NICE National Institute for Health and Care Excellence

2019 surveillance of transient loss of consciousness ('blackouts') in over 16s (NICE guideline CG109)

Surveillance report

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Surveillance decision

We will not update the guideline on transient loss of consciousness (TLoC).

During surveillance, editorial or factual corrections were identified. Details are included in the editorial amendments section.

Reasons for the decision

No new evidence was identified that suggested that the NICE guideline should be updated.

Feedback provided from topic experts suggested some areas that need to be reviewed. These areas are:

- Treatment of the causes of TLoC, primarily syncope and epilepsy. This was considered by some experts to be a gap in the guideline recommendations. However, the scope of the guideline states that it does not cover the treatment of syncope or epilepsy following diagnosis, but will signpost existing NICE guidance where this is available.
- Technological advances in implantable event recorders, which are not yet reflected in the guideline, and the need to update recommendations in this area. However, no evidence was cited and experts were not aware of any major, relevant new evidence.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in transient loss of consciousness (TLoC) remain up to date. The 2019 surveillance followed the 5-year static list review process, consisting of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews.
- Consideration of evidence from previous surveillance.
- Examining related NICE guidance and quality standards and National Institute for Health Research (NIHR) signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Consulting on the proposal with stakeholders.
- Considering comments received during consultation and making any necessary changes to the proposal.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Cochrane reviews

We searched for new Cochrane reviews related to the whole guideline. We found 1 relevant Cochrane review published between April 2014 and November 2018.

The Cochrane review (Solbiati et al. 2016) assessed the incidence of mortality, quality of life, adverse events and costs of implantable loop recorders (ILRs) compared with conventional diagnostic work-up in people with unexplained syncope. This is relevant to

recommendations 1.3.2.4 and 1.3.2.9 covering ambulatory electrocardiogram (ECG) recordings in assessment and diagnosis of unexplained syncope. The guideline recommends that 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 infrequently (less than once every 2 weeks), an implantable event recorder should be offered. A Holter monitor should not usually be offered unless there is evidence of a conduction abnormality on the 12-lead ECG.

The guideline committee concluded that the first choice of device should be based on the frequency of TLoC events previously experienced by the individual and that if this fails to capture an event, a device that monitors for a longer period should be considered at the discretion of the expert clinician, bearing in mind the clinical context and the patient's preference.

The results of the Cochrane review, based on very low-quality evidence, indicated that an ILR-based diagnostic strategy does not reduce long-term mortality compared with a standard diagnostic assessment, based on simple ECG recordings. No data were available for short-term all-cause mortality. Moderate-quality evidence showed that an ILR-based diagnostic strategy increases the rate of aetiologic diagnosis compared with a standard diagnostic pathway. Of the 4 included studies, 2 were already covered by the guideline in making its recommendations.

The review findings indicated that there is no strong evidence that an ILR-based diagnostic strategy might change patient-centred outcomes including mortality, adverse events, quality of life and syncope relapses. The review is therefore unlikely to impact on the guideline.

The following research recommendation from the guideline remains ongoing, in the light of the small number of studies of varying quality identified in the Cochrane review, and the highlighted need for further research:

- Under what circumstances is the implantable cardiac event recorder the investigation of choice for TLoC in people in whom a cardiac cause is suspected?

Previous surveillance

2014 surveillance

We also considered studies identified in previous surveillance. For the 4-year surveillance review in 2014, a search to identify new evidence was carried out for articles published between 4 October 2011 (the end of the search period for the evidence update) and 29 April 2014, and relevant abstracts were assessed. As a diagnostic guideline, the search strategy included observational studies in addition to randomised controlled trials and systematic reviews. Only evidence that met the criteria for inclusion detailed within the original guideline was included within this surveillance review. No new evidence was identified through the literature search that would invalidate the guideline recommendations. Clinical feedback was also obtained from members of the guideline committee through a questionnaire survey. Areas highlighted for potential updating, but with insufficient evidence to impact on the guideline were:

- The role of tilt testing compared with ILRs in patients with reflex syncope. However, further topic expert feedback indicated that reviewing the use of tilt testing would be premature and further studies would be needed to provide clarity on the use of the test for determining which patients need cardiac pacing.
- Diagnosis of psychogenic non-epileptic seizures. However, using the criteria detailed within the guideline, no substantial evidence relating to this area was identified.
- Telephone triage as an alternative route of presentation. The new evidence indicated that a pre-hospital triage via tele-cardiology for emergency medical service patients may be effective service delivery approach for detecting patients with cardiac arrhythmias. However, this study was not considered to have any impact on the guideline because of indirectness to the UK setting, and the absence of comparator approaches to arrhythmia detection.

The 4-year surveillance review concluded that the NICE guideline should not be considered for an update at that time.

