Appendix L: Interim process and methods for guidelines developed in response to health and social care emergencies

Audit and service improvement
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1 Introduction and overview

1.1 Information about the interim process and methods:

- The interim process and methods are for the development, surveillance and updating of guideline recommendations developed in response to urgent requests from NICE's guideline commissioners to respond to national health and social care emergencies.

- A national health and social care emergency refers to an event or circumstance that demands immediate action on a national level to preserve or protect the ability of the health and care sector to respond appropriately.

- The interim process and methods are an update of the process and methods published on 20 March 2020 (PMG35) and will have a public consultation in 2021/22.

- The interim process and methods only apply to developing guidelines in response to health and social care emergencies during and immediately after (recovery phase) the crisis.

- During health and social care emergencies, urgent guidelines are needed within a few days to 2 to 3 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.

- The short timeframe for guideline development in response to a health and social care emergency imposes trade-offs about 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 and standards. It ensures that users can make judgements on the credibility and applicability of the guideline recommendations.

- Independent advisory expert panels are convened to perform the role of the independent advisory committee in standard guidance development and update. NICE's policy on declaring and managing interests will apply to all panel members and NICE staff.
• The main stages of development include scoping, identifying and appointing the independent advisory expert panel, conducting evidence reviews, drafting recommendations and consulting stakeholders. Because of the short development timeframe, some of these stages may be undertaken iteratively or in parallel. When the guidance is needed urgently, publication of guideline recommendations will be prioritised, with a possible delay in the publication of accompanying evidence reviews and supporting documents.

• The interim process and methods described in this appendix should not be applied to the development, surveillance or updating of guidelines outside the context of health and social care emergencies.
2 Topic selection

2.1 Decisions on the topics for health and social care emergency guidelines, and their urgency for development, are agreed with the relevant body (for example, NHS England, Public Health England or the Department of Health and Social Care).
3 Who is involved

3.1 A health and social care emergency guideline development team is convened for each guideline topic. The team comprises NICE staff with responsibility for guideline development (see section 5) who work with an independent advisory expert panel (see section 4) to develop the guideline.

3.2 Pragmatic checks and review are undertaken iteratively throughout guideline development by NICE staff with responsibility for quality assurance (see section 16).

3.3 During guideline development, stakeholders are engaged in a consultation of the draft health and social care emergency guideline before publication. The length of consultation 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 section 13).

3.4 The NICE surveillance team undertakes a pragmatic targeted approach to the surveillance of health and social care emergency guidelines (see section 17).

3.5 Updating health and social care emergency guidelines is undertaken by a NICE health and social care emergency guideline development team. Stakeholders are engaged in a consultation of the draft update before publication. The length of consultation depends on the urgency of the update (see section 19).

3.6 All health and social care emergency guidelines and updates are signed off by NICE’s Guidance Executive.
4 Independent advisory expert panel

4.1 Because of the urgency and short timeframes for developing guidance in response to a health and social care emergency, open recruitment of a topic-specific guideline committee is not feasible or practical. Instead, rapid and independent advice and expertise is obtained from an independent advisory expert panel consisting of topic experts. 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.

4.2 Selection of topic experts is based on specific expertise required to develop recommendations in the areas defined by the guideline scope. To facilitate rapid appointment, topic experts may be:

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

4.3 The independent advisory expert panels should have representation from lay people with the condition, experience or knowledge of issues that are important to people using services, family members and carers, and the community affected by the guideline. This helps to ensure that the guideline is relevant to people affected by the recommendations and acknowledges general or specific preferences and choice.

4.4 Lay people will be identified and invited to join the independent advisory expert panels by contacting:

- people using services and carers who are existing or previous committee members for standard NICE guidelines for at-risk disease/care areas (for example, during the COVID-19 pandemic, at-risk disease areas included COPD and asthma)
• people using services and carers who are members of NICE's public involvement programme (PIP) expert panel and have personal experience of at-risk disease/care areas.

4.5 If the above 2 approaches are not possible, for example, because of the urgency of the guideline, a validation of draft recommendations could be used to incorporate lay people's views and experiences, through:

• a consultation with stakeholder organisations representing people using services and carers

• consulting with members of NICE's PIP expert panel who have personal experience of at-risk disease/care areas.

4.6 The independent advisory expert panel is convened and develops the scope, considers the evidence, develops the recommendations, and considers stakeholder feedback on the draft recommendations.

