Update processes for guidelines –

Systematic review

February 2022

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About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, the Health Information and Quality Authority (HIQA) was awarded the contract for the five-year period from 2017 to 2022. The HRB-CICER team comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups (GDGs), of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the GDGs provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

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Executive summary

Background

Clinical guidelines (CGs) are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service user decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system. The recommendations contained within CGs are primarily underpinned by evidence syntheses, that is, systematic reviews or adaptation of existing CGs and or recommendations. Ongoing evolution of the scientific literature brings the emergence of new evidence, which can change the findings of a systematic review and, as a consequence, change the recommendations made within a CG. As such, CGs need to be updated regularly to ensure the validity of the recommendations contained within. Updating CGs is an iterative process that is both resource intensive and time-consuming. Typically, CGs are updated in accordance with a pre-defined time-period. For example, the National Institute for Health and Care Excellence (NICE), American College of Physicians (ACP) and US Preventive Services Task Force (USPSTF) indicate that CGs should be updated every five years; in Ireland, the National Clinical Effectiveness Committee (NCEC) advise updating national CGs every three years.

While international organisations indicate arbitrary time-periods by which a guideline update should be completed, it is also acknowledged that deciding to update a CG depends on factors other than pre-defined time periods, such as the volume of new research published, the clinical burden, economic impact and the resources available to update a guideline. For that reason, policy makers and other stakeholders are advocating a move away from updating guidelines based on a pre-defined time-period and towards updating guidelines based on prioritisation criteria, to ensure appropriate use of resources. This systematic review identified and described the most recent CG update processes, including prioritisation methods, used by international or national groups who provide methodological guidance for developing and updating CGs. This will support the NCEC in considering amendments to the current update processes.

Methods

Search strategy

Due to changes in processes and methodologies in guideline development in the previous 10 years, the overall search span for this review was the last 10-years (2011-2021). Through scoping searches, we identified two published systematic reviews; one (by Vernooij et al.) was a systematic review of methodological handbooks that provide guidance for updating clinical practice guidelines, and the other (by Martínez García et al.) was a systematic review of peer-reviewed articles that describe prioritisation processes for updating guidelines. These

systematic reviews were considered index documents. Due to issues pertaining to the transferability of guidelines developed for specific diseases, disease-specific publications (handbooks and or peer-reviewed publications which described, or had implemented, guidance for updating disease-specific guidelines) were excluded.

The primary data source for this review was methodological handbooks that detail update processes, including prioritisation methods, used by international or national groups who provide methods guidance for developing and updating CGs. For methodological handbooks, data from 2011-2021 were gathered through a search of organisations' websites and grey literature. This was supplemented by the first systematic review (by Vernooij et al.) published in 2014 to identify additional methodological handbooks. The search for methodological handbooks was conducted by one reviewer, and relevant handbooks identified were reviewed by a second reviewer to confirm their eligibility.

The secondary data source was peer-reviewed articles detailing the development and or evaluation of guideline update processes. For peer-reviewed articles, data from 2011-2021 were gathered through a database search. Peer-reviewed articles served as "sign-posts" to the handbooks and provided qualitative and quantitative data relating to the usability of the handbooks and update processes. The second systematic review (by Martínez García et al.) was published in 2017 and was reviewed to identify any additional articles which might not have been identified in the database search. Title and abstracts and full texts were independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Citations excluded during the full-text review stage were documented alongside the reasoning for their exclusion and included in the PRISMA flow diagram.

Data extraction

Data were extracted from methodological handbooks by one reviewer and checked for accuracy and omissions by a second. Where disagreements occurred, discussions were held to reach consensus, and a third reviewer was involved where necessary. Data extraction was conducted using a predefined data extraction form.

Quality assessment

Methodological handbooks were quality assessed independently by two reviewers, and any disagreements were resolved by deliberation, or if necessary, a third reviewer. In the absence of an appropriate quality assessment tool specific to methodological handbooks or guidance, quality was assessed using the GIN-McMaster Guideline Development Checklist, which is a checklist of items to consider during the development of guidelines. The methodological quality of peer-reviewed articles was independently assessed by two reviewers using a slightly modified version of the Appraisal tool for Cross-Sectional studies (AXIS).

Results

Methodological handbooks

Fifteen handbooks from ten organisations were included (all published from 2011 to 2021). Four were developed by organisations in the UK (two each by the NICE and Scottish Intercollegiate Guidelines Network [SIGN]), three were developed by organisations in the US (the Clinical Guidelines Committee of the American College of Physicians [ACP], Institute of Medicine [IOM] and US Preventive Services Task Force [USPSTF]), three were developed by international organisations (two by the Guidelines International Network [GIN] and one by the World Health Organization [WHO]), two were developed through a collaboration between GIN and McMaster University and one each was developed by the Association of the Scientific Medical Societies (AWMF) in Germany, Estonian Health Insurance Fund and Swiss Centre for International Health. One handbook (*The UpPriority Tool*) described a prioritisation tool for updating clinical questions within a guideline; all other handbooks described the process of developing de novo CGs, and included varying levels of detail on the updating processes used. Of note, *Clinical practice guidelines we can trust* (by the IOM) outlined the processes guideline organisations should endeavour to achieve and was an aspirational document. Of the included handbooks, those produced by the AWMF, ACP, Estonian Health Insurance Fund and USPSTF provided the most comprehensive information relating to updating CGs. Data pertaining to the process of updating guidelines were extracted under explicit headings. Namely, types of update, events that trigger an update, retiring a CG, prioritisation of CGs, prioritisation of clinical questions, evidence synthesis methods, review, approval and dissemination of updated CGs and resources required for updating CGs.

Types of update and update triggers

- The types of update identified across the included handbooks were full (or major, or complete) and partial (or minor, or modular, or targeted, or individual questions).
- Rapid updates were another type of update identified, but these were specific to rapid guidelines (as described by the WHO, SIGN and NICE), developed in response to a public health emergency.
- SIGN and NICE described a process by which guidelines can be revalidated or refreshed; these are not considered updates and instead describe instances when changes do not require expert input.
- In the main, a review-by date indicated the need to update a guideline; the review-by date is either pre-defined by the Guideline Development Group (GDG) at the time of guideline development, or it is an arbitrary date applied to all guidelines across the organisation (this ranged from three to five years across the included handbooks).

- Other update indicators (or triggers) were:
    - publication of new evidence and or guidance, especially if the new evidence or guidance contradicts the recommendations within the current guideline
    - expert opinion from guideline developers and or feedback from those implementing the guideline
    - changes in policy and or legislation or, for example, withdrawal of a drug from the market.

Retiring a clinical guideline

- In general, a guideline is retired if:
    - a more recent or more comprehensive guideline is published
    - contextual changes render the guideline unnecessary (this is especially relevant for rapid guidelines produced in response to a public health emergency)
    - the guideline is no longer relevant to clinical practice (for example, due to changes in technology or a new understanding of the natural history of the disease)
    - the guideline relates to a topic that is now considered a low public health burden
    - the expiration date has passed and the guideline has not been updated (the expiration date ranged from 5-10 years across the included handbooks).

Prioritisation of clinical guidelines for updating

- In general, the criteria used to prioritise which guideline to update first are:
    - the review-by date
    - the rate of change of the evidence base on the topic
    - the likelihood that new evidence will be available to develop recommendations, particularly in areas of uncertainty or for questions where no evidence had been previously identified
    - the public health importance of the topic in terms of the clinical burden
    - the effect on mortality and morbidity
    - the prevalence of the condition

- the cost of the condition (for example, treatment, management and resources)
- the availability of effective healthcare and or treatment.

Prioritisation of clinical questions within a clinical guideline for updating

- *The UpPriority Tool* was developed specifically to standardise prioritisation processes used for clinical questions within a guideline scheduled for updating.
  - Each clinical question is scored against the following six priority items:
    - impact of outdated recommendations on safety
    - availability of new relevant evidence
    - context relevance of the clinical question
    - methodological applicability of the clinical question
    - users' interest
    - impact on access to health care.

Evidence synthesis methodologies used for updates

- In general, the same methodological principles (for example, a systematic review) as those used to develop a new guideline apply to updating a guideline.
- The AWMF recommend that literature searches and strategies are saved and reused when necessary.
- One handbook (*Procedure Manual*, USPSTF) suggested that the volume of evidence identified through scoping literature searches should help determine whether a systematic review is required for the update.
- The NICE handbook states that for rapid guidelines (developed in response to a public health emergency), targeted literature searches can be used for rapid updates to the original guideline; and economic evidence is not routinely considered unless it is likely to add value to the decision-making process.

Review of updated clinical guideline (internal and or external review)

- Eight of the included handbooks provided detail on the review processes for updated guidelines.
- The following exceptions to the review process for updated guidelines, were noted:

- for updates that add new evidence without changing the recommendations, review is not required unless the topic is particularly controversial (WHO)
- for guidelines that are undergoing a small change, no public consultation is held and instead, the revised section of the guideline is sent directly to the appropriate expert reviewers (SIGN)
- full updates are subject to the same review process as that for new guidelines whereas for partial updates, while subject to the same process, the process is typically shorter (NICE)
- for rapid updates to rapid guidelines (developed in response to a public health emergency), the length of the review period depends on the urgency of the guideline (NICE).

Approval and endorsement of updated clinical guideline

- For rapid updates to rapid guidelines (prepared in response to a public health emergency), NICE state that a pragmatic approach to quality assurance of a guideline update would be taken by NICE staff responsible for quality assurance.
- Four organisations confirmed that updated guidelines are subject to the same approval and or endorsement processes as new guidelines.

Dissemination of updated clinical guideline

- Seven of the included handbooks either stated, or the organisations confirmed via email, that the dissemination of updated guidelines is the same as that for new guidelines.
- The GIN-McMaster checklist for rapid recommendations stated that updates may be disseminated as 'staged releases' in an emergent or dangerous situation.

Resources required for clinical guideline updating process

- Seven of the included handbooks specified the resources required (that is, personnel, funding and time) to update guidelines.
- The GIN-McMaster Guideline Development Checklist recommends that resources for updating a guideline (including guideline group membership, funding and logistics) should to be planned at the time the original guideline is developed.
- Funding of guideline updates differs across the organisations included in this review and is largely dependent on the funding structure of the organisation itself.

- According to NICE, resourcing of updates to rapid guidelines depends on the urgency and complexity of the rapid update; the time taken to complete the update is likely to be slightly longer than development of the original guideline so as to enhance the quality and credibility of the rapid guideline.

Living guidelines

Only two handbooks included in this review (*SIGN 50: a guideline developer's handbook* and *AWMF Guidance Manual and Rules for Guideline Development*) described their approach to living guidelines; however, the handbook by the Association of the Scientific Medical Societies (AWMF) provided limited details. While a number of COVID-19 living guidelines were identified, these were not eligible for inclusion as they were disease-specific. Moreover, due to the need for rapid guidance in response to the COVID-19 pandemic, the methods used in these living guidelines were not included in organisations' general, non-disease-specific methods guidance.

Peer-reviewed articles

The search of electronic databases from 1 January 2011 to 27 October 2021, resulted in three articles being eligible for inclusion in this review; no additional articles were identified from the index documents. Of the three peer-reviewed articles eligible for inclusion, one (published in 2020) was an evaluation of additional search techniques employed by NICE. While no associated handbook was identified for this evaluation, the authors state that these additional search techniques are applied routinely by NICE in guideline surveillance when required. Overall, the authors reported that a combination of focused subject headings and frequency operators could improve the precision of surveillance searches; all studies included in the surveillance review were identified and, although some studies from the original search methods were not retrieved for two of the reviews, this would not have affected the surveillance decision on whether to update the review.

