NICE National Institute for Health and Care Excellence

Interim clinical guideline surveillance process and methods guide 2013

NICE process and methods

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Contents

1 Purpose

This is not the current manual. From January 2015, guidelines were checked according to Developing NICE guidelines: the manual.

This guide outlines the main elements of the interim NICE clinical guideline surveillance process and methodology, which was agreed by the NICE Board in July 2013. This process will be used to restart the Centre for Clinical Practice (CCP) clinical guideline surveillance (previously 'review') programme for deciding whether a published guideline needs to be updated (which was suspended in January 2013). The interim process and methods will replace the process and methods described in sections 14.1 and 14.2 of the NICE guidelines manual 2012. After evaluation (see section 8), the process will be used to inform the NICE guidance development project and will be subject to formal consultation.

2 Background

These interim process and methods aim to address concerns about the previous process (for example, the resource intensity of focused literature searching) while retaining best practice (for example, involving technical and methodological analysts and subject content experts from guideline development groups [GDGs]). In this interim surveillance process, there is a change in the frequency and type of surveillance evidence reviews from full reviews every 3 years to alternate rapid and full reviews every 2 years.

Clinical guidelines developed by NICE are published with the expectation that they will be regularly reviewed and updated as necessary. Any decision to update a guideline must balance the need to reflect changes in the evidence against the need for stability, because frequent changes to guideline recommendations would make implementation difficult. There are inherent risks that a new and less exhaustive surveillance methodology (for the 2-year, 6-year and 10-year reviews; see section 4) might have a lower sensitivity to determine which guidelines need updating, although these risks will be balanced against a new surveillance process that will allow decisions to be revisited more frequently.

The purpose of the guideline surveillance process is to maintain a clinically relevant library of guideline topics, because advances in medicines and technologies may lead to guideline recommendations becoming obsolete. There is little published evidence about guideline surveillance or review methodology, but a recent analysis found that 14% of NICE clinical guidelines need a substantial update 3 years after their publication; by 5 years this increases to approximately 50%. However, it has also been found that, although a guideline may not need a substantial update, there are often small discrete areas that could be updated, but previously NICE has not had the capacity or processes to deal with these. This is being addressed through a separate pilot programme for conducting rapid updates.

The process and methods described here do not affect reviews of published guidelines that arise as a result of exceptional circumstances (safety concerns, withdrawal of drugs or interventions, significant changes to legislation, etc.), as described in section 14.4 of the NICE guidelines manual 2012. These will continue to be assessed on a case-by-case basis without the need for a formal guideline surveillance review.

3 Principles of the interim surveillance process and methods

Given the number of guidelines that will make up the library of guideline topics, the number of surveillance reviews needed will be considerable. To address this, the new surveillance process and methods are more streamlined. The process is more adaptive, with a less resource-intensive surveillance at the 2-year, 6-year and 10-year time points, and a more thorough methodology at 4 and 8 years. At the same time, the threshold for proposing an update is reduced – that is, smaller rapid updates can be carried out. Overall, more surveillance reviews will be conducted using this model of 2-year intervals, but the most resource-intensive type of review will occur less often than before.

The interim surveillance process broadly relies on assessing 2 elements that influence the decision to update a published guideline:

- intelligence gathering on the perceived current relevance of the guideline (from a variety of sources, such as Guideline Development Group (GDG) questionnaires and topic searches by the NICE Information Services team) **and**
- primary or secondary evidence that has been published since guideline publication (which will be informed by the first element).

The surveillance review at each time point will be based on a cumulative assessment of all evidence published since guideline publication.

Although surveillance reviews are not formal NICE guidance and so are not subject to the same level of scrutiny as other NICE products, the underlying principles of transparency of process and methodological rigour still apply.

4 Structure of the surveillance process

A number of elements are common to all surveillance reviews, but for some time periods specific tasks need to be undertaken.

4.1 The 2-year review

The aim of the 2-year surveillance review is to assess quickly whether a recently published guideline needs updating. Therefore the process at 2 years after publication is to identify the occasional guideline that needs a rapid update.

The related NICE Evidence Update will be used as the basis for judgements about changes in evidence since guideline publication. Surveillance is limited to the scope of the existing guideline. As described in the current Evidence Updates process, the number of studies summarised is limited, following thorough sifting of search results and final prioritisation by the Evidence Update Assessment Group (EUAG) chair.

