NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Transient loss of consciousness (TLoC)

Date of Quality Standards Advisory Committee post-consultation meeting:
02 July 2014

2 Introduction

The draft quality standard for Transient loss of consciousness was made available on the NICE website for a 4-week public consultation period between 8 May and 5 June 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 13 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the

process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Overall, the Quality Standard was supported for its approach for reflecting the key areas of quality improvement and offering sensible measures to raise standards, with the recognition of potential risks, long term implications, and the importance of prompt diagnosis and treatment.
- A number of stakeholders requested to either combine Quality Statements 1 and 2 or an alternative suggestion was to delete Quality Statement 2 as this was reported as normal medical practice.
- For Quality Statements 3 and 4, a number of stakeholders requested inclusion of training and competencies for first-line carers and healthcare professionals when interpreting ECGs and their awareness and assessment of ‘red flag’ signs and symptoms.

- For each Quality Statement, the audience descriptors (service providers, healthcare professionals and commissioning services) need to be developed further with help from specialist committee members.

Consultation comments on data collection

- A stakeholder raised concern on data collection as being potentially complicated for Quality Statement 1. An incomplete record due to lack of eyewitnesses or an inability to remember what happened before or after the event may potentially reflect badly on the healthcare professional.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with suspected transient loss of consciousness have a detailed history recorded of the event.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Supported the need for recording a detailed history as being an important aspect of the assessment; contributing to accurate and prompt diagnosis and treatment.
- Suggested combining Quality Statement 1 and 2 on recording the detailed event history plus clinical history and physical examination. An alternative suggestion was to delete Quality Statement 2 as this was reported as normal medical practice.
- Highlighted training and competencies as being important for first-line carers and GPs in order to undertake a proper initial assessment and refer appropriately. GPs need to be confident in undertaking a risk assessment and patients need to be sufficiently reassured following this assessment which can be achieved by training to the Primary Healthcare team. Continuous training was also highlighted.

- Suggested to add the following wording ‘when they are first seen by a healthcare professional’ to the statement to reflect who is recording the event history.

- Highlighted the importance of obtaining witness history accounts in addition to personal patient history accounts in all witnessed TLoC episodes. It was suggested that the wording on this should be more explicit. It was also suggested that patients should facilitate a history from any witnesses if available.

- Highlighted the need for evidence of appropriate onward referral which needs to be regularly audited.

5.2 Draft statement 2

People who present with transient loss of consciousness have an initial assessment that includes recording clinical history and carrying out a physical examination.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Suggested combining Quality Statement 1 and 2 on recording the detailed event history plus clinical history and physical examination. An alternative suggestion was to delete Quality Statement 2 as this was reported to be normal medical practice.

- Suggested that the extent of the examination will be dependent on the clinical features so some of the specific examinations mentioned will not be needed in every case. It was advised not to list specific points.

- Highlighted that checking the cardiovascular signs and being able to do a quick neurological assessment are important in the initial risk assessment.

- Highlighted the importance of training. It was suggested that training packages need to take into account the time pressure in general practice and equip GPs and nurse practitioners with the appropriate skills to do these potentially life-saving assessments within the available timeframe. It was also suggested that GP training should include a practical aspect of examination.

5.3 Draft statement 3

People who have had transient loss of consciousness receive a 12-lead ECG during initial assessment.

- **Consultation comments**
- Stakeholders made the following comments in relation to draft statement 3:
- Supported the use of ECGs as being part of routine initial assessment but also highlighted the importance of training required in ECG interpretation. ECG machines are available in most practices but not all GPs and/or nurse practitioners are confident in interpreting them to the standard needed for measuring the QT interval or looking for heart blocks.
- Agreement that an ECG will normally be part of the initial investigation process however they felt that this was not necessary for younger people with clear signs of a simple vasovagal episode and a normal examination. Prevalence of cardiac abnormalities is low in this population which makes the performance of an ECG investigation unacceptably low which could potentially lead to harmful over-diagnosis. For this population the best approach is thorough history taking, targeted examination and then authoritative reassurance.
- Suggested that CCGs should commission device methods by which GPs can have their ECGs interpreted in a timely fashion by skilled practitioners.
- Query raised on whether a 12-lead ECG is appropriate for all ages including young adults ie 16 years and older who have had TLoC?

5.4 Draft statement 4

People who have had transient loss of consciousness and 1 or more ‘red flag’ signs or symptoms identified at initial assessment are referred within 24 hours for specialist cardiovascular assessment.