The other two peer-reviewed articles (published in 2020 and 2021) were an evaluation of *The UpPriority Tool*, developed by the GIN. In the 2020 publication, the authors piloted *The UpPriority Tool* with the NICE CG, Meningitis (bacterial) and meningococcal septicemia in under 16s: recognition, diagnosis, and management and reported that, across appraisers applying the tool, the overall degree of agreement was considered fair. In the 2021 publication, *The UpPriority Tool* was used to systematically assess 107 clinical questions from four guidelines developed in the Spanish National Health System. Each participant spent a mean of 3.8 hours evaluating the clinical questions with the tool. The degree of agreement (Intraclass correlation coefficient [ICC] and 95% confidence intervals [95% CI] among the participants was good for the CG on open-angle glaucoma (ICC 0.87 [95%CI 0.80–0.92]), moderate for the CGs on chronic heart failure (ICC 0.62 [95%CI 0.80–0.92]) and inherited

retinal dystrophies (ICC 0.63 [95%CI 0.41–0.78]), and poor for the CG on menopause (ICC 0.15 [95%CI -0.63–0.62]).

Conclusions

Of the handbooks included in this review, all provided some information on at least one of the criteria of interest to the review; none provided information on all of the criteria of interest. The following areas for consideration were noted:

- terminology and definitions used internationally were not standardised
- detail on the resources (time, funding, personnel) required to undertake an update to a CG, and who is responsible for each stage of the updating process, was poorly described
- methods used to determine if an update is indicated, as well as methods to prioritise CGs (and to prioritise clinical questions within a CG) for updating were not standardised
- evidence synthesis methods used to update CGs were generally the same as those used to develop guidelines de novo which are onerous and may represent inefficient use of resources.

This review identified 15 eligible handbooks from 10 organisations that described update processes and prioritisation methods for CGs. The most comprehensive information was obtained from the ACP, AWMF, Estonian Health Insurance Fund and USPSTF. Additionally, in terms of prioritisation, only *The UpPriority Tool* was identified; this tool is designed for prioritisation of clinical questions within a CG scheduled for updating, not prioritisation of the CGs themselves. However, the thresholds that the NCEC would accept as indicating the need to prioritise a clinical question for updating would need to be considered. Updating clinical guidelines is resource-intensive and time-consuming. International or national groups who provide methods guidance for developing and updating CGs should consider providing more comprehensive guidance and standardising the terminology used to facilitate optimal updating of CGs and prioritisation of CGs for updating. These findings may support the NCEC in considering and or modifying its current methodologies for updating clinical guidelines, to optimise the use of available resources. Comprehensive guidance from the NCEC on updating CGs and prioritisation of CGs for updating would be a valuable contribution to the international knowledge base.

List of abbreviations that appear in this report

ACP	American College of Physicians
AGREE	Appraisal of Guidelines for Research and Evaluation
AHRQ	Agency for Healthcare Research and Quality
AWMF	Association of the Scientific Medical Societies
AXIS	Appraisal tool for Cross-Sectional studies
CG	Clinical guideline
CheckUP	Checklist for the Reporting of Updated Guidelines
CIMO	Context, intervention, mechanism, outcome
GDG	Guideline development group
GIN	Guidelines International Network
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
ICC	Intraclass correlation coefficient
IOM	Institute of Medicine
KCE	Belgian Health Care Knowledge Centre
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NHMRC	Australian National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
PEWS	Paediatric Early Warning System
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SIGN	Scottish Intercollegiate Guidelines Network
USPSTF	US Preventive Services Task Force
WHO	World Health Organization

1 Background

1.1 Description of clinical guideline development

Clinical guidelines (CGs) are systematically developed statements, based on a thorough evaluation of the evidence to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system.[1] The recommendations contained within CGs are primarily underpinned by evidence syntheses, that is, systematic reviews or adaptation of existing CGs and or recommendations.[2] In September 2010, the National Clinical Effectiveness Committee (NCEC) in Ireland was established to prioritise, and quality assure National Clinical Guidelines (NCGs) so as to recommend them to the Minister for Health to become part of a suite of NCGs.[3] The NCGs are then implemented in the public healthcare system by the Health Service Executive and available to all healthcare providers. The NCEC has a mandate to provide methods guidance for the development of NCGs.[4] As such, the NCEC has published several guidance documents to support guideline developers in this process. Examples include the *Implementation Guide and Toolkit for National Clinical Guidelines*[5] and *How to develop a National Clinical Guideline: A manual for guideline developers*.[1]

Development of CGs is resource intensive and time-consuming. As such, the NCEC has developed prioritisation criteria to assist them in identifying the guidelines most significantly in need of development. These prioritisation criteria are:

- patient safety issue
- burden of clinical topic
- evidence analysis (for example, are the clinical guideline recommendations based on an analysis of the evidence, preferably a systematic review of high quality randomised controlled trials)
- economic impact
- variability in practice
- potential for addressing health issues
- CG implementation.[1]

Once prioritised, development of the guideline is an iterative process commencing with the establishment of the guideline development group (GDG). All stakeholders, that is, any entity or group with an interest in development of the guideline, should be represented on the GDG.[1] Having founded the GDG, the next step in the process is the establishment of the

evidence base. This is achieved through the formulation of the guideline questions, a review of existing international CGs (to determine if they can be adapted, adopted or contextualised for use in the Irish setting) and a literature review to identify, synthesise and appraise the evidence.[1] Having established the evidence base, recommendations are made based on that evidence, an implementation plan is developed, and a budget impact analysis is conducted. Once drafted by the GDG, the guideline is sent for external review by wider national stakeholders and international experts before it is submitted to the NCEC for quality assurance. Following this quality assurance process, the NCEC may require that the guideline be amended and or resubmitted for further quality assurance. When the quality assurance criteria are met, the guideline is recommended by the NCEC to the Chief Medical Officer for consideration and approval and if successful, onwards for Ministerial approval.[1]

1.2 Description of updating clinical guidelines

The ongoing evolution of the scientific literature brings the emergence of new evidence which can change the findings of a systematic review and, as a consequence, change the recommendations made within a CG. As such, CGs need to be updated regularly to ensure the validity of the recommendations contained within.[6] Updating CGs is an iterative process that is both resource-intensive and time-consuming. Typically, CGs are updated in accordance with a pre-defined time period. For example, the National Institute for Health and Care Excellence (NICE),[7] American College of Physicians (ACP)[8] and US Preventive Services Task Force (USPSTF)[9] indicate that CGs should be updated every five years.

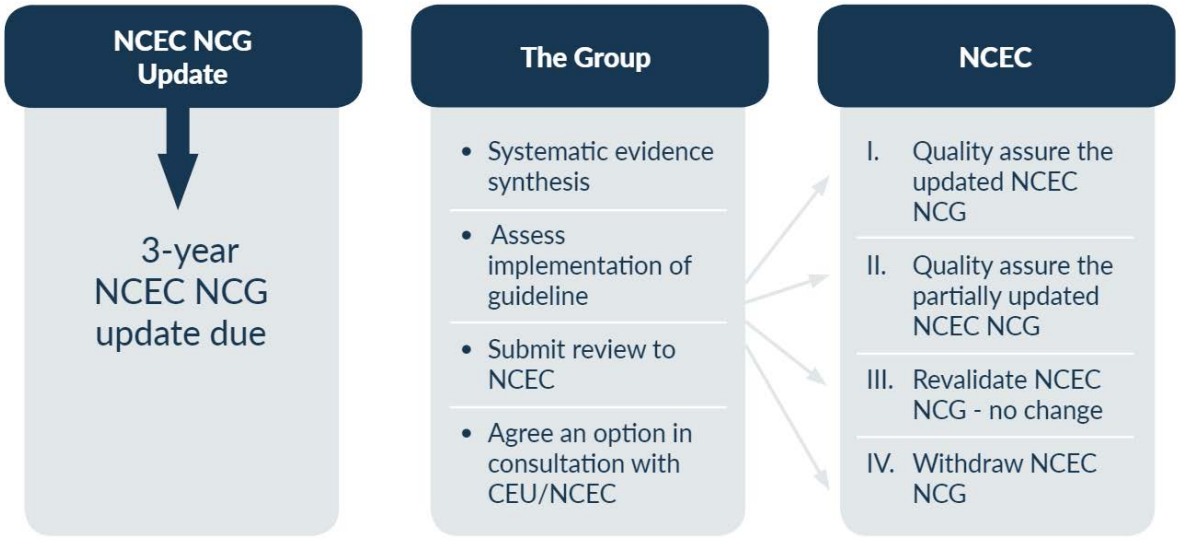
In Ireland, the NCEC advise updating NCGs every three years, recognising three types of update, namely, full, partial and rapid.[1] A full update is when the content, questions and recommendations within a guideline are completely updated. For example, in 2019 the Irish Maternity Early Warning System guideline[10] was fully updated and in 2020, the Irish National Early Warning System guideline[11] was fully updated. A partial update occurs when, following consideration of all sections within a guideline, only certain sections require updating; no NCEC guideline has been partially updated to date.[1] A rapid update occurs when new evidence emerges that could change a recommendation within a CG, such as following the publication of new studies, expert opinions or medicine alerts. For example, in 2016, the Irish Paediatric Early Warning System (PEWS) guideline[12] was rapidly updated, following feedback on the use of PEWS at four Irish hospitals and in anticipation of country-wide implementation of PEWS. The updates included, the addition of the term “child/children” to the glossary, an update to the audit outcomes, renumbering of the recommendations, changes to the wording of recommendations to provide clearer guidance and the addition of references to resources.

The NCEC guideline developers’ manual highlights that consideration of the following criteria can help determine the validity of an existing guideline, and the type of update required:

1. Have interventions (whether diagnostic or treatment) been superseded or replaced by other interventions?
2. Has new evidence altered the relationship between benefits and harms?
3. Have outcomes not considered at the time of the original guideline become important or have outcomes then considered important now become unimportant?
4. Is there evidence that current performance is optimal, and the guideline is no longer needed?[13]

Having decided upon the type of update indicated, and having reviewed any new and or emerging evidence, the GDG, will undertake an assessment as to whether the guideline is to be revised and updated, partially updated with changes to specific recommendations, retained unchanged or withdrawn.[1] This is then considered as part of the guideline update submission to the NCEC. Figure 1 provides a summary of the process of updating NCGs.