4.7 All members of the independent advisory expert panel are expected to adhere to NICE's policy on declaring and managing interests for NICE advisory committees. All NICE staff are expected to adhere to NICE's policy on declaring and managing interests for board members and employees (see section 14).

4.8 Names, affiliations and declaration of interests of the independent advisory expert panel are published on the NICE website together with the health and social care emergency guideline.
5 Health and social care emergency guideline development team

5.1 The independent advisory expert panel is supported by a health and social care emergency guideline development team from NICE. The team is responsible for scoping the guideline, conducting the evidence reviews, and documenting the methods and processes used, independent advisory expert panel discussions, decisions and recommendations, and themed responses to stakeholder comments. The health and social care emergency guideline development team usually comprises:

- a guideline lead, who is responsible for chairing the discussions and leading guideline development
- a clinical, public health or social care adviser
- technical analyst(s)
- an information specialist
- a medicines adviser
- an editorial lead
- a project manager or coordinator.
Main stages of guideline development

6.1 The development time for a health and social care emergency guideline is usually a few days to 2 to 3 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.

6.2 The main stages of development include scoping, identifying and appointing the independent advisory expert panel, conducting evidence reviews, drafting recommendations and consulting stakeholders. Because of the short development timeframe, some of these stages may be undertaken iteratively or in parallel. When services need guidance urgently, publication of guideline recommendations will be prioritised, with a possible delay in the publication of accompanying evidence reviews and supporting documents.
7 Scoping

7.1 The scope is drafted by the health and social care emergency guideline development team at NICE working with the independent advisory expert panel. The scope is agreed with the referring body.

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

- questions for addressing the issues
- review protocols (based on PICO) for the questions, with inclusion and exclusion criteria
- areas not covered by the guideline
- the target audience(s).

7.3 The scope is signed off by a senior member of NICE staff with responsibility for quality assurance and the referring body.

7.4 The scope will be made available on the NICE website.
8 Identifying the evidence

8.1 Targeted literature searches are conducted to identify published and preprint guidance and evidence relevant to the questions in the scope. Exhaustive literature searches (see section 5 of Developing NICE guidelines: the manual) are only conducted if guideline development time allows and published evidence is anticipated to address specific issues in the scope and review questions.

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

8.3 Where evidence is not expected to be available and indirect evidence is not suitable to support the development of recommendations, the independent advisory expert panel may develop recommendations through a process of informal consensus informed by their expert knowledge and experience.

8.4 The sources for targeted searches of relevant guidance should include, but not be limited to:

- WHO databases
- Public Health England guidance and advice
- NICE guidance
- NICE-accredited or endorsed guidance identified by NICE Evidence Search, or assessed as credible by ECRI (Emergency Care Research Institute)
- MHRA or National Patient Safety Alerts, or other official advice (for example, on infection control and prevention)
• guidance from professional bodies and royal colleges, prioritised as follows:
  – guidance from organisations in the UK
  – guidance from organisations in other countries (as required)
• other guidance repositories, 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).

8.5 The sources for targeted searches of published literature and preprints should include, but not be limited to:

• WHO databases of global research
• Medline, Embase and Cochrane Database of Systematic Reviews
• trials registries, for example, ClinicalTrials.gov
• preprints from medRxiv and bioRxiv
• other literature collections as appropriate to the topic, for example, Centre for Evidence-based Medicine (CEBM).

8.6 All search strategies are quality assured by a second information specialist.

8.7 All search strategies will be made available on the NICE website.
9 Selecting the evidence

9.1 After targeted searches are completed, potentially relevant guidance, published studies and preprints are selected based on title and abstract. Full papers are obtained if inclusion criteria are met (see section 7.2).

9.2 Because of the urgency for publishing guidelines in response to health and social care emergencies, a search for health economic evidence is not routinely conducted unless it is known that evidence is available, or there is a need to address the uncertainty around the cost effectiveness of treatments or interventions included in the evidence review.

9.3 For the types of question and most appropriate study designs, see section 4 of Developing NICE guidelines: the manual.

9.4 References for all included guidance, published studies and preprints are included in the health and social care emergency guideline.

9.5 All identified guidance (including relevant NICE guidance), published and preprint publications (both included and excluded) are downloaded and stored using a data management software such as EPPI-Reviewer 5.
10 Reviewing the evidence

10.1 All relevant recommendations from other guidance (related NICE guidance and guidance developed by other organisations) are summarised in an evidence table. Other information is also extracted, including title of the guidance, year of publication, the authors and their declarations of interests, and whether the recommendations are evidence or opinion based.

