NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Transient Loss of consciousness (TLoC)
Output: Prioritised quality improvement areas for development.
Date of Quality Standards Advisory Committee meeting: 4 March 2014

Contents

1	Introduction	2
2	Overview	2
3	Summary of suggestions	6
4	Suggested improvement areas	8
Арр	endix 1: Additional information	16
Арр	pendix 2: Key priorities for implementation (CG109)	25
Арр	pendix 3: Glossary	29
Арр	pendix 4: Suggestions from stakeholder engagement exercise	31

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for transient loss of consciousness (TLoC). It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development source referenced in this briefing paper is:

• <u>Transient loss of consciousness in adults and young people.</u> NICE clinical guideline 109 (2010).

2 Overview

2.1 Focus of quality standard

This quality standard will cover the assessment, diagnosis and specialist referral of adults and young people (aged 16 and older) who have experienced a blackout (the medical term for this is 'transient loss of consciousness' or TLoC for short).

2.2 Definition

TLoC may be defined as spontaneous loss of consciousness with complete recovery. In this context, complete recovery would involve full recovery of consciousness without any residual neurological deficit. An episode of TLoC is often described as a 'blackout' or a 'collapse', but some people collapse without TLoC. NICE clinical guideline 109 does not cover this situation.

The main causes of TLoC are:

- (a) syncope due to dysfunction of the cardiovascular system
- (b) epilepsy due to dysfunction of the nervous system and
- (c) psychogenic seizures due to dysfunction of the psyche.

TLoC is a symptom, not a disease, the causes of which are varied.

2.3 Incidence and prevalence

TLoC is very common: it affects up to half the population in the UK at some point in their lives¹.

Approximately 3–5% of adults who attend the emergency department do so because of TLoC and accounts for up to 6% of urgent hospital admissions. It is particularly common in people aged 65 and over; it has been estimated that up to 23% of this group experience syncope (Transient loss of consciousness due to a reduction in blood supply to the brain) over a 10-year period and there is a high rate of recurrence.

Hospital Episode Statistics for England for the year 2012-13 shows that the number of people admitted as inpatients with a primary diagnosis for syncope and collapse (code R55) and unspecified epilepsies (code G40) was approximately 90,000 and 41,000 respectively².

2.4 Management

The diagnosis of the underlying cause of TLoC is often inaccurate, inefficient and delayed. There is huge variation in the management of TLoC. A substantial proportion of people initially diagnosed with, and treated for, epilepsy have a cardiovascular cause for their TLoC. Some people have expensive and inappropriate tests or inappropriate specialist referral (unnecessary referral or referral to the wrong specialty); others with potentially dangerous conditions may not receive appropriate assessment, diagnosis and treatment.

NICE clinical guideline 109 aims to define the appropriate pathways for the initial assessment, diagnosis and specialist referral of people who have had TLoC, so that they receive the correct diagnosis quickly, efficiently and cost effectively, leading to a suitable management plan.

Clinical reasoning forms an important part of the process of ensuring that people who experience TLoC receive assessment, advice and treatment that is appropriate for each individual. Determination of the mechanism for TLoC in an individual requires collection of evidence (from a detailed history, from clinical assessment and from appropriate investigations), and interpretation of each piece of evidence in overall clinical context.

Unlike most NICE clinical guidelines, clinical guideline 109 does not address a condition, but a symptom. It suggests a pathway to follow to determine the cause of

¹ Fitzpatrick and Cooper 2006, quoted in NICE <u>costing statement</u> for TLOC clinical guideline 109. ² Health and Social Care Information Centre. <u>Hospital Episode Statistics, Admitted Patient Care,</u> <u>England - 2012-13</u>

the person's TLoC, advice on appropriate management until a diagnosis is made and to ensure that the correct referral is made.

The algorithms and pathway are provided in appendix 1.

2.5 National Outcome Frameworks

Tables 1–2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Domain	Overarching indicators and improvement areas				
1 Preventing people from dying prematurely	1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare*				
2 Enhancing quality of life for	Overarching indicator				
people with long-term conditions	2 Health-related quality of life for people with long-term conditions**				
	Improvement areas				
	Ensuring people feel supported to manage their condition				
	2.1 Proportion of people feeling supported to manage their condition**				
	2.2 Employment of people with long-term conditions.				
	Reducing time spent in hospital by people with long-term conditions				
	2.3i Unplanned hospitalisation for chronic ambulatory care sensitive conditions (adults)				
3 Helping people to recover	Overarching indicator				
from episodes of ill health or following injury	3a Emergency admissions for acute conditions that should not usually require hospital admission.				
4 Ensuring that people have	Overarching indicator				
a positive experience of care	4b Patient experience of hospital care				
	Improvement areas				
	Improving people's experience of outpatient care				
	4.1 Patient experience of outpatient services				
	Improving people's experience of accident and emergency services				
	4.3 Patient experience of A & E services				
	Improving children and young people's experience of healthcare				
	4.8 An indicator is under development				
Alignment across the health	Alignment across the health and social care system				
* Indicator shared with Public F	lealth Outcomes Framework (PHOF)				
** Indicator complementary with Adult Social Care Outcomes Framework (ASCOF)					

 Table 1 NHS Outcomes Framework 2014/15

Domain	Objectives and indicators			
4 Healthcare public health and preventing premature mortality	Objective Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities			
	Indicators			
	4.3 Mortality rate from causes considered preventable*			
	4.13 Health-related quality of life for older people (Placeholder)			
Alignment across the health and social care system				
* Indicator shared with NHS Outcomes Framework (PHOF)				

Table 2 Public health outcomes framework for England, 2013–2016

3 Summary of suggestions

3.1 Responses

In total 14 stakeholders responded to the 2-week engagement exercise held between 6 and 20 January 2014, this includes 4 stakeholders who responded but did not suggest any areas for quality improvement.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

Full details on the suggestions provided are given in appendix 4 for information.