Figure 1 Process of updating NCEC National Clinical Guidelines



Source: How to develop a National Clinical Guideline, Department of Health (Ireland), 2019.[1]

While international organisations indicate arbitrary time periods by which a guideline update should be completed, it is also acknowledged that deciding to update a CG depends on factors other than pre-defined periods, such as the volume of new research published on the topic, the clinical burden of the topic, economic impact and resources available to update a guideline.[1] For that reason, policy makers and other stakeholders are advocating for a move away from updating guidelines based on a pre-defined time period and moving towards updating guidelines based on prioritisation criteria, to ensure appropriate use of resources.[14]

1.3 Purpose of this systematic review

Just as the evolution of the scientific literature brings new clinical evidence that can impact the recommendations within a CG, it also brings advancement in methodologies used in development and updating of CGs.[6] One such advancement has been the emergence of rapid and living guidelines. These guidelines aim to provide timely advice for decision-makers by optimising the guideline development process whereby individual recommendations can be updated as soon as new relevant evidence becomes available.[15] The use of rapid and living guidelines has been especially evident throughout the COVID-19 pandemic with the emphasis on the development and implementation of strategies to manage the rapidly evolving evidence base in response to a public health emergency.[16] Previous systematic reviews on this topic have summarised guidance from methodological handbooks for updating clinical practice guidelines,[6] strategies for prioritisation of CGs that require updating[14] and prioritisation processes for the de novo development, updating or adaptation of guidelines.[17] However, the evidence synthesised within these systematic reviews was largely published over a decade ago and related to disease-specific guidelines or was specific to updating systematic reviews, not updating CGs.

Therefore, the purpose of this systematic review was to describe the most recent guideline update processes, including up-to-date prioritisation methods, used by international or national groups who provide methods guidance for developing and updating CGs. The focus of this systematic review was not on adaptation, contextualisation, or development of guidelines de novo, but on updating processes for existing guidelines. This will support the NCEC in considering amendments to the current update processes.

2 Methods

In reporting this systematic review we have adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria.[18] The protocol for this systematic review was agreed by the NCEC in August 2021, has been registered on the PROSPERO database of systematic review questions and meta-analyses (registration number: CRD42021274400) and published in HRB Open.[19]

2.1 Protocol deviations

The data extraction table in the protocol was modified to include the following question:

- *Does the organisation provide detail on living guidelines?*

2.2 Criteria for considering publications for this review

The aim of this systematic review was to answer the following question:

What are the most recent guideline update processes, including up-to-date prioritisation methods, used by international or national groups who provide methods guidance for developing and updating CGs?

The review question was formulated in line with the CIMO (Context, Intervention, Mechanism, Outcome) framework,[20] as presented in Table 1. The CIMO framework describes "the problematic Context, for which the design proposition suggests a certain Intervention type, to produce, through specified generative Mechanisms, the intended Outcome(s)."[20] The context describes the environment within which change occurs, the intervention is what influences a change, the mechanism is triggered by the intervention and this produces the outcome.[20]

Table 1 Context, Intervention, Mechanism, Outcome

Context	▪ Clinical guidelines require updating to maintain relevancy.
Intervention	▪ International or national groups provide methods guidance (in published handbooks and or peer-reviewed articles) for developing and updating clinical guidelines, as well as prioritising clinical guidelines for updating.
Mechanism	▪ Clinical guidelines considered for updating (includes full, partial (also referred to as modular), rapid updates). ▪ Tools or guidance available to support prioritisation.
Outcome	▪ Description of update (or retirement) process (including roles and responsibilities at each stage) o types of update that exist o criteria used to determine if update necessary o process for retiring a guideline o criteria to prioritise which guideline is updated first o criteria to prioritise which clinical questions within a guideline are updated o evidence synthesis methodologies used to update clinical questions o differences between review process for updated guideline verses original guideline o differences between approval and endorsement process for updated guideline versus original guideline o dissemination of updated guideline o resources required to undertake update o processes for living guidelines ▪ Evaluation of the process o usability and or critique of the updating methodology o timeliness, that is, specific processes that enable a more efficient and timely update.

The types of publications eligible for inclusion were:

- methodological handbooks that provided updating guidance, including prioritisation methods, for clinical practice guidelines
- peer-reviewed articles that implemented updating guidance, including prioritisation methods, and provided an evaluation of the process.

Due to changes in process and methodologies in guideline development in the last 10 years, the overall search span for this review was the previous 10 years (2011-2021). Through scoping searches, we identified two published systematic reviews; one (by Vernooij et al.) was a systematic review of methodological handbooks that provide guidance for updating clinical practice guidelines,[6] and the other (by Martínez García et al.) was a systematic review of peer-reviewed articles that describe prioritisation processes for updating guidelines.[14] These systematic reviews were considered index documents.

2.3 Exclusion criteria

The following exclusion criteria were applied:

- due to issues relating to transferability of guidelines developed for specific diseases, disease-specific publications (handbooks and or peer-reviewed publications which described, or had implemented, guidance for updating disease-specific guidelines).
- editorials, commentaries, opinion pieces.
- abstracts only.
- animal studies.
- non-English language publications.

2.4 Search methods for identification of studies

The primary data source for this review was methodological handbooks that detail update processes, including prioritisation methods, used by international or national groups who provide methods guidance for developing and updating CGs. As described in Section 2.2, two systematic reviews were identified through scoping searches. For methodological handbooks, data from 2011-2021 were gathered through a search of organisations' websites and grey literature. The first systematic review (by Vernooij et al.)[6] was published in 2014 and was reviewed to identify any additional methodological handbooks which might not have been identified through the search of organisations' websites and grey literature.

The secondary data source was peer-reviewed articles detailing the development and or evaluation of guideline update processes. For peer-reviewed articles, data from 2011-2021 were gathered through a database search. Peer-reviewed articles served as "sign-posts" to the handbooks and provided qualitative and quantitative data relating to the usability of the handbooks and update processes. The second systematic review (by Martínez García et al.)[14] was published in 2017 and was reviewed to identify any additional articles which might not have been identified in the database search.

2.4.1 Organisations

The websites of organisations listed in Appendix 1 were searched for relevant methodological handbooks. The organisations were chosen based identification of the organisations from previous systematic reviews on this topic, advice from the Clinical Effectiveness Unit of the Department of Health, and guidance being available in English.

All organisations were contacted (via email) to fill any gaps in information relating to guideline update processes (including prioritisation methods). Websites of other relevant organisations identified during the searching process were also searched.

2.4.2 Grey literature

Other sources of grey literature searched for relevant methodological handbooks were Google (first 10 pages) and reference chasing.

2.4.3 Databases

The following databases were searched for peer-reviewed articles using the search strategy defined in Appendix 2:

- Medline (EBSCO)
- Embase (OVID)
- The Cochrane Methodology Register.

These databases were chosen in accordance with two previous systematic reviews,[6, 14] identified through scoping searches.

2.5 Data collection and analysis

2.5.1 Selection of eligible publications

Methodological handbooks were identified through searching the websites of eligible organisations (see Appendix 1) and through screening the methodological handbooks included in Vernooij et al.[6] This was done by one reviewer and relevant handbooks were reviewed by a second reviewer to confirm their eligibility.

All citations identified from the collective search strategy (see Appendix 2), and through screening the peer-reviewed articles included in Martínez García et al.,[14] were exported to EndNote (Version X8) for reference management, where duplicates were identified and removed. Using Covidence (www.covidence.org), two reviewers independently reviewed the titles and abstracts of the remaining citations to identify those for full-text review. The full texts were obtained and independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Where disagreements occurred, discussions were held to reach consensus and where necessary, a third reviewer was involved. Citations excluded during the full-text review stage were documented alongside the reasoning for their exclusion and included in the PRISMA flow diagram.

2.5.2 Data extraction and management

Data were extracted from methodological handbooks by one reviewer and checked for accuracy and omissions by a second. Where disagreements occurred, discussions were held to reach consensus and a third reviewer was involved where necessary. Data extraction was conducted in Microsoft Word, using a predefined data extraction form. The data extraction form was piloted first by one reviewer and checked by a second; it was then refined to include a section on living guidelines.

Peer-reviewed articles were not the primary data source for this systematic review; the primary data source was the methodological handbooks. However, in addition to signposting to methodological handbooks, and providing supplemental data relating to update and prioritisation processes, peer-reviewed articles provided usability and process evaluation data (relating to the associated handbook); these data were also extracted.

2.5.3 Quality assessment

Methodological handbooks were quality assessed independently by two reviewers, and any disagreements were resolved by deliberation, or if necessary, a third reviewer. In the absence of an appropriate quality assessment tool specific to methodological handbooks or guidance, quality was assessed using the GIN-McMaster Guideline Development Checklist, which is a checklist of items to consider during the development of guidelines. Specifically, the six criteria relating to updating guidelines were utilised.[21] Reviewers assessed, whether the methodological handbook covered the following areas:

1. Addressed policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated.
2. Addressed who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available.
3. Set the conditions that will determine when a partial or a full update of the guideline is required.
4. Made arrangements for guideline group membership and participation after completion of the guideline.
5. Addressed plans for the funding and logistics for updating the guideline in the future.
6. Addressed documentation of the plan and proposed methods for updating the guideline to ensure they are followed.[21]

Methodological quality of peer-reviewed articles was independently assessed by two reviewers. This was completed using a slightly modified version of the Appraisal tool for Cross-Sectional studies (AXIS).[22] The AXIS tool has 20 questions, seven related to quality of reporting, seven related to study design quality and six related to the possible introduction of biases in the study; the modified version used in this review is presented in Appendix 7. Modifications included the addition of text (see example with modifications in bold) to some questions within the AXIS tool to enhance applicability of the criteria to this review. For example:

"Was the sample frame ***(that is, the guidelines/clinical questions selected for updating)*** *taken from an appropriate population base* ***(that is, guidelines that required updating)*** *so that it closely represented the target/reference population under investigation?*

Any disagreements were resolved by deliberation or, if necessary, a third reviewer.

2.5.4 Data synthesis

As the main data extracted for this review was descriptive in nature a narrative synthesis was undertaken.

3 Results

The results are presented in two main sections as follows:

- Organisation search results:
    - characteristics of organisations that had published handbooks eligible for inclusion in this review.
    - characteristics of included handbooks (that is, handbook title, author, year and country of publication).
    - approaches to updating guidelines (that is, the types of update and update triggers described in each handbook, processes for retiring a CG, prioritisation of CGs for updating, prioritisation of clinical questions within guidelines scheduled for updating, evidence synthesis methodologies used to update CGs, review, approval and or endorsement and dissemination of updated CGs, resources required for CG updating processes).
    - a description of the organisations' approach to living guidelines.
    - methodological quality of included handbooks assessed using the six criteria relating to updating guidelines in the GIN-McMaster Guideline Development Checklist.[21]
- Database search results:
    - characteristics of peer-reviewed articles.
    - evaluation of updating processes (such as usability and timeliness of the updating processes being implemented) as reported by the authors.
    - methodological quality of peer-reviewed articles assessed using the AXIS tool.[22]

3.1 Organisation search results (handbooks)

Eligible handbooks were identified from seven organisations of the 16 pre-defined organisations (see Appendix 1). The grey literature search identified a further six handbooks. In total, 15 handbooks from 10 organisations were eligible for inclusion.

Of note, (the National Health and Medical Research Council (NHMRC) in Australia) is in the process of developing a section entitled *Updating your guideline* in their handbook, *Guidelines for Guidelines*.[23] This section will include methodological guidance and incorporate the

organisation's experience of working with guideline developers; there is currently no projected publication date for this section. In their report, *Towards tailoring of KCE guidelines to users' needs* (published in 2017), the Belgian Health Care Knowledge Centre reported that they had no formal procedure for monitoring the validity of recommendations over time. It concluded that the organisation needs to be more proactive in updating its guidelines and that, in general, guidelines are considered out-of-date five years after the publication date.[24]

An overview of the ten organisations included in this review is provided in Table 2. Seven of the included organisations, (the Clinical Guidelines Committee of the ACP, World Health Organization [WHO], Association of the Scientific Medical Societies [AWMF], USPSTF, Scottish Intercollegiate Guidelines Network [SIGN], NICE and Estonian Health Insurance Fund) are responsible for development and dissemination of CGs. The remaining three included organisations (the Institute of Medicine [IOM], Swiss Centre for International Health and Guidelines International Network [GIN]), while not responsible for development of CGs, do provide advice to guideline developers, policy-makers and professionals relating to healthcare.

