Board meeting

22 September 2022

Public consultation on the update of developing NICE guidelines: the manual

Purpose of paper

For decision

Board action required

The Board is asked to agree to proceed to public consultation of this update to sections 1, 4, 6 and 7 of developing NICE guidelines: the manual.

Brief summary

This report gives details of the changes to the manual for developing NICE guidelines. This is the first modular update of the manual and builds on the initial changes made in the January 2022 update. It incorporates updates to our methods for synthesising evidence and health economics, and how health inequalities and real-world data are considered. This update also outlines the areas and timelines for future changes to methods and processes, to meet the digital living guideline recommendation objective.

Board sponsor

Paul Chrisp, Director, Centre for Guidelines

Introduction

Developing NICE guidelines: the manual, outlines the methods and processes used to develop and update NICE guidelines.

The NICE Strategy (2021-2026) outlines the vision for NICE to develop dynamic living guidelines that are useful, useable and rapidly updated. To be able to deliver the NICE Strategy, NICE needs to make changes to update the guideline manual.

Additionally, in the 2022/23 business plan, one of the four priority business objectives is to improve ‘the usefulness and usability of our guidelines by developing digital living guideline recommendations…’. The update to the guideline manual supports this priority objective.

The first update of the guideline manual was developed during 2021 and published in January 2022. This first update set out that in future the entire manual would not be updated together, but as discrete sections, to allow new methods and processes to be incorporated more quickly.

This paper outlines the first of 4, more substantial, modular updates of the guideline manual, which will run in 4 separate blocks of consultation and publication throughout 2022-23 (see Appendix B for details).

This first update includes changes to the following sections (and associated appendices) of the guideline manual (see Appendix C for details):

* Section 1: Introduction
* Section 4: Developing review questions and planning the evidence review
* Section 6: Reviewing research evidence
* Section 7: Health economic evaluation

The Board are asked to review the proposed changes to the manual and approve the draft for consultation.

Background to this update

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 manual was last updated during 2021 and published in January 2022, with changes that laid the foundations for more significant changes to support delivery of the NICE strategy (2021-2026). Prior to this, the last major update of the manual was in 2014.

The changes to the chapters 1, 4, 6 and 7 of the manual in this update are set out below in the section 'main changes in this update' (a full summary of changes to each section can be found in appendix C).

 The update (2022-23) will reflect changes to our methods and processes that map across the 4 digital living guideline recommendations objective:

* Publish a selected living guideline recommendation on the NICE website and make it available for third party decision support and content aggregators
* Design a sustainable future operating model to accommodate new ways of working for guideline production
* Produce methods and processes for digital living guideline recommendations
* Deliver a bespoke implementation approach in partnership with national organisations, including an automated measurement framework.

The proposed changes to the manual have been developed by working groups for each section, considered by a cross-organisational steering group (see Appendix A for details) and have undergone an internal consultation process.

In light of the scale of change being implemented across the programme, and the varying rates at which changes are tested and implemented, we will consult on and publish this update to the manual in discrete sections (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 methods and processes (workstream 2) and operating model (workstream 3) for the development of living guideline recommendations.

An overview of the timeline for consultation and publication of updated sections of the guidelines manual can be found in Appendix B.

Summary of changes in this update

Changes have been made to section 1 to reflect changes that have been made in this first modular update to sections 4, 6 and 7. Changes to section 1 also signpost intended changes planned for future update modules to methods and processes as NICE moves towards digital living guideline recommendations.

## Reflecting changes in Technology Appraisal methods and processes (CHTE 2020)

Revisions have been made to section 7, to ensure that the guideline manual aligns with changes to Centre for Health Technology Evaluation methods and processes (published 31 January 2022), with one exception:

* For NICE guidelines, the severity of the condition is captured within the QALY benefits and then deliberatively within decision making. Severity modifiers introduced by CHTE to technology appraisal guidance will not be applied to guideline analyses because: the pathway approach of guidelines means that applying severity modifiers would be highly complex as different ICER thresholds would have to be used within the guideline for decision-making; the single condition nature of severity modifiers as applied in technology appraisals does not take account of multi-morbidities. Such complications mirror the rationale for not applying the severity modifier within the Diagnostics Programme in CHTE.