Consultation comments

- Stakeholders made the following comments in relation to draft statement 4:
- Supported the 24 hour referral timeframe for those identified as being at high risk of a serious event.
- Supported prompt referral for specialist cardiovascular assessment however it was felt referral within 24 hours was unnecessary as waits for specialist opinion can take several months. Length of stay was reported as being more important than presentation to referral.
- Supported awareness of ‘red flags’ and their assessment as being a crucial part of the initial risk assessment Local training on this for first-line practitioners should also be encouraged.
- Supported that young adults who had TLoC on exertion should be seen within 24 hours by a specialist even if 12-lead ECG looks normal. However a query was raised on whether this is necessary for people who have had TLoC with history of mild heart failure as although this was felt as being important, it was reported as less life-threatening than the potential fatal dysrrhythmia of young adults.
- Highlighted that remote access (by phone, fax or email) to a specialist practitioner within 24 hours is important, more practical and achievable than this statement’s suggested referral of all suspected cases within 24 hours.
- Suggested that the cardiovascular specialist team practitioner can be community based but it is important to be part of a multi-disciplinary team (MDT) that includes a Heart Rhythm Specialist and Epileptologist with access to event recorders, echocardiogram and neuro-physiology.
- Query raised on the statement wording- Does it mean assessment within 24 hours, not just referral within 24 hours?

- Concern raised on stating the need for every TLoC patient and a murmur to be referred for urgent cardiovascular assessment within 24 hours as this could potentially be a resource burden (cost and time) plus uncertainty was raised about the absolute benefits of daily TLoC clinics.

- Suggested deleting the **'**Consider referring sentence' from page 18 of the consultation document version to limit confusion.

5.5 Draft statement 5

People who have had transient loss of consciousness are not routinely offered an EEG to investigate the event.

Consultation comments

- Stakeholders made the following comments in relation to draft statement 5:

- Overall, stakeholders supported this statement, its context and rationale as a key area for improvement but they also raised concern about the wording of 'not routinely offering'. Rewording this statement was suggested as being a positive step in tackling the misdiagnosis of epilepsy.

- Suggested to clearly state why not to offer an EEG routinely in the supporting information (rationale or definition section).

- Suggested re-wording statement - 'In people who have had transient loss of consciousness, a brain scan (CT or MRI) and electroencephalogram (EEG) should be considered but not performed as a matter of routine.'

- Suggested to clearly state why not to offer an EEG routinely and also state epilepsy referral in the definitions section.

5.6 Draft statement 6

People with a suspected cardiac arrhythmic cause of syncope are offered an ambulatory ECG as a first-line investigation with the type of ECG chosen based on the person's history and frequency of transient loss of consciousness.

Consultation comments

- Stakeholders made the following comments in relation to draft statement 6:
- Overall, stakeholders supported this quality statement with appropriate measures.
- Suggested deleting this quality statement and combine with Quality Statement 4 as the decision should be left with the specialist.
- Suggested re-wording a measure ‘For people who have TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder.’ to add greater clarity for selecting the most appropriate method of ambulatory ECG for detecting cardiac arrhythmias.
- Query raised on why we state ‘syncope’ in this quality statement whereas the other quality statements state ‘transient loss of consciousness’. Any reason for this inconsistency?
- Suggested defining ambulatory ECGs (implantable loop recorders) and any other appropriate devices for this quality statement.

5.7 Draft statement 7

People who have had transient loss of consciousness, who have been referred and are awaiting specialist assessment, are advised not to drive.