Table 2 Overview of the organisations included in this report

Organisation Country Date founded	Funding	Remit
Clinical Guidelines Committee of the American College of Physicians (ACP) USA 1915 The ACP have been producing clinical practice guidelines since 1981	▪ Guideline development started as a three-year grant called the Clinical Efficacy Assessment Project. ▪ Due to the success of this programme, it was given permanent status at ACP, and the project is carried out under the aegis of the Clinical Guidelines Committee. ▪ Guidelines are developed by the Clinical Guidelines Committee and the staff of the Clinical Policy Department at ACP.	▪ To enhance the quality and effectiveness of healthcare by fostering excellence and professionalism in the practice of medicine.
World Health Organization (WHO) International 1948	▪ Member States paying their assessed contributions (countries' membership dues), and voluntary contributions from Member States and other partners.	▪ To advocate for universal healthcare, monitor public health risks, coordinate responses to health emergencies, and promote health and well-being. ▪ To provide technical assistance to countries, set international health standards, and collect data on global health issues.
Association of the Scientific Medical Societies (AWMF) Germany 1962	▪ Funded by 180 Scientific Medical Societies in Germany for which the AWMF is an umbrella organisation.	▪ To advise the government of the Federal Republic of Germany as well as the governments of the German federal countries in all topics of scientific medicine and medical research and classification.
National Academy of Medicine (known as the Institute of Medicine prior to 2015) USA 1970	▪ Relies on a volunteer workforce of scientists and other experts, operating under a formal peer-review system. ▪ The handbook[25] included in this review was requested and funded by the US Congress.	▪ To provide unbiased, evidence-based and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society and the public at large.
US Preventive Services Task Force (USPSTF) USA 1984	▪ The Agency for Healthcare Research and Quality (AHRQ) supports the USPSTF through the funding of Evidence-based Practice Centers, which are academic or research organisations with expertise in conducting systematic evidence reviews.	▪ An independent, volunteer panel of national experts in prevention and evidence-based medicine. ▪ To improve the health of people nationwide by making evidence-based recommendations about clinical preventive services such as screenings, counselling services, and preventive medications.
Scottish Intercollegiate Guidelines Network (SIGN)	▪ SIGN is part of the Evidence Directorate of Health Improvement Scotland (HIS) and core funding supports	▪ To improve the quality of healthcare for patients in Scotland by reducing variation in practice and outcome, through the

Organisation Country Date founded	Funding	Remit
Scotland 1993	the SIGN guideline programme. SIGN is editorially independent from HIS and the Scottish Government which funds HIS. ▪ Members of SIGN guideline development groups do not receive payment for their participation, although independent practitioners and patient representatives claim expenses.	development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence
Swiss Centre for International Health Switzerland 1997	▪ A public organisation that currently receives 20% of its annual income from the cantons of Basel-Stadt and Basel-Landschaft, the Swiss Federal Government and the University of Basel. ▪ 80% is competitively obtained through funding agencies, foundations or clients.	▪ To generate knowledge on disease and health systems and develop new tools and interventions. ▪ To inform health policies, strengthen health systems and implement tools and interventions for high-quality health services and public health at a local, national and global scale. ▪ To share knowledge and practical expertise with partners, students, professionals, beneficiaries, organisations and society.
National Institute for Health and Care Excellence (NICE) UK 1999	▪ NICE is funded by and accountable to the Department of Health and Social Care.	▪ To improve outcomes for people using the NHS and other public health and social care services. ▪ To produce evidence-based guidance and advice for health, public health and social care practitioners. ▪ To develop quality standards and performance metrics for those providing and commissioning health, public health and social care services. ▪ To provide a range of information services for commissioners, practitioners and managers across health and social care.
Estonian Health Insurance Fund Estonia 2001	▪ Government of Republic (designated social tax).	▪ To organise national health insurance to provide insured people with access to necessary healthcare services, medicines, medical equipment and cash benefits.
Guidelines International Network International 2002	▪ Member contributions.	▪ To improve the quality of healthcare by promoting systematic development of clinical practice guidelines and their application into practice, through supporting international collaboration. ▪ Four handbooks[21, 26-28] included in this review were published by GIN, a collaboration between GIN and McMaster University or by the GIN Updating Guidelines Working Group and collaborators

3.2 Characteristics of included handbooks

Fifteen handbooks from ten organisations were included (all published from 2011 to 2021). Four were developed by organisations in the UK (two by NICE[7, 29] and two by SIGN[30, 31]), three were developed by organisations in the US (Clinical Guidelines Committee of the ACP,[8] IOM[25] and USPSTF[9]), three were developed by international organisations (two by GIN[26, 28] and one by WHO[32]), two were developed through a collaboration between GIN and McMaster University[21, 27] and one each was developed by AWMF[33] in Germany, Estonian Health Insurance Fund[34] and Swiss Centre for International Health.[35] One handbook (*The UpPriority Tool*) described a prioritisation tool for updating clinical questions within a guideline;[28] all other handbooks described the process of developing de novo CGs, and included varying levels of detail on the updating processes used.[7-9, 21, 25-27, 29-35] Of note, *Clinical practice guidelines we can trust* (IOM)[25] outlined the processes guideline organisations should endeavour to achieve and was more an aspirational document. See Table 3 for an overview of the characteristics of the included handbooks and Appendix 4 for the data extraction table.

Table 3 Characteristics of included handbooks

Title of the publication	Year	Organisation	Country
Clinical practice guidelines we can trust[25]	2011	IOM	USA
Handbook for Supporting the Development of Health System Guidance[35]	2011	Swiss Centre for International Health	Switzerland
Guidelines International Network: Toward International Standards for Clinical Practice Guidelines[26]	2012	GIN (Qaseem A et al.)	International
AWMF Guidance Manual and Rules for Guideline Development[33]	2013	AWMF	Germany
WHO handbook for guideline development, 2nd Edition[32]	2014	WHO	International
GIN-McMaster Guideline Development Checklist[21]	2014	GIN-McMaster	International
Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations[27]	2018	GIN-McMaster (Morgan RL et al.)	International
The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline[28]	2019	GIN Updating Guidelines Working Group and collaborators	International
Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods[8]	2019	Clinical Guidelines Committee of the ACP	USA
SIGN 50: a guideline developer's handbook[30]	2019	SIGN	Scotland
Developing NICE guidelines: the manual (PMG20)[7]	2020	NICE	UK
Interim process and methods for guidelines developed in response to health and social care emergencies[29]	2020	NICE	UK
Estonian Handbook for Guidelines Development 2020[34]	2020	Estonian Health Insurance Fund	Estonia
Rapid guideline methodology[31]	2021	SIGN	Scotland
Procedure Manual[9]	2021	USPSTF	USA

Key: ACP - American College of Physicians; AWMF - Association of the Scientific Medical Societies; GIN - Guidelines International Network; IOM - Institute of Medicine; NICE - National Institute for Health and Care Excellence; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventative Services Task Force; WHO - World Health Organization.

3.3 Approaches to updating clinical guidelines

A summary of the data extracted is presented in Table 4. Of the included handbooks, those produced by the AWMF,[33] ACP,[8] Estonian Health Insurance Fund[34] and USPSTF[9] provided details on most of the criteria outlined in the pre-defined data extraction table.

Table 4 Summary of the data extracted from included handbooks

	Update types	Update triggers	Retire CG	CG prioritisation	CQ prioritisation	Evidence synthesis methods	Review	Approval	Disseminate	Resources	Living guidelines
Clinical practice guidelines we can trust (2011)[25] ***IOM***	N/R	✓	✓	N/R	N/R	N/R*	N/R*	N/R	N/R	N/R	N/R
Handbook for Supporting the Development of Health System Guidance (2011)[35] ***Swiss Centre for International Health***	Minor Major	✓	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
GIN: Toward International Standards for Clinical Practice Guidelines (2012)[26] ***GIN (Qaseem et al.)***	N/R	✓	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
AWMF Guidance Manual and Rules for Guideline Development (2013)[33] ***AWMF***	Complete Modular Key questions	✓	✓	N/R	N/R	✓	✓	✓	✓	✓	✓
WHO handbook for guideline development, 2nd Edition	N/R	✓	N/R	✓	N/R	✓	✓	N/R*	N/R*	N/R	N/R

	Update types	Update triggers	Retire CG	CG prioritisation	CQ prioritisation	Evidence synthesis methods	Review	Approval	Disseminate	Resources	Living guidelines
(2014)[32] *WHO*											
GIN-McMaster Guideline Development Checklist (2014)[21] *GIN-McMaster*	Full Partial	✓	N/R	N/R	N/R	N/R	N/R	N/R	N/R	✓	N/R
Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations (2018)[27] *GIN-McMaster (Morgan et al.)*	N/R	✓	N/R	N/R	N/R	N/R	N/R	N/R	✓	N/R	N/R
The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline (2019)[28] *GIN Updating Guidelines Working Group and collaborators*	N/A	✓	N/A	N/A	✓	N/R	N/A	N/A	N/A	✓	N/R
Development of Clinical	Full	✓	✓	✓	N/R	✓	✓	✓	✓	✓	N/R

	Update types	Update triggers	Retire CG	CG prioritisation	CQ prioritisation	Evidence synthesis methods	Review	Approval	Disseminate	Resources	Living guidelines
Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods (2019)[8] *Clinical Guidelines Committee of the ACP*	Partial										
SIGN 50: a guideline developer's handbook (2019)[30] *SIGN*	Update Minor revision	✓	✓	N/R*	N/R	✓	✓	N/R	N/R*	N/R*	✓
Developing NICE guidelines: the manual (PMG20)[7] (2020) *NICE*	Full Partial	✓	✓	N/R*	N/R	✓	✓	N/R*	✓	N/R*	N/R
Interim process and methods for guidelines developed in response to health and social care emergencies (2020)[29]	Rapid	✓	✓	N/R	N/R	✓	✓	✓	✓	✓	N/R

	Update types	Update triggers	Retire CG	CG prioritisation	CQ prioritisation	Evidence synthesis methods	Review	Approval	Disseminate	Resources	Living guidelines
NICE											
Estonian Handbook for Guidelines Development 2020[34] ***Estonian Health Insurance Fund***	Full Partial Individual questions	✓	✓	✓	N/R	✓	✓	✓	✓	✓	N/R
Rapid guideline methodology (2021)[31] ***SIGN***	N/R	✓	✓	N/R	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Procedure Manual (2021)[9] ***USPSTF***	Full Targeted Reaffirm	✓	✓	✓	N/R	✓	✓	✓	✓	✓	N/R

Key: ACP - American College of Physicians; AWMF - Association of the Scientific Medical Societies; CG - clinical guideline; CQ - clinical question; GIN - Guidelines International Network; IOM - Institute of Medicine; N/A - not applicable; NICE - National Institute for Health and Care Excellence; N/R - not reported; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventative Services Task Force; WHO - World Health Organization.

*Details not reported, but it was assumed that these processes are the same as those for development of new guidelines, processes for the latter are reported in the handbook.

