# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Developing NICE guideline recommendations: the manual

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## Appendix L: Process and methods for guidelines developed in response to health and social care emergencies

### Introduction and overview

These process and methods are for the development, surveillance, updating and withdrawal of guideline recommendations developed in response to national health and social care emergencies.

The Civil Contingencies Act 2004 defines national health and social care emergencies. We will consider developing emergency guidelines in these situations if immediate action is needed on a national level to preserve or protect the ability of the health and social care sector to respond appropriately (for example the COVID-19 pandemic).

During health and social care emergencies, urgent guidelines are needed within a few days to a few weeks. The development time depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed, and the likely volume of evidence.

Depending on the nature of the health and social care emergency and how urgently the system needs advice, it may be the case that guidelines are developed first and recommendations on medicines are then superseded by NICE technology appraisal guidance. In this scenario, the relevant teams will discuss the most appropriate approach for integrating the NICE technology appraisal guidance into the guideline and when this should happen.

The recommendations developed to support the system during the emergency are subject to a living approach consisting of a frequent review of the evidence and regular updating as needed.

The short development time imposes trade-offs around shortening, omitting or accelerating the processes and methods used for developing standard NICE guidelines. However, transparency of decision making and reporting is one of NICE's core principles, underpinning the development of all NICE guidance. Transparency ensures that users can make judgements on the credibility and applicability of the guideline recommendations.

The short development time also means it is not possible to recruit a full independent advisory committee, as we do for standard guidelines. However, emergency guidelines still have an independent panel of experts to provide advice (see the section on independent advisory expert panel for more information).

### Topic selection

The topics to cover and how quickly emergency guidelines are needed is agreed with the relevant commissioning body (for example, NHS England, the UK Health Security Agency (UKHSA) or the Department of Health and Social Care).

### Who is involved

The guideline is developed by a development team (see the section on the health and social care emergency guideline development team), working with an independent advisory expert panel (see the section on the independent advisory expert panel).

Pragmatic checks and reviews are carried out iteratively throughout guideline development by staff with responsibility for quality assurance (see the section on guideline review and signoff).

During guideline development, we engage with stakeholders on the draft guideline. The length of time for this engagement depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed, and the likely volume of evidence (see the section on consultation).

Staff with responsibility for guideline surveillance undertake a pragmatic targeted approach to surveillance for emergency guidelines (see the section on surveillance and updating process).

Updating emergency guidelines is undertaken by staff with responsibility for guideline development. Targeted stakeholders are consulted on the draft update before publication. The length of time for this consultation depends on the urgency of the update (see the section on rapid evidence-based updates to recommendations).

All emergency guidelines and evidence-based updates are signed off by NICE's guidance executive.

**Independent advisory expert panel**

Because of the short development time for emergency guidelines, open recruitment of a topic-specific guideline committee is not feasible or practical. An independent advisory expert panel consisting of topic experts is used instead. The number of topic experts in the independent advisory expert panel depends on the urgency of the referral, the complexity of the topic, the number of questions to be addressed and the likely volume of evidence.

When possible, the same independent advisory expert panel that developed the original recommendations should be used when updating a guideline.

**Selecting topic experts**

Selection of topic experts is based on the expertise needed to develop recommendations in the areas defined by the guideline scope. When selecting topic experts, decisions are underpinned by the seven principles of public life from the Committee on Standards in Public Life. To allow for rapid appointment, topic experts may be:

- identified by recommendations from national professional organisations, such as the royal colleges
- chosen from NICE's Centre for Guidelines' expert panel database
- existing or previous committee members for other NICE guidance.

### Selecting lay members

The independent advisory expert panels should include lay members. This helps to ensure that the guideline is relevant to people affected by the recommendations and acknowledges general or specific preferences and choice. When updating guideline recommendations, the development team should review the composition of the independent advisory expert panel and recruit additional lay members if needed.

The process for selecting lay members is the same as outlined in the guideline manual chapter on decision-making committees, with the exception that charities and patient organisations are contacted to establish if they can nominate someone with relevant experience to join the independent advisory expert panel.

### What the panel does

See the guideline manual chapter on decision-making committees for information on what the panel does. In addition to information outlined in this section, members of the independent advisory expert panel also contribute to decisions to update recommendations.

### Health and social care emergency guideline development team

See the guideline manual section on who is involved for information on who develops guideline recommendations.