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

10.3 For all included published studies and preprints, population characteristics and key findings are summarised in an evidence table.

10.4 Risk of bias is assessed for included published studies and preprints using checklists appropriate for the study design (see appendix 1). The overall quality of the study is documented in the evidence table.

10.5 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, a large amount of data with competing benefits and harms of a specific treatment or intervention.

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

10.7 All evidence tables and supporting documents will be made available on the NICE website (appendix 2).
11 Drafting the health and social care emergency guideline

11.1 The guideline is drafted by the health and social care emergency guideline development team (see section 5) to reflect the discussions and interpretation of the evidence by the independent advisory expert panel. When a recommendation is made because of a legal duty or the consequences of not following a course of action, the guideline refers to the relevant supporting documents.

11.2 The health and social care emergency guideline development team identifies any existing NICE guidance covering the same areas as the new guideline and clarifies the status of the existing guidance during the health and social care emergency.

11.3 A high level summary table (see appendix 2), linked to the evidence tables, is included to document which identified evidence or expert opinion each recommendation is based on.
12 Health and social care emergency guideline recommendations

12.1 The health and social care emergency guideline development team drafts a brief evidence to decision table (see appendix 2) that outlines brief rationales and discussions for each recommendation or group of recommendations. These include the independent advisory expert panel’s consideration of:

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

12.2 Health and social care emergency guideline recommendations fall broadly into 1 of 4 categories (see appendix 3):

- Category 1: service delivery/organisation recommendations: modified care processes to reduce people’s (people using services, family members, carers or staff) risk, while not changing the treatment/service received.
- Category 2: service delivery/organisation recommendations: changes to care/service to be used if service capacity is limited (for example, treatment or intervention not given solely because there are no staff or facilities).
- Category 3: treatment/intervention recommendations: specific management of the health and social care emergency or its complications.
- Category 4: treatment/intervention recommendations: guidance on how routine treatments or interventions for existing conditions should be modified (or not modified).

12.3 Where appropriate, recommendations from category 3 and 4 are mapped onto related existing NICE guidance, and any duplications, overlaps and
inconsistencies are recorded. This mapping can be completed after guideline publication or during surveillance of the guideline.

12.4 All health and social care emergency guideline recommendations are labelled to indicate that they have been developed using a different approach to standard NICE guideline recommendations.

12.5 Because of the urgency for publishing guidelines in response to health and social care emergencies, consideration of the cost effectiveness or resource impact of guideline recommendations is not routinely conducted, unless it is likely to add value to the decision-making process. It should be noted that all recommendations made within the guidelines may impose an opportunity cost and resource impact on the healthcare system.

12.6 If there is a lack of evidence and/or recommendations are based on independent advisory expert panel's knowledge and experience, research recommendations may be made to stimulate more research in the topic area.
13 Consultation

13.1 The health and social care emergency guideline undergoes a consultation in which a range of stakeholders, including relevant national professional and user/patient or carer groups, are invited to take part. The length of the consultation depends on the urgency and complexity of the guideline (and may range from half a day to a week).

13.2 The health and social care emergency guideline development team collates all comments from consultation for consideration by the independent advisory expert panel. The panel then advises on refinements to the guideline and thematic responses to stakeholder comments.

13.3 All stakeholder comments and thematic responses will be made available on the NICE website.
14 Declarations of interest

14.1 All members of the independent advisory expert panel are asked to declare all interests that are relevant or potentially relevant to the guideline, in line with NICE’s declaration of interests policy for NICE advisory committees. All NICE staff are asked to declare all interests in line with NICE’s policy on declaring and managing interests for board members and employees.

14.2 Decisions on managing interests balance the need for specialist clinical, public health or social care advisers offering expertise with maintaining objectivity.

14.3 Declarations of interest are not sought from stakeholders taking part in the consultation of the draft health and social care emergency guideline.
15 Equalities considerations

15.1 The impact on people with characteristics protected under the Equality Act 2010 is considered during development of the health and social care emergency guideline in line with NICE's equality objectives and equality programme 2016 to 2020. An equalities impact assessment is completed and reviewed by the NICE quality assurance team before submission of the draft guideline to NICE’s Guidance Executive. The equalities impact assessment will be made available on the NICE website.
16  NICE quality assurance and sign-off

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

16.2 The health and social care emergency guideline is reviewed by the referring body before publication.

16.3 NICE’s Guidance Executive signs off the health and social care emergency guideline before publication.
17 Surveillance

17.1 To ensure that surveillance and updating of guidelines developed in response to health and social care emergencies is manageable, a pragmatic targeted approach to surveillance is adopted. This process is based on the types of recommendations and the expected 'shelf-life' of the guideline (see section 12), the evolving system and policy context, and emerging evidence base.

- For category 1 recommendations, modified care processes to reduce people's risk, there is no routine search of the published evidence. Instead a 'reactive' surveillance approach is triggered by feedback and intelligence, and any substantial policy or context changes.

- For category 2 recommendations, changes to care/service because of capacity constraints, there is no surveillance or update activity. NICE will agree with the referring body when to stand down these recommendations, which are likely to have limited relevance for the service beyond the timeframe of the health and social care emergency. This will be considered on a case-by-case basis.

- For category 3 recommendations, specific management of the health and social care emergency or its complications, there is proactive surveillance and updating.

- For category 4 recommendations, treatment or intervention considerations for existing conditions:
  - There is proactive surveillance and updating for those recommendations recommending a treatment or intervention modification that is not evidence based.
  - There is no surveillance for those recommendations recommending a treatment or intervention that is in line with existing NICE guidance.

For more details see appendix 4.

Frequency of surveillance review

17.2 For proactive surveillance of category 3 and category 4 recommendations:
• There will be frequent update searches of literature and guidance conducted by NICE's information services team. The frequency of searching will be reviewed over time, depending on the amount of new evidence being published.

• There will be ongoing sifting of new evidence identified. The frequency of sifting will be reviewed over time, depending on the frequency and amount of new evidence identified by searches.

Identifying the evidence

17.3 The approach to identifying evidence will be driven by the categorisation of recommendations and context of the health and social care emergency. For example, in the early stages of the emergency, intelligence from the system may be most relevant.

17.4 Because of the urgency of updating guidelines in response to health and social care emergencies, health economic evidence will not be considered as part of this surveillance process.

New and updated guidance from other organisations

17.5 Surveillance searching of guidance will include all sources listed in section 8 as a minimum. Where available, searches will be limited to those judged as high quality or credible (for example, by ECRI assessments).

Literature searching

17.6 For ongoing update searches of primary literature, the same approach to searching will be used as during development of the health and social care emergency guideline (see section 8).

17.7 For inclusion of primary studies, initially no restrictions on study designs will be applied if limited evidence is available. The inclusion criteria will be reviewed over time, depending on the volume and quality of the emerging evidence base. Reasons for any change of inclusion criteria will be documented.

17.8 When a large number of studies are available, a systematic approach to inclusion will be used as in section 9.
Intelligence gathering

17.9 A pragmatic targeted intelligence gathering approach, based on the evolving system and policy context and emerging evidence base, will be used to gather feedback from the broader health and care system and NICE stakeholders.

17.10 Intelligence gathering will also include identifying any relevant datasets (for example, administrative data, datasets published alongside peer-reviewed manuscripts, preliminary reports and experiential feedback from front-line workers, and others) that could be used to address areas of uncertainty within the guidelines.

17.11 If relevant datasets are identified, NICE's data and analytics team will be asked for advice on the appropriateness and quality of the data sources and which analytic methods might be applied to address identified areas of uncertainty within the guidelines.

17.12 Intelligence gathering also includes other related NICE guidance (for example, technology appraisal guidance, diagnostic guidance, medical technologies guidance, interventional procedures guidance) developed since the guideline was published.

Event tracking

17.13 An event tracking approach will be used to supplement literature searches and intelligence gathering. Relevant studies, systematic reviews, policies and data sources will be identified throughout development and surveillance. Information will be considered for its impact on the guidelines as it becomes available, and may inform the decision to update.

Summarising process

17.14 When a definite impact of new evidence on the guideline is identified, a concise evidence report is written to present the rationale for updating the guideline or its recommendations, including reference(s) to key evidence and the recommendations to be updated. Abstract-level summaries can be used to produce the evidence report with the option of obtaining full text if needed. Relevant intelligence gathering will be included in the evidence report as well as published evidence.
18 Surveillance decisions and outcomes

Surveillance decisions and outcomes are based on assessing the impact of all the new evidence and intelligence identified. There are 4 possible surveillance outcomes:

- no update
- refresh the guideline
- rapid update of the guideline
- withdraw the guideline.

Types of decision and outcome

No update

A 'no update' decision is reached when identified new evidence or intelligence (including from topic experts, implementation, related guidance and policy) does not indicate any change to the health and social care emergency guideline recommendations. Alternatively, new evidence or intelligence may increase certainty in the current advice. This may apply to categories 1, 3 and 4 in section 12.2.

Refresh the health and social care emergency guideline

When simple changes to sections of the guideline are needed that do not require further ratification from a clinical, public health or social care adviser or topic expert, the recommendations are refreshed by the editorial team. Examples include:

- changing existing hyperlinks
- adding new hyperlinks
- adding new guidance or a cross-reference
- changing terminology
• changes to ensure consistency across the suite of guidelines

• updating advice taken from other guidelines if the source guidance changes

• amending text for clarity and to aid implementation.

18.4 This refreshing approach may apply to categories 1, 3, 4 and category 2 before the guidelines or recommendations are stood down (see section 12.2).

**Rapid update of the health and social care emergency guideline**

18.5 Rapid update of the guideline may or may not involve formal evidence reviews.

18.6 Updating the guideline could be an outcome from surveillance if:

- Changes to the guideline are needed but would only need clinical, public health or social care input, views and expertise from the topic experts (see section 4) and the referring body, without a formal evidence review. Examples include:
  - adding recommendations to expand or bridge existing content rather than adding new actions
  - amending existing recommendations for other reasons, for example, if government policy changes (such as adding safety information to a recommendation if lockdowns affecting outpatient treatment change).

- New content is needed or there are significant changes to the intent or strength of recommendations, based on new evidence and intelligence. This will need a formal evidence review and an independent advisory expert panel involvement (see section 19). Examples include:
  - an expansion of the scope to include additional populations, settings or new questions that need addressing
  - changes to the original questions, which mean a new search of the evidence is needed
  - new evidence contradicting existing recommendations.

18.7 This may apply to categories 1, 3, 4 and category 2 before the recommendations are stood down (see section 12.2).
For process and methods of rapid update see section 19.

Withdraw the health and social care emergency guideline or recommendations

The guideline or some of its recommendations will be considered for withdrawal if:

- They are no longer needed or are redundant because service delivery has changed (for example, normal services have resumed, category 2, section 12.2) or the recommendations are likely to have limited relevance for the service beyond the health and social care emergency (category 2, section 12.2). The latter will be discussed with the referring body to agree a decision.

- There are safety issues, for example, the recommendations may harm people who use services or health and social care practitioners.

- There is duplication of recommendations if the guideline content or some of its recommendations are merged with another guideline within the suite.

NICE quality assurance and sign-off of surveillance decisions

A pragmatic approach is taken to quality assurance of surveillance decisions:

- Technical quality assurance is done by senior technical staff as and when work is available for surveillance review (flexible and proactive approach).

- Quality assurance by the NICE clinical, public health or social care adviser focuses specifically on the decision-making and outputs based on the clinical, healthcare or social care context and relevance, and safety implications.

NICE's Guidance Executive will only be asked to approve surveillance decisions for withdrawal or updating. A summary of new evidence from surveillance and its impact, and changes will be provided to Guidance Executive each time a decision is made.

There will be no public consultation for a surveillance decision to refresh or withdraw the guideline. Topic experts (see section 4) will be asked to validate
the surveillance decision instead.
19 Rapid updating of the health and social care emergency guideline

19.1 A pragmatic and flexible approach to updating guideline recommendations will be adopted to ensure a rapid response to emerging evidence.

19.2 The development time for the rapid update is likely to be slightly longer than the short timeframe for developing the original health and social care emergency guideline. This allows for more robust update process and methods to be applied to enhance the quality and credibility of guidelines.

19.3 Because of the urgency in updating guidelines for health and social care emergencies, consideration of the cost effectiveness or resource impact of guideline recommendations is not routinely conducted, unless it is likely to add value to the decision-making process.

19.4 The NICE health and social care emergency guideline development team is responsible for updating the guideline, supporting the rapid update independent advisory expert panel, and documenting the recommendations, discussions and decisions, evidence reviews, and methods used.

Rapid update independent advisory expert panels

19.5 Because of the short timeframes for updating health and social care emergency guidelines, open recruitment of a topic-specific guideline committee is not feasible or practical. Independent advisory expertise is instead obtained from independent advisory expert panels.

19.6 A broad pool of experts across a wide range of specialties will first be convened. The pool will be drawn from NICE's Centre for Guidelines' expert panel, existing or previous committee members for other NICE guidance, and topic experts involved in developing the health and social care emergency guidelines.

19.7 For each rapid update, a selected group of experts will be drawn from the broad pool to form a bespoke independent advisory expert panel based on the specific needs for the guideline recommendations being updated. The rapid update
independent advisory expert panel will convene to interpret new evidence and intelligence gathered from surveillance (see section 18), and make decisions on recommendations. The number of topic experts in the rapid update independent advisory expert panel depends on the urgency and complexity of the rapid update.

19.8 Where appropriate, the rapid update independent advisory expert panel can be formed to update a suite of guidelines rather than for each rapid update. For example, an independent advisory expert panel with respiratory expertise can be convened to update a suite of health and social care emergency guidelines on different respiratory conditions.

19.9 All rapid update independent advisory expert panels should have representation from lay people with the condition, experience or knowledge of issues that are important to people using services, family members and carers, and the community affected by the guideline. This helps to ensure that the guideline is relevant to people affected by the recommendations and acknowledges general or specific preferences and choice.

19.10 Lay people will be identified and invited to join the rapid update independent advisory expert panels by contacting:

- stakeholder organisations who have commented on the health and social care emergency guideline
- people using services and carers who are existing or previous committee members for standard NICE guidelines for at-risk disease/care areas (for example, during the COVID-19 pandemic, at-risk disease areas included COPD and asthma)
- people using services and carers who are members of NICE’s public involvement programme (PIP) expert panel and have personal experience of at-risk disease/care areas.

19.11 If the above 3 approaches are not possible, a validation of draft recommendations could be used to incorporate lay people's views and experiences, through:

- a consultation with stakeholder organisations representing people using services and carers
• consulting with members of NICE's PIP expert panel who have personal experience of at-risk disease/care areas.

All lay panel members will be paid in line with the NICE involvement policy.

19.12 As for standard NICE guidelines, all members of the rapid update independent advisory expert panel and NICE staff will be expected to adhere to NICE's declaration of interests policy for NICE advisory committees and for NICE employees (see section 14).

Identifying the evidence and rapid evidence review

Literature searching

19.13 Update searches will be conducted using sources in sections 8.4 and 8.5. Additional searching of ongoing reviews will be conducted through existing collaborative links with established national or international networks and repositories, where available (see section 8.4).

19.14 Because of the urgency in updating guidelines in response to health and social care emergencies, a search for health economic evidence is not routinely conducted unless it is likely to add value to the decision-making process.

19.15 When no relevant, high-quality systematic reviews are identified (either published or in development):

• Opportunities will be explored for progressing relevant reviews and event tracking through existing collaborative links (for example, Cochrane).

• Rapid evidence reviews will be undertaken and published by NICE.

19.16 NICE's 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.

Rapid evidence review

19.17 A pragmatic, flexible approach to rapid evidence review will be used to allow a rapid response to emerging evidence. The rapid evidence review should include:
• Review protocol, with PROSPERO registration encouraged but depending on the urgency of the update.

• References of all included studies, and references of all excluded studies with reasons for exclusion.

• Evidence tables for included studies, including health economic studies if considered (see section 19.14).

• Critical appraisal of included studies with documented risk of bias judgement using appropriate checklists (see appendix 1). GRADE will be used where appropriate.

• Summary of included studies with overall assessment of certainty.

• Summary of published international guidelines and quality assessment (using the AGREE II instrument, see appendix 1) if used as a main source of evidence.

• Data synthesis such as meta-analysis, where applicable.

• A brief report on expected resource impact, where applicable, prepared by NICE's resource impact team.

• Equalities impact assessment.

19.18 Health economic evaluation is not routinely conducted unless it is likely to add value to the decision-making process.

Rapid update independent advisory expert panel decision-making

19.19 In line with the core principles that guide all NICE's work, all recommendations should be underpinned by a transparent and accountable decision-making process, which should include:

• labelling all recommendations to make it clear that they have been developed using a different approach to standard NICE guidelines

• categorising updated recommendations as in section 12
• rationales for each recommendation or group of recommendations that are published alongside the updated recommendations and cover:
  - the overall quality and certainty of evidence
  - the trade-off between benefits and harms
  - the impact on equity and equality
  - health economic evaluation (if conducted)
  - the feasibility of implementation (for example, resources, capacity, settings, acceptability).

Consultation on rapid updates

19.20 A consultation will be conducted for a rapid update. The length of the consultation will depend on the urgency of the rapid update, the complexity and amount of new evidence.

19.21 A broader range of stakeholders, particularly those groups who might not have been included in any previous consultation, should be engaged for the rapid update consultation.

19.22 Thematic responses to stakeholder comments will be made available on the NICE website.

NICE quality assurance and sign-off of a rapid update

19.23 A pragmatic approach to quality assurance of a guideline update will be taken by NICE staff responsible for quality assurance:

• Technical quality assurance will be done by a senior technical lead as and when work is available for quality assurance (flexible and proactive approach).

• Quality assurance by the NICE clinical, public health or social care adviser will focus specifically on the decision-making and outputs based on clinical, healthcare or social care context and relevance, and safety implications.

19.24 NICE’s Guidance Executive will be asked to approve and sign off the rapid update before publication.
Equalities considerations

19.25 The impact on people with characteristics protected under the Equality Act 2010 will be assessed during the rapid update and before publication, according to NICE’s equality objectives and equality programme 2016 to 2020. An equalities impact assessment form is completed and approved by NICE staff with responsibility for quality assurance, and NICE’s Guidance Executive discusses any issues raised. The equalities impact assessment will be made available on the NICE website.
20 Terms used

NICE Accreditation

The accreditation programme assesses the processes used to produce guidance and advice. This will help to raise standards in guidance production. Please continue to use NICE Evidence Search to search for accredited guidance. The accreditation programme no longer accepts new applications but continues working with guidance producers looking to renew their existing accreditation.

NICE’s Centre for Guidelines' expert panel database

Members of the panel are selected for their knowledge and experience, and do not represent their organisation(s).

NICE may invite individual panel members to contribute or may ask for expressions of interest from all panel members in a particular specialist area.

Members of the panel 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 as topic specialist members
- perform peer reviews – for example, reviewing a part of the guideline such as an evidence review.

Thematic responses to stakeholder comments

Comments from stakeholders are collated and grouped under 'themes'. Thematic responses are provided to address the specific themes, instead of responding to individual comments.

Topic expert

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

Appendix 1. Critical appraisal

For critical appraisal checklists, please see appendix H of Developing NICE guidelines: the manual (2014, updated 2018)

For the AGREE II instrument, please see the AGREE website

Appendix 2. Reporting of 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 conducted

• evidence to decisions table with brief rationales

• equalities impact assessment form

• names of stakeholders, stakeholder comments and thematic responses to stakeholder comments
• contact details and declaration of interests of the health and social care emergency guideline development team, including members of the independent advisory expert panel

• EPPI-5 files (for surveillance and update only).

Templates will be developed for the following:

• the scope

• high level summary table

• evidence to decision table with brief rationales.

Appendix 3. Types of recommendations

Categorisation of recommendations from health and social care emergency guidelines

<table>
<thead>
<tr>
<th>Category</th>
<th>Types and expected 'shelf-life' of health and social care emergency guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Service delivery/organisation recommendations</td>
</tr>
<tr>
<td>1.</td>
<td>Definition. Substitution of care processes to reduce people's (people using services, family members, carers or staff) risk to the health and social care emergency, while not changing the treatment/service received. Notes on classification. Recommendations that involve a change in both care process and treatment/intervention should be assigned to category 4, not category 1. Expected 'shelf-life' of recommendations. Unlikely to be needed when the risk reduced, so most of these recommendations are likely to be stood down once the risk is reduced to an acceptable level, with these or similar recommendations then brought back should the risk increase again in the future. A small number of these recommendations may be retained if they are found to be more efficient than current service models.</td>
</tr>
<tr>
<td>2.</td>
<td>Definition. Alterations of care/service to be used if service capacity is limited, for example, treatment or intervention not given solely because of no staff or facilities. Expected 'shelf-life' of recommendations. Likely only to be needed while service capacity is severely limited by the health and social care emergency. These recommendations are likely to be stood down once the current acute capacity constraints are resolved, and only to be brought back should similar constraints reapply in the future.</td>
</tr>
</tbody>
</table>
### Appendix L: Interim process and methods for guidelines developed in response to health and social care emergencies

<table>
<thead>
<tr>
<th>Category</th>
<th>Types and expected 'shelf-life' of health and social care emergency guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Treatment or intervention recommendations</td>
</tr>
<tr>
<td>3.</td>
<td>Definition. Specific management of the health and social care emergency or its complications. Notes on classification. Management in this instance is being used as a broader term than simply treatment or intervention, so this category should include any recommendation on what to do in a specific health and social care emergency or on managing its complications (for example, recommendations on contact tracing after diagnosis). Expected 'shelf-life' of recommendations. Likely to be needed for a considerable time, and may have relevance beyond the health and social care emergency, because they are likely to still apply to the management of individual cases, in a situation where the prevalence of such cases is considerably reduced.</td>
</tr>
<tr>
<td>4.</td>
<td>Definition. Recommendations on how treatments or interventions for existing conditions should be modified (or not modified). Notes on classification. This category includes recommendations on alterations of therapy or intervention, for example, to reduce immunosuppression (often with presumed reduced efficacy for the primary condition), recommendations for changes to normal regimens for reasons other than immunosuppression, and recommendations that treatments or intervention not be changed. Expected 'shelf-life' of recommendations. Unlikely to be needed when the risk reduced but may have continued relevance in individual cases when a 'second-best' option is needed to avoid immunosuppression (or for other reasons).</td>
</tr>
</tbody>
</table>

### Appendix 4. Approaches to surveillance and updating

**Approaches to surveillance and update of health and social care emergency guidelines**

<table>
<thead>
<tr>
<th>Category</th>
<th>Types of health and social care emergency guideline recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>Service delivery/organisation recommendations</td>
</tr>
</tbody>
</table>
### Types of health and social care emergency guideline recommendations

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Implications for surveillance/updating</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Definition. Substitution of care processes to reduce people's (people using services, family members, carers or staff) risk to the health and social care emergency, while not changing the treatment or intervention received.</td>
<td>Limited value in these recommendations being checked for new published evidence in the short term because they are expected to be time limited. However, if any processes are considered to be more efficient and thus planned to be retained in NICE guidance even when they are no longer needed to manage the risk, then arguably these should be evaluated more fully through our standard processes for effectiveness and cost effectiveness. This will ensure there are no downsides to such systemic changes.</td>
<td>-</td>
</tr>
<tr>
<td>2.</td>
<td>Definition. Alterations of care/service to be used if service capacity is limited, for example, treatment or intervention not given solely because of no staff or facilities.</td>
<td>Limited value in these recommendations being checked for new published evidence, because they are likely to be driven primarily by constraints within the system, rather than research evidence.</td>
<td>-</td>
</tr>
<tr>
<td>3.</td>
<td>Definition. Specific management of the health and social care emergency or its complications.</td>
<td>These recommendations are likely to be the ones most affected by ongoing research, and therefore the ones most relevant for surveillance in the short term. In the longer term, it is likely all these recommendations could be subsumed into a simple guideline on the diagnosis or management of the health and social care emergency or its complications (should such a guideline provide value). This would provide an opportunity to update all these recommendations using our standard processes for effectiveness and cost effectiveness to ensure that they reflect NICE’s standard approaches.</td>
<td>-</td>
</tr>
</tbody>
</table>
### 4. Definition

Recommendations on how treatments or interventions for conditions should be modified (or not modified).

**Implications for surveillance/updating.** Most of these recommendations are likely to be uncontroversial and not require surveillance, particularly when they either state that no changes should be made, or give a second choice that is already the established second choice in an existing piece of NICE guidance. However, it will be important to identify the small subset of these recommendations that recommend a change in treatment or intervention that is not evidence based. These are the recommendations with the highest potential to cause harm if a suboptimal second choice has been made. For these recommendations, there is likely to be value both in surveillance and updating through our standard processes for effectiveness and cost effectiveness.

### Appendix 5. Acknowledgements

The interim process and methods were developed by the Centre for Guidelines (CfG) methods and economic team, with contributions from:

- CfG surveillance team
- CfG clinical, public health and social care advisers
- Guideline developers from COVID-19 guidelines
- NICE information services team
- NICE public involvement programme
- NICE data and analytics team.