to clot
<b>interquartile range (IQR)</b>	The range between the 25 <sup>th</sup> and 75 <sup>th</sup> centile which is equivalent to the middle half of all values
<b>ipsilateral</b>	Same side as the carotid artery which is being operated on
<b>ischaemic heart disease</b>	Disease of the blood vessels supplying the muscles of the heart
<b>ischaemic stroke</b>	Stroke caused when a <u>blood</u> clot blocks an <u>artery</u> and so restricts the amount of <u>blood</u> that can reach the <u>brain</u> .
<b>magnetic resonance angiography (MRA)</b>	Using a large, powerful magnet, rather than X-rays, to create pictures of the blood vessels (arteries and veins)
<b>magnetic resonance imaging (MRI)</b>	A type of scan that, instead of X-rays, uses a large, powerful magnet to create an image (picture) of part of the body
<b>median</b>	The middle point of a data set; half of the values are below this point, and half are above this point
<b>mortality</b>	Death
<b>magnetic resonance imaging (MRI)</b>	A non-invasive imaging technique allowing detailed examination of the brain.
<b>myocardial infarct</b>	Heart attack
<b>NASCET</b>	North American Symptomatic Carotid Endarterectomy Trial
<b>National stroke strategy</b>	A ten-year framework that aims to improve standards of care to reduce mortality and morbidity. It was launched in 2007.
<b>neurologist</b>	Doctor specialising in diseases of the nervous system
<b>neurosurgeon</b>	Surgeon specialising in the diagnosis and treatment of disease of the central and peripheral nervous system, including the skull, spine and blood vessels
<b>National Institute for Health and Clinical Excellence (NICE)</b>	A special health authority set up within the NHS to develop appropriate and consistent advice on health care technologies, and to commission evidence-based guidelines
<b>occlusion</b>	blockage in the blood vessel
<b>ophthalmology</b>	Medical specialty involving diseases of the eye
<b>organisational survey</b>	Survey of the service organisation of surgical practice
<b>outcome</b>	The expected result of the operation including the possible complications
<b>pathology</b>	Study and diagnosis of disease through the study of organs and tissues
<b>perioperative</b>	The period surrounding the operation
<b>peripheral vascular disease</b>	Disease of blood vessels outside the heart, usually the lower limbs
<b>physicians</b>	Doctors specialising in medicine (as opposed to surgery)

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<b>postoperative</b>	After the operation
<b>post-operative assessment</b>	Measurement of change before and after surgery
<b>post-operative stroke</b>	Having a stroke after surgery
<b>prognosis</b>	Expected outcome
<b>randomised research trials</b>	These are research studies which include at least 2 different groups in the trial and those taking part are put into one or other group at random.
<b>Rankin score</b>	Scoring system to define the level of disability following a stroke
<b>randomised control trial (RCT)</b>	A trial in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. Such trial designs help minimize experimental bias.
<b>risk factors</b>	The possible underlying causes (for the stroke) e.g. smoking, high blood pressure, ethnic group, family history of stroke
<b>seroma</b>	Collection of fluid in a wound following an operation
<b>Side effect</b>	An adverse event that occurs because of a therapeutic intervention
<b>specialist</b>	A clinician whose practice is limited to a particular branch of medicine or surgery, especially one who is certified by a higher medical educational organisation
<b>specialist registrar (SpR)</b>	A doctor in specialist training
<b>statin</b>	A drug designed to reduce cholesterol levels
<b>stenosis</b>	Abnormal narrowing of a blood vessel
<b>stenting</b>	A metal mesh tube is placed in an artery or blood vessel to increase blood flow to an area blocked by stenosis
<b>stroke</b>	The damaging or killing of brains cells starved of oxygen as a result of the blood supply to part of the brain being cut off.
<b>surgical outcome</b>	The results of the surgery which may be benefit or harm
<b>symptomatic carotid stenosis</b>	patients who have suffered a transient ischemic attack or completed stroke this contrasts with <i>asymptomatic stenosis</i>
<b>synchronous heart surgery</b>	Heart surgery performed at the same time
<b>transient ischaemic attack (TIA)</b>	A stroke that fully recovers within 24 hours of the start of symptoms. Sometimes described as a 'mini stroke'
<b>Vascular surgeon</b>	A surgeon with an interest in Vascular Surgery should have: A sound training in General Surgery The necessary clinical and surgical skills relating to the management of relevant diseases of arteries, veins and lymphatics. The necessary clinical and surgical skills to maintain an emergency surgical service in General Surgery (where appropriate) and in Vascular Surgery. A sound knowledge of the role of interventional radiology in the management of vascular disease. A sound knowledge of the role of angiology in the management of vascular disease. Knowledge of relevant diagnostic imaging investigations. Knowledge of the role of a Vascular Laboratory in diagnosis and management of vascular disease. Knowledge of the relevant aspects of basic sciences and critical care as applied to vascular disease.
<b>Vascular surgery</b>	Surgery on patients diagnosed with diseases of the arterial, venous, and lymphatic systems (excluding the intracranial and coronary arteries).
<b>Web tool</b>	Software used to collect outcome data

## Foreword

Carotid Endarterectomy (CEA) is an operation performed in order to prevent stroke. It is carried out on people with narrowing of the neck arteries to remove a diseased area of the main blood vessel supplying the brain. Removing this diseased area helps to prevent small particles breaking off and passing up into the brain, one of the major causes of stroke. To maximise benefit, CEA should be performed as soon as possible after the patient experiences relevant symptoms e.g. facial weakness, arm weakness, speech problems or loss of blurring of vision. Vascular surgeons almost exclusively carry out this surgery, with the remainder being carried out by a few neurosurgeons (surgeons specialising in brain operations).

Currently in the UK, approximately 6 CEAs are carried out per 100 000 population each year. Other countries do many more: such as the US and Australia where incidence is higher (USA ~80 per 100 000, Australia 60 per 100 000 and Canada 45 per 100 000).

For this round 240 (61%) of the eligible surgeons participated. Each individual surgeon was asked to send data on all the CEA cases they carried out. One hundred and two (76%) of the trusts providing CEA in England, Northern Ireland, Scotland and Wales contributed 5513 cases making this one of the largest samples of CEA published. According to Hospital Episodes Statistics (HES) 9913 CEAs were undertaken nationally (operation dates Dec 2005 to Dec 2007) and therefore this report covers 56% (5513/9913) of these CEA operations according to HES for the same period.

This report summarises the national results of the first round of the audit. Over this period participation in the audit has steadily grown as has the completeness of data input. It has to be recognised that the audit cannot at this stage provide a fully comprehensive picture of surgery for CEA and results must be interpreted with some caution. Nevertheless this is a comprehensive robust audit of patients who have undergone carotid endarterectomy in the UK.

This round has clearly demonstrated unacceptable delays at all stages of the patient pathway from symptom to referral to investigation to surgery. Whilst there is a clear need to improve waiting times it should be noted that in order to achieve even the 2 week standard recommended by the National Institute for Health and Clinical Excellence (NICE), for many centres this will require a major change in the way vascular investigation and surgical services are organised and provided. If the 48-hour target (National Stroke Strategy) is to be achieved then carotid surgery will need to be performed urgently at the weekend.

The evidence base for performing carotid endarterectomy to prevent stroke continues to grow and this is a particularly good time to address vascular services as a whole. Public and professional awareness of the findings of this audit and implementation of the recommendations should be a key objective for all relevant health care organisations.

Plans are being developed to work with the teams of professionals that look after CEA patients to raise awareness of these findings and address how the CEA service as a whole can be improved. Data collection for Round 2 of the audit (operation dates Jan 2008 to Sept 2009) is underway and progressing well. The results will be reported in spring 2010. Please contact us if there are any comments you may wish to make. Contact: [ceaaudit@rcplondon.ac.uk](mailto:ceaaudit@rcplondon.ac.uk)

Tim Lees  
Chairman

## EXECUTIVE SUMMARY

### Background

A firm evidence base supports the role of carotid endarterectomy (CEA) and its urgency in the prevention of stroke. This prospective audit aims to inform current provision of services within all hospitals that offer CEA. The Healthcare Commission initially funded the audit, although funding passed to the Healthcare Quality Improvement Partnership (HQIP) in April 2008, and it is being undertaken in collaboration between the Vascular Society of Great Britain and Ireland and the Royal College of Physicians. All surgeons who undertake CEA in Great Britain and Ireland are eligible to participate in the audit and surgeons register individually irrespective of the number of CEAs they perform each year.

The round of CEA Audit reported here includes operations performed between December 1<sup>st</sup> 2005 and December 31<sup>st</sup> 2007. Round 2 of CEA Audit is underway and will include operations performed between January 1<sup>st</sup> 2008 and September 30<sup>th</sup> 2009. The results from Round 2 will be reported in spring 2010.