S	uggested area for improvement	Stakeholders				
In	itial assessment of TLoC including urgent referral for					
Ca	ardiac assessment	AA, STARS,				
•	Gathering information about the event and initial decision-making	RC, BN, SCM				
•	Risk assessment and access to a 12-lead electrocardiogram (ECG) to rule out obvious cardiac disease or an underlying cardiac arrthymias					
•	Red flags: people requiring urgent assessment and treatment					
S	pecialist cardiovascular assessment and diagnosis					
•	Syncope during exercise	RC, BCS,				
•	Ambulatory electrocardiogram (ECG)	AA, STARS, MLtd,				
•	Tilt test	BCS, SCM				
•	Implantable loop/event recorders					
In	formation for people with TLoC	BN				
•	Driving advice					
A	dditional areas					
•	Triage	AA, STARS				
•	Ambulance involvement and referral pathways	EMAS NHS Trust,				
•	Electroencephalogram (EEG)	MLtd, RC, SCM				
•	Use of nurse led implant services					
•	Ambulance crew training					
•	 Identification of cause of TLoC in young people 					
A/ Bl B(AA, Arrhythmia Alliance 3N, Association of British Neurologists BCS, British Cardiovascular Society					

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
EMAS NHS Trust, East Midlands Ambulance Service NHS Trust	
MLtd, Medtronic Limited	
RC, Resuscitation Council (UK)	
STARS, Syncope Trust and Reflex anoxic Seizures	
SCM, Specialist Committee Member	

4 Suggested improvement areas

4.1 Initial assessment

4.1.1 Summary of suggestions

Initial assessment of TLoC including urgent referral for cardiac assessment

Stakeholders highlighted that there is often inaccurate, inefficient and delayed diagnosis of the underlying cause of TLoC which leads to inappropriate referrals and tests.

Stakeholders highlighted the need for correct initial assessment of people who have had a suspected TLoC to diagnose the underlying cause early and provide the appropriate treatment and care pathway.

Areas of importance highlighted by stakeholders within the initial assessment include:

- 1. Gathering information about the event and initial decision-making
- 2. Risk assessment and access to a 12-lead electrocardiogram (ECG) to rule out obvious cardiac disease or an underlying cardiac arrthymias
- 3. Urgent referral for specialist cardiovascular assessment if indicated from red flag findings

It was noted that all people who experience a TLoC should receive a 12-lead ECG if after initial assessment there is uncertainty as to the cause of their TLoC. This applies to emergency services, primary care and secondary care.

Stakeholders highlighted that patients with TLoC who have an ECG abnormality (red flag) on initial assessment should be referred to cardiology within 24 hours. While most patients who blackout have uncomplicated vasovagal syncope (please see definition in glossary-appendix 3) there is a small number in whom the blackout is an indication of potentially life threatening cardiac disease. An abnormal ECG can identify such patients, and they warrant urgent cardiac assessment. One stakeholder also highlighted that history of bleeding as a red flag at initial assessment.

One stakeholder further highlighted the importance of the role of clear cardiac markers in the initial assessment as they can both reduce unnecessary admissions and reduce those being sent home with cardiac problems. It was reported that these markers are beneficial in admitted patients, but are currently unclear in the initial stages of TLoC assessment.

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full to inform the Committee's discussion.

Suggested quality improvement area	Selected source guidance recommendations
Initial assessment of TLoC including urgent referral for cardiac assessment	Gathering information about the event and initial decision-making NICE CG109 Recommendation 1.1.1.2 (KPI)
	Obtaining patient history, physical examination and tests NICE CG109 Recommendations 1.1.2.1, 1.1.2.2 (KPI), 1.1.2.3 and 1.1.2.4
	Red flags: people requiring urgent assessment and treatment NICE CG109 Recommendation 1.1.4.2 (KPI)

Table 4 Specific areas for quality improvement

Gathering information about the event and initial decision-making

NICE CG109 Recommendation 1.1.1.2 (Key Priority for Implementation)

Ask the person who has had the suspected TLoC, and any witnesses, to describe what happened before, during and after the event. Try to contact by telephone witnesses who are not present. Record details about:

- circumstances of the event
- person's posture immediately before loss of consciousness
- prodromal symptoms (such as sweating or feeling warm/hot)
- appearance (for example, whether eyes were open or shut) and colour of the person during the event
- presence or absence of movement during the event (for example, limb-jerking and its duration)
- any tongue-biting (record whether the side or the tip of the tongue was bitten)
- injury occurring during the event (record site and severity)

- duration of the event (onset to regaining consciousness)
- presence or absence of confusion during the recovery period
- weakness down one side during the recovery period.

Obtaining patient history, physical examination and tests

NICE CG109 Recommendation 1.1.2.1

Assess and record:

- details of any previous TLoC, including number and frequency
- the person's medical history and any family history of cardiac disease (for example, personal history of heart disease and family history of sudden cardiac death)
- current medication that may have contributed to TLoC (for example, diuretics)
- vital signs (for example, pulse rate, respiratory rate and temperature) repeat if clinically indicated
- lying and standing blood pressure if clinically appropriate
- other cardiovascular and neurological signs.

NICE CG109 Recommendation 1.1.2.2 (Key Priority for Implementation)

Record a 12-lead electrocardiogram (ECG) using automated interpretation.

Treat as a red flag (see recommendation 1.1.4.2) if any of the following abnormalities are reported on the ECG printout:

- conduction abnormality (for example, complete right or left bundle branch block or any degree of heart block)
- evidence of a long or short QT interval, or
- any ST segment or T wave abnormalities.

NICE CG109 Recommendation 1.1.2.3

If a 12-lead ECG with automated interpretation is not available, take a manual 12lead ECG reading and have this reviewed by a healthcare professional trained and competent in identifying the following abnormalities.

- Inappropriate persistent bradycardia.
- Any ventricular arrhythmia (including ventricular ectopic beats).
- Long QT (corrected QT > 450 ms) and short QT (corrected QT < 350 ms) intervals.
- Brugada syndrome.
- Ventricular pre-excitation (part of Wolff-Parkinson-White syndrome).
- Left or right ventricular hypertrophy.
- Abnormal T wave inversion.
- Pathological Q waves.
- Atrial arrhythmia (sustained).
- Paced rhythm.

NICE CG109 Recommendation 1.1.2.4

If during the initial assessment, there is suspicion of an underlying problem causing TLoC, or additional to TLoC, carry out **relevant** examinations and investigations (for example, check blood glucose levels if diabetic hypoglycaemia is suspected, or haemoglobin levels if anaemia or bleeding is suspected; see also recommendation 1.2.2.1 for information about the use of electroencephalogram [EEG]).

Red flags: people requiring urgent assessment and treatment

NICE CG109 Recommendation 1.1.4.2 (Key Priority for Implementation)

Refer within 24 hours for specialist cardiovascular assessment by the most appropriate local service, anyone with TLoC who also has any of the following.

- An ECG abnormality (see recommendations 1.1.2.2 and 1.1.2.3).
- Heart failure (history or physical signs).
- TLoC during exertion.

- Family history of sudden cardiac death in people aged younger than 40 years and/or an inherited cardiac condition.
- New or unexplained breathlessness.
- A heart murmur.

Consider referring within 24 hours for cardiovascular assessment, as above, anyone aged older than 65 years who has experienced TLoC without prodromal symptoms.

4.1.3 Current UK practice

NICE costing analysis of clinical guideline 109 predicted increased use of 12-lead electrocardiogram (ECG) using automated interpretation and referrals for assessment within 24 hours as a result of implementation of the clinical guideline. Conversely, it was estimated that improvements in initial assessment have the potential for fewer inappropriate admissions and tests, and lower risk of misdiagnosis.