3.3.1 Types of update and update triggers

Key points: Types of update and update triggers

- The types of update identified across the included handbooks were full (or major, or complete) and partial (or minor, or modular, or targeted, or individual questions).
- Rapid updates were another type of update identified, but these were specific to rapid guidelines (as described by the WHO, SIGN and NICE), developed in response to a public health emergency.
- SIGN and NICE also described a process by which guidelines can be revalidated or refreshed; these are not considered updates and instead describe instances when changes do not require expert input.
- In the main, a review-by date indicates the need to update a guideline; the review-by date is either pre-defined by the GDG at the time of guideline development, or it is an arbitrary date applied to all guidelines across the organisation (this ranged from three to five years across the included handbooks).
- Other update indicators (or triggers) were:
    - publication of new evidence and or guidance, especially if the new evidence or guidance contradicts the recommendations within the current guideline
    - expert opinion from guideline developers and or feedback from those implementing the guideline
    - changes in policy and or legislation or, for example, withdrawal of a drug from the market.

Eight[7-9, 21, 30, 33-35] of the 15 included handbooks differentiated between the types of update that can be applied to a guideline. In general, the types of update were full (or major, or complete) and partial (or minor, or modular, or targeted, or individual questions); the terminology differed depending on the organisation; see Appendix 4. Of the eight handbooks that acknowledged the need for different types of update, that is, full versus partial, only three[7, 33, 34] outlined the criteria used to determine the type of update required; these are summarised in turn below.

The *AWMF Guidance Manual and Rules for Guideline Development*[33] stated that the extent of a revision (that is, complete, modular or limited to individual key questions) to a guideline depends on:

- whether the guideline has been updated recently
- results of any updated guidelines searches
- results of new, relevant research findings from systematic literature searches
- judgment of the experts in the guideline development group
- obtaining targeted feedback from the field on the successes and or problems associated with implementing the guideline
- status analyses, needs analyses and prioritising (although it is unclear from the handbook what this specifically involves); see Appendix 4.4.

The *Developing NICE guidelines: the manual (PMG20)*[7] indicated that any of the following events could affect the update status of a guideline:

- publication of a study that is directly relevant to NICE guidance and has the potential to affect recommendations
- substantial changes in policy or legislation (for example, 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 and or Commission on Human Medicines.

It is also acknowledged that this list is not exhaustive and individual events are considered on a case-by-case basis. Events are identified through constant intelligence gathering, for example, the standard check (that is, all NICE guidelines are checked every five years to ensure they are up-to-date), the guideline development process and stakeholder correspondence, as well as enquiries sent to NICE; see Appendix 4.11.

According to the *Estonian Handbook for Guidelines Development 2020* (Estonian Health Insurance Fund)[34] a review of the guideline is arranged by the Guideline Unit by requesting – at the latest during the fourth year after a guideline's approval – an expert opinion from the Chair and or the members of the Panel that prepared the existing guideline. The following criteria are used to inform the type of update required:

- new evidence suggests any substantial change in the content of the current recommendations is needed

- any organisational changes to the health-care system occur
- assessment of the implementation of the guidelines indicates a review of the recommendations is necessary; see Appendix 4.13.

In addition to full and partial updates, rapid updates were described in three of the handbooks,[29, 31, 32] the *WHO handbook for guideline development, 2nd Edition*[32] (see Appendix 4.5), *Rapid guideline methodology (SIGN)*[31] (see Appendix 4.14) and *Interim process and methods for guidelines developed in response to health and social care emergencies (NICE)*[29] (see Appendix 4.12). Rapid guidelines are used to communicate guidance in response to an emergency, urgent need or when new evidence has emerged. As is the case with full and partial updates, a rapid update may be required when new content is needed or there are significant changes to the intent or strength of recommendations, based on new evidence and intelligence. However, the timeframe for such updates is much shorter and could be anything from a few days to a few months.[31] For guidelines produced in response to an emergency or urgent need, the *WHO handbook for guideline development, 2nd Edition*[32] differentiates between emergency (rapid response) guidelines and rapid advice guidelines. For public health emergencies that necessitate a response from WHO within hours to days, emergency (rapid response) guidelines are developed.[32] If a public health event continues for an extended period, the initial emergency (rapid response) guidelines must be reviewed to take into account both the evidence emerging from the event and a systematic review of the relevant evidence, becoming a rapid advice guideline. Such rapid advice guidelines will follow WHO processes more closely and must meet the standards for guideline development at WHO. These guidelines are published with a review-by date that indicates when the guidance may become invalid or when it will be updated or converted to a standard guideline;[32] see Appendix 4.5.

While not all handbooks differentiated between different types of update, all did acknowledge that guidelines require review after a specific time-period. For some organisations,[21, 26, 27, 32, 35] the review-by date of a guideline is pre-defined by the GDG at the time of development. For other organisations,[7-9, 30, 33, 34] an arbitrary time-period is applied to all guidelines developed by the organisation. For example, the AWMF,[33] ACP,[8] NICE[7] and USPSTF[9] handbooks defined this as five years, while the Estonian Health Insurance Fund (as stated above) handbook described initiation of this process during the fourth year after approval of the guideline.[34] Alternatively, in *Clinical practice guidelines we can trust* (IOM),[25] *Rapid guideline methodology* (SIGN)[31] and *Interim process and methods for guidelines developed in response to health and social care emergencies* (NICE),[29] it was advised that guidelines are updated when sufficient new evidence emerges; see Appendix 4. According to the *SIGN 50: a guideline developer's handbook*, the currency of guidelines is categorised as:

- current (within three years of publication or over three years old and revalidated)

- over three years old and not revalidated
- over seven years old and not revalidated.[30]

The UpPriority Tool,[28] while it did not specify types of update, outlined a process to identify the clinical questions within a guideline that require updating. The authors suggest that this process be undertaken every two years, ideally by the original GDG; see Appendix 4.8.

In the handbooks produced by SIGN[30] and NICE,[7] a decision to "revalidate" or "refresh" a guideline could also be taken. The *SIGN 50: a guideline developer's handbook*[30] indicated "revalidate" as an option when an update is not required because no evidence was identified to indicate a need to change any of the recommendations within; see Appendix 4.10. Similarly, *Developing NICE guidelines: the manual (PMG20)*[7] indicated that "refreshing" a guideline can occur when a decision has been made not to update the guideline, but instead small changes are made that do not require expert input on the topic. This could include amending or adding cross references, hyperlinks or footnotes, or changing an organisation's name, changes in service configuration, changes in government policy or guidelines, or amending recommendations to reflect the current practice context; see Appendix 4.11.

3.3.2 Retiring a clinical guideline

Key points: Retiring a clinical guideline

- In general, a guideline is retired if:
  - a more recent or more comprehensive guideline is published
  - contextual changes render the guideline unnecessary (this is especially relevant for rapid guidelines produced in response to a public health emergency)
  - the guideline is no longer relevant to clinical practice (for example, due to changes in technology or a new understanding of the natural history of the disease)
  - the guideline relates to a topic that is now considered a low public health burden
  - the expiration date has passed and the guideline has not been updated (the expiration date ranged from 5-10 years across the included handbooks).

Nine[7-9, 25, 29-31, 33, 34] of the 15 included handbooks outlined the process for retiring a CG. *Clinical practice guidelines we can trust* (IOM)[25] stated that a priority-setting procedure might be useful to identify clinical practice guidelines that may be withdrawn from the National Guideline Clearinghouse (an online repository for guidelines). Additionally, it was

recommended that the National Guideline Clearinghouse should eliminate clinical practice guidelines for which trustworthiness cannot be determined, and confirm the trustworthiness of those retained. However, it should be noted that the National Guideline Clearinghouse ceased operations on 16 July 2018, after this handbook was published; see Appendix 4.1.

The *AWMF Guidance Manual and Rules for Guideline Development*[33] stated that the AWMF administrative offices notify the guideline development group of the impending expiry of the guidelines with a formal letter about six months before the expiration date. The expiration date is defined as five years after the creation of the original guideline. If the GDG has not registered any updates or submitted any updated guidelines for publication, the previous guideline file will be deleted after the expiration date. Previously, a guideline that was not updated was labelled with a red mark, moved to a separate directory and no longer included in the internal keyword search system for AWMF guidelines. As of October 2008, this directory was completely deleted;[33] see Appendix 4.4.

According to *Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods*[8] all ACP CGs and guidance statements are considered automatically withdrawn or invalid five years after publication or once an update has been issued. However, expired documents are still available in an inactive clinical guidance section on the ACP website, as well as in the app; see Appendix 4.9.

According to the included handbooks from SIGN, proposals to withdraw guidelines which are outdated or no longer relevant are submitted initially to SIGN Guideline Programme Advisory Group and, if it agrees with the proposal, it is submitted to SIGN Council for final approval. Once it has been agreed to withdraw a guideline, all versions of the text and any associated material are removed from the SIGN website. The list of published guidelines is amended to show the guideline as withdrawn and the reason for withdrawal.[30] Both the *SIGN 50: a guideline developer's handbook*[30] (see Appendix 4.10) and *SIGN Rapid guideline methodology*[31] (see Appendix 4.14) stated that guidelines may be withdrawn for any of the following reasons:

- superseded by a more recent or more comprehensive guideline
- evidence that the guideline is fully complied with by NHS Scotland, and has become accepted practice
- emergence of new treatments or preventive measures that render the guideline irrelevant
- the guideline is over 10 years old
- contextual changes render the guideline unnecessary.

Developing NICE guidelines: the manual (PMG20)[7] stated that proposals for withdrawal of a guideline are based on an assessment of the relevant evidence published since guideline publication (abstracts of primary or secondary evidence), information obtained through intelligence gathering and feedback from stakeholder consultation. When a full update is published the old guideline is withdrawn; see Appendix 4.11.

Similarly, in *Interim process and methods for guidelines developed in response to health and social care emergencies (NICE)*[29] it is stated that withdrawal of a guideline occurs if the guideline is no longer needed or is redundant because service delivery has changed or the recommendations are likely to have limited relevance for the service beyond the health and social care emergency. This may also occur if there are safety issues or there is duplication of recommendations if the guideline content or some of its recommendations are merged with another guideline within the suite. There is no public consultation for a surveillance decision to withdraw the guideline; see Appendix 4.12.

According to the *Estonian Handbook for Guidelines Development 2020* (Estonian Health Insurance Fund),[34] retired guidelines are stored in an online repository, (www.ravijuhend.ee) managed by the Estonian Health Insurance Fund, until the new updated guideline is approved; see Appendix 4.13.

The *Procedure Manual* (USPSTF)[9] referred to active and inactive topics. Inactive topics are those that have been inactivated for one or more of the following reasons:

- the topic is no longer relevant to clinical practice because of changes in technology, new understanding of the natural history of the disease
- the topic is not relevant to primary care because the service is not implemented in a primary care setting or not referable by a primary care provider
- the topic has a low public health burden
- the topic is otherwise outside of the Task Force's scope.

Previously inactivated topics are eligible as new topic nominations, if appropriate. Topics are to be listed as "inactive" on the Task Force website after five years from the date of the original recommendation, unless considerations arise beforehand to change the status;[9] see Appendix 4.15.