## Health inequalities

There is more emphasis throughout the manual on the importance of addressing health inequalities:

* Section 1: more information on NICE’s overall approach to reducing health inequalities.
* Section 4: a new section on consideration of health inequalities when preparing review protocols has been added, and it has been clarified that the aim of a review question can include to address equalities and health inequalities
* Section 6: added that in addition to meeting legal obligations, NICE considers the 4 dimensions of health inequality and that both equalities and health inequalities should be addressed during guideline development
* Section 7: details about a prototype distributional cost-effectiveness tool developed by the University of York that provides quantitative estimates of the impact of NICE recommendations on deprivation-based health inequalities has been included. The manual states that opportunities to pilot this tool should be encouraged, to help facilitate NICE’s approach to considering health inequalities.

## Real world data and digital technologies (including automation)

The recently launched real-world evidence framework developed by the Science, Evidence and Analytics directorate has been signposted or incorporated at all relevant points in sections 4, 6 and 7.

## Approaches to enable rapid updating of recommendations

In order to realise efficiencies around the time and cost of guideline development, and to build relationships with external organisations, there is more detail on:

* reusing existing, high quality systematic reviews from non-NICE producers within NICE guidelines, both through formal collaborations with other organisations (such as our links with Cochrane and the soon to be formed NIHR evidence synthesis groups), and through use of other published reviews and evidence syntheses.
* reusing published guideline recommendations from other guideline producing organisations. This may involve either using the evidence syntheses from those organisations or using the recommendations to fill gaps or complete pathways within NICE guidance.

## Ensuring our methods are current and reflect best practice

More details are included on methods that are increasingly common within NICE guidelines, including mixed-methods reviews, qualitative methods, assessing complex interventions and alternative ways of considering imprecision.

More guidance is provided on how medicines safety information and antimicrobial stewardship should be considered during development (e.g. during protocol development and when reviewing the evidence). This update also incorporates the previously separate methods for producing antimicrobial prescribing guidance within the NICE guideline manual.

Next steps of the manual update

Once sections 1, 4, 6 and 7 and the associated appendices have undergone public consultation, the comments will be considered and changes made to the draft sections. Any substantial changes will come back to the Board for consideration and then the final sections will be published.

 Work on the changes to the remaining sections is already well underway (see appendix B for the full schedule). The next 3 blocks of consultation will come to the Board for review prior to consultation in December 2022, March 2023 and July 2023, and will cover:

* December 2022: Sections on decision making committees, validation and consultation, identifying the evidence and scoping surveillance and updating; changes will focus on changes to reflect methods and process for a prioritised portfolio and digital living guidelines.
* March 2023: Sections on linking to other guidelines, writing the guideline, finalising and publishing the guideline and resources to support putting the guideline into practice; changes will focus on methods for integrating technology appraisals, will incorporate learnings from Digital Living Guidelines workstream, including shared-decision making, and will be updated to reflect the implementation strategy and incorporate living system feedback.
* July 2023: Finalisation of manual to incorporate outputs from Digital Living Guidelines workstream, including content design and structuring and approaches to stakeholder engagement during the development of guidelines. It will also include 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.

A parallel stream of work is also underway to support implementation of the changes in the manual, once they are published. As an example, as well as greater information about the use of real-world evidence being given within the manual, work is also underway on:

* Training for staff on methods for analysing real-world data, and critiquing published real-world evidence studies.
* Training for committees on interpreting and using real-world evidence.
* Developing collaboration with external organisations, both data holders and organisations producing real-world data analyses.

Conclusion

These proposed changes to the manual build on key concepts introduced in the January 2022 update and align guideline development methods with the NICE 5-year strategy and the prioritised business plan area of delivery of digital living guidelines.

Board action required

The Board is asked to:

* 1. Approve the plans to proceed to public consultation on the proposed update to sections 1,4, 6 and 7 of developing NICE guidelines: the manual.

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Appendix A

Members of the cross-organisational steering group

The core membership of the cross-organisational steering group is set out below. People with specific expertise (such as health inequalities) were co-opted onto the group as required.