### Aims of the Clinical Audit

1. To assess the current speed of delivery of carotid endarterectomy in the UK
2. To assess variations in provision of imaging and CEA to encourage national and local action to improve quality and increase capacity
3. To assess 30-day mortality and complications at follow-up against the available evidence base

### Participation

This report covers the first two years of data collection (Round 1). 61% (240/396) of eligible UK surgeons contributed 5513 cases. 23/5513 cases were performed in private healthcare settings. The 5490 NHS-based cases were collected from 102 of the 135 eligible trusts (76%). The most common reasons given by non-participation surgeons for failure to contribute to this round of the audit were insufficient time/resource and/or they already involved in local audits to collect similar data.

According to Hospital Episodes Statistics (HES) 9913 CEAs were undertaken nationally (operation dates Dec 2005 to Dec 2007) and therefore this report covers 56% (5513/9913) of the operations according to HES for the same period.

### Evidence base

The evidence used for setting standards is derived from two main documents:

1. National Institute for Health and Clinical Excellence Guideline - Stroke: Diagnosis and initial management of acute stroke and transient ischaemic attack (TIA) (2008)  
<http://www.nice.org.uk/Guidance/CG68>

Recommendation 14 (R14) recommends that people with stable neurological symptoms from acute non-disabling stroke or TIA who have symptomatic carotid stenosis of 50%-99% according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria, or 70-99% according to the European Carotid Surgery Trialists' (ECST) Collaborative Group criteria, should:

- be assessed and referred for carotid endarterectomy (CEA) within 1 week of onset of stroke or TIA symptoms
- undergo surgery within a maximum of two weeks of onset of stroke or TIA symptoms

2. National Stroke Strategy (2007) <http://www.dh.gov.uk> and Implementing the National Stroke Strategy – an imaging guide which was published in 2008

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This is a ten year strategy with a quality marker (QM6) that carotid intervention for recently symptomatic severe carotid stenosis should be regarded as an emergency procedure in patients who are neurologically stable, and should ideally be performed within 48 hours of a TIA or minor stroke.

The National Stroke Strategy Imaging Guideline indicates that access to carotid duplex scanning should be available 7 days a week.

## Priority findings

1. This audit is one of the largest samples of CEA published with 5513 cases complete from referral to discharge and 4964/5513 (90%) of these complete with follow-up data
2. This audit has demonstrated unacceptable delays at all stages of the patient pathway from symptom to referral to investigation to surgery.
3. At most 37% of patients are achieving the standards set in the NICE stroke and TIA guideline (2 weeks from symptom onset to carotid endarterectomy).
4. Thirty percent of patients had their operation performed beyond the time when the benefits outweigh best medical treatment, thereby losing the opportunity for the prevention of early stroke.
5. More than 90% did not meet the Stroke Strategy standard of 48 hours. CEA needs to be regarded as an operation that should be performed as quickly as possible and if the 48 hour target is to be achieved this operation needs to be on the next day's vascular list.
6. Once the patient had been admitted to hospital it took a median of 1 day to undergo the operation.

## Key messages and recommendations for action

### A. General

1. CEA is performed predominantly in the elderly (mean age 70 years) and in men (68%). Patients also tend to be of White British ethnicity (95%). This is consistent with the fact that carotid artery disease is seen only rarely in non Caucasians.
2. CEA is almost exclusively carried out by consultant level anaesthetists (97%) and surgeons (97%). These surgeons are to be congratulated on their commitment to the audit, to improving outcomes for patients, and on the completeness of their data entry.

#### **ACTION:**

**All surgeons performing CEA should be encouraged to contribute to Round 2 of the audit for 2008 to 2010. Trusts should ensure that surgeons are provided with the necessary time and resource to participate and submit data.**

### B. Delays in Treatment

Carotid endarterectomy needs to be regarded as an operation that should be performed as rapidly as possible. If the Department of Health Stroke Strategy guideline target of 48 hours is to be achieved organisation of diagnostic and surgical vascular services will need to incorporate provision for operating on these patients on the next day's vascular operating list. Even a target time of 2 weeks (NICE guidelines) will require changes to the way the service is currently delivered.

1. This audit has demonstrated unacceptable delays at all stages of the patient pathway from symptom to referral to investigation to surgery.
2. At most 37% of patients are achieving the standards set in the NICE stroke and TIA guideline (2 weeks from symptom onset to carotid endarterectomy). Thirty percent of patients had their operation performed beyond the time when the benefits outweigh best medical treatment, thereby losing the opportunity for the prevention of early stroke. More than 90% did not meet the Stroke Strategy standard of 48 hours of TIA or minor stroke. CEA needs to be regarded as an operation that should be performed as quickly as possible and if the 48 hour target is to be achieved this operation needs to be on the next day's vascular list.
3. Some referral routes seem to be more efficient than others. The reasons are not clear but the data suggest that the system that works best is one where the neurologists and stroke physicians work in partnership with the vascular surgeons to provide a streamlined service.
4. It is encouraging that the median time from referral to surgery decreased from 43 to 34 days during the course of the audit.
5. The National Stroke Strategy Imaging Guideline indicates that access to carotid duplex scanning should be available 7 days a week. Healthcare professionals investigating and treating carotid endarterectomy patients should have access to magnetic resonance imaging (MRI) and computerised tomography (CT) scanning. This will need to be available at all times, including out of hours and at weekends if the 48 hour target is to be achieved, and even a 2 week target will require rapid access to imaging services. Carotid artery and brain imaging should follow the guidelines in the National Stroke Strategy Imaging Guide.

#### **ACTION:**

**Public and professional awareness of what to do in the event of a TIA or stroke should be a key objective for Primary Care Organisations and Acute Trusts.**

**Processes must be developed to speed up every stage of the pathway from symptom to referral and then to investigation and surgery. CEA needs to be regarded as an operation that should be performed as rapidly as possible and organisation of diagnostic vascular surgical services needs to incorporate provision for operating on these patients on the next day's operating list. This requires education of the general public, doctors (including both general practitioners and hospital doctors), and other healthcare professionals.**

**Healthcare providers also need to understand the requirement to see and treat these patients more rapidly.**

**Vascular surgeons and physicians should be encouraged to work in partnership in order to provide the most efficient service.**

### **C. Complications and mortality during hospital stay and within 30-days**

The reason for performing a carotid endarterectomy in patients who have had a previous transient ischaemic attack (TIA) or minor stroke, is to prevent a more major disabling or fatal stroke. However, as with any operation, there are risks associated with surgery. In the case of carotid endarterectomy the most serious complications which can occur are stroke, heart attack, and death. For the operation to benefit patients it is essential that these risks of surgery are as low as possible and it is therefore important to monitor complication rates following surgery.

1. The results of this round of CEA audit showed that following carotid endarterectomy the rate of stroke whilst the patient is still in hospital (in-hospital stroke) is 1.8% and the death rate is 0.5%. Recently, a research trial comparing General Anaesthetic and Local Anaesthetic in CEA (GALA) the reported in-hospital stroke rate to be 4.5% and the in-hospital death rate to be 4.8%

2. The lower stroke and death rate in such a large patient sample is to be applauded. However this may also reflect the high number of asymptomatic patients treated (patients who although they have narrowing of the carotid artery, no symptoms such as stroke or TIA have been caused) and in the context of a voluntary audit such as this possible non-reporting and selective reporting must be considered.

#### **ACTION:**

**This disparity with the randomised controlled trials (RCTs) in relation to outcomes emphasises the importance of universal contribution and complete reporting.**

**It should be recognised that as carotid endarterectomy is performed more expeditiously in the future the complication rates including stroke may rise, but this should be outweighed by the increase in benefit that early surgery offers.**

### **D. Follow-up after hospital discharge**

Some complications of carotid endarterectomy occur following discharge from hospital. A follow-up appointment to assess outcome from surgery is an important part of care and quality control in this group of patients. This should be recognised in the current environment of reducing hospital appointments.

1. Ninety five percent of patients were offered a follow-up appointment and were seen predominantly by the surgical team. We would expect all patients to be offered a follow-up appointment.

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2. This round demonstrated a stroke rate by the time of the follow-up appointment of 2.4% and a combined rate of stroke and death up to 30-days after undergoing carotid endarterectomy, of 2.5%. The risk of major complication, particularly death and perioperative stroke is lower than that reported in the randomised controlled trials of CEA that were available when the audit started (Dec 2005), where rates of 6 to 7% were experienced. The results of the General Anaesthetic versus Local Anaesthetic trial (GALA) which were announced in November 2008 reported 4.5% and 4.8% respectively.
3. Only 91% of patients were on an antithrombotic agent and 84% on a statin at follow-up.
4. Six percent were reported to have had a complication following discharge.

### **ACTION:**

**Post discharge follow-up is an important part of care and quality control. This should be recognised within the current environment of reducing hospital review appointments.**

**Consideration should be given to providing independent neurological follow-up for these patients.**

## **Section 1 - METHODS**

### **1.1 Project Management**

The audit is led by a multidisciplinary Steering Group on which professional organisations and patients are represented (Appendix 1).

### **1.2 Recruitment**

Every acute hospital in England, Wales, Scotland and Northern Ireland was contacted to ascertain the number of surgeons who performed CEA. The 396 consultant surgeons were written to individually and invited to participate to submit all the CEA cases that they perform during the audit period.