It was proposed that the guideline should be transferred to the static guidance list because it fulfilled the following criteria:

- No evidence was identified that would impact on the current guidance and no major ongoing studies or research had been identified as due to be published in the near future (that is, within the next 3–5 years).

Evidence update (2012)

We also considered studies identified in an evidence update in 2012. Evidence updates were produced by NICE to highlight new evidence relating to published NICE guidelines. The evidence update indicated that there was new evidence worthy of consideration in future reviews of the guideline in 2 areas:

- The clinical history, including immediate pre-event symptoms such as breathlessness, which may distinguish between non-cardiac syncope and cardiac syncope. Breathlessness is a red flag symptom for cardiac syncope (recommendation 1.1.4.2) and, as such, the included study supported current recommendations. It also emphasised the importance of a detailed clinical history, and suggested that pre-event symptoms may play a useful role in distinguishing between non-cardiac and cardiac syncope. These findings were deemed worthy of consideration in later reviews of the NICE guideline, but no new evidence was identified in the current surveillance review to impact in this area.
- Psychogenic non-epileptic seizures (PNES) are a common cause of TLoC. This fact is already highlighted within the guideline but the study included in the evidence update is not a diagnostic accuracy study and hence does not meet the criteria set within the guideline for inclusion within the evidence base. The guideline committee did not carry out a full review of the literature on psychogenic pseudosyncope or PNES, outside diagnostic test accuracy studies. They considered that this topic should be dealt with as a separate guideline. Meanwhile, the guideline committee recognised that some guidance in the TLoC guideline was needed for people with suspected psychogenic pseudosyncope or PNES and made a recommendation accordingly (recommendation 1.4.1.1).

Related NICE guidance

The NICE guideline is listed as related guidance in the NICE medtech innovation briefing on CareLink network service for remote monitoring of people with cardiac devices. The CareLink network service allows a person's implanted Medtronic cardiac device to be remotely monitored by a health professional. Data collected from the device are

transferred securely to their clinician for review. CareAlert notifications are also generated and sent to the clinician if a clinical event or a problem with the device or device leads is detected.

The NICE guideline on TLoC does not make recommendations for remote monitoring of cardiac device data, but an amendment will be made to include the NICE briefing on CareLink network service in the NICE Pathway on TLoC, alongside the related briefing on remote ECG interpretation consultancy services for cardiovascular disease. NICE Pathways bring together everything NICE has said on a topic in an interactive flowchart.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, none were assessed as having the potential to change recommendations.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to the NICE guideline.

We sent questionnaires to 9 topic experts and received 4 responses. The topic experts were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

Technological advances

Topic experts noted that the recommendations reflected clinical practice, and technology available, at the time of publication, and that some recommendations now look out of date. The implantable event recorders were stated to have evolved, being smaller, easier to insert, and more widely used. Mobile phone videos were also highlighted as being widely used by specialists in current practice. However, no evidence was cited that would impact on recommendations and experts were not aware of any major new evidence.

Treatment

Some expert opinion also highlighted that the NICE guideline has dealt with only risk stratification and not treatment of patients with TLoC. However, the scope of the guideline states that it does not cover the treatment of syncope or epilepsy following diagnosis, but will signpost existing NICE guidance where this is available. In the absence of NICE guidance on syncope, some experts considered that an extension to the scope could potentially add value in this area. The only evidence cited was the European Society of Cardiology's guidelines for the diagnosis and management of syncope, which are listed as related guidance in the NICE guideline. In the consultation, stakeholders did not consider it necessary to expand the scope to incorporate syncope.

Experts also raised the question of whether there should be a recommendation about when to refer to a syncope unit, but no evidence was cited.

Implementation of the guideline

In terms of implementation and uptake of the guideline, experts indicated that:

- There has been an increase in the use of ILRs for investigating patients with TLoC.
- There are challenges to the full implementation of this guideline because TLoC is not on the top of the priority list of many clinical commissioning groups, due to competing interests from other disease conditions.
- More needs to be done to educate primary care about the appropriate assessment of these patients to reduce the significant amount of inappropriate referrals to neurology, which in the first instance, should have been referred to cardiologists instead. This results in a delay of assessment and treatment of patients with syncope.

These areas will be passed on to the NICE implementation team to address in supporting the implementation of the guideline. To assist in primary care education about appropriate assessment, NICE will include a link to its forthcoming guidance on suspected neurological conditions from its pathway on TLoC.

Other sources of information

We considered all other correspondence received since the guideline was published. An enquiry was received from the NHS Business unit relating to a Coroner's report on the

death of a man due to arrhythmogenic right ventricular cardiomyopathy. The report highlighted the following areas:

- The evidence revealed inconsistent approaches to advising fit young athletes with syncope about future exercise. The Coroner acknowledged that syncope was a red flag prompt in this context. Although the person was advised to avoid rigorous exercise, this was not further defined, and professional opinion as to the level of acceptable activity in the circumstances differed.
- Although there has been greater awareness since 2010 both locally and nationally of the need for timely and appropriate management of syncope in young athletes, the approach to the problem does not appear to be consistent nationally and there is a continuing need to emphasise and act on this issue.