NICE

Nichole Taske Associate Director, Methods & Economics

Bhash Naidoo Senior Technical Adviser, Health Economics

Toni Tan Senior Technical Adviser, Surveillance Team

Martin Allaby Clinical Adviser

Kay Nolan Associate Director, Surveillance Team

Chris Carmona Technical Adviser, Guideline Development Team

Simon Ellis Associate Director, Commissioning

Seamus Kent Associate Director, Data Analytics

Louise Foster Senior Information Manager; Guidelines Information Service

Ann Horrell Senior Editorial Adviser

Kathryn Hopkins Technical Adviser, Guidelines Update Team

Emma McFarlane Technical Adviser, COVID-19 Team

Louise Picton Senior Medicines Advisor, Medicines Optimisation Team

Jane Cowl Senior Public Involvement Adviser, Patient Involvement Programme

Richard Diaz Associate Director, Centre for Health technology Evaluation

Craig Grime Technical Adviser, Quality Standards

Alexa Forrester Adoption and Implementation Manager, Adoption & implementation team (from April 2022)

Serena Carville Director of Methods and Service Development, GDT NGC

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

Sabina Keane Technical Analyst, Content Transformation (from April 2022)

Johanna Hulme Associate Director, Content Transformation (up to April 2022)

Sarada Chunduri-Shoesmith Associate Director, System Support (up to April 2022)

Appendix B

Timeline for guideline manual updates

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| --- | --- |
| Sections of manual | Timescales |
| Section 1- IntroductionSection 4 - Developing review question and planning the evidence reviewSection 6 – Reviewing research evidenceSection 7 – Incorporating economic evaluation | Pre-consultation board meeting: September 2022Public consultation: October 2022Post-consultation board meeting: March 2023Publication: April 2023 |
| Sections 2, 13 and 14 – Scoping, surveillance and updatingSection 3 – Decision-making committeesSection 5 - Identifying the evidenceSection 10 – Validation | Pre-consultation board meeting: December 2022Public consultation: January 2023Post-consultation board meeting: May 2023Publication: May 2023 |
| Section 8 – Linking to other guidanceSection 9 – Writing the guidelineSection 11- Finalising and publishing the guidelineSection 12 – Implementation | Pre-consultation board meeting: March 2023Public consultation: April 2023Post-consultation board meeting: July 2023Publication: July 2023 |
| All sections:Finalisation of manual to incorporate outputs from Digital Living Guidelines workstream, including: content design approaches to stakeholder engagement guidance on our approach to Portfolio Management, including processes for forming guideline suites and amalgamating and standing down recommendations | Pre-consultation board meeting: July 2023Public consultation: July 2023 Post-consultation board meeting: September 2023Publication: October 2023 |

Appendix C

Outline of main changes to sections 1, 4, 6 and 7 of the manual

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| --- | --- |
| Sections of manual | Summary of changes made |
| Section 1- Introduction | * Refer to 'guideline recommendations' throughout.
* Including references to move towards delivering digital living guidelines
* Expanded section on reducing health inequalities and NICE's approach to this.
* Updated information on topic selection and the Cross Agency Topic Prioritisation Group.
* More emphasis on updating recommendations.
* Updated information on teams that support guideline recommendation development
* Removal of linear figure of guideline development
* Update on how implementation of guideline recommendations will be supported
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| Section 4 - Developing review question and planning the evidence review | * Addition of information that review protocols can be used to inform surveillance and future updates
* Consideration of review questions for specific questions on the views and experiences of people using services, family members and the public
* Consideration of information needed to inform economic modelling
* More information on conceptual frameworks and logic models
* More information on how medicines issues should be handled in guideline recommendation development (including consideration of antimicrobial stewardship issues)
* More information on how to approach mixed methods reviews; updated information on considerations for prognostic reviews and qualitative evidence synthesis
* Using previously published systematic reviews
* Reference to the real world evidence framework and inclusion of information about when to consider using RWE
* More information on considering health inequalities when preparing review protocols
 |
| Section 6 – Reviewing research evidence | * More information on updating previous NICE reviews
* Updated information on checklists
* More information on assessing the quality of network meta-analyses
* More information on reviewing complex interventions, qualitative reviews and other types of review.
* Alternative approaches to assessing imprecision
* Presenting different types of evidence reviews
 |
| Section 7 – Incorporating economic evaluation | * Alignment with updated Technology Appraisal manual, where appropriate
* Information about when there is not enough effectiveness evidence to inform modelling
* More information on evaluations of diagnostic testing
* Updated information on measures of HRQoL in children and young people
* More information on appraisal of interventions funded by public sector
* Addition of real world data and reference to real world evidence framework
* More information about consideration of health inequalities
* Encourages use of a pilot tool using distributional cost-effectiveness analysis to model changes in health inequalities
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