### **1.3 Data collection**

The audit asks for data that are routinely collected within the hospitals' information system. The questionnaire was designed to follow the patient care pathway. Each surgeon was asked to submit data via a password-protected web tool, for each CEA case performed. Codes are used for each patient, surgeon and hospital to maintain anonymity. Data collection for Round 1 was between December 2005 and March 2008. Information was collected at the following points (see Appendix 2):

- Data for referral to hospital discharge after undergoing carotid endarterectomy
- Thirty day survival
- After hospital discharge for those patients who attended a follow-up appointment

The surgeons have overall responsibility for the quality of the submitted data.

### **1.4 Case selection**

This audit only captures patients who underwent CEA and cannot comment on patients who may have been suitable but did not receive the operation.

This round also excludes other carotid interventions that suitable patients may have undergone as an alternative to CEA i.e. angioplasty/stenting.

### **1.5 Operations carried out during data collection period**

This is a report of the first two years of the CEA Audit (Round 1) for the number of CEAs performed between December 2005 and December 2007.

The number of CEAs that were performed at each trust between December 2005 and December 2007 were obtained from Hospital Episode Statistics and used to compare the total number reported to ascertain data completeness.

### **1.6 Limitations to the study**

As with all studies of this nature, it is important to acknowledge the limitations. The data are self-reported by the proportion of UK surgeons who took part and a significant number of surgeons did not contribute for a variety of reasons. Accuracy of HES data is contingent on clinical coding and therefore should be interpreted with caution. However, it is important that self-reporting (i.e. participation in this audit) is compared to the HES data which inform government decisions. Some of the contributing surgeons may not have submitted all their cases if HES figures are correct. Not all the patients in the survey attended a follow-up appointment. In addition, the survey captured only those patients undergoing surgery and there may have been other patients potentially eligible for CEA who did not receive surgery. Nevertheless, the process data are likely to be reasonably reliable and have important implications for routine clinical practice, particularly in relation to delays in investigation and treatment.

## Section 2 – RESULTS

### Chapter 1 – Participation rates

#### 2.1.1 Trust participation rate

Carotid endarterectomy is performed at 135 trusts across England, Wales, Northern Ireland and Scotland, 102 (76%) of these trusts participated in this round of the audit. All 135 are expected to participate in Round 2 and a report on trust participation will be sent to the Healthcare Quality Improvement Partnership/Healthcare Commission. The term eligible trusts is used throughout the report to describe all trusts where CEA is performed.

#### 2.1.2 Surgeon participation rate

396 consultant surgeons are known to perform CEA across England, Wales, Northern Ireland and Scotland: England 86% (341/396), Northern Ireland 2% (10/396), Scotland 7% (26/396) and Wales 5% (19/396). These are subsequently referred to as eligible surgeons. Some surgeons undertake more CEAs than others so these data cannot be used to compare availability of CEA in each country. Two hundred and forty (61%) of eligible surgeons participated in this round of the audit by contributing at least one case and all 396 are expected to contribute to the next round.

**Figure 2.1.1 Regional participation (trusts/surgeons)**

Region	Number of eligible TRUSTS (N)	Number and (percentage) of contributing TRUSTS (at least 1 case by 31st Mar 08) N (%)	Number of eligible SURGEONS (N)	Number and (percentage) of contributing SURGEONS (at least 1 case by 31st Mar 08) N (%)
ENGLAND	114	88 (77%)	341	211 (62%)
N IRELAND	3	3 (100%)	10	8 (80%)
SCOTLAND	9	7 (78%)	26	12 (46%)
WALES	9	4 (44%)	19	9 (47%)
<b>TOTAL</b>	<b>135</b>	<b>102 (76%)</b>	<b>396</b>	<b>240 (61%)</b>

#### 2.1.3 Case submission rate

The total number of CEA cases listed on Hospital Episode Statistics (HES) for England, Wales, Scotland and Northern Ireland was 9113. The percentage (of HES cases) varies widely between individual Trusts, with a median of 71% and Inter quartile range (IQR) 37% - 96% (excluding the Northern Ireland estimates where trust level data were not available).

A total of 6188 (56%) cases were entered on the web tool by 31 March 2008. Once incomplete cases and duplicates were excluded, 5513 (from 240 surgeons for 102 trusts) remained for analysis. The median number of cases contributed per surgeon was 18 IQR 8-32, range 1-109. There remains a significant number of surgeons 161/396 (41%) who did not contribute to this round. These surgeons have been encouraged to contribute to the next round and trusts should facilitate this by ensuring surgeons have the necessary time and resource to allow them to submit data.

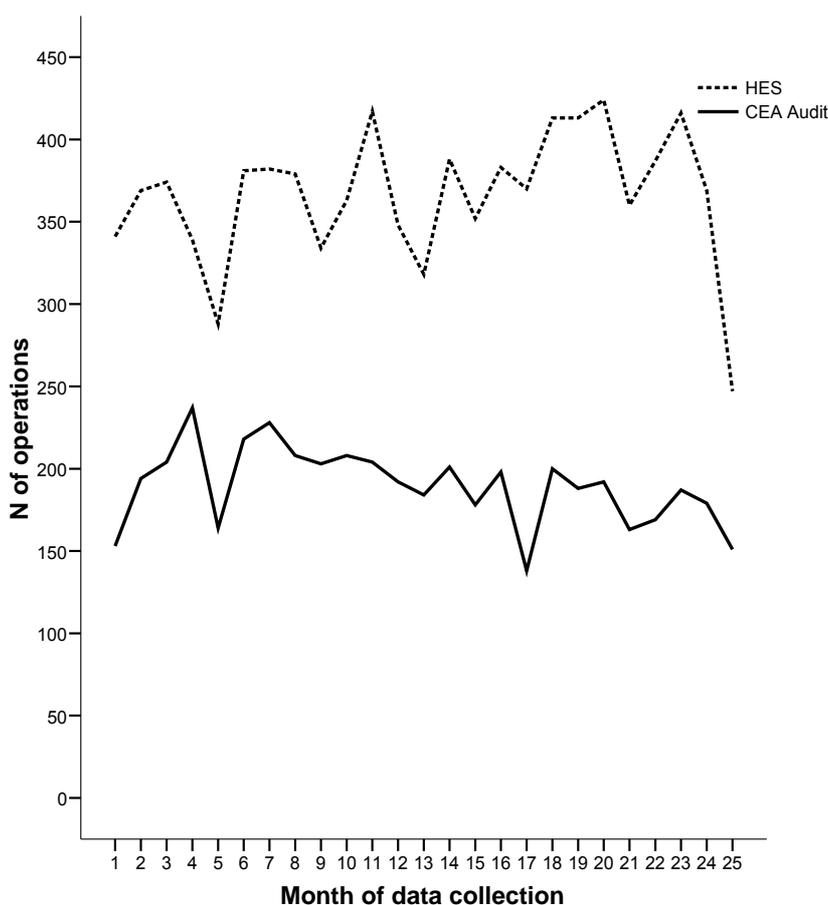
**Figure 2.1.2 Regional contribution of CEA cases (operations dates 1<sup>st</sup> Dec 05 to 31<sup>st</sup> Dec 07)**

Region	HES total (based on contributing Trusts only) (N)	Total number and (percentage) of cases contributed for this round by 31 <sup>st</sup> Mar 08 (% of HES data)
ENGLAND	7056	4718 (67%)
N IRELAND	324*	162 (50%)
SCOTLAND	793	376 (47%)
WALES	530	234 (44%)
UK	8703	5497 (63%)

We compared the total number of cases contributed to this audit in England each month between December 2005 (month 1) and December 2007 (month 25) against the total number of cases recorded by HES for the same month (see **Graph 2.1**). The month represents the month during which the operation was performed.

Data collection for this audit is continuous and the last month is therefore an ‘unnatural break’, rather than being a ‘drop’ in the number of operations being performed and/or the number of operations being contributed to the audit.

**Figure 2.1.3 A comparison of the total number of operations contributed to the audit each month against the number recorded by HES for the same month (for England only)**



There is a time lag in cases being entered into HES which is reflected here in the decrease in cases in the final (most recent) month. (Month 1 = December 2005)

### 2.1.4 Data returns at 31 March 2008 (by phase)

The 5513 cases that were included in the analyses had to have been completed to at least Phase 1, which asked for information about referral, surgery and hospital stay.