However, no data were identified to estimate current practice in the initial assessment of TLoC for this briefing report.

4.2 Specialist cardiovascular assessment and diagnosis

4.2.1 Summary of suggestions

Syncope during exercise

A stakeholder highlighted that TLoC may be the first indication of inherited cardiac pathology predisposing to sudden and premature cardiac death. It was reported that there are a number of features which identify those at high risk and failure to recognise or ignoring these features will put people at risk of sudden, preventable death. The most common cause of non-traumatic death in sport was reported to be cardiac with increased incidence reported.

Ambulatory electrocardiogram (ECG)

Stakeholders highlighted the need for improvements in first-line specialist investigation for suspected cardiac arrthymias and unexplained syncope (please see definition in glossary-appendix 3) ambulatory ECG rather than a tilt table test, as per the NICE guidance.

When investigating syncope, it was reported that physicians still perform short periods of ambulatory monitoring with low likelihood that this will provide the information needed to establish a correct diagnosis. This often gives false reassurance. The key element in establishing the correct diagnosis is recording the habitual spontaneous episodes. This may require prolonged monitoring. It was further highlighted that the type of ambulatory ECG should be chosen depending on the basis of the person's history in particular the frequency of TLoC episodes.

Tilt test

A stakeholder suggested not to carry out a tilt test for vasovagal syncope; and for anyone with unexplained syncope to always perform an ambulatory ECG before arranging a tilt test. The key element is recording a spontaneous TLoC episode and it was reported that tilt table testing may precipitate a syncopal episode in a susceptible individual, without this necessarily being the cause of their usual episodes.

Implantable loop/event recorders

A stakeholder commented that if physicians are to be able to reliably correlate ECG with symptoms, different periods of ambulatory monitoring are crucial in line with frequency of symptoms. In particular, the use of implantable loop recorders was recommended for investigation of infrequent syncope (less than 1 every 2 weeks).

Stakeholders highlighted improvements in access to implantable event recorders for patients with unexplained syncope. They supported these recorders for giving information in blackout cases where no other investigation can, because they are capable of monitoring the heart rhythm for up to 3 years. It was suggested that offering these recorders could also improve the cost effectiveness of TLoC services.

A stakeholder also commented that by including these recorders within the Quality Standard would positively provide a metric against which CCGs and Provider Trusts could be measured. This would give an incentive to drive adoption of the guidance which could then improve the quality of diagnosis for patients with TLoC and unexplained syncope.

These recorders were also reported as valuable where multi-disciplinary assessment cannot easily distinguish between very different health conditions such as urine incontinence, jerking and twitching of limbs and slow recovery after an abrupt collapse without warning.

4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full to help inform the Committee's discussion.

Suggested quality improvement area	Selected source guidance recommendations	
Syncope during exercise	Diagnostic tests for different types of syncope	
	NICE CG109 Recommendations 1.3.2.1, 1.3.2.2 and 1.3.2.3	
Ambulatory electrocardiogram (ECG)	Diagnostic tests for different types of	
	syncope NICE CG109 Recommendations 1.3.2.4 (KPI) and 1.3.2.9 (KPI)	
Tilt test	Diagnostic tests for different types of	
	syncope	
	NICE CG109 Recommendations 1.3.2.5 (KPI) and 1.3.2.6	
	**Tilt tests are not recommended as a first- line investigation.	
Implantable event/loop recorders	Diagnostic tests for different types of	
	syncope NICE CG109 Recommendations 1.3.2.4 (KPI) and 1.3.2.10	

Table 5 Specific areas for quality improvement

Syncope during exercise

NICE CG109 Recommendation 1.3.2.1

Use the person's history to distinguish people whose exercise-induced syncope occurred **during exercise** (when a cardiac arrhythmic cause is probable) from those whose syncope occurred **shortly after stopping exercise** (when a vasovagal cause is more likely).

NICE CG109 Recommendation 1.3.2.2

For people who have experienced syncope **during exercise**, offer urgent (within 7 days) exercise testing, unless there is a possible contraindication (such as suspected aortic stenosis or hypertrophic cardiomyopathy requiring initial assessment by imaging). Advise the person to refrain from exercise until informed otherwise following further assessment.

NICE CG109 Recommendation 1.3.2.3

If the mechanism for exercise-induced syncope is identified by exercise testing, carry out further investigation or treatment as appropriate in each individual clinical context. Otherwise, carry out further investigations assuming a suspected cardiac arrhythmic cause.

Ambulatory electrocardiogram (ECG)

NICE CG109 Recommendation 1.3.2.4 (Key Priority for Implementation)

For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC. For people who have:

- TLoC at least several times a week, offer Holter monitoring (up to 48 hours if necessary). If no further TLoC occurs during the monitoring period, offer an external event recorder that provides continuous recording with the facility for the patient to indicate when a symptomatic event has occurred.
- TLoC every 1–2 weeks, offer an external event recorder. If the person experiences further TLoC outside the period of external event recording, offer an implantable event recorder.

NICE CG109 Recommendation 1.3.2.9 (Key Priority for Implementation)

For all people with unexplained syncope (including after negative carotid sinus massage test in those for whom this is appropriate), offer ambulatory ECG (see recommendation 1.3.2.4). Do not offer a tilt test before the ambulatory ECG.

Tilt Test

NICE CG109 Recommendation 1.3.2.5 (Key Priority for Implementation)

Do not offer a tilt test to people who have a diagnosis of vasovagal syncope on initial assessment.

NICE CG109 Recommendation 1.3.2.6

For people with suspected vasovagal syncope with recurrent episodes of TLoC adversely affecting their quality of life, or representing a high risk of injury, consider a tilt test only to assess whether the syncope is accompanied by a severe cardioinhibitory response (usually asystole).

Implantable loop/event recorders

NICE CG109 Recommendation 1.3.2.4 (Key Priority for Implementation)

For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC. For people who have:

- TLoC at least several times a week, offer Holter monitoring (up to 48 hours if necessary). If no further TLoC occurs during the monitoring period, offer an external event recorder that provides continuous recording with the facility for the patient to indicate when a symptomatic event has occurred.
- TLoC every 1–2 weeks, offer an external event recorder. If the person experiences further TLoC outside the period of external event recording, offer an implantable event recorder.

NICE CG109 Recommendation 1.3.2.10

When offering a person an implantable event recorder, provide one that has both patient-activated and automatic detection modes. Instruct the person and their family and/or carer how to operate the device. Advise the person that they should have prompt³ follow-up (data interrogation of the device) after they have any further TLoC.

