NICE National Institute for Health and Care Excellence

Processes and methods for NICE-wide guidance surveillance

NICE process and methods
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NICE-wide guidance surveillance

This guide describes the methods and processes that NICE follows to assess the impact of new evidence, changes to the health and care system, or other new, relevant information that has come to light after NICE guidance has published.

Previously, processes and methods for guidance surveillance were set out separately in the process and methods guides for each NICE guidance-producing programme. This guide replaces these individual documents, bringing together the processes and methods for surveillance activity across NICE.

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Aims of surveillance

During surveillance, NICE identifies information that contradicts, reinforces or clarifies our guidance recommendations. This process informs decisions on whether guidance recommendations should be updated, amended, retired, or incorporated into another guidance product.

The surveillance process must therefore gather enough information to inform these decisions.

The NICE prioritisation board makes some of the decisions on whether to change guidance. It follows the methods and processes set out in the NICE-wide topic prioritisation manual.

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Planning surveillance activity

Surveillance activity must be proportionate and targeted so that it identifies information that is most likely to have an impact on guidance recommendations.

As a minimum, NICE considers:

- evidence (including research or other data) or system intelligence (that is, information about how the health and care system operates, including about policy, and service organisation and delivery) provided by individuals, organisations or groups; we call this reactive monitoring
- MHRA safety information, including from the NHS Central Alerting System (CAS) and as Drug Safety Updates.

In addition, for each piece of guidance, or group of recommendations within a piece of guidance, we consider whether further proactive surveillance is needed. This can include:

- proactive tracking of other events (such as ongoing clinical trials or anticipated changes to technologies) that are expected to have an impact on guidance recommendations
- a planned surveillance review after publication of the guidance.

For priority areas, we also gather system intelligence and seek information about trends in emerging evidence that might impact NICE guidance (see NICE's webpage on priority topics).

Decisions about what surveillance activity is needed for each piece of guidance, or group of recommendations within a piece of guidance, are taken when the guidance is published. We may also change a decision when information becomes available to suggest we need to take a different approach (such as information gathered through reactive monitoring).

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Monitoring

Reactive monitoring

We assess information that comes from individuals, organisations or groups through NICE's topic suggestion webpage to see if it could impact on our guidance. We may also receive information, for example about guidance that is potentially outdated or inconsistent with new evidence, through other teams at NICE, including the enquiry handling team and guidance-producing teams.

Monitoring of safety information

NICE's patient safety oversight group receives and considers safety information from:

- the Health Services Safety Investigations Body (HSSIB)
- Reports to Prevent Future Deaths (also known as regulation 28 or Prevention of Future Death [PFD] reports) from the Courts and Tribunals Judiciary
- the MHRA, through Drug Safety Updates and alerts from the NHS Central Alerting System
- other key external partners, including NHS England's National Patient Safety Committee, the Patient Safety Commissioner, NHS Resolution, the Care Quality Commission and the Maternity and Newborn Safety Investigations programme
- NICE's medicines optimisation team, the enquiry handing team and other internal teams.

The patient safety oversight group, in collaboration with other key NICE teams, looks for and shares safety information that may have an impact on guidance recommendations, and proposes the actions to be taken (see NICE's webpage on patient safety).

Proactive tracking

NICE keeps track of potential developments that are likely to have an impact on guidance recommendations. These include developments that could lead to a change in the

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strength of a guidance recommendation or the action we are recommending. For example, changing a recommendation:

- that a technology should not be used to a recommendation that it can be used, and vice versa
- from use only in research to use in routine care.

See the types of recommendations NICE can make and the section on strength of recommendations in the NICE guidelines manual.

NICE identifies areas where there may be future developments that it needs to proactively track:

- when the guidance is published
- if new information is identified after publication (for example, through reactive monitoring).

Potential developments could include:

- ongoing research studies
- a generic or biosimilar medicine becoming available at a lower cost
- planned changes to the health and care system
- anticipated changes in the regulatory status of a technology or medicine, or regulatory extensions to its approved indication (for example, if the licence for a medicine or technology is anticipated to be changed so that it covers a larger group of people).

Proactive information seeking

For areas that have been identified as priorities in the NHS 10 Year Health Plan for England, NICE proactively gathers system intelligence and seeks information about trends in emerging evidence that might impact NICE guidance, through engagement with NHS organisations, Royal Colleges and other national bodies. NICE also gathers intelligence internally through the work of its Impact and Partnerships directorate and other teams who do horizon scanning.

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Responding to information identified through monitoring

NICE considers the impact of information identified through monitoring and decides whether further action is needed. Further actions could include:

- changing the wording of recommendations (for example, to add clarity to or reduce ambiguity of a recommended action).
- carrying out a surveillance review, if more information is needed to inform a proposal as to whether to update NICE guidance.

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Surveillance reviews

During a surveillance review, NICE actively seeks new evidence and other information, such as topic expert feedback, changes to legislation or policy, and information about implementation. When appropriate, routinely collected health data, such as real-world evidence, may be sought. This information is brought together and assessed against the guidance to inform a proposal as to whether the recommendations should be updated, amended, retired, or incorporated into other guidance.

A surveillance review can be done in response to information identified through monitoring (reactive surveillance review), or it can be planned.

Reactive surveillance reviews

Subject to constraints on capacity, NICE carries out reactive surveillance reviews if new information is received through monitoring that is likely to have an impact on guidance recommendations and needs further investigation. This informs a decision on whether to make any changes to guidance.

Planned surveillance reviews

A surveillance review may be planned if there is uncertainty around the evidence used to develop guidance recommendations (for example, if there is a close balance between benefits, harms and costs, or there is a lack of high-quality evidence), and research is planned, or underway, that could address this uncertainty.

NICE plans when the surveillance review will be done, based on when the new information is likely to become available.

Activities included in surveillance reviews

How NICE carries out surveillance reviews depends on the nature of the guidance, the evidence that informed the guidance recommendations, and any new information identified through monitoring. The aim of the review is to provide enough information to allow a decision on whether to make any changes to guidance. A review could involve:

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- searching for new evidence
- seeking the views of topic experts (for example, current and previous NICE committee members)
- requesting information from the company that produces a medicine, technology or device
- examining and analysing routinely collected data (for example, on the uptake of a procedure, technology or medicine)
- seeking information on the current price of a technology, medicine, test or other intervention
- searching for guidance produced on the same or related topic by other health technology assessment agencies or guidance developers
- seeking the views of other teams within NICE or external organisations.

Surveillance review outcomes

NICE produces a surveillance report that summarises the evidence and intelligence identified through the surveillance process and explains the reasons for the proposed outcome or outcomes. For topics considered by NICE's prioritisation board, we publish a short summary of this surveillance decision.

Possible outcomes include:

- updating or amending the guidance (which could involve collaborating with another organisation)
- retiring guidance or guidance recommendations
- incorporating recommendations into other NICE guidance
- proactively tracking developments that are likely to have an impact on guidance recommendations in the future
- doing a planned future surveillance review
- publishing a supplementary document that includes technical and pricing information

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to allow the 2 technologies to be compared, if the guidance remains valid but a newer version of a technology is available

- no further action.

NICE's prioritisation board uses information gathered in surveillance reviews to make decisions about our future work, as set out in the NICE-wide topic prioritisation manual.

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