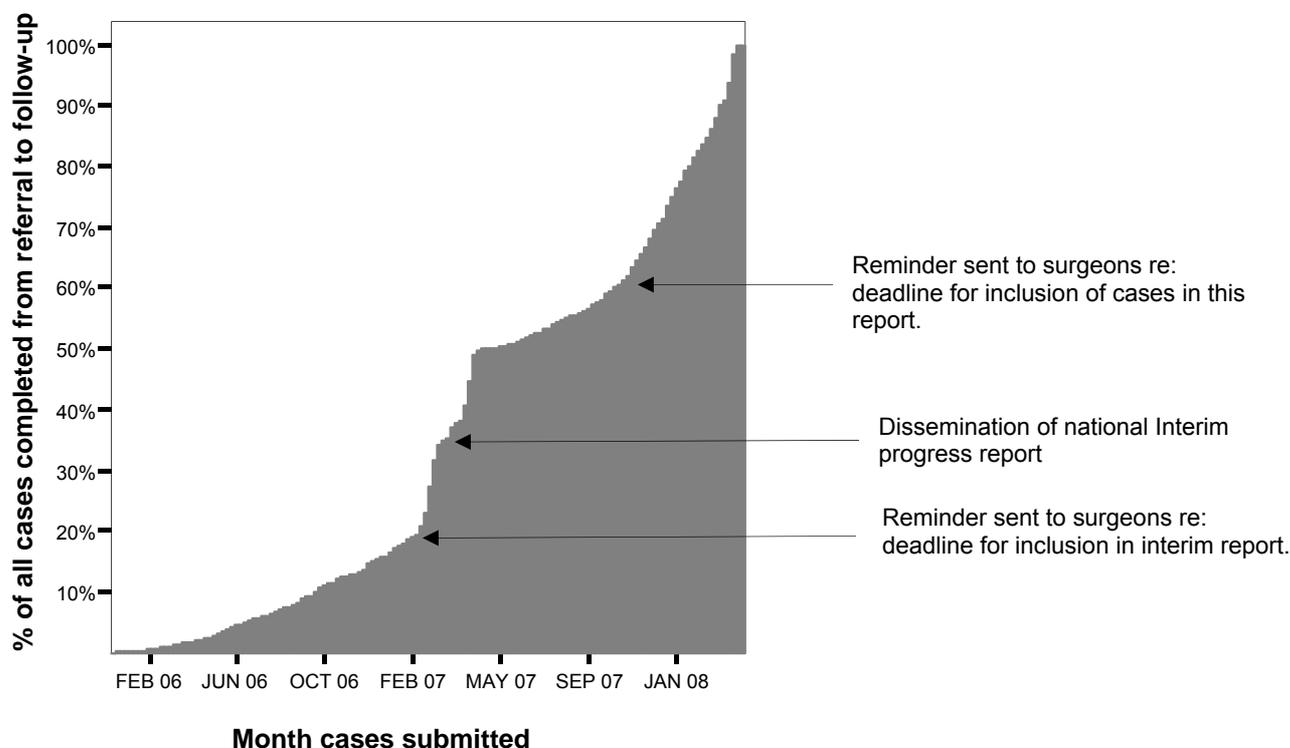
Phase 2, which asked for information about 30-day survival following surgery and the time that the patient was seen at a follow-up appointment was complete for 4964. This is not complete for all 5513 patients

- either because the question that asks about whether the patient was offered a follow-up appointment was not completed (n=146)
- or the patient was offered a follow-up appointment but did not attend (n=189)
- or because the patient was not offered a follow-up appointment (n=225)

**Figure 2.1.4 Case completeness**

As at 31 <sup>st</sup> March 2008	Number of patients	Number of surgeons	Number of hospitals
Cases with data complete to discharge (Phase 1)	5513	240	120
Cases with data complete to follow-up (Phase 2)	4964	206	105

**Figure 2.1.5 Completed cases accrued month on month**



It is encouraging to see that the rate of cases being submitted continues to grow steadily and the contributors are to be congratulated for their support for this important audit and we hope to have higher participation in Round 2.

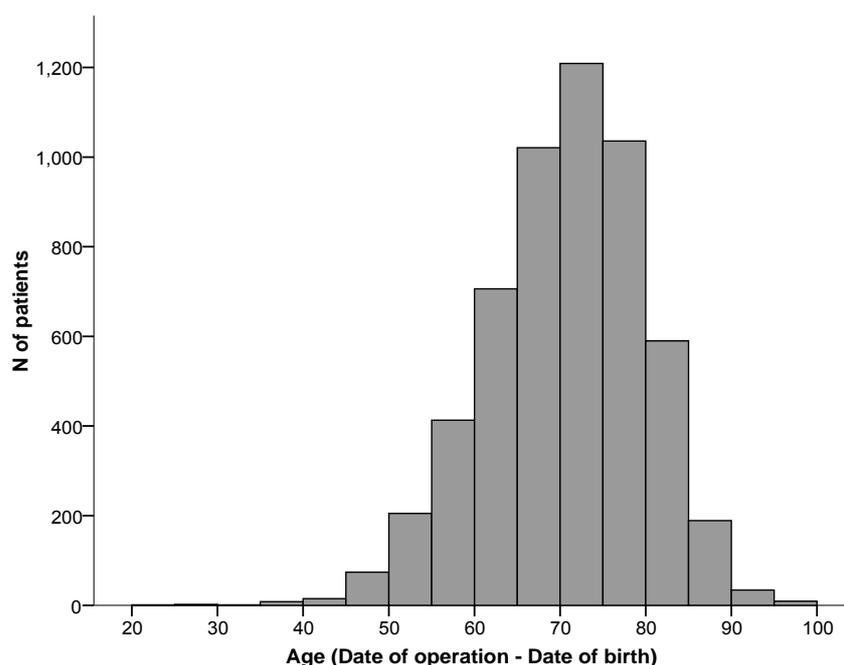
## Chapter 2 - Characteristics of the patients who had surgery

### 2.2.1 Age and gender of CEA patients

Age is an important predictive factor for outcome. The risk of complications from surgery increases with age.

For the 5513 patients in this round the median age at operation was 71 years and the average was 70 years. Sixty eight percent (3751/5513) of the patients in this round were men, for whom the median age was 71 years. The median age for women (n=1762) was 72 years.

**Figure 2.2.1 Age at operation**



The average age of 70 years is consistent with the randomised controlled trials of CEA. Approximately twice as many men are having CEA as women. This may reflect the difference in the incidence of carotid artery disease between the genders but further work is needed to ensure that there are no other factors that lead to increased referrals in males.

### 2.2.2 Ethnicity of CEA patients

Ethnicity is important for informing prognosis, histology and pathology. It is an important risk factor for peripheral vascular disease and coronary heart disease.

The patients were reported to be predominantly white (95%). Carotid artery disease is seen only rarely in non Caucasians and the predominance of surgery being carried out in the British White group is consistent with this finding.

### 2.2.3 Medical history of CEA patients

The patients that are suitable candidates for carotid endarterectomy are also at high risk of stroke with the following risk factors which may determine outcome from surgery: diabetes, ischaemic heart disease, smoking and hypertension. The balance between the risk of future stroke versus the risk of complications from the operation should be carefully considered when selecting whether a patient is suitable for CEA.

**Figure 2.2.2 Risk factors of stroke**

Risk factor	%
Diagnosed diabetic	21
Current symptoms of or treatment for heart disease	32
Smoker	31
Hypertension:	80
- treated	79
- untreated	1

### 2.2.4 CEA for symptomatic carotid disease

In the UK 110,000 patients per annum suffer first stroke and 30,000 suffer transient ischaemic attack (TIA). The evidence base for CEA is strong for symptomatic patients. Patients who have not experienced symptoms (asymptomatic) of carotid disease but have narrowing of the carotid artery can also benefit from surgery, but considerably less than for symptomatic patients. Effective timely management of TIAs reduces mortality, morbidity and healthcare costs. Urgent preventative treatment following a TIA could significantly reduce stroke incidence in the UK. Patients with a carotid artery related stroke but without severe disability should be considered for CEA.

The majority of the patients (4624) in this audit were symptomatic as defined by being referred with one of the following three major symptoms: stroke (35%), TIA (41%) and amaurosis fugax (20%). Three percent had other symptoms. The remaining 889 patients were asymptomatic.

**Figure 2.2.3 Symptom that triggered referral**

Symptom that triggered referral for surgery (4624 symptomatic patients)	%
Amaurosis fugax	20
Transient ischaemic attack (TIA)	41
Stroke	35
None of the three listed above	3

### 2.2.5 Carotid stenosis

Carotid imaging should be performed on all patients being considered for CEA to measure the narrowing (stenosis) of the carotid arteries. The percentage (grade) of carotid stenosis is an important selection criterion for CEA. Randomised controlled trials have demonstrated that not all patients with a carotid stenosis will benefit from CEA but in broad terms the greatest benefit is obtained in those with higher degrees of stenosis and is the treatment of choice in patients with recently symptomatic 50%-99%.

In symptomatic patients carotid imaging should be performed as close as possible to the time that the patient presents with relevant symptoms. In this audit initial carotid imaging refers to first imaging from which the operable stenosis was found and used to inform the recommendation for surgery.

**Figure 2.2.4 Grade of stenosis on initial imaging**

Grade of carotid stenosis on initial imaging (5513 patients)	Stenosis (%)
<70%	73
90-99%	31

## Chapter 3 - Delays between symptoms, initial imaging, referral, admission and surgery

### Standards of care

The NICE Guidelines on acute Stroke and TIA recommend that patients with TIA should have a risk score completed and anyone at high risk of stroke (e.g. ABCD<sup>2</sup> score of 4 or more)\* should be seen by a specialist and investigated within 24 hrs.