4.2.3 Current UK practice

On the basis of stakeholder knowledge opinion, ambulatory ECG monitoring continues to be used inappropriately. No UK data are reported.

³ The timing of the follow-up is dependent on the storage on the device and the condition of the person.

According to expert opinion, there has been a significant increase in the use of implantable recorder devices since the publication of NICE clinical guidance 109 in 2010. No published data on current practice are available. However, a stakeholder reported analysis of hospital episodes statistics (HES) for England which highlighted wide variation in implant rates between Clinical Commissioning Groups.

4.3 Information for people with TLoC

4.3.1 Summary of suggestions

Driving advice

One stakeholder highlighted the need to improve the quality of driving advice given to people with TLoC at presentation as current advice was reported to be variable and often incorrect. This has important legal and road safety implications.

4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full to help inform the Committee's discussion.

Suggested quality improvement area	Selected source guidance		
	recommendations		
Driving advice	Information for people with TLoC		
	NICE CG109 Recommendations 1.5.2.1		
	and 1.5.2.2		

Table 6 Specific areas for quality improvement

Driving advice

NICE CG109 Recommendation 1.5.2.1

Give advice about eligibility to drive when a person first presents with TLoC⁴

NICE CG109 Recommendation 1.5.2.2

Advise all people who have experienced TLoC that they must not drive while waiting for a specialist assessment. Following specialist assessment, the healthcare professional should advise the person of their obligations regarding reporting the TLoC event to the Driver and Vehicle Licensing Agency (DVLA)⁸

4.3.3 Current UK practice

No published studies on current practice were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

⁴ Please refer to the <u>DVLA</u> for further information.

The Driver and Vehicle Licensing Agency (DVLA) in the United Kingdom provides guidance on fitness to drive for patients with a number of medical illnesses, including epilepsy and psychogenic non-epileptic seizures (PNES).

The Association of British Neurologists surveyed its members on the driving advice they offer patients with PNES, and their awareness of current DVLA guidelines. Of 54 completed responses⁵ 19 were epilepsy specialists. 11/54 respondents were unaware of any DVLA guidance regarding PNES. Of 43/54 aware of DVLA guidance, only 7% felt that it was sufficient. 40% of respondents did not recommend any driving restriction. It was concluded that there is a need to seek consensus on driving advice amongst clinicians and provide sufficient evidence-based guidance regarding driving for both patients with PNES and their clinicians. This is a very small study and therefore the results may be unrepresentative and should be considered with caution.

Driving regulations and psychogenic non-epileptic seizures: Perspectives from the United Kingdom, Seizure Journal, Volume 20, Issue 2, March 2011; 177-180

4.4 Additional areas

4.4.1 Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise however these felt either to be outside the remit of the quality standard referral and the development source (NICE guidance) or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 4 March 2014.

• Triage

A stakeholder reported the need for a triage step for TLoC patients between first responders and specialist care, when patient history is recorded, an ECG is used to rule out obvious cardiac disease and a risk assessment is done. It was highlighted using TLoC triage would help reduce unnecessary hospital admissions, inappropriate referrals to neurology and prolonged length of hospital stay.

It was also reported by a stakeholder that TLoC patients are frequently misdirected to incorrect services so therefore neurological, cardiovascular and psychological causes of TLoC need to be considered together in triage clinics.

**Please note the NICE guideline does not specifically name rapid access blackout/TLoC clinics. Where appropriate the guideline recommends referral for a specialist cardiovascular assessment (by the most appropriate local service) or referral to a specialist in epilepsy.

• Ambulance involvement and referral pathways

A stakeholder highlighted that the ambulance service is often the first on the scene to patients with TLoC, however they are not best served by the single access point of the Emergency Department. Non-emergencies may be more appropriately referred to specialised cardiologists thereby bypassing the emergency department. It was suggested that this could both benefit the rapid intervention in patient assessment and treatment and reduce Emergency Department pressure. Anonymised ECG recordings by the ambulance crews could be sent to an independent cardiologist specialist for a second opinion and screening. If a concern is highlighted, the patient could be recalled for further screening or assessment.

• Electroencephalogram (EEG)

A stakeholder commented that an EEG should not be routinely used in the investigation of TLoC as they have low sensitivity and poor specificity. It was reported that undue reliance is placed on obtaining an EEG by non-specialists and patients after a blackout and the misuse of EEG is well recognised as a major cause of epilepsy misdiagnosis.

• Use of nurse led implant services

A stakeholder highlighted that quality of access is increased where services for implantable loop recorders for patients with unexplained syncope are led by nurse implanters or cardiac physiologists.

Ambulance crew training

A stakeholder raised that ambulance crews should have a mandatory training package to identify various TLoC criteria with referral flow charts utilising appropriate hospital services.

• Identification of cause of TLoC in young people

A stakeholder raised that young people involved in sporting activities were highlighted to be at particular risk with outcome from cardiac arrest in this group reported to be poor. Recognition of this and the initiation of an appropriate response was highlighted as important for the management of people with TLoC.

It was suggested that any healthcare organisation responsible for managing young adults with TLoC should have appropriate policies and procedures to ensure correct management of these patients to reduce the risk of premature death.

Appendix 1: TLoC care pathway (NICE full clinical guideline)

Box A





On the basis of this assessment, assign the person to one of the following causes of suspected syncope:

- suspected structural heart disease
- suspected cardiac arrhythmia
- suspected neurally mediated, or
- unexplained.

Offer further testing see page 3 or other tests as clinically appropriate.





- monitoring period, offer an external event recorder that provides continuous recording with the facility for the patient to indicate when a symptomatic event has occurred.
- TLoC every 1-2 weeks, offer an external event recorder'. If the person experiences further TLoC outside the period of external event recording, offer an implantable event recorder.
- TLoC infrequently, (less than once every 2 weeks): offer an implantable event recorder. A Holter monitor should not usually be offered unless there is evidence of a conduction abnormality on the 12-lead ECG.
- "Excludes event recorders that do not perform continuous" ECG monitoring (and therefore are not capable of documenting cardiac rhythm at the moment of TLoC)

When offering a person an implantable event recorder, provide one that has both patient-activated and automatic detection modes. Instruct the person and their family and/or carer how to operate the device. Advise the person that they should have prompt" follow-up (data nterrogation of the device) after they have any further TLoC.