The views of the original Guideline Development Group (GDG) members will not formally be sought, because these will be captured through comments on the new evidence from the EUAG, which will regularly include former GDG members. However, the decision about whether to update the guideline or not will be discussed with the GDG chair and/or clinical adviser.

See appendix A for an algorithm outlining the process for the 2-year review (and also those for other time points).

4.2 The 4-year and 8-year reviews

The surveillance reviews at 4 and 8 years after guideline publication will involve a more rigorous exploration of any changes in the evidence base than those undertaken at other time points. A broad search will be used to identify any new studies available. This process is similar to that used previously for 3-year reviews.

The focus of the surveillance review will be on the original scope of the guideline, but any additional clinical areas or changes in clinical practice that are identified during intelligence gathering will also be considered.

Information about the existing guideline will be sought from a number of standard sources by the NICE Information Services team, including a check of the status of related NICE guidance. The original GDG members will be surveyed to get their opinions on the relevance of the existing guideline, recent developments in the topic area and their knowledge of any new important evidence since publication of the guideline.

A thorough literature search will be conducted by Information Services across a range of databases (for example, Medline, Medline In-Process, Embase and Cochrane as standard sources).

4.3 The 6-year and 10-year reviews

The 6-year and 10-year surveillance reviews offer additional rapid assessments of whether a published guideline needs updating. At 6 and 10 years, the task will be to identify the topics for which a substantial update is still not needed. These reviews will be limited to the scope of the existing guideline.

Intelligence about the existing guideline will be sought from a number of standard sources and the original GDG members will be surveyed as described in section 4.2.

A limited literature search will be conducted by NICE Information Services identifying systematic reviews only. The same range of databases will be searched as for the 4-year and 8-year surveillance evidence reviews.

4.4 All review time points

All new evidence will be summarised in a surveillance decision document by a Centre for Clinical Practice (CCP) analyst, and any studies that may have an important impact on one or more recommendations will be highlighted. An overall summary of the main themes of the new evidence across the guideline will also be provided. This information will form the basis of either a public consultation document or a NICE Guidance Executive decision paper.

5 Stakeholder consultation

As agreed by the NICE Board in December 2012, there will be no consultation on surveillance decisions resulting from the 2-year, 6-year or 10-year reviews. Consultations will take place at the 4-year and 8-year time points (and at every 4-year time point thereafter) when a 'no update' decision is being considered.

We will also consult with stakeholders when it is proposed that a clinical guideline should be either withdrawn or placed on the static list (see section 14.3.3 of the NICE guidelines manual 2012).

6 Key elements of the surveillance process

Table 1 summarises the key elements at each review point.

Table 1 Key elements of the surveillance process

Time since publication	Key elements of the surveillance process
2 years	• Surveillance limited to scope of existing guideline • Surveillance review based on related Evidence Update product • No public consultation
4 years	• Surveillance will also consider key areas outside the scope of the existing guideline • NICE Information Services literature search, and summary of new evidence • Intelligence gathering (including Information Services topic search of standard sources and guideline development group [GDG] questionnaire) • Public consultation only on 'no update' decisions
6 years	• Surveillance limited to scope of existing guideline • Limited surveillance evidence review and summary of new evidence (with limits imposed, such as including evidence from systematic reviews only) • Intelligence gathering (including Information Services topic search of standard sources and GDG questionnaire) • No public consultation

Time since publication	Key elements of the surveillance process
8 years	• Surveillance will also consider key areas outside the scope of the existing guideline • Information Services literature search, and summary of new evidence • Intelligence gathering (including Information Services topic search of standard sources and GDG questionnaire) • Public consultation only on 'no update' decisions.
10 years	• Surveillance limited to scope of existing guideline • Limited surveillance evidence review and summary of new evidence (with limits imposed, such as including evidence from systematic reviews only) • Intelligence gathering (including Information Services topic search of standard sources and GDG questionnaire) • No public consultation

7 Decisions about whether an update is needed

The decision-making process will be the same at all surveillance time points.

It will be based on a balanced assessment of new evidence that has become available since guideline publication and the views of the Guideline Development Group (GDG) and other sources of information about the continued relevance of the guideline. The findings of the surveillance review and the proposed decision will be discussed with the chair or clinical adviser of the original GDG. A surveillance review proposal will be made initially by the Centre for Clinical Practice (CCP) analysts who conducted the review, and will reflect their knowledge of the existing guideline and experience of undertaking reviews of this nature. All surveillance review proposals will go through an internal validation process (including sign-off by the Technical Adviser, Associate Director and CCP Director) before submission to NICE Guidance Executive.