\* ABCD<sup>2</sup> score: A score that predicts the risk of a person having a stroke within a few days of a having TIA

If surgery is needed then it should be completed within 2 weeks of the first symptom. The Department of Health National Stroke Strategy (2007) is even more ambitious. It has set objectives for the next 10 years, one of which is that patients needing CEA should receive surgery within 48 hours of their symptom. The evidence behind these recommendations are based on the observations from the Oxford Vascular Study (OXVASC) that the highest risk of stroke after TIA is in the first few days and weeks and that CEA is only effective if performed within 12 weeks of symptoms in men and 2 weeks in women.

It is clear from this audit data that there are unacceptable delays at all stages of the pathway from referral to investigation to surgery, and this needs further action.

It is important to note, however that this applies to patients with TIA and minor stroke. In patients with more severe strokes the risk of surgery will be greater and the benefits less

### 2.3.1 Delay between index symptom and referral

**Figure 2.3.1 Timing of the symptom that triggered referral for surgery**

Timing of the symptom that triggered referral for surgery (4624 symptomatic patients)	%
< 1 week	18
1-2 weeks	19
3-4 weeks	18
5-7 weeks	12
8-12 weeks	13
> 12 weeks	19

In this round 4624/5513 (84%) patients were reported to have undergone carotid endarterectomy for symptomatic carotid disease. The recently published NICE stroke and TIA guidelines set a target of 2 weeks from symptom onset to intervention. In this audit's data, at most 37% of patients would have achieved this. We intend to audit this standard in more detail in future rounds of the audit.

These delays are likely to be the result of a combination of factors e.g.:

- i) Patient factors – usually a delay in patients seeking help
- ii) Referral delays i.e. primary care or A & E departments failing to treat TIA as an emergency or failing to establish the correct diagnosis
- iii) Hospital delays – waiting time to see surgeons or physicians, and lack of rapid access to investigations and to theatre.

In the round of CEA that is currently underway, we have asked surgeons to specify the reasons for delayed surgery.

One of the key objectives for all primary care organisations and acute trusts must to be better public and professional awareness of what to do in the event of possible TIA or stroke and clearer care pathways so that patients can be seen quickly. This requires education of the general public,

doctors (including both general practitioners and hospital doctors), and other healthcare professionals. Healthcare providers also need to understand the requirement to see and treat these patients more rapidly.

### **2.3.2 Delays between referral, admission and surgery**

The estimated risk of stroke after a TIA or minor stroke is 8 to 12% at 7 days and 11 to 15% at 1 month.

This round reported that the delay is greatest between the time the patient is referred and the time the patient is admitted (median 39days). Once the patient had been admitted to hospital it took a median of 1 day to undergo the operation.

There is considerable delay in performing CEA in acute hospital trusts. This audit has demonstrated a median of 40days from referral to surgery. Therefore with existing practice a significant number of patients may have a stroke whilst waiting for investigation and surgery. However it is encouraging to note that by dividing the data collection period into three equal parts, there has been a consistent trend to improvement in waiting time during the course of the audit with a reduction of median waiting time from 43 (IQR 19-88) to 38 (IQR 16-81) to 34 (IQR 13-79) days respectively.

## Chapter 4 - Referral and admission for CEA

### 2.4.1 Referral sources for CEA operation

Symptomatic patients should be referred to surgeons within two weeks of presenting with symptoms. The source of referral influences the level and speed of access to CEA services and ultimately surgery itself. Referrals for CEA come from a variety of specialists.

**Figure 2.4.1 Referring professional**

Who referred the patient to the surgeons? (5513 patients)	%
GP	13
Neurologist	11
Stroke physician	38
Care of Elderly consultant	13
Other*	25

\*Other commonly reported referral sources include: cardiology (7%), ophthalmology (6%), other physicians (6%), vascular surgeons (4%).

It is important that any recommendations regarding practice prior to surgical referral are disseminated to all these specialties.

To shorten the time between symptoms and surgery specialist clinics with same day diagnostic services (e.g. neurovascular clinics) could identify patients that are at high risk of stroke with high carotid stenosis, offering emergency admission to the vascular unit for urgent intervention.

**Figure 2.4.2 Time from referral to surgery compared across referring specialists**

Source of referral (5508 patients)	Days from referral date to surgery	
		Median
GP (N=701)		68 days
Neurologist (N=595)		25 days
Stroke physician (N=2115)		30 days
Care of Elderly consultant (N=716)		48 days
Other (N=1381)		59 days

Stroke physicians and neurologists appear to be more efficient routes of referral to surgeons than other professional groups. The reasons for this are unclear but may include:

- i) Pathways have already been defined between these clinicians
- ii) Appropriate investigations have already been performed by the time the patients are referred
- iii) Assessments are deemed to be more reliable from these professional groups

However these data do suggest that the system that works best is one where neurologist and stroke physicians work in partnership with the vascular surgeon or neurosurgeon to provide a streamlined service. Open access TIA clinics may be required in order to reduce waiting time from GP to acute Trust.

## Chapter 5 - Pre-operative drug therapy

Antithrombotic drugs reduce the risk of stroke and should be prescribed for the vast majority of patients with previous ischaemic stroke and TIA. Current evidence would suggest that most patients should be receiving a combination of aspirin and dipyridamole. Clopidogrel is appropriate for some patients, particularly those intolerant of aspirin. Most patients should also be taking a statin and where there is co-morbid cardiovascular disease beta blockers are usually indicated. Thus most patients referred for CEA should be taking a combination of these drugs. Warfarin is the most effective secondary prevention measure for patients who are thought to have a stroke resulting from cardiac embolism but is rarely indicated for other types of stroke. It would therefore be expected that most patients being treated with CEA will not be taking warfarin or other anticoagulants.

Before they underwent surgery, 4982/5513 (90%) patients were on a statin, 1781/5512 (32%) patients were on a beta-blocker. The vast majority of patients 5378/5513(98%) were taking antithrombotic medication prior to surgery with aspirin being the most frequent, being taken by 4671/5374 (87%) of patients. Seventeen percent (935/5362) of patients were on clopidogrel, 1505/5362 (28%) were on dipyridamole and 289/5363 (5%).

## Chapter 6 - Complications and mortality

In previous CEA studies the combined inpatient death and stroke rate following CEA has varied from 1 to 7%, though rates of 3 to 5% and under are generally considered usual. Haemorrhage of the wound bed is potentially life-threatening and can require a return to theatre for evacuation and haemostasis. Cranial nerve injury is also a significant complication of this procedure. Risk increases substantially in patients over the age of 80 years. Mortality rises with increasing age and is higher in women than men.

**Figure 2.6.1 Reported mortality/complications**

Mortality / complication	Inpatient % (Number)	Inpatient and/or within 30 days of surgery % (Number)
Death	0.5% (29/5512)	1.0% (48/4944)
Stroke	1.8% (101/5512)**	2.6% (124/4681)***
Death and/or stroke	2.1% (118/5512)	2.5% (124/4918)

\*\* - "perioperative" as classified by surgeons retrospectively

\*\*\* - Post-discharge strokes could be reported at any point. A date was recorded in 24/30 post-discharge strokes; 18 of these occurred within 30 days of the operation, but for the 6 missing a date the total within 30-days could be as high as 24.

Time from operation to death was known for 28/29 inpatient deaths, Median 8.5 days.

The risk of major complication, particularly death and perioperative stroke is lower than that reported in the randomised controlled trials of CEA where rates of 6 to 7% were experienced. Whether this is because of differences in case mix (note some of the patients in this audit were having asymptomatic CEA which carries a lower complication rate), selective case reporting, failure to document complications that did occur or improvements in operative techniques since the trials 10 or more years ago cannot be said. This audit includes patients having combined coronary artery bypass surgery and carotid endarterectomy. These patients might be expected to have a higher complication rate.

## Chapter 7 - Postoperative stay

Patients following CEA require careful monitoring, particularly in the early postoperative period. This is most likely to be achieved on a dedicated vascular ward or a high dependency unit. Patients should be managed at least on a surgical ward used to dealing with CEA patients. This will normally be a vascular surgery ward although it could be a general surgery ward that regularly admits vascular patients.

**Figure 2.7.1 Admitted immediately postoperatively**

Where the patient admitted immediately postoperatively (5481 cases)	%
Intensive care unit (ICU)	3
High dependency unit (HDU)	45
Level 1 care unit	23
Ward	29

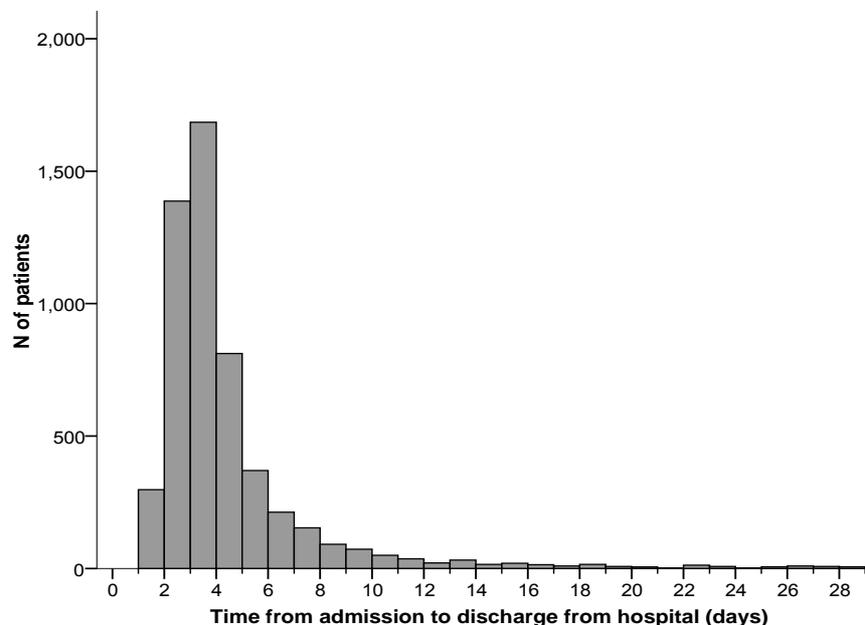
Nearly one in three patients are managed on an ordinary surgical ward immediately after their surgery rather than one with higher levels of nursing support. However this and other studies indicate that postoperative critical care is not necessary for all patients undergoing CEA. Guidelines on which patients will require critical care may be helpful in the management of CEA patients.