"The timing of the follow-up is dependent on the storage on the device and the condition of the person

- example.
 - the nature of the event changes over time
 - there are multiple unexplained physical symptoms
 - there are unusually prolonged events
 - Refer for neurological assessment
- Advise people who have experienced TLoC to try to record any future events (for example, a video recording or a detailed witness account of the event) particularly if the diagnosis is unclear or taking a history is difficult
- If, after, further assessment the cause of TLoC remains uncertain or the person has not responded to treatment, consider other causes of TLoC, including the possibility that more than one pathology may co-exist, for example lotal arrythmias

Appendix 2: Key priorities for implementation (CG109)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Initial assessment

Ask the person who has had the suspected TLoC, and any witnesses, to describe what happened before, during and after the event. Try to contact by telephone witnesses who are not present. Record details about:

- circumstances of the event
- person's posture immediately before loss of consciousness
- prodromal symptoms (such as sweating or feeling warm/hot)
- appearance (for example, whether eyes were open or shut) and colour of the person during the event
- presence or absence of movement during the event (for example, limb-jerking and its duration)
- any tongue-biting (record whether the side or the tip of the tongue was bitten)
- injury occurring during the event (record site and severity)
- duration of the event (onset to regaining consciousness)
- presence or absence of confusion during the recovery period
- weakness down one side during the recovery period.
- Record a 12-lead electrocardiogram (ECG) using automated interpretation. Treat as a red flag (see recommendation 1.1.4.2) if any of the following abnormalities are reported on the ECG printout:
 - conduction abnormality (for example, complete right or left bundle branch block or any degree of heart block)
 - evidence of a long or short QT interval, or
 - any ST segment or T wave abnormalities.
- Record carefully the information obtained from all accounts of the TLoC. Include paramedic records with this information. Give copies of the ECG record and the

patient report form to the receiving clinician when care is transferred, and to the person who had the TLoC.

- Refer within 24 hours for specialist cardiovascular assessment by the most appropriate local service, anyone with TLoC who also has any of the following.
 - An ECG abnormality (see recommendations 1.1.2.2 and 1.1.2.3).
 - Heart failure (history or physical signs).
 - TLoC during exertion.
 - Family history of sudden cardiac death in people aged younger than 40 years and/or an inherited cardiac condition.
 - New or unexplained breathlessness.
 - A heart murmur.

Consider referring within 24 hours for cardiovascular assessment, as above, anyone aged older than 65 years who has experienced TLoC without prodromal symptoms.

- Diagnose uncomplicated faint (uncomplicated vasovagal syncope) on the basis of the initial assessment when:
 - there are no features that suggest an alternative diagnosis (note that brief seizure activity can occur during uncomplicated faints and is not necessarily diagnostic of epilepsy) **and**
 - there are features suggestive of uncomplicated faint (the 3 'P's) such as:
 - Posture prolonged standing, or similar episodes that have been prevented by lying down
 - **P**rovoking factors (such as pain or a medical procedure)
 - **P**rodromal symptoms (such as sweating or feeling warm/hot before TLoC).

Further assessment and referral

- Refer people who present with one or more of the following features (that is, features that are strongly suggestive of epileptic seizures) for an assessment by a specialist in epilepsy; the person should be seen by the specialist within 2 weeks (see 'The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care [NICE clinical guideline 20]).
 - A bitten tongue.

- Head-turning to one side during TLoC.
- No memory of abnormal behaviour that was witnessed before, during or after TLoC by someone else.
- Unusual posturing.
- Prolonged limb-jerking (note that brief seizure-like activity can often occur during uncomplicated faints).
- Confusion following the event.
- Prodromal déjà vu, or jamais vu (please definition in glossary- appendix 3).
- Consider that the episode may not be related to epilepsy if any of the following features are present.
- Prodromal symptoms that on other occasions have been abolished by sitting or lying down.
- Sweating before the episode.
- Prolonged standing that appeared to precipitate the TLoC.
- Pallor during the episode.

Do not routinely use electroencephalogram (EEG) in the investigation of TLoC (see 'The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care' [NICE clinical guideline 20]).

Specialist cardiovascular assessment and diagnosis

- Carry out a specialist cardiovascular assessment as follows.
 - Reassess the person's:
 - o detailed history of TLoC including any previous events
 - medical history and any family history of cardiac disease or an inherited cardiac condition
 - o drug therapy at the time of TLoC and any subsequent changes.
 - Conduct a clinical examination, including full cardiovascular examination and, if clinically appropriate, measurement of lying and standing blood pressure.
 - Repeat 12-lead ECG and obtain and examine previous ECG recordings.

- On the basis of this assessment, assign the person to one of the following suspected causes of syncope.
- Suspected structural heart disease.
- Suspected cardiac arrhythmic.
- Suspected neurally mediated.
- Unexplained.

Offer further testing as directed by recommendations 1.3.2.1 to 1.3.2.10 or other tests as clinically appropriate.

- For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC.
 For people who have:
 - TLoC at least several times a week, offer Holter monitoring (up to 48 hours if necessary). If no further TLoC occurs during the monitoring period, offer an external event recorder that provides continuous recording with the facility for the patient to indicate when a symptomatic event has occurred.
 - TLoC every 1–2 weeks, offer an external event recorder. If the person experiences further TLoC outside the period of external event recording, offer an implantable event recorder.
 - TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder. A Holter monitor should not usually be offered unless there is evidence of a conduction abnormality on the 12-lead ECG.

Do not offer a tilt test to people who have a diagnosis of vasovagal syncope on initial assessment.

• For all people with unexplained syncope (including after negative carotid sinus massage test in those for whom this is appropriate), offer ambulatory ECG (see recommendation 1.3.2.4). Do not offer a tilt test before the ambulatory ECG.

Appendix 3: Glossary

A comprehensive glossary of terms is given in the full guideline.

Cardiac arrthymia An arrhythmia is an abnormality in the heart's rhythm, or heartbeat pattern.

Convulsive syncope Loss of consciousness caused by transient insufficiency of blood supply to the brain accompanied by jerky or posturing movements, generally involving the limbs.

Déjà vu An intense sensation that what is happening for the first time has already occurred previously. This is common particularly in adolescence, but may be a manifestation of a partial seizure" (rather than "occurring immediately before an epileptic seizure).

ECG (electrocardiogram) A test which records electrical signals from your heart and check for any problems.

EEG (electroencephalogram) A test which records the brain's electrical activity.

12-lead ECG A test which records the heart's electrical signals obtained by attaching electrodes in ten standard positions on the limbs and the surface of the chest. This provides a display of the electrical activity of the heart viewed from 12 different directions.

Ambulatory ECG A test which records the electrical activity of your heart when the person is walking about (ambulatory) and doing normal activities.

Implantable event recorder Small implantable device capable of monitoring and storing ECG recordings of the heart's rhythm. It is also known as an implantable/insertable loop recorder.

Jamais Vu A feeling of lack of familiarity, that what should be familiar is happening for the first time; it is usually abnormal, it doesn't commonly occur in healthy people.

Red flags For this guideline, the term 'red flags' indicates that the person is considered to be at high risk of a serious adverse event and should be referred for urgent specialist assessment.