3.3.3 Prioritisation of clinical guidelines for updating

Key points: Prioritisation of clinical guidelines for updating

- In general, the criteria used to prioritise which guideline to update first are:

- the review-by date
- the rate of change of the evidence base on the topic
- the likelihood that new evidence will be available to develop recommendations, particularly in areas of uncertainty or for questions were no evidence had been previously identified
- the public health importance of the topic in terms of the clinical burden
- the effect on mortality and morbidity
- the prevalence of the condition
- the cost of the condition (for example, treatment, management and resources)
- the availability of effective healthcare and or treatment.

Seven[9, 25, 28, 32-34, 36] of the 15 included handbooks referenced the need to prioritise between guidelines scheduled for updating; four organisations outlined the criteria used to prioritise which guideline to update first.

Three[25, 28, 33] of the included handbooks referenced the need to prioritise between guidelines scheduled for updating, but did not provide detail on the methods used to do so. In *Clinical practice guidelines we can trust* (IOM)[25] the authors suggested that a priority-setting procedure could prove useful in identifying clinical practice guidelines that should be prioritised for updating;[25] no details were given on what this priority-setting procedure should involve, nor were there any details gives on who should be responsible for undertaking this priority-setting procedure; see Appendix 4.1.

The authors of *The UpPriority Tool*[28] advised that, before application of the tool (that is, to prioritise clinical questions within a CG that has been scheduled for updating), a prioritisation process should be undertaken to determine which CGs should be scheduled for updating. However, details on this prioritisation process were not described as the focus of the tool is on within-guideline prioritisation of clinical questions, rather than selecting between guidelines; see Appendix 4.8.

The *AWMF Guidance Manual and Rules for Guideline Development*[33] reported that the extent of the revision depends on status analyses, needs analyses and prioritising. No detail was provided on what this prioritisation process involves; however, following communication with the organisation it was confirmed that prioritisation between guidelines is the responsibility of the leading medical society.[37] See Appendix 4.4.

Four[9, 32, 34, 36] of the included handbooks outlined the criteria used to prioritise which guideline to update first, should a number of guidelines require updating. The *WHO handbook for guideline development, 2nd Edition*[32] stated that the review-by date specified for a guideline should be informed by the rate of change of research on the topic, questions for which no evidence has been found, and the potential need for new advice; see Appendix 4.5.

Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods[8] did not report details on the methods used to prioritise between CGs for updating. However, following contact with the organisation,[38] it was confirmed that the criteria outlined in the 2010 handbook[36] are used to prioritise both the development of new CGs and updating of CGs (see Appendix 4.9); this handbook was not included in this review as it was published before 2011. However, these criteria (which are evaluated by the Clinical Guidelines Committee) are noted below:

- effect of the condition on morbidity and mortality
- prevalence of the condition
- whether effective healthcare is available
- areas of uncertainty and evidence that current performance does not meet best practices
- cost of the condition
- relevance to internal medicine
- likelihood that evidence is available to develop recommendations.[36]

The *Estonian Handbook for Guidelines Development 2020* (Estonian Health Insurance Fund)[34] stated that during the fourth year after a guideline's approval, a review is arranged by the Guideline Unit. Following communication with the organisation,[39] it was confirmed that, while there are no formal criteria for prioritising which guideline to update first, prioritisation is guided by any external information, such as new research evidence that changes the management of patients with a certain disease or important changes in the healthcare system that would mean any recommendation(s) in the guideline do not align with these changes; for example, inclusion of additional target groups in a guideline. A general assessment on whether a guideline needs to be updated is made by experts (the Chair or a member of the current Guideline Panel and one other expert in the field). The initiation of the updating process may be affected by the current financial and human resource restrictions, and or any additional factors that would likely affect the updating process (for example, awaiting results of a clinical audit). After this process, and on the basis of the information provided, the Guideline Unit presents an annual overview (to the Guideline Advisory Board) of guidelines

that require updating, together with proposals for the content and volume of the updates. In addition, the Guideline Advisory Board considers the need to update the guidelines on the basis of the results of relevant statistics, audits or applied research, or based on feedback from interested parties; see Appendix 4.13.

The USPSTF *Procedure Manual*[9] outlined their processes for prioritisation and selection of active topics (this includes updated topics). This process starts approximately three years after the previous publication and it is undertaken by the Topic Prioritisation Workgroup. There are five steps involved in this process and steps 2 to 5 are repeated annually; see Appendix 4.15 for more detail on each step. In short, topics are categorised as high-, moderate- or low-priority for review in the next 12 to 18 months, based on the following criteria:

- public health importance (that is, clinical burden and expected effectiveness of the preventive service to reduce that burden)
- potential for a recommendation to affect clinical practice (based on existing controversy or the belief that a gap exists between evidence and practice)
- new evidence (for example, new studies or new analyses of previous data) that has the potential to change the prior recommendation
- need for a balanced portfolio of topics.

Additionally, the *SIGN 50: a guideline developer's handbook*[30] and *Developing NICE guidelines: the manual (PMG20)*[7] detailed the criteria used for prioritisation of guideline topics in general. However, it was unclear whether these are relevant to the prioritisation of guidelines that require updating; see Appendix 4.10 and Appendix 4.11 for an overview of these criteria.

3.3.4 Prioritisation of clinical questions within a clinical guideline for updating

Key points: Prioritisation of clinical questions within a clinical guideline for updating

- The UpPriority Tool was developed specifically to standardise prioritisation processes used for clinical questions within a guideline scheduled for updating.
    - Each clinical question is scored against the following six priority items:
        - impact of outdated recommendations on safety
        - availability of new relevant evidence

- context relevance of the clinical question
- methodological applicability of the clinical question
- users' interest
- impact on access to health care.

Only one handbook[28] outlined criteria to prioritise and or identify the clinical questions within a guideline that require updating. *The UpPriority Tool*[28] was developed by the GIN Updating Guidelines Working Group and collaborators. Using the criteria outlined in the tool, users score individual clinical questions within a guideline and calculate an overall priority score to inform decision-making as to whether a clinical question requires updating or not. Each clinical question is scored against the following six priority items:

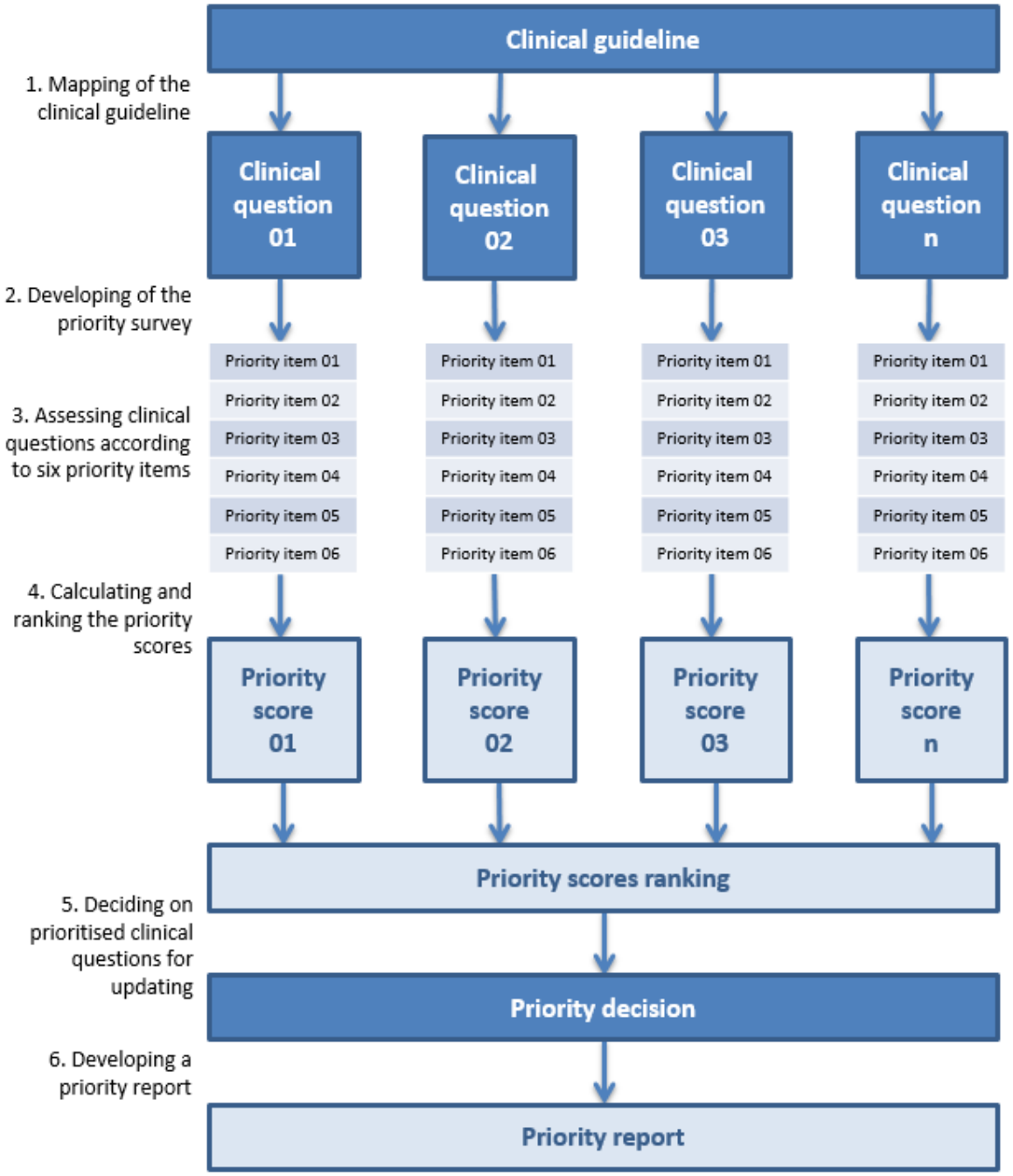
- Item 1 – Impact of outdated recommendations on safety
- Item 2 – Availability of new relevant evidence
- Item 3 – Context relevance of the clinical question
- Item 4 – Methodological applicability of the clinical question
- Item 5 – Users' interest
- Item 6 – Impact on access to healthcare.

After scoring, clinical questions are classified into one of three categories based on the ranking of priority scores (highest to lowest):

1. clinical questions prioritised for updating
2. clinical questions that could be prioritised for updating
3. clinical questions not prioritised for updating.[28]

Figure 2 provides an overview of the step-by-step process to prioritise clinical questions for updating within a CG and Appendix 4.8 provides further detail on *The UpPriority Tool* itself.

Figure 2 Step-by-step process to prioritise clinical questions for updating within a clinical guideline



Adapted from: The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline, Guidelines International Network Updating Guidelines Working Group and collaborators (International), 2019.[28]

A further two handbooks[30, 32] stated that there is a need to prioritise sections of guidelines, but they did not provide any detail on how this prioritisation is undertaken. The *WHO handbook for guideline development, 2nd Edition*[32] stated that it is important to give priority to controversial areas, or those in which new evidence has emerged. However, no further

detail was given on how such areas are actually prioritised; see Appendix 4.5. Similarly, the *SIGN 50: a guideline developer's handbook* stated that updates could apply either to sections of guidelines or individual recommendations. It recommended that processes be in place to address both of these options; however, no further detail was provided;[30] see Appendix 4.10.

Similar to the prioritisation between clinical guidelines, the AWMF confirmed that prioritisation of clinical questions within clinical guidelines is the responsibility of the GDG;[37] see Appendix 4.4.