Reliable data on the duration and intensity of postoperative monitoring are lacking. Awareness of this needs to be raised amongst the professionals that are involved in the care of carotid endarterectomy patients and improvements made.

### 2.7.1 Length of inpatient stay (LOS)

Length of inpatient stay was known for 5483/5513 (99%) patients and the median was 3 days.

**Figure 2.7.2 Time from admission to discharge from hospital (days)**



5192/5477 (95%) of patients were discharged from hospital the same day as they were discharged from the surgeon's care. The median length of stay was three days. Some of the variation will be related to complications but there are a lot more patients staying longer than three days than are recorded as having postoperative complications suggesting that some surgeons are keeping their patients in hospital much longer than others without clear reason. There may be an opportunity to reduce resource use by reviewing this variability in care.

Whilst the length of stay for CEA patients is relatively short, studies have demonstrated that both same day and following day discharge can be achieved in selected patients. Combined with day of surgery arrival there may be opportunity to reduce the average length of stay of CEA patients.

Very few patients were operated on at the weekend in keeping with the predominantly elective surgery performed. If the National Stroke Strategy recommendations of 48 hours are to be adopted urgent CEA surgery at the weekend will become commonplace.

## 2.7.2 Discharge destination

**Figure 2.7.3 Discharge destination**

Discharge destination (5473 cases)	%
Usual place of residence	96
Nursing home	0.6
Residential home	0.3
Other hospital	2
Other	1

From this point on, only those cases for which data for Phase 2 was available at March 31<sup>st</sup> 2008 are included. The denominator drops from 5513 cases to 4964.

## Chapter 8 - Patient survival 30days postoperatively

Data were missing for 46/4964 (1%) of the patients for whom Phase 2 was completed. Of the remaining 4918 (4964-46) patients, 4870 were reported to be alive within 30-days of undergoing CEA and 48 (1%) were reported to have died within 30 days of undergoing the operation. The cause of death was known for 41/48: 19 cardiovascular, 13 stroke, 7 respiratory, 2 other. The date of death (within 30-days) was known for 43/48 patients. The median time from operation to death was 11 days.

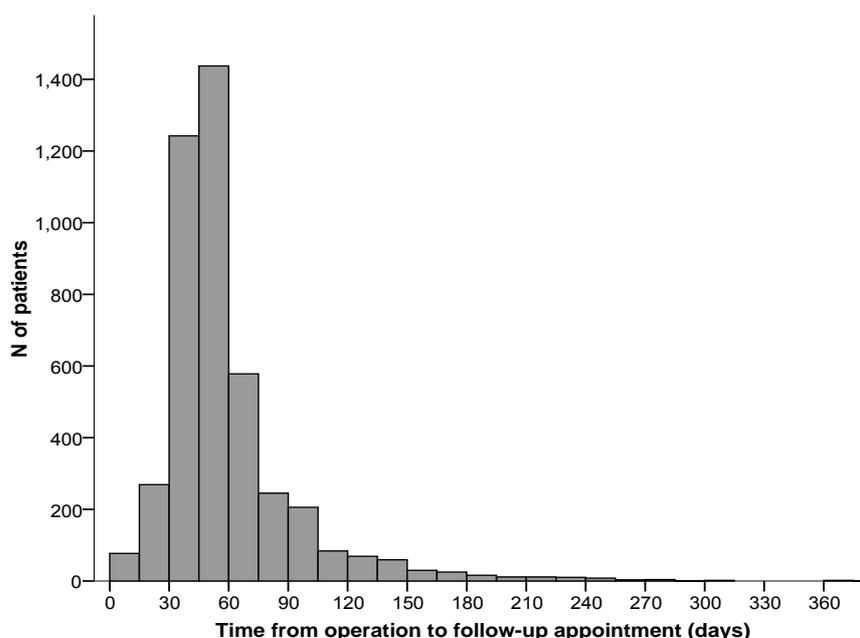
## Chapter 9 - Patient follow-up to assess surgical outcome

Post discharge follow-up is an important part of care and quality control.

Of the 4964 patients for whom Phase 2 was completed, data on whether the patient had been offered a follow-up appointment were missing for 3% (146/4964). For the remaining 4818, five percent (225) were not offered a follow-up appointment and 95% (4593) were. Nationally, of those offered a follow-up appointment, 96% (4404) attended.

### 2.9.1 Time to post operative follow-up appointment

Figure 2.9.1



Some patients appear to have been followed-up for a long time after their surgery and the reason for this is not clear.

### 2.9.2 Specialty of professional assessing patients at post operative follow-up

Figure 2.9.2

Specialist who assessed the patient at follow-up (4391 cases)	%
Surgeon	82
Neurologist	2
Stroke physician	4
Care of the Elderly Consultant	2
Other	11

The vast majority of patients were offered and attended a follow-up appointment. The specialist who assessed the patient was known for 4391 out of the 4404 patients that attended a follow-up appointment, with 82% of the appointments being with the surgeon.

The audit also asks for the date the patient attended a follow-up appointment, and this information was given for 4403 of the 4404 attendees. Median time from operation to follow-up appointment was 50 days.

### 2.9.3 Complications since discharge

Complications after discharge were picked up only for those patients who were invited to and attended a follow-up appointment and the table below gives results for these. 30-day mortality includes patients who died prior to discharge. We have not collected the reasons (or the date) for return to theatre post-discharge but this information will be collected in the next round. The web tool did not ask for every complication at follow-up, only those that are in the table below.

**In this round, 252/4404 (6%) of patients who attended a follow-up appointment were reported to have had a complication following discharge. These complications may have otherwise been missed.**

## Conclusion

There is good evidence that patients who have had a TIA or minor stroke are at risk of having a further more major disabling or fatal stroke. The greatest risk of this is in the first few days or weeks following the TIA or stroke. Therefore, for patients with carotid artery disease who require surgery after such an event, the greatest benefit is obtained the earlier this can be performed. For this reason the National Institute of Clinical Excellence (NICE) has set a 2-week target time for performing this procedure after the TIA or stroke.

The most important finding of this audit is that only 20% of symptomatic patients had surgery within this 2-week target time. It is likely that some patients suffered disabling or fatal stroke whilst awaiting surgery and therefore that strokes may have been prevented by more rapid access to surgery. Major improvements in services are necessary to enable early surgery in appropriate patients in order to prevent strokes.

Delays occurred at all stages of the pathway from the patient having the initial symptom to having treatment. Alongside improvement in services there also needs to be education of the public and professionals who manage this condition with regard to the urgency of treatment. Stroke and TIA should be regarded as a “brain attack” and managed with similar urgency to a heart attack.

This condition is taken very seriously by the medical profession and surgery is nearly always done or directly supervised by a consultant surgeon and anaesthetist. The complication rates of surgery found in this audit are very low but continual monitoring of outcomes should be encouraged in order to maintain and improve these results. Some surgeons did not contribute data to this audit and they should be encouraged to do so.

**Appendix 1 Membership of Steering Group**

Co-Chairs	Mr Tim Lees	Consultant Vascular Surgeon, Newcastle
	Dr Tony Rudd	Consultant Stroke Physician, London
Vascular Society representatives	Professor Mike Horrocks	Professor of Vascular Surgery, Bath
	Professor Alison Halliday	Professor of Vascular Surgery, London
	Professor Ross Naylor	Professor of Vascular Surgery, Leicester
	Mrs Sara Baker	Research Associate, Bournemouth
Medical representatives	Professor John Potter	Professor of Ageing & Stroke Medicine, Leicester
	Professor Peter Rothwell	Professor of Clinical Neurology, Oxford
Society of Vascular Technology	Mr Tim Hartshorne	Chief Vascular Technician, Leicester
Healthcare Quality Improvement Partnership	Ms Helen Laing	Contracts and Procurement Manager, London
Patient representatives	Mr Roy Griffiths	Bath
	Mr William Nicklin	Warwickshire
Royal College of Physicians	Mrs Alex Hoffman	Stroke Programme Manager, London
	Ms Dora Kamugasha	CEA Audit Project Manager, London
Society of Vascular Nurses	Ms Shelagh Murray	Vascular Nurse Consultant, London
Royal College of Anaesthetists – AAGBI	Dr Mark Stoneham	Honorary Senior Clinical Lecturer (Anaesthesia), Oxford
British Society of Interventional Radiologists	Dr Sumaira Macdonald	Consultant Vascular Radiologist, Newcastle
	Dr Iain Robertson	Consultant Vascular Radiologist, Newcastle

**Appendix 2: The information that was collected (dataset)**

# UK CAROTID ENDARTERECTOMY (UKCEAA) – CLINICAL AUDIT DATASET

[Insert date of birth]

[Insert patient audit no.]