Situational syncope A form of neurally mediated syncope occurring in certain specific situations (for example, cough syncope, micturition syncope, or swallowing syncope).

Syncope Transient loss of consciousness due to a reduction in blood supply to the brain.

Tilt test A test in which a patient is exposed to passive head-up tilt, during which they have beat-to-beat measurement of heart rate and blood pressure.

Transient loss of consciousness (TLoC) Preferred term for a blackout.

Triage The process of determining the priority of patients' treatments based on the severity of their condition.

Vasovagal syncope A form of neurally mediated syncope. This is often, but not always, triggered by circumstances such as pain, prolonged standing (especially in a warm environment), or emotional stress. This commonly presents as an identifiable "uncomplicated faint" but can present as sudden unprovoked syncope.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
001	East Midlands Ambulance Service NHS Trust	Ambulance involvement and referral pathways	The Ambulance Service is often the first on scene to a TLoC referral pathways for patients are not best served by the single access point of the Emergency Department. Non emergency and incidental findings may be more appropriately referred to specialised cardiologists bypassing the ED.	On numerous levels, this could benefit the rapid intervention in patient assessment and treatment but also to reduce the pressure in the ED. Ambulance crews have the ability to send ECGs through telemetry for confirmation to the cardiology department in a referral access capacity. Ambulance crews should have a mandatory training package to identify various TLoC criteria with referral flow charts utilising appropriate hospital services. Copies of the ECGs by ambulance crews should be duplicated and archived. The ECG will be anonymised and sent to an independent cardiologist specialist for a second opinion and screening. If a concern is highlighted, the patient could be recalled for further screening or assessment.	Incidental findings are often discovered in the pre hospital environment and national screening could be supported by ambulance clinician involvement and inclusion. The East Midlands Ambulance Service is currently conducting an ECG evaluation until May 2014, forwarding anonymised ECGs taken from ages 14 to 35 year olds in the emergency pre hospital environments to specialist cardiologists for review, screening and reassessment if required. Please contact Mr Gareth J Mallon on 07854686192 for further details.
002	Arrhythmia Alliance	TLoC assessment steps and flags for judgement	The first step in assessment of a patient with TLOC is for first responders to note any acute cardiorespiratory or other decompensation, and record any data available. The second step is to make a risk assessment. This should be done to inform the care- pathway, because patients with	There are at least 75,000 patients in England who are misdiagnosed with epilepsy and are taking epilepsy drugs inappropriately. Most of these probably have had convulsive syncope. Many lives and families are blighted by this. The reason for this occurring is a lack of appreciation that syncope can cause twitching, jerking, incontinence and prolonged TLOC.	The Manchester Heart Centre started it's Specialist Nurse Lead Rapid Access Blackouts Triage Clinic in 2007. 2790 patients have been triaged in Manchester and ≈ 2000 in Middlesborough, using a web-based database/clinical assessment tool. Red Flag patients have required significantly more investigations,

Appendix 4: Suggestions from stakeholder engagement exercise

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			certain "Red Flags" should be managed differently from patients with a "Green Flag". This will become much more important for triage to high level or low level secondary care. The NICE TLOC guideline treated neurological causes of TLOC as a completely separate issue, and this was wrong. Most TLOC is due to syncope, and most of this is reflex syncope. However, patients are frequently misdirected to neurological services when some aspect of their syncope has been convulsive. Neurological, cardiovascular and psychological causes of TLOC need to all be considered together in triage clinics.	There is a lack of appreciation that good clinical skills and an ECG are by far the most effective way of reaching a diagnosis in TLOC. All patients need a triage step between "first responders" and "specialist care", where the history is carefully taken from a patient and witness, and ECG is used to rule out obvious cardiac disease, and a risk assessment is done. Patients are then assigned a Red Flag(s), or a Green Flag. Patients can have onward referral to a First Fit clinic if the clinical characteristics genuinely contain seizures markers. Using TLOC triage can help reduce unnecessary hospital admission or prolonged stay. TLOC triage helps identify more patients requiring pacemakers. UK pacing numbers are half those of Western Europe, but in the UK, 70% of paced patients present with syncope. Therefore, we need to triage syncope patients more effectively in order to find those who need pacing.	referrals and pacemakers, Green Flag patients have responded significantly better to life-style changes. Despite the large number of syncope patients typically found in "first fit" clinics, we only referred 10% of patients for neurological review, and only 3% were thought to have epilepsy. Triage would therefore significantly reduce the inappropriate referrals to neurology caused by a failure of referrers to appreciate convulsive syncope. This would make it much easier for neurologists to meet the target of seeing all new ?epilepsy patients within 2 weeks. In Middlesborough, the consultant arrhythmia nurse running the RABTC has calculated that the methods save approximately £1000 per case over conventional management, freeing up resources for investment elsewhere. Initial experience with the RABTC can be found in:- Petkar S, Bell W, Rice N, Iddon P, Cooper P, McKee D, Curtis N, Hanley M, Stuart J, Mackway Jones K, Fitzpatrick AP Initial experience with a