Consultation comments

- Stakeholders made the following comments in relation to draft statement 7:
- Supported this quality statement as being very important and agreed that if the structures and systems were in place, it would be possible to collect the data for the proposed measures for this quality statement.
- Query raised on who is legally liable for this? Suggestion to state ‘healthcare professionals’ to advise.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- All patients aged over 60 with unexplained TLoC who do not have ‘red flag’ features should be offered carotid sinus massage as an initial investigation before ECG monitoring is undertaken.
- Length of total patient journey. This was felt as being more important than presentation to referral time in Quality Statement 4.
- CT head scan should not be routinely performed to investigate TLoC.
- Recognition of older peoples’ needs within TLoC services as this population are more likely to suffer from TLoC and have a different pattern to the underlying cause. It was also reported that structural and arrhythmic heart disease is more common in old age but older patients are also more likely to also have postural blood pressure changes and autonomic failure.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comment on	Comments[1]
1	Epilepsy Action	Question 1	Question 1	Epilepsy Action believes that this standard does accurately reflect the key areas for quality improvement, with the recognition of potential risks, long term implications and the importance of swift diagnosis and treatment.
2	The Primary Care Neurology Society	Question 1	Question 1	Yes it does but once more failed to take into account the constraints on general practice – see comments below.
3	Epilepsy Action	Question 2	Question 2	We feel that this question may lead to misleading feedback as inevitably if the systems and structures were available, it would be possible to collect the data. The issue would be implementing the systems and structures.
4	Epilepsy Action	Question 2	Question 2	The data collection is potentially complicated, as a patient that does not have a complete and / or detailed history due to a lack of eyewitnesses or an inability to remember what happened before or after the event may reflect badly on the healthcare professional.
5	The Primary Care Neurology Society	Question 2	Question 2	It is possible if appropriate READ Codes were agreed to the collect the necessary data
6	Epilepsy Action	Introduction	Why this quality standard is needed paragraph	Epilepsy Action supports the aim of the quality standard to contribute improvements in the listed areas, however we would suggest that the word 'reduce' be put in front of 'Mortality from causes considered preventable'.
7	British Geriatrics Society	General	General	The document details 7 quality standards based on the NICE TLoC guidelines published in 2010. The standards have been drawn up to ensure that TLoC is investigated appropriately and in a timely fashion by focussing on the initial clinical assessment of TLoC patients. The quality standards are comprehensive and cover all areas of potential TLoC causes. The standards are applicable in any health care setting where TLOC patients can present, such as A&E, primary care or secondary care.

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comment on	Comments[1]
				The emphasis on clinical assessment and especially obtaining a detailed history is very welcome. All 7 standards are sensible and, if applied, should result in a high quality syncope service. From an elderly care perspective I would suggest some additional standards. All patients over the age of 60 with unexplained TLOC who do not have 'red flag' features should be offered carotid sinus massage as an initial investigation before ECG monitoring is undertaken. Also, a CT head should not be routinely performed to investigate TLOC. There is no recognised structure to a syncope investigation facility and there are many different approaches to providing TLOC investigation and management. It is difficult therefore to offer quality standards governing the structure of syncope services. However, there should be some recognition of the needs of older people with TLOC services. Older people with syncope can present as unexplained falls. The structure of a syncope service should include close liaison with elderly care services and especially falls services so patients can have access to syncope investigation where appropriate. Also, older patients are more likely to suffer from TLOC and have a different pattern to the underlying cause. Structural and arrhythmic heart disease is more common in old age but older patients are more likely to also have postural blood pressure changes and autonomic failure. The quality standards do not mention these areas. Clinical services, possibly within elderly care or elsewhere, that can investigate and manage these patients could be part of a TLOC quality standard.
8	Medtronic Ltd	General	General	Medtronic supports all 7 Quality Statements in the Draft Quality Standard for Transient Loss of Consciousness
9	Epilepsy Action	General	General	Overall Epilepsy Action feels that this is a good draft quality standard, largely reflecting the key areas for quality improvement, and offering sensible measures to raise standards.
10	Department of Health	General	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
11	Royal College of Nursing	General	General	Nurses working in this area of practice were invited to review the draft quality standard on transient loss of consciousness. There are no further comments to make on this document on behalf of the Royal College of Nursing.
12	Digital Assessment Service – NHS Choices	General	General	We welcome the quality statement and have no comments on its consultation