[Insert gender]

[For your reference only, insert patient's local Hospital No.]

## PHASE 1

### Section 1: Demographics [Questions 1.1,1.2,1.3, 1.5,1.6,1.7 are mandatory] [You will not be able to proceed on the web tool if these items are missing]

- 1.1 Date of operation:  [dd/mm/yyyy]
- 1.2 Hospital code:  [Unique hospital code allocated at registration]
- 1.3 Hospital name:  [Name of hospital where the patient underwent CEA]
- 1.4 Consultant No:  [Unique consultant code allocated at registration]
- 1.5 Date of birth:  [Allocate the patient a number between 1-999. NB Each number can only be allocated once]
- 1.6 Patient audit number:  [Allocate a number between 1-999. Each number can only be allocated once]
- 1.7 Gender: Male  Female
- 1.8 Ethnicity: 

British White	British Black	British Asian	British
Other Black Caribbean	Black African	Indian	Pakistani
Bangladeshi	African	Any other black background	Any other Asian background

 [Select 1 option]
- 1.9 Inter-rater case Yes  No  [Select Yes if the record is a double entry (reliability/quality check)]

### Section 2: Admission [Questions 2.1, 2.2 are mandatory & must be completed before the record can be submitted]

- 2.1 Date of admission under surgeon:  [dd/mm/yyyy]
- 2.2 Mode of admission: Elective  Emergency  Unplanned  Transfer   
[Can select >1 option. If 'Transfer', you can also specify whether it was 'Unplanned' or 'Emergency'. If 'Elective' the rest of the options are automatically disabled]

### Section 3: Medical history [Questions 3.2 is mandatory & must be completed before the record can be submitted]

- 3.1 Diagnosed Diabetic: Yes  No
- 3.2 Any current symptoms of ischaemic heart disease, congestive heart failure or treatment for it? Yes  No   
[e.g. angina]
- 3.3 Smoker: Yes  No
- 3.4 Hypertension: Yes, Treated  Yes, Untreated  No

### Section 4: Referral to surgeon [Questions 4.1, 4.2 are mandatory & must be completed before the record can be submitted]

- 4.1 Who referred the patient to the surgeons?  
 General Practitioner  Neurologist  Stroke Physician  Care of the Elderly Consultant  Other   
[If NOT 'Other' go to 4.2]
- 4.1a If other referrer, specify
- 4.2 Date of referral to surgeons:  [dd/mm/yyyy]

## UK CAROTID ENDARTERECTOMY (UKCEAA) – CLINICAL AUDIT DATASET

[Insert date of birth]

[Insert patient audit no.]

[Insert gender]

[For your reference only, insert patient's local Hospital No.]

### Section 5: Indications that triggered referral [Questions 5.1 is mandatory & must be completed before the record can be submitted]

5.1 Was the patient symptomatic for carotid disease? Yes  No   
[[if 'No', go to 5.4]

5.2 If yes, what was the symptom that triggered referral for surgery? [Select the index symptom only]

Amaurosis fugax  Transient ischaemic attack  Stroke  None of these

5.2a Specify timing of symptom that triggered referral for surgery [Select timing of the index symptom]

<1week  1-2weeks  3-4weeks  5-7weeks  8-12weeks  >12weeks

5.3 Pre coronary artery bypass graft/heart valve surgery? Yes  No

5.4 Other relevant indication(s) [specify]

### Section 6: Initial carotid/brain imaging that triggered referral [Questions 6.1 is mandatory & must be completed before the record can be submitted]

6.1 Date of initial carotid imaging that triggered referral:  [dd/mm/yyyy]

6.1a Specify imaging modality used (for initial carotid imaging):

Duplex  Magnetic resonance angiogram  Catheter angiogram

Computerised tomography angiogram  Not documented

6.1b Grade of ipsilateral carotid stenosis:

<50%  50%-69%  70%-89%  90%-99%

6.1c Grade of contralateral carotid stenosis:

Not done  <50%  50%-69%  70%-89%  90%-99%  Occluded

6.2 Has the patient had pre-operative brain imaging?

Yes, magnetic resonance imaging only  Yes, computerised tomography only

Yes, magnetic resonance imaging & computerised tomography  No

### Section 7: Confirmatory carotid imaging

7.1 Has the patient had confirmatory carotid imaging pre-operatively? Yes  No  [If 'No' go to 8.1]

7.1a If yes, give date of confirmatory carotid imaging:  [dd/mm/yyyy]

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7.1b Specify imaging modality (for confirmatory carotid imaging):

Duplex  Magnetic resonance angiogram  Catheter angiogram  Computerised tomography

7.1c Grade of confirmatory ipsilateral carotid stenosis:

<50%  50%-69%  70%-89%  90%-99%

7.1d Grade of confirmatory contralateral carotid stenosis:

Note done  <50%  50%-69%  70%-89%  90%-99%  Occluded

### Section 8: Most recent symptoms [Question 8.2 is mandatory & must be completed before the record can be submitted]

8.1 Timing of most recent symptom (prior to surgery):

<1 week  1 week  >1≤2weeks  >2≤4 weeks  >4≤6weeks   
 >6≤8weeks  >8≤10weeks  >10≤12weeks  >12weeks

8.2 Rankin score immediately pre-operatively [From the list below circle the appropriate option]

#### Rankin score

- Asymptomatic
- Non-disabling symptoms, no interference with lifestyle
- Minor disability, some restriction in lifestyle but does not interfere with patient's capacity to look after self
- Moderate disability, symptoms significantly interfere with lifestyle or prevent totally independent existence
- Moderately severe, symptoms prevent independent existence but patient does not need attention for 24hrs
- Severely disabled, totally dependent day and night

### Section 9: Previous carotid interventional procedures [Question 9.1, 9.2 are mandatory & must be completed before the record can be submitted]

9.1 Previous ipsilateral carotid surgery: Yes  No

9.2 Previous ipsilateral carotid angioplasty: Yes  No

### Section 10: Pre-operative tests [All the questions in this section are mandatory. They are required for risk adjustment.]

10.1 Normal electrocardiogram (ECG): Yes  No  [If 'Yes', go to 10.2]

10.1a Atrial fibrillation 60-90: Yes  No  Not documented

10.1b Atrial fibrillation greater than 90: Yes  No  Not documented

10.1c >5 ectopics/min: Yes  No  Not documented

10.1d Q wave or ST/T wave changes: Yes  No  Not documented

10.1e Any other abnormal rhythm or change:

10.2 Systolic blood pressure (mmHg):  Not documented

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- |       |  |                      |                                      |
|-------|--|----------------------|--------------------------------------|
| 10.3  | Pulse (per min):                             | <input type="text"/> | Not documented <input type="radio"/> |
| 10.4  | Haemoglobin (g/dl):                          | <input type="text"/> | Not documented <input type="radio"/> |
| 10.5  | White blood cell count (10 <sup>9</sup> /L): | <input type="text"/> | Not documented <input type="radio"/> |
| 10.6  | Urea (mmol/L):                               | <input type="text"/> | Not documented <input type="radio"/> |
| 10.7  | Creatinine (mmol/L):                         | <input type="text"/> | Not documented <input type="radio"/> |
| 10.8  | Sodium (mmol/L):                             | <input type="text"/> | Not documented <input type="radio"/> |
| 10.9  | Potassium (mmol/L):                          | <input type="text"/> | Not documented <input type="radio"/> |
| 10.10 | INR:   | <input type="text"/> | Not documented <input type="radio"/> |

### Section 11: Pre-operative drug therapy [Question 11.1 is mandatory & must be completed before the record can be submitted]

- 11.1. Was the patient on anti-thrombotic drugs prior to surgery?    Yes  No     [If 'No', go to 11.7]
- 11.2.                    Is the patient normally on ASPIRIN?                    Yes  No     [If 'No', go to 11.3]
- 11.2a                    Was ASPIRIN stopped prior to surgery?                    Yes  No     [If 'No', go to 11.3]
- 11.2b                    If ASPIRIN was stopped, specify the number of days it was stopped prior to surgery  days
- 11.3                    Is the patient normally on CLOPIDOGREL?                    Yes  No     [If 'No', go to 11.4]
- 11.3a                    Was CLOPIDOGREL stopped prior to surgery?                    Yes  No     [If 'No', go to 11.4]
- 11.3b                    If CLOPIDOGREL was stopped, specify the number of days it was stopped prior to surgery  days
- 11.4                    Is the patient normally on DIPYRIDAMOLE?                    Yes  No     [If 'No', go to 11.6]
- 11.4a                    Was DIPYRIDAMOLE stopped prior to surgery?                    Yes  No     [If 'No', go to 11.6]
- 11.4b                    If DIPYRIDAMOLE was stopped, specify the number of days it was stopped prior to surgery  days
- 11.5                    Is the patient normally on WARFARIN?                    Yes  No     [If 'No', go to 11.6]
- 11.5a                    Was WARFARIN stopped prior to surgery?                    Yes  No     [If 'No' is selected, go to 11.6]
- 11.5b                    If WARFARIN was stopped, specify the number of days it was stopped prior to surgery  days
- 11.6                    The patient is on NONE of these anti-thrombotic drugs     [11.6 is automatically disabled if patient is on any of the listed drugs]
- 11.7                    Was the patient on statin therapy prior to surgery?                    Yes  No
- 11.8                    Was the patient on beta-blocker therapy prior to surgery?                    Yes  No