NICE was asked to address these concerns. The NICE guideline on TLoC was highlighted in response, with recommendation 1.1.4.2 advising referral within 24 hours for specialist cardiovascular assessment by the most appropriate local service, for anyone with TLoC who also has TLoC during exertion.

NICE has not made any specific recommendations on the acceptable level of exercise a person should undertake. However, recommendation 1.3.2.2 advises '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'.

It is important to note that the scope of the NICE guideline does not include the development of specific recommendations on the amount of exercise that would be appropriate for people with differing levels of fitness. In addition, although the guideline covers the initial management of people who have experienced a TLoC and further diagnostic investigations within secondary care, including specialist blackout clinics, it does not cover treatment in secondary care following diagnosis. NICE has not published any advice on the management of syncope post diagnosis.

The NICE guideline makes recommendations on the general management of TLoC. It does not cover the specific needs of individual patients after treatment in primary care. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the

recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

No further action is considered necessary.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to not update the guideline, we consulted with stakeholders.

Overall, 8 stakeholders commented, of whom 6 agreed with the proposal to not update the guideline and 2 disagreed. The stakeholders comprised professional bodies, government organisations, an NHS trust and a medical technology company.

Telephone triage

One stakeholder commented that the guideline refers to 'presentation to the ambulance service', without recognising that in many instances the ambulance service will receive contact about a person with TLoC via a telephone call to 1 of its call handlers. These are non-clinicians and follow a menu of prompts and responses to achieve 'telephone triage'. According to the stakeholder, they are not able to carry out many of the actions recommended in the guideline, see section 1.1 on initial assessment. For those to be carried out promptly and effectively, the stakeholder commented that the only option would be to commit an emergency ambulance crew or first-responder paramedic to attend many low-risk cases of TLoC. It was further stated that the majority would need to be taken to the nearest hospital emergency department, potentially adding unnecessary burdens to the workload of both the ambulance service and the emergency department. However, no evidence was submitted, or identified in the current or previous surveillance review, about ambulance telephone triage and how to determine, by this medium, whether or not a patient requires urgent assessment for TLoC in emergency care.

To explore this issue further, additional consultation was undertaken with experts, including those with paramedic expertise. This led to the following feedback:

- The initial 999 call to the ambulance service is handled by an emergency medical dispatcher call handler trained to operate algorithmic software and to provide pre-arrival instructions. In some cases, this would result in the immediate dispatch of an ambulance, or in other cases the call would be diverted to NHS111 or placed in a queue for a healthcare professional to call the patient back from the ambulance control room.
- Healthcare professionals who call patients back and conduct telephone assessments are able to use further professional discretion and judgement in managing patients and would be able to assess some cases of TLoC remotely.
- In some cases, an emergency response and face-to-face assessment will be the most appropriate course of action. However, paramedics are registered healthcare professionals trained in initial assessment and it is not the case that most of the low-risk patients would need to be taken to hospital. NICE's guideline on emergency and acute medical care covers emergency and acute medical care in the community, including the role of advanced paramedic practitioners, to reduce the need for unnecessary hospital admissions.
- The outcome from the call would be the most appropriate response for the individual patient based on evidence-based protocols or algorithms and would not result in an emergency ambulance if not warranted.

In contrast to the stakeholder's comment, the collective expert feedback indicated that the initial assessment recommendations can be implemented by ambulance services. However, expert feedback did indicate the need to amend the text of the recommendation on further immediate management, as detailed below, to clarify the presentation of people with TLoC to ambulance services.

Ambulance service assessment

A stakeholder commented that there is a need for more guidance for ambulance services in the initial assessment of patients presenting with non-life threatening or incidental findings. However, an existing implementation tool slide set aims to ensure that relevant recommendations are made available to ambulance services in a digestible format.

The same stakeholder stated that the ambulance service can also screen for potential undiagnosed cardiac conditions, by forwarding ECGs to specialists in secondary care. However, new recommendations in this area would need supporting evidence in local settings to demonstrate the benefits. In the absence of such evidence, no impact on the

guideline is anticipated. New evidence will be considered at the next surveillance review.

See appendix A for full details of stakeholders' comments and our responses.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Editorial amendments

During surveillance of the guideline, we identified the following points in the guideline that should be amended.

Initial assessment: further immediate management

Following expert and stakeholder feedback, recommendation 1.1.4.6 should be amended to the following text:

'If the person contacts the ambulance service, take them to the emergency department unless they express symptoms of an uncomplicated faint or situational syncope. See NICE's guideline on emergency and acute medical care for further advice on providing emergency and acute medical care in the community to reduce the need for hospital admissions.'

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that no update is necessary.

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