## Main stages of emergency guideline development

The development time for an emergency guideline is usually a few weeks (from receiving the referral to publication), depending on the urgency of the referral, complexity of the topic, number of questions to be addressed, and the amount of evidence.

The stages of development for an emergency guideline are the same as the main stages of development outlined in the guideline manual. However, because of the short development time, some of these stages may be done iteratively or in parallel. When the guideline is needed urgently, publication of recommendations will be prioritised, and publication of accompanying evidence reviews and supporting documents may be delayed.

### Scoping

The scope is drafted by staff with responsibility for guideline development, working with the independent advisory expert panel.

The scope covers the issues set out in the topic referral from the referring body, and should include:

- questions for addressing the issues
- information on PICOs
- areas not covered by the guideline
- the target audience.

Staff with responsibility for guideline development identify any existing NICE recommendations covering the same areas as the new guideline.

The scope is signed off by a senior member of staff with responsibility for quality assurance and published on the NICE website.

### Identifying the evidence

Targeted literature searches are conducted to identify published and preprint guidance and evidence relevant to the questions in the scope. Exhaustive literature searches (see the guideline manual chapter on identifying the evidence: literature searching and evidence submission) are only conducted if guideline development time allows, and if published evidence is expected to address specific review questions.

If there is likely to be a shortage of published and preprint guidance and evidence, indirect evidence on other related or similar situations could also be searched for (for example, information on severe acute respiratory syndrome (SARS) and middle east respiratory syndrome (MERS) was used to inform early guidance in the COVID-19 pandemic). In this situation, advice is sought from the independent advisory expert panel. The rationale for any indirect evidence searches will be made clear in the review protocol.

If evidence is not expected to be available and indirect evidence is not suitable for developing recommendations, the independent advisory expert panel may develop recommendations through a process of informal consensus, informed by their expert

knowledge and experience. If appropriate, they may also consider a call for unpublished evidence or draw on expert witnesses (see the appendix on call for evidence and expert witnesses).

The sources for targeted searches of relevant guidance could include:

- WHO databases
- UKHSA guidance and advice
- NICE guidance
- NICE-accredited or endorsed guidance or assessed as credible by the Emergency Care Research Institute (ECRI)
- Medicines & Healthcare products Regulatory Agency (MHRA), NHS England or National Patient Safety Alerts, or other official advice (for example, on infection control and prevention)
- guidance from professional organisations, with guidance from organisations in the UK prioritised over organisations in other countries
- other sources of guidance, as appropriate (for example, BMJ Best Practice, ECRI Guidelines Trust)
- national or international initiatives or networks established in response to a specific health and social care emergency (for example, COVID-END and ECC-19 for the COVID-19 pandemic).

The sources for targeted searches of published literature and preprints should include:

- WHO databases of global research
- Medline, Embase, the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials
- trials registries, for example, ClinicalTrials.gov
- preprints from Europe PMC
- other literature collections as appropriate to the topic, such as the Centre for Evidence-based Medicine.

All search strategies are quality assured by a second information specialist and made available when the guideline is published.

**Selecting the evidence**

For information about literature searching and evidence submission, see the guideline manual section on identifying the evidence: literature searching and evidence submission.

Because these guidelines are urgent, a search for health economic evidence is not routinely conducted. A search can be conducted if evidence is known to be available, or if there is uncertainty around the cost effectiveness of treatments or interventions included in the evidence review.

For the types of question and most appropriate study designs, see the guideline manual chapter on developing review questions and planning the evidence review.

References for all included guidance, published studies and preprints will be published.

**Reviewing the evidence**

For guidance sources that have not been NICE accredited, or assessed as credible by independent sources (such as ECRI), the AGREE II instrument (or a subset of the domains used in AGREE II) is used to assess quality if feasible.

For all included published studies and preprints, population characteristics and key findings are summarised.

See the guideline manual chapter on reviewing evidence for information about assessing risk of bias. The overall quality of the study is stated in the evidence review document.

Formal statistical analyses (for example meta-analysis) are not routinely conducted unless they are likely to add value to the decision-making process. For example, these analyses could be useful if there is a large amount of data for a specific treatment or intervention, with competing benefits and harms.

Health economic evaluation (literature review or new health economic analysis) is not routinely conducted unless it is likely to add value to the decision-making process.