ID	Stakeholder	Statement No	Comment on	Comments[1]
13	Royal College of Physicians	General	General	Please take this email as confirmation that the RCP wishes to endorse the comments submitted by the British Geriatrics Society on the above draft Quality Standard.
14	Association of British Neurologists	General	General	ABN is happy with the proposed standards which follow on logically from the guideline
15	Epilepsy Action	1	QS1	"People with suspected transient loss of consciousness have a detailed history recorded of the event" We feel that this should be re-worded to reflect who is taking the history, for example "…by their healthcare professional"
16	Epilepsy Action	1	QS1	We feel that this quality standard does accurately reflect the key areas for quality improvement, as it recognises that a detailed history contributes to accurate and speedy diagnosis and treatment.
17	The Primary Care Neurology Society	1	QS1	Detailed history is the most important aspect of the assessment as the majority of TLoC presenting to general practice are benign and likely to be secondary to Reflux Vagal Syncopal attacks or related to Postural Hypotension in the elderly population who are on antihypertensive or anti-heart failure medications.
18	The Primary Care Neurology Society	1	QS1	The majority of the patients do however, fear the worst suspecting that the event was either cerebral (epileptic) in the young age group, or cerebro-vascular (stroke) in the older group.
19	The Primary Care Neurology Society	1	QS1	In order to do proper assessment and refer appropriately, GPs need to be confident in their risk assessment and patients need to be reassured sufficiently following that assessment. This can be achieved by training to the PHC team.
20	The Primary Care Neurology Society	1	QS1	NICE Guidance should clearly acknowledges this and reflects the importance of the continuous training of the first-line carers
21	NHS England	1	QS1	You could combine the first two quality standards which would allow you another. Nothing more than a good history and examination- something. There needs to be some quality assurance that doctors assessing these patients routinely have the appropriate competencies. Do A & E trainees get these? Do AMU doctors? This needs to be part of the quality standards. There should be evidence of appropriate onward referral. Regular audit of this needs to be incorporated
22	Association of British	1	QS1	We feel it should be essential to try and obtain witness history account in addition to personal patient history account in all witnessed TLOC episodes. We think this has to be really explicit.

ID	Stakeholder	Statement No	Comment on	Comments[1]
	Neurologists			
23	British Medical Association	1	QS1	We agree that people with suspected transient loss of consciousness should have a detailed history recorded of the event. This will include a history from witnesses if available, and usually patients themselves will facilitate this, or can be encouraged to do so.
24	Epilepsy Action	2	QS2	We feel that this quality standard should be number 1 rather than 2; given that number 1 (a full clinical history) is a component of quality standard 2.
25	Epilepsy Action	2	Quality measures process	We feel that it would be possible to collect the data for this proposed measure.
26	British Medical Association	2	QS2	This seems to be duplication of Quality Statement 1. It is normal medical practice for a GP to record clinical history and carry out a physical examination. The extent of the examination will depend on the clinical features, and some of the specific examinations mentioned will not be needed in every case. It would therefore be better not to list specific points.
27	The Primary Care Neurology Society	2	QS2	Checking the cardiovascular and be able to do a quick neurological assessment are important in the initial risk assessment. Training of the GPs should include a practical aspect of examination keeping in mind that the majority of these patients will chose to be seen on the same day appointments. These are usually 7-10 mins appointments and the clinicians including Nurse Practitioners (NP) are usually rushed and inundated with the sheer volume of patients to be seen on the day, in a typical general practice setup.
28	The Primary Care Neurology Society	2	QS2	Training packages need to take into account the time pressure in general practice and equip GPs and NPs with the appropriate skills to do these potentially life-saving assessments within the available time-frame.
29	NHS England	2	QS2	You could combine the first two quality standards which would allow you another. Nothing more than a good history and examination- something. There needs to be some quality assurance that doctors assessing these patients routinely have the appropriate competencies. Do A & E trainees get these? Do AMU doctors? This needs to be part of the quality standards. There should be evidence of appropriate onward referral. Regular audit of this needs to be incorporated
30	Epilepsy Action	3	QS3	Epilepsy Action believes that this standard accurately reflects the key areas for quality improvement.
31	Epilepsy Action	3	QS3	Epilepsy Action feels that it will be possible to collect the data for the proposed quality measures.
32	British Medical Association	3	QS3	An ECG will normally be part of the initial investigation process, however we do not believe an ECG is necessary for younger people with clear pointers to a simple vasovagal episode and a normal