The surveillance review proposal will be one of the options shown in table 2.

Table 2 Possible surveillance review proposal options

Decision	Outcome and actions
Substantial update	Commissioned using standard guideline development process (see the NICE guidelines manual 2012).
Rapid update	Commissioned using the Updates Standing Committee process (in development).
No update	• Review again at next surveillance time point **or** • Bring forward next surveillance evidence review time point. This decision would be made exceptionally – for example, if it is clear that new evidence critical to the decision is in the process of being published. Consultation with stakeholders only at 4-year and 8-year surveillance evidence reviews.

Decision	Outcome and actions
Transfer to the static list	Topics that have undergone a full surveillance evidence review with 'no update' proposed will be considered for the 'static list', with public consultation on the decision. Guidelines on the static list will remain extant and will be assessed again after 5 years.
Withdraw the guideline	The guideline no longer applies. This decision would be made exceptionally – for example, it may be decided that the recommendations in a guideline no longer apply but that the guideline is not of sufficiently high priority for updating. In this case the guideline will be withdrawn. Consult with stakeholders on the decision.

The final decision on whether to update a clinical guideline in whole or in part (the surveillance review decision) will be taken by NICE Guidance Executive following advice from the CCP Director.

8 Evaluation of interim guideline surveillance process and methods

The interim process and methods will be evaluated over a 12-month period from August 2013, to test whether reproducible and valid review decisions are being made, and whether the programme can be delivered with the resources available. After evaluation, this process and methods guide will be used to inform the guidance development project methods and process manual, which will be consulted on.

Appendix A: Interim clinical guideline surveillance process and methodology: algorithms at different time points