If relevant, recommendations from other guidance (related NICE guidance and guidance developed by other organisations) can be used. When using recommendations from other guidance, the following information is documented:

- title of the guidance
- year of publication
- the authors and their declarations of interests (if available)
- whether the recommendations are based on evidence or opinion (or if it is unclear what they are based on).

All supporting documents will be made available on the NICE website (see the section on reporting information).

**Writing the health and social care emergency guideline**

A high-level summary of the evidence should be included, and it should be clear what evidence or expert opinion each recommendation is based on.

Staff with responsibility for guideline development draft a summary (see the section on reporting information) giving brief explanations for each recommendation or group of recommendations. These include the independent advisory expert panel's discussions of:

- the overall quality of the evidence or confidence in the expert opinion
- the trade-off between benefits and harms
- the impact on equity, equality and health inequalities
- health economic evaluation (if conducted)
- the feasibility of implementation (for example resources, capacity, settings, and acceptability).

All emergency guidelines are labelled to indicate that they have been developed using a different approach to standard NICE guidelines.

Because these guidelines are urgent, the cost effectiveness and resource impact of recommendations is not routinely considered, unless it is likely to add value to the decision-making process. All recommendations made in these guidelines may

impose an opportunity cost and resource impact on the health and social care system.

See the guideline manual section on formulating recommendations for research.

**Consultation**

The emergency guideline undergoes a targeted peer review. A range of stakeholders are invited to take part, including relevant national professional and patient or carer groups. The length of the consultation depends on the urgency and complexity of the guideline and may range from 1 day to 2 weeks.

Staff with responsibility for guideline development collate all comments from stakeholders, so the independent advisory expert panel can consider them. The panel then advises on changes to the guideline and responses to stakeholder comments. Comments from stakeholders are grouped in 'themes'. Thematic responses are provided to address these themes, instead of responding to individual comments.

All stakeholder comments and thematic responses will be made available on the NICE website.

**Declarations of interest**

See the guideline manual section on code of conduct and declaration of interests.

**Equalities and health inequalities considerations**

See the guideline manual for how equalities and health inequalities are considered throughout development.

**Guideline review and sign-off**

Pragmatic checks and review are undertaken iteratively throughout guideline development by staff with responsibility for quality assurance.

NICE's guidance executive signs off the guideline before publication.

## Surveillance and updating process

See the guideline manual chapter on ensuring that published guidelines are current and accurate for information about the surveillance process.

### Identifying the evidence as part of a surveillance process

The approach to identifying evidence will depend on the context of the health and social care emergency. For example, in the early stages of the emergency, feedback from the health and social care system may be most relevant.

The information services team will conduct frequent update searches of literature and guidance. The frequency of searching will be reviewed over time, depending on the amount of new evidence being published.

Depending on the nature of the health and social care emergency, a surveillance repository of evidence may be set up. This will help with reuse of data in guideline updates (see the section on surveillance decisions and outcomes).

There will be ongoing screening of any new evidence that is identified. The frequency of screening will be reviewed over time, depending on the frequency and amount of new evidence identified by searches.

For primary studies, there will initially be no restrictions on study designs if only limited evidence is available. The inclusion criteria will be reviewed over time, depending on the amount and quality of the emerging evidence.

As additional review questions are prioritised and new recommendations developed, existing search methods for surveillance will be checked to make sure that they cover the PICOs of the new questions. We will update or expand the surveillance search as needed.

Because these guidelines are urgent, health economic evidence will not usually be considered as part of this surveillance process.

### Identifying new and updated guidance from other organisations

At a minimum, surveillance searching of guidance from other organisations will include all sources listed in the section on identifying the evidence. When available, searches will be limited to sources judged as high quality or credible (for example, by ECRI assessments).

### Intelligence gathering and event tracking

See the guideline manual section on surveillance assessment process for details.

### Documenting surveillance reviews

A concise report will be written for each surveillance review, documenting the factors that were considered and presenting a rationale for updating (or not updating) the guideline.

### Surveillance decisions and outcomes

Surveillance decisions and outcomes are based on continual assessment of the impact of all the new evidence and intelligence that has been identified. There are 4 possible surveillance outcomes:

- no update
- amend the recommendations
- rapid update of the recommendations
- withdraw the recommendations.

NICE's guidance executive will only be asked to approve surveillance decisions if the proposal is to withdraw or update the guideline. A summary of new evidence from surveillance, the impact of this evidence, and planned changes to the guideline will be provided to guidance executive each time they are asked to make a decision.