Following communication with the Estonian Health Insurance Fund,[39] it was confirmed that the number of clinical questions to be updated depends on the current guideline and, typically, only selected questions and recommendations are reviewed. A general assessment as to whether a guideline needs to be updated is made by Chair and or the members of the Panel that prepared the existing guideline;[34] however, no detail on how individual clinical questions are prioritised was provided. See Appendix 4.13.

Communication with the USPSTF Coordinator,[40] confirmed that a new research plan is created for each update in order to guide the breadth of the evidence review. The research plan includes the key questions to be systematically reviewed, an analytic framework and eligibility criteria to be applied. The previous research plan used for the topic is reviewed and considered in formulating the new research plan. As such, the new research plan may be the same or similar to the previous one, or it may be revised to include new or additional key questions and new or revised eligibility criteria. However, detail on how individual clinical questions are prioritised was not provided; see Appendix 4.15.

3.3.5 Evidence synthesis methodologies used

Key points: Evidence synthesis methodologies used for updates

- In general, the same methodological principles (for example, a systematic review) as those used to develop a new guideline apply to updating a guideline.
- The AWMF recommend that literature searches and strategies are saved and reused when necessary.
- One handbook (Procedure Manual, USPSTF) suggested that the volume of evidence identified through scoping literature searches should help determine whether a systematic review is required for the update.
- The NICE handbook states that for rapid guidelines (developed in response to a public health emergency), targeted literature searches can be used for rapid updates to the

original guideline; and economic evidence is not routinely considered unless it is likely to add value to the decision-making process.

Eight[7-9, 29, 30, 32-34] out of 15 included handbooks made some reference to the evidence synthesis methodologies used. The *WHO handbook for guideline development, 2nd Edition*[32] did not specifically refer to methods for evidence synthesis when conducting an update of an existing guideline. However, it stated that all recommendations in WHO guidelines should be based on a systematic review of the scientific literature guided by specific key questions about the intervention, exposure or approach under consideration. It is assumed this is the case for updated guidelines also; see Appendix 4.5.

In the *AWMF Guidance Manual and Rules for Guideline Development,*[33] while detail on the methodologies used were not reported, the handbook stated that the original guideline should be systematically developed to enable continuous updating. It recommended that literature searches and strategies for answering clinically relevant questions are saved and reused when necessary; updated searches need only cover the period after publication of the earlier guideline version. See Appendix 4.4.

Evidence synthesis methodologies were not reported in *Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods.*[8] However, following contact with the organisation,[38] it was confirmed that a full systematic review is conducted when updating a guideline; see Appendix 4.9.

The *SIGN 50: a guideline developer's handbook*[30] described methodology to be used for updating a guideline and when the update is limited to a small change. The same methodological principles apply as for when conducting a new guideline except the update can limit the focus to sections of the original guideline in need of updating, as identified through scoping. For guidelines that require a small change, the methodologies are largely the same, the only difference being the level of involvement of the GDG; this will depend on the nature of the changes to the guideline, see Appendix 4.10.

The *Developing NICE guidelines: the manual (PMG20)*[7] specified that for both a full update and a partial update, the same methods and processes as that for development of a new guideline are used. The underlying principles of transparency of process and methodological rigour continue to hold; see Appendix 4.11.

The *Interim process and methods for guidelines developed in response to health and social care emergencies* (NICE)[29] handbook details the evidence synthesis methodologies used to conduct a rapid update. It states that update searches should be conducted using targeted literature searches. Additional searching of ongoing reviews should be conducted through existing collaborative links with established national or international networks and

repositories, where available. A search for health economic evidence is not routinely conducted, due to time restrictions, unless it is likely to add value to the decision-making process. Similarly, 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.[29] All recommendations should be underpinned by a transparent and accountable decision-making process; see Appendix 4.12.

The *Estonian Handbook for Guidelines Development 2020* (Estonian Health Insurance Fund)[34] recommended that updated guidelines are developed using the same principles and methodologies as those used to prepare a new guideline and should be based on existing Evidence to Decision frameworks; see Appendix 4.13.

According to the USPSTF *Procedure Manual*,[9] the Topic Prioritisation Workgroup decide, based on the volume of evidence identified through scoping literature searches, whether a systematic review is required for the update; see Appendix 4.15.

Additionally, in *Clinical practice guidelines we can trust* (IOM),[25] evidence synthesis methodologies for new CGs were described, but it did not confirm whether these processes are also used for updates to said guidelines; see Appendix 4.1.

3.3.6 Review of updated clinical guideline (internal and or external review)

Key points: Review of updated clinical guideline (internal and or external review)

- Eight of the included handbooks provided detail on the review processes for updated guidelines.
- The following exceptions to the review process for updated guidelines, were noted:
    - for updates that add new evidence without changing the recommendations, review is not required unless the topic is particularly controversial (WHO)
    - for guidelines that are undergoing a small change, no public consultation is held and instead, the revised section of the guideline is sent directly to the appropriate expert reviewers (SIGN)
    - full updates are subject to the same review process as that for new guidelines whereas partial updates, while subject to the same process, the process is typically shorter (NICE)
    - for rapid updates to rapid guidelines (developed in response to a public health emergency), the length of the review period depends on the urgency of the guideline (NICE).

Eight[7-9, 29, 30, 32-34] of the included handbooks outlined their methods for reviewing updated guidelines.

The *WHO Handbook for Guideline Development, 2nd Edition*,[32] stated that the Guideline Review Committee must review any update that involves changing recommendations. While updates that add new evidence without changing the recommendations do not require review. Under certain circumstances, if the topic or new evidence is highly controversial, review by the Guideline Review Committee may be advisable; see Appendix 4.5.

The *SIGN 50: a guideline developer's handbook*[30] specified that for updates to existing guidelines, national open meetings are only held if the content of the guideline has significantly changed. Otherwise, the guideline is made available for open consultation on the SIGN website for one month. For published guidelines that are undergoing a small change, no consultation meeting is held. Instead, the revised section of the guideline is sent directly to the appropriate expert reviewers;[30] see Appendix 4.10.

According to the NICE guidance, *Developing NICE guidelines: the manual (PMG20),*[7] full updates are subject to the same consultation process (that is, review process) as newly developed guidelines. This involves a draft version of the guideline (including recommendations, rationales, committee discussions, evidence reviews and methods) being posted on the NICE website alongside pre-specified questions for consultation with registered stakeholders. Stakeholders are also asked to comment on recommendations that are likely to substantially increase costs. The duration for consultation is decided by NICE staff and depends on the size of the guideline and the number of review questions: a full update (consisting of 15 to 20 review questions) usually lasts for six weeks; partial updates (consisting of less than 15 review questions), usually last four weeks; updates with one or two review questions normally last two weeks;[7] see Appendix 4.11 for more detail.

The NICE guidance, *Interim process and methods for guidelines developed in response to health and social care emergencies,*[29] states that rapid updates are also subject to a consultation period; the length of which depends on the urgency of the rapid update, the complexity and volume of new evidence. A broader range of stakeholders are engaged in the rapid update consultation and thematic responses to stakeholder comments are made available on the NICE website; see Appendix 4.12.

Following communication with the AWMF,[37] ACP,[38] Estonian Health Insurance Fund[39] and USPSTF,[40] it was confirmed that the review process for updates is the same as that for new guidelines that have been developed;[8, 9, 33, 34] Appendix 4.4, Appendix 4.9, Appendix 4.13 and Appendix 4.15 provide more information on the reviewing processes for new CGs used by the AWMF, ACP, Estonian Health Insurance Fund and USPSTF, respectively.

Additionally, in *Clinical practice guidelines we can trust* (IOM),[25] the methods for reviewing new CGs were described, but it did not confirm whether these processes are also used for updates to said guidelines. Appendix 4.1 provides more detail on the reviewing processes for new CGs.

3.3.7 Approval and or endorsement of updated clinical guideline

Key points: Approval and endorsement of updated clinical guideline

- For rapid updates to rapid guidelines (prepared in response to a public health emergency) NICE state that a pragmatic approach to quality assurance of a guideline update would be taken by NICE staff responsible for quality assurance.
- Four organisations confirmed that updated guidelines are subject to the same approval and or endorsement processes as new guidelines.

In *Interim process and methods for guidelines developed in response to health and social care emergencies* (NICE),[29] it stated that a pragmatic approach to quality assurance of a guideline update is taken by NICE staff responsible for quality assurance. This includes technical quality assurance (by a senior technical lead) and quality assurance (by the NICE clinical, public health or social care adviser). The Guidance Executive at NICE approves and signs off the rapid update before publication;[29] see Appendix 4.11.

Four organisations (the AWMF,[37] ACP,[38] Estonian Health Insurance Fund[39] and USPSTF),[40] confirmed (via email) that approval and or endorsement processes for updated CGs are the same as those for new guidelines, as described in their associated handbooks.[8, 9, 33, 34] In *AWMF Guidance Manual and Rules for Guideline Development*,[33] it specified that after the structured consensus development process is completed (this includes external review and final editing by the coordinators), the overall guideline is adopted by all members of the guideline development group, usually in an e-mail resolution procedure. The next step is formal adoption by the boards of the participating medical societies; see Appendix 4.4.

According to *Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods,*[8] all ACP clinical guidelines are posted for review and comments by the ACP Board of Governors. The Board of Regents, ACP's highest governing body, provides comments and final approval of the guideline as ACP policy. The Board of Regents votes to approve Clinical Guideline Committee papers with a simple yes-or-no vote and cannot make changes to the recommendations. Clinical guidelines also undergo a thorough peer review on submission to a journal for publication consideration; see Appendix 4.9.

The Estonian Health Insurance Fund confirmed that to approve an updated guideline and its implementation plan, the Guideline Advisory Board must evaluate whether the guideline has been developed according to the principles and methodology set out in the *Estonian Handbook for Guidelines Development 2020*. The focus of the evaluation is not the content of the guideline, but the rigor of its development.[34] Appendix 4.13 outlines the key questions that help the Guideline Advisory Board evaluate the quality, clarity and consistency of the guideline.

The USPSTF confirmed that the topic leads present the updated evidence and CG to the Task Force, this is followed by a discussion. The Chair then calls for a vote. A "yes" vote from two thirds of the Task Force membership is needed to pass the updated CG.[9] Appendix 4.15 provides more information on this process.

Additionally, in *Clinical practice guidelines we can trust* (IOM),[25] and *Developing NICE guidelines: the manual (PMG20)*,[7] methods for approval and or endorsement of new CGs were described, but it did not confirm whether these processes are also used for updates; Appendices 4.1 and 4.12 provide more detail on the approval and or endorsement processes for new CGs.

3.3.8 Dissemination of updated clinical guideline

Key points: Dissemination of updated clinical guideline

- Seven of the included handbooks either stated, or the organisations confirmed via email, that the dissemination of updated guidelines is the same as that for new guidelines.
- The GIN-McMaster checklist for rapid recommendations stated that updates may be disseminated as 'staged releases' in an emergent or dangerous situation.

Six organisations (the AWMF, ACP, GIN-McMaster, NICE, Estonian Health Insurance Fund and USPSTF), with seven associated handbooks[7-9, 27, 29, 33, 34] provided information on the dissemination of updated guidelines; the AWMF,[37] ACP,[38] NICE,[41] Estonian Health Insurance Fund[39] and USPSTF[40] provided this information via email.