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					rapid access blackouts triage clinic. Clin Med. 2011 Feb; 11: 11-6
003	Resuscitation Council (UK)	Identification of cause of TLoC in a young adult.	TLoC may be the first indication of inherited cardiac pathology predisposing to sudden and premature cardiac death.	There are a number of features which identify those at high risk. Failure to recognise or ignoring these features will put people at risk of sudden, preventable death. Young people involved in sporting activities are particularly at risk. The commonest cause of non-traumatic death in sport is due to a cardiac cause, at the incidence is increasing. Outcome from cardiac arrest in this group is poor. Recognition and initiation of an appropriate response should be a quality standard in the management of people with TLoC. Any healthcare organisation responsible for managing young adults with TLoC should have appropriate policies and procedures to ensure correct management of these patients to reduce the risk of premature death. One of the key aspects is provision of timely access to a 12-lead ECG and expert interpretation and reporting.	Numerous publications in peer- reviewed medical journals. European Society of Cardiology Guidelines. <u>Priori SG, Wilde AA, Horie M</u> , et al. HRS/EHRA/APHRS expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes: document endorsed by HRS, EHRA, and APHRS in May 2013 and by ACCF, AHA, PACES, and AEPC in June 2013. <u>Heart Rhythm.</u> 2013 Dec;10(12):1932- 63.
004	Association of British Neurologists	Red flags		We consider the topic overview to be uncontroversial. The red flags are particularly important	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
005	Association of British Neurologists	Improve quality of driving advice given at the time of presentation	Advice currently given variable and often incorrect	Important legal and road safety implications	
006	Syncope Trust And Reflex anoxic Seizures (STARS)	TLoC assessment steps and flags for judgement	The first step in assessment of a patient with TLOC is for first responders to note any acute cardiorespiratory or other decompensation, and record any data available. The second step is to make a risk assessment. This should be done to inform the care- pathway, because patients with certain "Red Flags" should be managed differently from patients with a "Green Flag". This will become much more important for triage to high level or low level secondary care. The NICE TLOC guideline treated neurological causes of TLOC as a completely separate issue, and this was wrong. Most TLOC is due to syncope, and most of this is reflex syncope. However, patients are frequently misdirected to neurological services when some aspect of their syncope has been convulsive. Neurological,	There are at least 75,000 patients in England who are misdiagnosed with epilepsy and are taking epilepsy drugs inappropriately. Most of these probably have had convulsive syncope. Many lives and families are blighted by this. The reason for this occurring is a lack of appreciation that syncope can cause twitching, jerking, incontinence and prolonged TLOC. There is a lack of appreciation that good clinical skills and an ECG are by far the most effective way of reaching a diagnosis in TLOC. All patients need a triage step between "first responders" and "specialist care", where the history is carefully taken from a patient and witness, and ECG is used to rule out obvious cardiac disease, and a risk assessment is done. Patients are then assigned a Red Flag(s), or a Green Flag. Patients can have onward referral to a First Fit clinic if the clinical characteristics genuinely contain seizures markers.	The Manchester Heart Centre started its Specialist Nurse Lead Rapid Access Blackouts Triage Clinic in 2007. 2790 patients have been triaged in Manchester and ≈ 2000 in Middlesborough, using a web-based database/clinical assessment tool. Red Flag patients have required significantly more investigations, referrals and pacemakers, Green Flag patients have responded significantly better to life-style changes. Despite the large number of syncope patients typically found in "first fit" clinics, we only referred 10% of patients for neurological review, and only 3% were thought to have epilepsy. Triage would therefore significantly reduce the inappropriate referrals to neurology caused by a failure of referrers to appreciate convulsive syncope. This would make it much easier for neurologists to meet the target of seeing all new epilepsy patients within 2 weeks.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			cardiovascular and psychological causes of TLOC need to all be considered together in triage clinics.	Using TLOC triage can help reduce unnecessary hospital admission or prolonged stay. TLOC triage helps identify more patients requiring pacemakers. UK pacing numbers are half those of Western Europe, but in the UK, 70% of paced patients present with syncope. Therefore, we need to triage syncope patients more effectively in order to find those who need pacing.	In Middlesborough, the consultant arrhythmia nurse running the RABTC has calculated that the methods save approximately £1000 per case over conventional management, freeing up resources for investment elsewhere. Initial experience with the RABTC can be found in:- Petkar S, Bell W, Rice N, Iddon P, Cooper P, McKee D, Curtis N, Hanley M, Stuart J, Mackway Jones K, Fitzpatrick AP Initial experience with a rapid access blackouts triage clinic. Clin Med. 2011 Feb; 11: 11-6

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
007	Syncope Trust And Reflex anoxic Seizures (STARS)	Key area for quality improvement 2	Implantable loop recorders can give information in blackout cases where no other investigation can, because they are capable of monitoring the heart rhythm for up to 3 years. Transtelephonic telemedicine is used to download ECG recordings to the following centre, avoiding the cost, inconvenience and carbon emissions of attendence at the hospital.	One of the greatest problems in the management of patients with blackouts is distinguishing convulsive syncope from epilepsy. There may be many similarities to an eye-witness including abrupt collapse without warning, jerking and twitching of the limbs, incontinence of urine and slow recovery. Where multi-disciplinary assessment cannot easily distinguish between these very different conditions, implantable ECG loop recorders may be valuable	Petkar S, Hamid T, Iddon P, Clifford A, <u>Rice N, Claire R, McKee D, Curtis N,</u> <u>Cooper PN, Fitzpatrick AP</u> Prolonged implantable electrocardiographic monitoring indicates a high rate of misdiagnosis of epilepsyREVISE study. Europace. 2012 Nov;14(11):1653-60.
008	Syncope Trust And Reflex anoxic Seizures (STARS)	Key area for quality improvement 3	The terminology of blackouts is very confused. Clear terminological leadership from NICE would be very helpful for clinical management of patients with TLOC/blackouts.	Collapse = abrupt loss of postural control Blackout/T-LoC = transient loss of consciousness without neurological deficit Syncope = T-LoC due to transient global impairment of cerebral perfusion Epilepsy = repeated episodes of excessive asynchronous discharge of cortical neurones leading to a clinical event Psychogenic Blackouts = A cause of apparent blackouts without evidence of syncope or epilepsy Fall = Patient goes down freely under the influence of gravity TIA = Transient neurological deficit without T-LoC	Sander JWAS, Shorvon SD. Epidemiology of the epilepsies. J Neurol Neurosurg Psychiatry 1996;61:433–43. Brignole M, Alboni P, Benditt DG, Bergfeldt L, Blanc JJ, Bloch Thomsen PE, van Dijk JG, Fitzpatrick A P, Hohnloser S, Janousek J, Kapoor W, Kenny RA, Kulakowski P, Masotti G, Moya A, Raviele A, Sutton R, Theodorakis G, Ungar A, Wieling W; Task Force on Syncope; European Society of Cardiology. Guidelines on management (diagnosis and treatment) of syncopeupdate 2004. Europace. 2004;6(6):467-537.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
009	Syncope Trust And Reflex anoxic Seizures (STARS)	Key area for quality improvement 4	Every patient presenting with an unexplained blackout/T-LOC should be given a 12-lead ECG.	To rule out an underlying heart rhythm disorder.	National Service Framework Chapter 8, Arrhythmias and Sudden Cardiac Death, Quality Requirement Two: Diagnosis and Treatment. Information about NICE clinical guidelines 109. Issue date: August 2010.
010	Medtronic Limited	Key area for quality improvement 2 Implementation of TLOC Clinics and Pathways	Quality Improvements are needed in the accuracy and speed of diagnosis for people who have experienced TLOC and have unexplained syncope NICE CG 109 provides guidelines about assessment, diagnosis and specialist referral for adults and young people (16 years and over) who have experienced TLOC. Recommendations are made for people with unexplained syncope who require an Implantable Loop Recorder: <i>"For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of</i>		