<b>Key</b> Green – Data item required for the NVD only Black – Data item required for both projects (UKCEAA & NVD)	Blue – data item required for the UKCEAA only Grey – Text to give instructions on how to navigate the questionnaire or other help notes
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### Section 12: Operation details

[Questions 12.1, 12.5, 12.7, 12.8 are mandatory & must be completed before the record can be submitted]

12.1 Date of operation:  [dd/mm/yyyy] [NB 12.1 will be automatically populated with the date given in 1.1]

12.2 Which carotid artery was operated on? Left  Right

12.3 Start time (hrs:mins):  :  Not documented

12.4 Finish time (hrs:mins) :  :  Not documented

12.5 Grade of most senior surgeon scrubbed:

Consultant  Non consultant career grade (NCCG)  Specialist registrar (SpR)

12.6 Type of surgery: Elective  Unplanned  Emergency

[NB If "Unplanned", you can also specify whether it "Emergency" and vice versa]

12.7 What type of anaesthetic was used? General  Local/Block

12.8 Grade of most senior anaesthetist in theatre:

Consultant  Non consultant career grade (NCCG)  Specialist registrar (SpR)

12.9 Lowest systolic blood pressure (mmHg) :

12.10 Highest pulse at time of surgery:

### Section 13: Procedure specific operative data

13.1 Was a carotid shunt used? Yes  No  [NB Excludes ATTEMPTED shunting]

13.2 Type of endarterectomy: Standard  Eversion  Other  [If NOT 'Other', go to 13.3]

13.2a Specify other type of carotid endarterectomy:

13.3 Was a carotid patch used? Yes  No

13.4 Were distal tacking sutures used? Yes  No

13.5 Was heart surgery undertaken synchronously? Yes  No

### Section 14: Destination immediately post-operatively

14.1 Where was the patient admitted immediately post-operatively?

Intensive care unit  High dependency unit  Level 1 care unit  Ward

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### Section 15: Complications [Questions 15.1, 15.2, 15.4, 15.5 are mandatory & must be completed before the record can be submitted]

15.1 Did the patient suffer any complications during inpatient stay? Yes  No  [If 'No' is selected, go to 16.1]

15.2 Did the patient die during inpatient stay? Yes  No  [If 'No' is selected, go to 15.3]

15.2a If yes, give the date that the patient died:  [dd/mm/yyyy]

15.2b Specify the cause of death:

15.3 Did the patient have a myocardial infarct? Yes  No

15.4 Did the patient return to theatre for bleeding: Yes  No

15.5 Did patient have perioperative stroke? Yes  No  [If 'No' is selected, go to 15.6]

[NB If the patient had >1 perioperative stroke, the answer given in 15.5a should reflect the timing of the FIRST perioperative stroke]

15.5a If yes, specify timing of perioperative stroke:  $\leq 24$ hrs of operation   $> 24$ hrs and prior to discharge   
[If ' $\leq 24$ hrs of operation', go to 15.5b] [If ' $> 24$ hrs of operation', go to 15.5c]

15.5b Severity of perioperative stroke  $\leq 24$ hrs: [From the list below circle the appropriate option]

- Rankin Score**

  - Asymptomatic
  - Non-disabling symptoms, no interference with lifestyle
  - Minor disability, some restriction in lifestyle but does not interfere with patient's capacity to look after self
  - Moderate disability, symptoms significantly interfere with lifestyle or prevent totally independent existence
  - Moderately severe, symptoms prevent independent existence but patient does not need attention for 24hrs
  - Severely disabled, totally dependent day and night

15.5c Severity of perioperative stroke  $> 24$ hrs: [From the list below circle the appropriate option]

- Rankin Score**

  - Asymptomatic
  - Non-disabling symptoms, no interference with lifestyle
  - Minor disability, some restriction in lifestyle but does not interfere with patient's capacity to look after self
  - Moderate disability, symptoms significantly interfere with lifestyle or prevent totally independent existence
  - Moderately severe, symptoms prevent independent existence but patient does not need attention for 24hrs
  - Severely disabled, totally dependent day and night

15.6 Cranial nerve injury: Yes  No

15.7 Other complication(s), specify:

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## Section 16: Final discharge data [Questions 16.2, 16.4 are mandatory & must be completed before the record can be submitted]

16.1 Date patient was discharged by surgeons:  [dd/mm/yyyy]

16.2 Date patient was discharged from hospital:  [dd/mm/yyyy]

16.3 Discharge Destination:

Usual place of residence  Nursing Home  Residential Home  Other Hospital  Other

[If NOT 'Other', go to 16.4]

16.3a Other discharge destination, specify:

16.4 What was the Rankin score at hospital discharge? [From the list below circle the appropriate option]

### Rankin Score

- Asymptomatic
- Non-disabling symptoms, no interference with lifestyle
- Minor disability, some restriction in lifestyle but does not interfere with patient's capacity to look after self
- Moderate disability, symptoms significantly interfere with lifestyle or prevent totally independent existence
- Moderately severe, symptoms prevent independent existence but patient does not need attention for 24hrs
- Severely disabled, totally dependent day and night

The free text box below is for comments regarding the answer(s) given to any question(s) in Sections 1-16 if required.  
For each comment given, specify the question number to which it applies.

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[Insert gender]

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## PHASE 2

### Section 17: Patient status at 30 days post-operatively

[Questions 17.1 is Mandatory & must be completed before the record can be submitted]

17.1 Was the patient alive at 30 days post-operatively? Yes  No  [If 'Yes' is selected, go to 18.1]

17.1a If no, give date patient died  [dd/mm/yyyy]

17.1b Indicate whether the cause of death is known: Unknown  Known  [If 'Unknown' is selected, go to 18.1]

17.1c Specify the cause of death:

### Section 18: Post-operative follow-up attendance

[Questions 18.1, 18.2, 18.3 are mandatory & must be completed before the record can be submitted]

18.1 Was the patient offered a post-operative follow-up appointment? Yes  No  [If 'No', go to the free text box after section 19]

18.2 If yes, did the patient attend post-operative follow-up appointment? Yes  Did not attend  [If 'Did not attend', go to 18.2a]

18.2a If patient did not attend, specify reason: [After 18.2a, go to the free text box after section 19]  
Patient cancelled  Clinic cancelled  DNA – no advance warning   
DNA-left without being seen  DNA-arrived late  Other

18.3 Give date patient attended post-operative follow-up:  [dd/mm/yyyy]

18.4 Specify specialty of professional that assessed the patient:

Surgeon  Neurologist  Stroke Physician  Care of the elderly Consultant  Combination  Other   
[If NOT 'Other', go to 19.1]

18.4a If other clinician, specify specialty: [  ] [e.g. Vascular SpR]

### Section 19: Post-operative follow-up data

[19.1– 19.5 are mandatory & must be completed before the record can be submitted]

19.1 Did the patient return to theatre <30 days after operation? Yes  No  [NB 19.1 will be automatically populated with the value given in 15.4]

19.2 Was evidence of cranial nerve injury found at follow-up? Yes  No

19.3 Has the patient had a stroke since discharge? Yes  No  [If 'No', go to 19.4]

19.3a If yes, specify date patient suffered stroke:  [dd/mm/yyyy]  
[NB If only year/month (mm/yyyy) is available, (dd) should be entered as 15<sup>th</sup>]

19.4 Rankin score at this visit (follow-up): [From the list below circle the appropriate option]

#### Rankin Score

- Asymptomatic
- Non-disabling symptoms, no interference with lifestyle
- Minor disability, some restriction in lifestyle but does not interfere with patient's capacity to look after self
- Moderate disability, symptoms significantly interfere with lifestyle or prevent totally independent existence
- Moderately severe, symptoms prevent independent existence but patient does not need attention for 24hrs
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19.5 What drug therapy is the patient on post-operatively? Anti-thrombotic  Statin  Beta-blocker   
[If NOT on 'Anti-thrombotic', go to the free text box after section 19]

19.5a If the patient is on anti-thrombotic drug(s) specify which one(s) [Tick all appropriate drugs]

Aspirin  Clopidogrel  Dipyridamole  Warfarin

The free text box below is for comments the regarding the answer(s) given to any question(s) in Sections 17-19 if required.  
For each comment given, specify the question number to which it applies.