There will be no public consultation on surveillance decisions if the proposal is to refresh or withdraw the guideline. Instead, topic experts (see the section on selecting topic experts) will be asked to review the surveillance decision.

### Types of surveillance decisions and outcomes

See the guideline manual section on surveillance assessment process.

## Rapid evidence-based updates to recommendations

A pragmatic and flexible approach is used for updating guideline recommendations. This allows for rapid changes in response to emerging evidence. When possible, work conducted during surveillance will be reused (including evidence searches, data extraction and intelligence gathering).

Cost effectiveness and resource impact is not routinely conducted during updates, unless it is likely to add value to the decision-making process.

**Independent advisory expert panel for rapid updates**

See the section on independent advisory expert panel for more information.

**Literature searching**

To speed up the development of new and updated recommendations for health and social care emergencies, the following approaches could be considered for identifying evidence:

- new update searches
- a search for relevant studies within the surveillance repository of evidence
- reusing data from a directly relevant, recently published systematic review (such as a Cochrane review)
- working with other organisations that are developing guidance in the same area, to share evidence identified through their processes.

**New update searches**

New update searches are recommended when there is likely to be evidence not identified by the surveillance searches, or if additional subject-specific resources are needed.

New update searches will be conducted using sources specified in the section on identifying the evidence.

**Searching the surveillance repository**

Searching the surveillance repository may be appropriate if the surveillance searches are likely to have identified all relevant evidence (for example, for simple updates of existing review questions in the guideline). A search of the surveillance repository can also be supplemented with a search of additional sources not covered by surveillance searches, or a call for evidence (see the appendix on call for evidence and expert witnesses), if necessary.

**Use of a directly relevant systematic review**

See the guideline manual chapter on reviewing research evidence for details.

The data and analytics team will be contacted with specific questions that cannot be answered using available evidence. These questions can then be matched to

relevant data sources if available. Prioritisation for analysis, either internally or commissioned externally, will be considered.

**Reviewing the evidence for rapid updates**
See the section on reviewing the evidence.

**Consultation on rapid updates**
See the section on consultation for details.

**Guideline quality assurance and sign-off for rapid updates**
See the guideline manual sections on quality assurance and signing off the guideline.

## Reporting information

List of information that should be available on the NICE website to meet minimum reporting standards:

- the scope, including questions and review protocols (based on PICO) with inclusion and exclusion criteria
- all search strategies
- references of included guidance, published studies and preprints
- evidence tables with information on quality assessment (including health economic evidence tables if included)
- high-level summary table (linked to the evidence tables) that documents which identified evidence or expert opinion each recommendation is based on
- findings from analysis (for example forest plots) if meta-analysis is conducted
- GRADE profiles if GRADE is used
- health economic evaluation report if health economic evaluation is conducted
- evidence to decisions table, with brief rationales
- equality and health inequalities assessment form
- names of stakeholder organisations that are commenting on the guideline, stakeholder comments and thematic responses to stakeholder comments
- declaration of interests of the independent advisory expert panel.

Templates are available for the following:

- the scope

- high-level evidence summaries
- evidence to decision tables, with brief rationales.

## Terms used

### NICE's Centre for Guidelines' expert panel database

A database of clinicians and practitioners from a variety of specialties. The database is designed to give better access to expert advice when developing and updating NICE guidance.

Experts are selected for their knowledge and experience, and do not represent their organisations.

When recruiting from the database, we may invite specific experts or may ask for expressions of interest from all experts in a particular specialist area.

Experts may be invited to:

- give advice – for example, to advise on the impact of new evidence on existing guidance or to advise on current practice
- participate in committees or independent advisory expert panels as topic specialist members
- perform peer reviews – for example, reviewing part of the guideline, such as an evidence review.

### Surveillance repository

The surveillance repository is an EPPI-Reviewer review that includes all search results from when surveillance searches for a health and social care emergency begin, up to the current date. Studies are allocated to relevant codes in EPPI-Reviewer as part of screening, or excluded if not relevant to the guideline. The repository is designed so that studies can be identified and retrieved using the search and filter function in EPPI-Reviewer.

### Topic expert

Experts on the topic of a guideline who join an expert panel to work on that guideline. They may include practitioners, service providers and commissioners.