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			particular, frequency) of TLoC. For people who have TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder."		
011	Medtronic Limited	Key area for quality improvement 3 Quality Performance Measurements for TLOC services	Improvements in quality performance measurements. NICE CG 109 provides guidelines about assessment, diagnosis and specialist referral for adults and young people (16 years and over) who have experienced TLOC	Currently within NICE CG 109 there are no targets for recommended implant rates of Implantable Loop Recorders for patients with unexplained syncope requiring this service Inclusion of clear targets for Implantable Loop Recorders within the Quality Standard will provide a metric against which CCG's and Provider Trusts can be measured, giving an incentive to drive adoption of the guidance to improve the quality of diagnosis for patients with TLOC and unexplained syncope. Currently Implant rates per million of population (PMP) for Implantable Loop Recorders range from 11 implants PMP (NHS North Kirklees CCG) to 353 PMP (NHS Eastbourne, Hailsham And Seaford CCG). Analyses of HES data and an algorithm using the FAST study and the PICTURE study suggests that 1 in 5 patients with unexplained syncope should receive an Implantable Loop Recorder.	 The PICTURE Study <u>http://europace.oxfordjournals.org/content/early/2010/11/18/europace.euq418</u> The FAST Study http://www.medscape.com/view article/570089 HES data <u>http://www.hscic.gov.uk/hes</u> Medtronic Analyses of TLOC and Implantable Loop Recorder Services

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
012	Medtronic Limited	Key area for quality improvement 4 TLOC Clinics and Pathways; Implantable Loop Recorder Service	Improvements in the quality of access for patients to TLOC services NICE CG 109 provides guidelines about assessment, diagnosis and specialist referral for adults and young people (16 years and over) who have experienced TLOC	Quality for improved access to Implantable Loop Recorders for patients with unexplained syncope as part of the TLOC service can be improved by the use non- physician implanters. HES data shows that where Nurse Implanters or Cardiac Physiologist Implanters run the implant service and implant ILR's that quality of access is increased	 HES data <u>http://www.hscic.gov.uk/hes</u> Medtronic Analyses of TLOC and Implantable Loop Recorder Services
013	Medtronic Limited	Key area for quality improvement 5 TLOC Clinics and Pathways; Implantable Loop Recorder Service	Improvements in the quality of cost effective services for patients with unexplained syncope requiring an implantable Loop recorder as part of the TLOC service	Improvements can be made in the quality of cost effectiveness of TLOC services by moving the implantation of Implantable Loop Recorders out of the Catheter Lab into a clean room clinic environment.	 United Lincolnshire Hospitals NHS Trust have experience of implanting over 300 patients with ILR's outside the cath lab in a clean room environment with a good safety and efficacy profile. A European study (including two UK sites) is currently being conducted on behalf of Medtronic to evaluate the economic value of moving implants of Implantable Loop Recorders out of the Cath Lab. The intention is for the results to be published later this year. A copy of the study protocol is enclosed
014	British Cardiovascular Society	Key area for quality improvement 1 Use of	NICE guidelines recommend different periods of ambulatory monitoring based on frequency of symptoms ie TLoC. This is crucial if physicians are to be	 Physicians still perform short periods of ambulatory monitoring with low diagnostic yields when investigating syncope. This often gives false reassurance. 	Edvardsson et al (2001). Use of the implantable loop recorder to increase the diagnostic yield in unexplained syncope. Europace 13:262-9

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
		appropriate ambulatory monitoring to diagnose cardiac arrhythmia.	able to reliably correlate ECG with symptoms. In particular, use of implantable loop recorders is recommended for investigation of infrequent syncope (less than 1 every 2 weeks). There is good evidence that implantable loop recorders (ILR) can improve diagnostic yield in patients with infrequent syncope.	2) There has been significant growth in the use implantable of loop recorder devices (ILR) since the publication of NICE TLoC guidance 109 (2010). However, implant rates vary between centres and have not been reported in the National Device Survey. There are therefore no data to confirm that ILRs are being implanted appropriately and achieving expected diagnostic yields. Anecdotal evidence is that ILRs are underutilised and that short periods of external ambulatory monitoring continue to be used inappropriately.	ILRs represent a major advance in our ability to diagnose unexplained syncope yet there is no national data relating to their use.
15	SCM1	Manual review of ECG. Can automated ECG be relied on compared with expert review?	Possible inaccuracies of automated printouts.	Missed diagnosis. False confidence in automated print out.	
16	SCM2	Clarification over the role of cardiac markers in the initial evaluation	Has been deemed valuable in admitted patients, but unclear in initial stages.	Could reduce admissions if clear and reduce those sent home with cardiac problems i.e. risk stratification.	
17	SCM2	Use of history of bleeding as red flag in initial assessment	May improve decrease in inappropriate d/c		Int J Cardiol. 2013 Jul 15;167(1):57-62. doi: 10.1016/j.ijcard.2011.11.083. Epub 2011 Dec 20.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
18	SCM3	EEG	Do not routinely use EEG in the investigation of transient loss of consciousness. ("blackout")	EEG has low sensitivity and poor specificity. Misuse of EEG is well recognised as a major cause of misdiagnosis of epilepsy. Non-specialists, and indeed their patients, place undue reliance on obtaining an EEG after a blackout, and on the results of that EEG.	NICE CG 137 Epilepsy and CG 109 Transient Loss of Consciousness
19	SCM3	ECG using automated report	Record an ECG using automated report in anyone with transient loss of consciousness. Refer within 24 hours, to cardiology, those with an ECG abnormality. (Significant ECG abnormalities are as listed in the guideline)	Most patients who blackout have uncomplicated vasovagal syncope (fainting), but there is a small number in whom the blackout is an indication of potentially life threatening cardiac disease. An abnormal ECG can identify such patients, and they warrant urgent cardiac assessment. At present they might be referred to neurology, to do so results in unnecessary delay.	European Society of Cardiology clinical guidelines on Syncope 2009. NICE CG 109 Transient Loss of Consciousness
20	SCM3	Ambulatory ECG	For suspected cardiac arrhythmias arrange ambulatory ECG, rather than a tilt table test, as the first-line investigation. The type of ambulatory ECG should be chosen depending on the frequency of the episodes. (See guideline for details)	The key element in establishing the correct diagnosis is recording the habitual spontaneous episodes. This may require prolonged monitoring, and new technology can provide this. Often patients have insufficiently long monitoring which fails to record an episode, doesn't establish the diagnosis, and may provide false reassurance. Such inadequate monitoring is also costly, and although the technology required for prolonged monitoring is more expensive, use of this technology is in fact cost effective.	NICE CG 109 Transient Loss of Consciousness

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
21	SCM3	Do not carry out a tilt test for vasovagal syncope	Do not carry out a tilt test for vasovagal syncope; and for anyone with unexplained syncope always perform an ambulatory ECG before arranging a tilt test.	As noted above the key is to record a spontaneous episode. Tilt table testing may precipitate a syncopal episode in a susceptible individual, without this necessarily being the cause of their habitual episodes.	
22	Royal College of Nursing	No comments			
23	NHS Direct	No comments			
23	NHS England	No comments			

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
24	Royal College of Paediatrics and Child Health	No comments			