Figure 1: 2-year time point

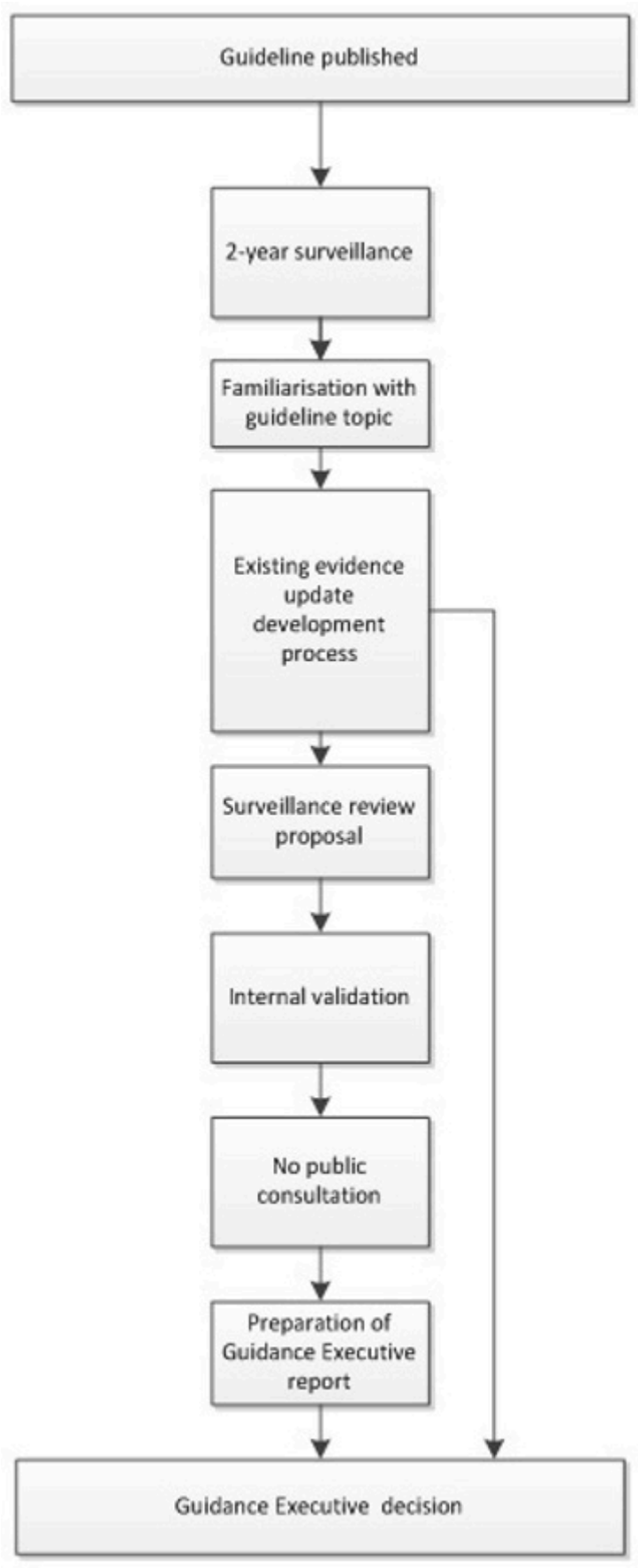


Figure 2: 4-year and 8-year time points

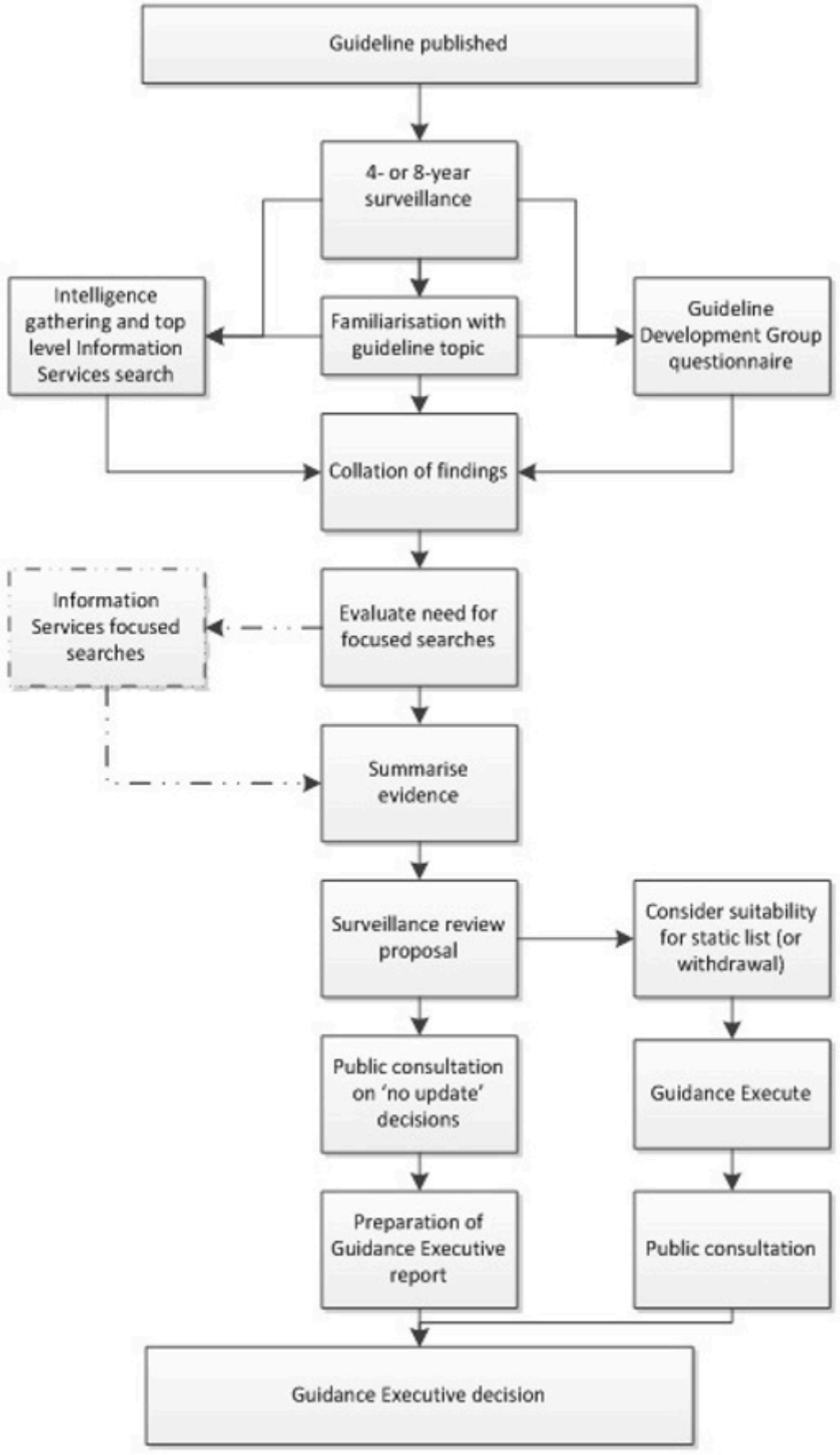
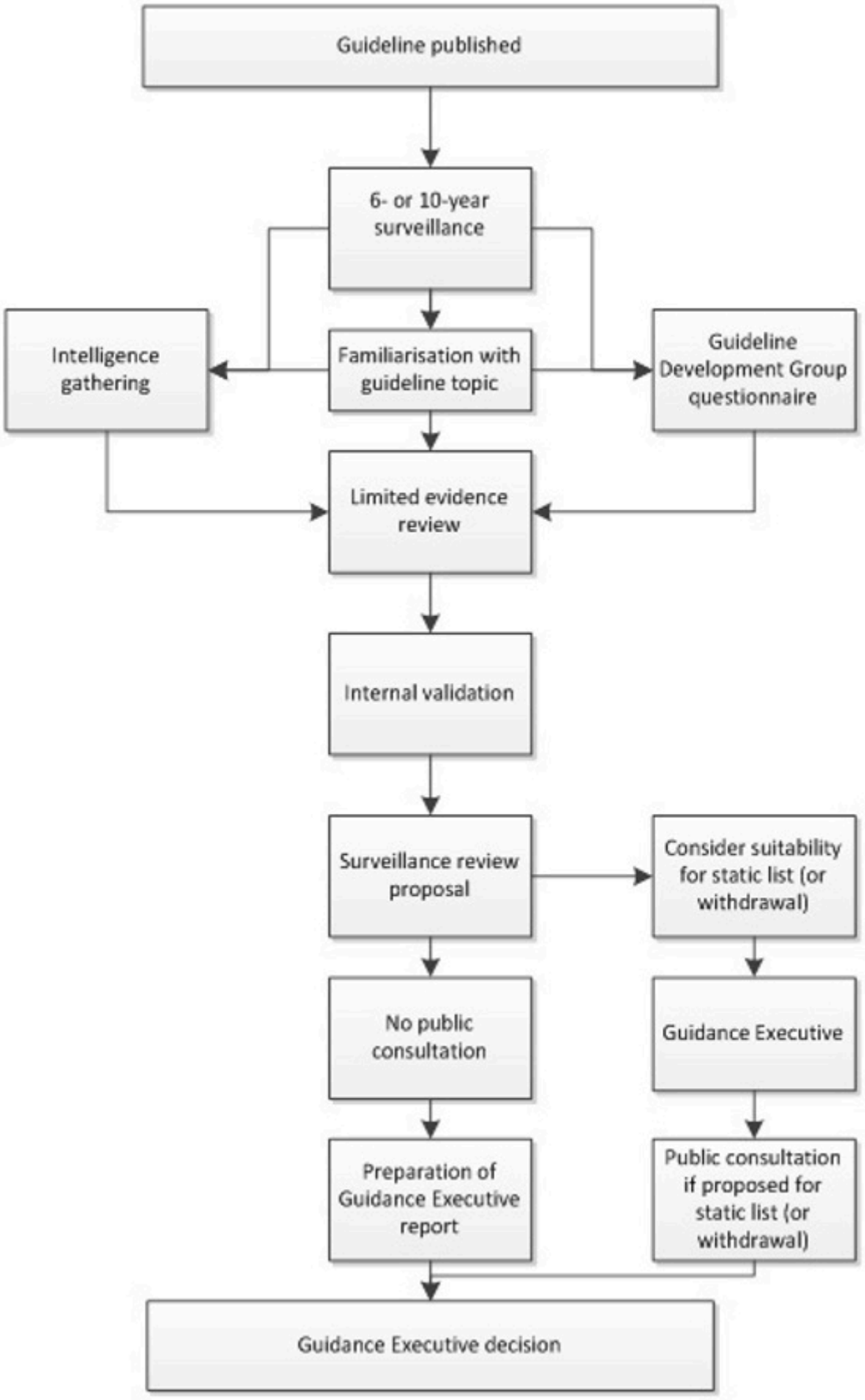


Figure 3: 6-year and 10-year time points



Update information

Minor changes since publication

September 2013: Editorial changes and clarification.

About this guide

This guide describes the NICE interim clinical guideline surveillance process and methodology. It will be updated as described in section 8.

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