

Surveillance proposal consultation document

2019 surveillance of [Transient loss of consciousness](#) (NICE guideline CG109)

Surveillance proposal

We propose to not update the guideline on transient loss of consciousness.

During surveillance editorial or factual corrections were identified, which will be addressed through editorial amendments.

Reasons for the proposal to not update the guideline

No new evidence was identified which suggested NICE guideline CG109 should be updated.

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

- Treatment of the causes of transient loss of consciousness (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. The guideline will also link to the updated European Society of Cardiology's [guidelines on diagnosis and management of syncope](#).
- Technological advances in implantable event recorders. However, no evidence was cited and experts were not aware of any major new evidence.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in [Transient loss of consciousness](#) (NICE guideline CG109) remain up to date. The 2019 surveillance followed the 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 NIHR signals.
- A search for ongoing research.

- Examining the NICE event tracker for relevant ongoing and published events.
- Consulting on the proposal with stakeholders (this document).

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 workup 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 which 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 to 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](#) 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 4th October 2011 (the end of the search period for the evidence update) and 29th 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 were included within this surveillance review. Clinical feedback was also obtained from members of the guideline committee through a questionnaire survey. Generally the guideline committee felt that the guideline did not need to be updated. 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 CG109 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 to potentially generate future change in 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 future reviews of NICE CG109, 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 (1.4.1.1).

Ongoing research

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

Related NICE guidance

NICE guideline CG109 is listed as related guidance in the NICE Medtech innovation briefing [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 is 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.

CG109 does not make recommendations for remote monitoring of cardiac device data, but an amendment will be proposed to include NICE Medtech innovation briefing 64 in the NICE Pathway for TLoC, alongside the related briefing on [Remote ECG interpretation consultancy services for cardiovascular disease](#).

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 NICE guideline CG109.

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 NICE guideline CG109 has dealt with only risk stratification and not treatment of patients with TLoC. Healthcare professionals treating such patients would welcome direction about the utility or futility of various treatment options available for managing these patients which they encounter in day to day clinical practice. For example, the role of various medications or pacemakers, and optimum treatment of patients between the ages of 18 and 40 years. 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 were the European Society of Cardiology's [Guidelines for the diagnosis and management of syncope](#), which are listed as related guidance in the short version of the NICE guideline. The link to this will be updated to the current version as an editorial amendment.

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 the implantable loop recorder for investigating patients with TLoC.

- There are challenges to the full implementation of this guideline as, due to competing interests from other disease conditions, TLoC is not on the top of the priority list of many clinical commissioning groups.
- 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.

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.
- While 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. NICE guideline CG109 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, 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 NICE guideline CG109 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 black-out clinics, it does not cover

treatment in secondary care following diagnosis. NICE has not published any advice on the management of syncope post diagnosis.

NICE guideline CG109 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 is to not update the guideline, we are consulting with stakeholders.

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.

Short version of NICE guideline

- The link to the European Society of Cardiology guidelines on diagnosis and management of syncope in footnote 6 of the short version of NICE guideline CG109 is broken. It should be replaced by the following URL for the updated version of the guidelines:
 - <https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Syncope-Guidelines-on-Diagnosis-and-Management-of>
- The following link in footnote 8 of the short version of NICE guideline CG109 (footnote 2 of the full guideline) is broken:

Please refer to the [DVLA](#) for further information.

This broken URL should be replaced by the following URL:

<https://www.gov.uk/guidance/neurological-disorders-assessing-fitness-to-drive>

Overall surveillance proposal

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

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