ID	Stakeholder	Statement No	Comment on	Comments[1]
				examination. In this population in general practice there is a real danger of psychological consequences of a simple faint and the best defence against this is thorough history taking, targeted examination and then authoritative reassurance. In this group the prevalence of cardiac abnormalities is low and this makes the specificity of an ECG as an investigation unacceptably low, and the risks of harm through over-diagnosis becomes significant.
33	The Primary Care Neurology Society	3	QS3	ECG machines are available in most practices but not all GPs and/or NPs are confident in interpreting them to the standard needed for this condition. Measuring the QT interval or looking for heart blocks is something the average GP can not do with ease. This needs to be acknowledge by NICE when suggesting that ECG to be part of the routine initial assessment.
34	The Primary Care Neurology Society	3	QS3	Training does help but it is a skill that can easily be lost if not practiced constantly. Guidance to encourage training in ECG interpretation is important. Also CCGs to device methods by which GPs can have their ECGs interpreted in a timely fashion by skilled practitioners.
35	Epilepsy Action	4	QS4	We believe that this draft quality statement accurately reflects the key areas for quality improvement. It is pleasing to see that 24 hours has been set as the referral time for those who have been identified as being at high risk of a serious event.
36	Epilepsy Action	4	Quality measures process	Yes, it will be possible to collect the data for the proposed quality measures.
37	British Medical Association	4	QS4	Referral for specialist cardiovascular assessment is reasonable and should be prompt but there is little to be gained by referral within 24 hours when waits for the opinion can run to several months. The length of the total patient journey is more important than presentation to referral time.
38	The Primary Care Neurology Society	4	QS4	Being aware of the red flags and assessing them is a crucial part of the initial risk assessment. Again this is an area that NICE should encourage local training for first-line practitioners
39	The Primary Care Neurology Society	4	QS4	I would suggest that a young adult who had TLoC on exertion should be seen within 24 hours by a specialist even if 12 lead ECG looked normal. This is not true however, for someone who had TLoC with history of mild heart failure. Although important, it is less life-threatening than the potential fatal dyrrhythmia of the formal
40	The Primary Care Neurology Society	4	QS4	Remote access to a specialist practitioner is important as this will ensure timely and appropriate advice as part of the assessment. First-line practitioners to conduct the initial assessment and have access for advice within 24hrs by phone, fax or email. This is more practical and achievable than the

ID	Stakeholder	Statement No	Comment on	Comments[1]
				suggested referral of all suspected cases within 24 hours.
41	The Primary Care Neurology Society	4	QS4	The specialist practitioner can be community based but important to be part of a MDT that includes a Heart Rhythm Specialist and Epiliptologist with access to event recorders, echocardiogram and neuro-physiology
42	Royal College of Paediatrics and Child Health	4	QS4	Clarify: Presumably it means assessed within 24 hours, not just referred within 24 hours.
43	Association of British Neurologists	4	QS4	We have some reservations for the need for every patient with TLOC and a murmur to be referred for urgent cardiovascular assessment in 24 hours. Not sure we have the capacity to see every elderly patient who may have postural hypotension and an aortic sclerotic murmur in an urgent 7 day access clinic. This would be a huge financial cost and feel uncertain about the absolute benefits. I am not sure daily TLOC clinics justified to meet this statement.
44	Epilepsy Action	5	QS5	We feel that this statement is not worded particularly well, although we understand the context and rationale. It would be a positive step in tackling the misdiagnosis of epilepsy.
45	Epilepsy Action	5	QS5	Epilepsy Action feels that although this statement is strangely, it does reflect the key areas for improvement and is a sensible and appropriate concept.
46	Epilepsy Action	5	Quality measures process	Epilepsy Action believes that it would be possible to collect the data for the proposed quality measures.
47	Royal College of Paediatrics and Child Health	5	QS5	Rephrase: In people who have had transient loss of consciousness, a brain scan (CT or MRI) and electroencephalogram (EEG) should be considered but not performed as a matter of routine.
48	Epilepsy Action	6	QS6	We believe that this does accurately reflect the key areas for quality improvement.
49	Epilepsy Action	6	Quality measures process	We believe that it would be possible to collect such data for the proposed quality measures.
50	Royal College of Paediatrics and Child Health	6	QS6	Omit and combine with Statement 4 (decision should be left with specialist).
51	Medtronic Ltd	6	Quality measures process	Medtronic welcomes the introduction of this Quality Standard to offer an ambulatory ECG as a FIRST LINE investigation for people with a suspected cardiac arrhythmic cause of syncope. Medtronic suggest an addition in the "Process" section of Quality Measure 6. From CG109 : *" **For people who***

ID	Stakeholder	Statement No	Comment on	Comments[1]
				have TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder." The addition of this information will provide greater clarity for selecting the most appropriate method of ambulatory ECG for detecting cardiac arrhythmias.
52	Epilepsy Action	7	QS7	This statement does reflect the key area for quality improvement; Epilepsy Action believes that it is incredibly important that people awaiting specialist assessment following transient loss of consciousness are advised not to drive.
53	Epilepsy Action	7	Quality measures process	If the structures and systems were in place, we do feel that it would be possible to collect the data for the proposed quality measures.

Stakeholders who submitted comments at consultation

- Association of British Neurologists
- British Geriatrics Society
- British Medical Association
- Department of Health
- Epilepsy Action

- Medtronic
- NHS England
- NHS Choices - Digital Assessment Service
- The Primary Care Neurology Society
- Royal Brompton Harefield NHS Foundation Trust
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians