National Institute for Health and Care Excellence

Publication of the update of developing NICE guidelines: the manual

This report gives details of the changes to the manual for developing NICE guidelines.

The Board is asked to agree to proceed to publication of this update to developing NICE guidelines: the manual, which lays the foundations for more substantive changes in 2022-23, including a prioritised portfolio, living guidelines and user-centred design.

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Introduction

1. Developing NICE guidelines: the manual, outlines the methods and processes used to develop and update NICE guidelines.
2. Since the last update to the manual, there have been important changes to the context in which NICE operates. The NICE Strategy (2021-2026) outlines the vision for NICE to be more flexible, faster and user-focussed when developing its guidelines.
3. To be able to deliver the NICE Strategy, NICE needs to make changes to update the manual. These changes have been planned over 2 financial years. This paper refers to the first update (2021-22). A second update is planned for 2022-23.
4. The Board is asked to review the proposed changes to the manual and approve the draft for publication.

Background to this update

1. We regularly review the processes and methods for developing NICE guidelines to ensure our approach is fit-for-purpose and reflects recognised best practice in guideline development. The last major update of the manual was the publication of the unified manual for social care, public health and clinical guidelines in 2018.
2. This update will lay the foundations for more substantive changes in the planned update of the manual that will be introduced alongside the redesign of the Centre's operational model.
3. The changes to the manual in this update are set out below in the section 'main changes in this update'.
4. The proposed update (2022-23) will reflect changes to our methods and processes that map across the 4 pillars:

* Rapid update of technology appraisals and integration into guidelines (pillar 1)
* Develop quicker and more flexible methodology to develop guidance that answers the most important questions (pillar 2).
* Prioritisation of areas where we can make the greatest impact on health inequalities (pillar 3).
* Appropriate use of real-world data or evidence to inform recommendations (pillar 4).

1. The proposals have been considered by a cross-organisational steering group (see Appendix A for details) and have undergone an internal consultation process (including both internal and external development teams, details can be found in Appendix B).

Summary of changes in this update

There are two main changes in the update of the manual that affect the way NICE interacts with its external stakeholders:

Agile and flexible methods and processes

1. Emphasis on proactive surveillance and removal of 5-year routine surveillance. Future developments will be informed by the Guideline portfolio prioritisation work being led by the Centre for Guideline surveillance team.
2. Addition of:

* a new rapid process for scoping
* a 2-week consultation for small updates (1 or 2 review questions)

The original and revised wording for these sections are given in Appendix C.

Additionally, a number of other changes have been made to methods and processes, that do not directly impact on the way NICE interacts with its external stakeholders (more detail on these changes is given in Appendix D):

Manual format

1. In light of the scale of change being implemented across the programme, and the varying rates at which changes are tested and implemented, we propose to publish this update to the manual in discrete chapters (rather than one, large manual). For future updates to the manual, this 'modular' format will allow for quicker, dynamic updates of discrete topics, in line with changes to the operating model for the development of living guideline recommendations.

Health inequalities

1. There is more emphasis throughout the manual chapters on importance of addressing health inequalities across all stages of guideline development from scoping to evidence reviews and recommendations. It also updates the definition of health inequalities to align it with Public Health England (now the Office for Health Improvement and Disparities [OHID]) report on place-based approaches for reducing health inequalities. Future developments will be informed by the cross-institute health inequalities methods workstream being led by the Centre for Guidelines.

Real world data and digital technologies (including automation)

1. Addition of guidance on the use of digital and technical innovations in identifying the evidence (e.g. RCT classifier), and addition of sources of real-world data. Future developments will be informed by the work being led by the Data and Analytics team, which includes a real world evidence framework, data access activities and research on the applicability of real world data in guidance development.

Shared decision making

1. More emphasis on shared decision making, and integrating this into standard methods for guideline development, including reference to the [GIN Public Toolkit](https://g-i-n.net/toolkit/), which gives practical advice on involving patients and the public in guidelines and includes best practice examples from NICE and other guideline developers.

Ensuring our methods are current and reflect best practice

1. Refinement of methods and processes for guidelines developed in response to health and social care emergencies, reflecting experience of the ongoing response to COVID-19.
2. More details on methods including mixed-methods reviews, prediction models and Network Meta-analyses.
3. More guidance on and clarification of differences between additional consultation and commissioned primary research.
4. More guidance on when broader sources of evidence such as call for evidence or expert witnesses could be considered.

Reflecting changes in Technology Appraisal methods and processes

1. Revisions to ensure the guidelines manual reflects changes to CHTE methods and processes (publication due 2022).

Next steps of the manual update

A second manual update will start in April 2022 and will include the following changes:

1. Guidance on our approach to Portfolio Management, including processes for forming guideline suites, amalgamating and standing down existing recommendations, and ensuring those guidelines that are prioritised reflect the needs of both guideline users and the broader health and social care system.
2. Incorporate flexible and agile methods and processes for developing guideline recommendations in a range of different scenarios, including:

* exploration of approaches to making consensus-based recommendations
* developing rapid processes for small updates
* approaches to stakeholder engagement during the development of guidelines.

1. More guidance on appropriate use of real-world data and digital technologies in guideline development.
2. Aligning the manual with changes made to the way NICE works in other areas, such as accreditation, quality standards, resource impact and content design and structuring.
3. Further work on ensuring our methods are current and reflect best-practice and user needs.

Conclusion

1. These proposed changes to the manual introduce key concepts which align guideline development methods with the NICE 5-year strategy, and lay the foundations for a more substantive update, starting in 2022.

Recommendation

1. The Board is asked to:

* Approve the plans to publish the proposed update to developing NICE guidelines: the manual.

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November 2021

Appendix A

Members of the cross-organisational steering group

NICE

Nichole Taske Associate Director (Methods & Economics)

Bhash Naidoo Senior Technical Adviser (Health Economics)

Toni Tan (Chair) Senior Technical Adviser (Methodology)

Martin Allaby Clinical Adviser

Kay Nolan Associate Director (Surveillance Team)

Chris Carmona Technical Adviser (Public Health Guideline Development Team)

Simon Ellis Associate Director (Commissioning)

Seamus Kent Associate Director, Data Analytics

Louise Foster Senior Information Manager; Guidelines Information Service

Alison Wray Senior Editorial Adviser

Kathryn Hopkins

(deputised by Shreya Shukla) Technical Adviser (Guidelines Update Team)

Justine Karpusheff/ Sara Buckner Associate Director/Technical Adviser (COVID-19)

Louise Picton Senior Medicines Advisor (Medicines Evidence & Advice)

Pall Jonsson Senior Scientific Adviser (Science Policy and Research Programme)

Jane Cowl Senior Public Involvement Adviser, Patient Involvement Programme

Richard Diaz Associate Director (Centre for Health technology Evaluation)

Craig Grime Technical Adviser (Quality Standards)

Sarada Chunduri-Shoesmith Associate Director (System Support for Implementation Team)

Hilary Baker NICE Acting Programme Director (Transformation Programme Team)

National Guideline Centre

Serena Carville Director of Methods and Service Development

National Guideline Alliance

Mia Schmidt-Hansen Head of Evidence Reviews, National Guideline Alliance

Appendix B

Process for internal consultation

First draft of revised manual sent to steering group for comment

First steering group meeting (June 2021)

Manual revised in response to steering group comments and re-circulated

Second steering group meeting to sign off final version (August 2021)

Revised manual circulated to teams not represented on steering group

Publication of updated manual (proposed November 2021)

Appendix C- changes that affect the way NICE interacts with its external stakeholders

| **Area changed** | **Original wording** | **New wording** |
| --- | --- | --- |
| Consultation (Chapter 10) | Consultation usually lasts for 6 weeks. A 4-week consultation may be used for partial updates of guidelines or small guidelines (for example, guidelines on systems and processes that relate to the use of medicines in different care settings and within provider and commissioning organisations). | The length of time for consultation depends on the size of the guideline and the number of review questions. Consultation on a new guideline or full update consisting of 15 to 20 review questions usually lasts for 6 weeks. A 4 week consultation may be used for partial updates of guidelines with less than 15 review questions, while small updates with 1 or 2 review questions will normally have a 2-week consultation. NICE staff with responsibility for quality assurance will decide how long the consultation will last, and stakeholders will be told well in advance |
| Surveillance (Chapter 13) | The median lifespan of a clinical guideline is 60 months (Alderson et al. 2014). More recent work within NICE incorporating data for public health guidelines supports this conclusion. Therefore, all NICE guidelines will be checked every 5 years using the approach described in the rest of this section. | Some topic areas change frequently, and this increases the risk of guidelines having out-of-date recommendations. NICE takes a proactive approach to surveillance, and monitors key events (such as ongoing studies) that are judged to be relevant to the guideline.  Events are identified through constant intelligence gathering. This starts during initial guideline development, as the guideline committee and stakeholders can flag up future events that need to be monitored for impact. Ongoing studies are typically identified through discussions with the National Institute for Health Research. This approach means that NICE can quickly identify changes in the evidence base, and assess the impact on recommendations and the need for any changes.  An event that could affect the guideline could include:  publication of a study that is directly relevant to NICE guidance and has the potential to affect recommendations  substantial changes in policy or legislation (an example includes changes to the UK physical activity guidelines by the Chief Medical Office)  development of a related piece of NICE guidance that contradicts recommendations in another NICE guideline  withdrawal of a drug from the market, or a clinically significant drug safety update from the Medicines and Healthcare products Regulatory Authority (MHRA) or the Commission on Human Medicines.  This list is not exhaustive and individual events will be considered on a case-by-case basis. To make the most efficient use of resource, events are:   * triaged, to determine whether surveillance assessment is needed * prioritised based on: * safety (always prioritised first) * Health and social care system priorities * burden on services * population impact * potential impact on addressing health inequalities * evidence base: is it changing frequently and what is the degree of uncertainty? * what value NICE could add by incorporating the new information into a guideline. |

Appendix D - examples of minor changes to the manual

The below are some examples of the more minor changes made in this update of the manual, to illustrate the types of changes that have been made.

|  |  |  |
| --- | --- | --- |
| **Chapter** | **Original wording** | **New wording** |
| Chapter 1- Introduction | There are 2 main ways to get involved: organisations can register as a stakeholder and individuals can join (or advise) a committee that works on guidelines. | There are 2 main ways to get involved:   * organisations can register as a stakeholder * individuals can join a committee that works on guidelines, or advise a committee as co-opted experts on a particular issue |
| Chapter 5- Identifying the evidence: literature searching and evidence submission | Depending on the review question, it may be appropriate to limit searches to particular study designs. For example, for review questions on the effectiveness of interventions, it may be more efficient to search for systematic reviews, followed by controlled trials followed by observational studies. This prevents unnecessary searching and review work. The best way to limit searches by study design is to use an appropriate search filter (strings of search terms), rather than using database publication type field limits, to ensure the search strategy is transparent and reproducible. | Depending on the review question, it may be appropriate to limit searches to particular study designs. For example, for review questions on the effectiveness of interventions, it may be more efficient to search for systematic reviews, followed by controlled trials followed by observational studies. This prevents unnecessary searching and review work. The best way to limit searches by study design is to use an appropriate search filter (strings of search terms), rather than using database publication type field limits, to ensure the search strategy is transparent and reproducible. Additional classifiers, such as the Cochrane RCT classifier, could be used to limit the search to particular study types. |
| Chapter 6- Reviewing research evidence |  | New addition to manual:  **Analysing and presenting results of mixed methods reviews**  All qualitative evidence from a mixed methods review should be synthesised and then summarised in GRADE-CERQual. Where appropriate, all quantitative data (for example, for intervention studies) should be presented using GRADE. An overall summary of how the quantitative and qualitative evidence are linked should be presented in either simple matrices or simple thematic diagrams |
| Chapter 9- Writing the guideline | If evidence of efficacy or effectiveness for an intervention is either lacking or too low quality for firm conclusions to be reached, the committee has several options. It may:  make a 'consider' recommendation based on the limited evidence (see the section on wording the recommendations)  decide not to make a recommendation, and make a recommendation for research (see the section on formulating research recommendations)  recommend that the intervention is used only in the context of research  recommend not to offer the intervention. | If evidence of efficacy or effectiveness for an intervention is either lacking or too low quality for firm conclusions to be reached, the committee has several options. It may:  make a 'consider' recommendation based on the limited evidence (see the section on wording the recommendations)  decide not to make a recommendation, and make a recommendation for research (see the section on formulating research recommendations)  decide not to make a recommendation or a recommendation for research (they should include a rationale for this decision in the guideline)  recommend that the intervention is used only in the context of research  make a ‘do not offer’ recommendation for the intervention. |
| Appendix F- Suggested sources for scoping |  | Addition of websites of devolved nations organisations (including Public Health Wales, NHS Scotland and Public Health Agency- NI) as suggested sources for scoping. |