According to *AWMF Guidance Manual and Rules for Guideline Development*,[33] updated guidelines are published on the websites of the GDG, guideline program or scientific medical society that produced the updated guideline. Dissemination activities are the responsibility of the GDG, scientific medical society and AWMF administration office; see Appendix 4.4.

According to *Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods,*[8] all ACP

clinical guidelines are submitted for publication in a high-impact journal. In addition to journal publication and website posting, ACP clinical guidelines are presented at ACP's annual meeting, announced in ACP newsletters, published in the free ACP Clinical Guidelines app and covered by national media outlets. Guidelines are submitted to the Guidelines International Network library, where they are accompanied by a checklist of guideline standards; see Appendix 4.9.

NICE does not directly inform health and social care professionals about the publication of new or updated guidelines, but health professionals are encouraged to subscribe to receive NICE newsletters and alerts about topics that may be of interest to them. There is an expectation that all health professionals keep up-to-date with developments and new guidance relevant to their setting as part of their continuing professional development.[41] In addition, NICE publish news articles and blogs on their website and social media. They issue press releases and updates to a wide range of media outlets, including TV and radio, about new guidance; the decision on whether to feature them is taken by the editors at the respective organisations. See Appendix 4.11 and Appendix 4.12.

The *Estonian Handbook for Guidelines Development 2020*,[34] states that the final stage of the guideline update process is communication and dissemination of the updated guideline, this includes all assessments, comments, reviews of interested parties, a working copy of the guideline, summaries of the evidence gathered by the team and protocols; all of which are made publicly available on the organisation's website. Appendix 4.13 includes specific details of the information that should be published with the updated guideline, such as the implementation plan and the final scope of the guideline.

According to the *Procedure Manual* (UPPSTF),[9] the Task Force disseminates its research plans, methods, evidence reviews, and recommendation statements through:

- USPSTF website
- Prevention Task Force app
- Journal of record (currently the Journal of the American Medical Association)
- Dissemination and Implementation Partners.

Dissemination is undertaken by the Dissemination and Implementation Workgroup; see Appendix 4.15 for more information.

Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations,[27] specified that Rapid Guideline updates may be disseminated as 'staged releases' in an emergent or dangerous situation. The first release

being to protect public health and respond to the crisis, and the second to address planned updates and changes in values; see Appendix 4.7.

A further two handbooks[30, 32] outlined their methods for dissemination of newly developed CGs, but did not confirm whether these processes are also used for updates; Appendix 4 provides more detail on the dissemination process, outlined by each handbook, for new CGs.

3.3.9 Resources required for clinical guideline updating processes

Key points: Resources required for clinical guideline updating process

- Seven of the included handbooks specified the resources required (that is, personnel, funding and time) to update guidelines.
- The GIN-McMaster Guideline Development Checklist recommends that resources for updating a guideline (including guideline group membership, funding and logistics) should to be planned at the time the original guideline is developed.
- Funding of guideline updates differs across the organisations included in this review and is largely dependent on the funding structure of the organisation itself.
- According to NICE, resourcing of updates to rapid guidelines depends on the urgency and complexity of the rapid update; the time taken to complete the update is likely to be slightly longer than development of the original guideline so as to enhance the quality and credibility of the rapid guideline.

Seven[8, 9, 21, 28, 29, 33, 34] included handbooks provided some information on the resources required to update CGs. The *GIN-McMaster Guideline Development Checklist*[21] is a checklist of items to consider during the development of guidelines; it includes six criteria specific to the updating of guidelines. Within these criteria, it stated that guideline group membership and participation after completion of the guideline, as well as funding and logistics should to be planned for when the guideline is updated in the future; see Appendix 4.6. Authors of *The UpPriority Tool*[28] recommended that at least four appraisers apply the tool to each of the clinical questions within a guideline that is scheduled for updating; see Appendix 4.8.

The NICE handbook (*Interim process and methods for guidelines developed in response to health and social care emergencies*)[29] stated that a rapid update is likely to take slightly longer than developing the original health and social care emergency guideline. This permits a robust update process to be conducted which, in turn, enhances the quality and credibility of the guideline. The NICE health and social care emergency guideline development team is responsible for updating the guideline. They are supported by the rapid update independent advisory expert panel who convene to interpret new evidence and intelligence gathered from

surveillance, and so make decisions on the guideline recommendations. The number of topic experts in the rapid update independent advisory expert panel depends on the urgency and complexity of the rapid update. Furthermore, it should include 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;[29] see Appendix 4.12.

Following communication with the AWMF[37] it was confirmed that the German Guideline Program in Oncology and the Programme for National Treatment Guidelines provide institutional resources for updating oncology guidelines. Other guidelines are updated with resources of the scientific medical societies. The *AWMF Guidance Manual and Rules for Guideline Development*[33] states that most members of the GDG do their work on an honorary basis; exceptions might be external moderators or methodologists. The costs for a guideline may vary, depending on the topic to be addressed, methods used and time required. For this reason, they advise that a rough financial framework is developed in advance. The AWMF supports the guideline development groups with basic advice free-of-charge and information as outlined in the handbook; see Appendix 4.4.

Following communication with the ACP,[38] it was confirmed that financial support for the development of ACP clinical guidelines commissioned by ACP comes exclusively from the ACP operating budget, as described in *Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods*;[8] see Appendix 4.9.

The Estonian Health Insurance Fund[39] confirmed that updating of guidelines is financed according to the contract between the University of Tartu and the Estonian Health Insurance Fund. Updating and composing guidelines is funded solely by the Estonian Health Insurance Fund;[34] see Appendix 4.13.

The *Procedure Manual*[9] (USPSTF) outlined the key players in the review process for a new or updated topic. This includes a topic team consisting of several Task Force leads (including one of the Task Force Chairs), at least one AHRQ Medical Officer to oversee the topic, the Evidence-based Practice Center review team (lead by the lead investigator) and the Task Force Scientific Director and or Associate Scientific Director.[9] Following communication with the USPSTF Coordinator,[40] it was confirmed that the 1998 Public Health Service Act and the 2010 Patient Protection and Affordable Care Act authorise and require the AHRQ to convene the USPSTF and to provide scientific, administrative, and dissemination support to the USPSTF; see Appendix 4.15.

A further two handbooks[7, 30] outlined some detail of the resources (namely funding source and suggested personnel) required to develop new CGs, but did not confirm whether these resources are also applicable to guideline updates; Appendix 4 provides more detail on

resource allocation, outlined by each handbook, for new CGs. For information on the funding of individual organisations, see Table 2.

3.4 Living guidelines

As described in Section 1.3, this systematic review also aimed to find guidance on the production of living guidelines. Living guidelines are defined as 'an optimisation of the guideline development process to allow updating individual recommendations as soon as new relevant evidence becomes available.'[15] It should be noted that a living guideline is distinct from a living systematic review that is defined as a systematic review which is continually updated, incorporating relevant new evidence as it becomes available.[42] While only two handbooks in this review (*SIGN 50: a guideline developer's handbook*[30] and *AWMF Guidance Manual and Rules for Guideline Development)*[33] described their approach to living guidelines, five organisations are giving thought to a move towards this (as outlined below), and some have partially implemented a living guideline approach for a specific project, for example, COVID-19.

The *SIGN 50: a guideline developer's handbook*[30] outlined that the main difference between a living guideline and others is that a living guideline is developed on a rolling programme of regular updates. The frequency of updating will depend on the pace at which new evidence is emerging but will normally be annual or biennial. Each update focuses only on those areas of the guideline where new evidence has been identified; see Appendix 4.10. To date, SIGN, together with NICE and Royal College of General Practitioners, has developed one living guideline using this approach (*SIGN 161: Managing the long-term effects of COVID-19)*.[43]

Additionally, following communication with the AWMF,[37] it was confirmed that to keep guidelines continuously up to date, a living guideline approach can be taken, whereby the guideline is updated at least once a year. In the updated guideline, the most important innovations should be set out at the beginning ("what's new?") and the recommendations should be marked with "verified", "modified" or "new" and dated accordingly. However, limited detail was provided on this process; see Appendix 4.4.

As described in Section 3.2, the Australian NHMRC is in the process of updating its handbook, *Guidelines for guidelines*;[23] the updated version will include a section on living guidelines. The Canadian Agency for Drugs and Technologies in Health has trialled Recommendation Mapping, which is a new approach to digitising and presenting living guidelines, in a recent Tuberculosis guideline[44] but the method does not appear in their handbook as of October 2021. In the NICE Strategy 2021 to 2026, there is a commitment to 'Provide dynamic, living guideline recommendations that are useful and useable, rapidly updated, and incorporate the latest evidence and newly-recommended technologies to maximise uptake and access for patients.'[45] Following communication with NICE,[41] it was confirmed that as part of the NICE Strategy 2021 to 2026, a prioritisation exercise is underway to determine which parts of the

guideline portfolio will be actively maintained; this includes revising the process for reacting to events (such as enquiries) and performing updates. This is part of the move away from standard surveillance reviews, towards living guidelines. Details on the processes NICE will use to produce these living guidelines has yet to be decided. For guideline users, practitioners, and commissioners, the aim is that they will have access to guideline recommendations that use up-to-date evidence and data, rapidly incorporating information on the relative effectiveness of new technologies, medicines and interventions. There will be a focus on topic areas that represent key priorities to ensure the greatest impact on health and on reducing health inequalities. They hope that the living guidelines methodologies will be quicker, more flexible and will answer the most important questions.

Several agencies publish rapid recommendation or practice points that are consistently updated until a full guideline can be published. The *Estonian Handbook for Guidelines Development 2020* (Estonian Health Insurance Fund)[34] referred to small informative recommendation units (SIRUs); these are recommendations only and can be published online in advanced of full authorisation of guidelines. The number of recommendations in a SIRU is typically one to four. This approach allows for rapid feedback by patients, health professionals and policy-makers. It also supports maintaining SIRUs in a live or updated format, where required. These recommendations can be published on the website sooner after approval than full guideline documents. They require the same approval processes, but the review will take less time because the amount of information is reduced;[34] see Appendix 4.13.

In response to the COVID-19 pandemic, the Scientific Medical Policy Committee of the ACP began developing rapid living practice points to provide clinical advice based on the best available evidence for the public, patients, clinicians, and public health professionals.[46] The overarching aim of practice points is to answer targeted key questions for which there is a timely need to synthesise evidence for decision making. The committee believes these methods can potentially be adapted to address various clinical and public health topics beyond the COVID-19 pandemic. The development of the practice points followed conventional processes for the development of recommendations, with two important modifications.[47] First, their initial development was fast-tracked using methods for rapid reviews and recommendations. Second, the practice points are being maintained in a living, frequently updated state to incorporate new research as it becomes available.

The WHO has specifically implemented a living guideline for recommendations for the use of therapeutics in the treatment of COVID-19;[48] this handbook was not eligible for inclusion as it is disease-specific.

The KCE in Belgium takes a more cautious view of living guidelines suggesting that constantly changing recommendations could cause frustration, scepticism and non-adherence.[24]

3.5 Methodological quality of handbooks

In the absence of an appropriate quality assessment tool specific to methodological handbooks or guidance, the quality of methodological handbooks was assessed using the GIN-McMaster Guideline Development Checklist,[21] which is a checklist of items to consider during the development of guidelines. Specifically, the six criteria relating to updating guidelines were used; see Section 2.5.3.

A summary graph is presented in Figure 3, and the detailed quality assessment of each handbook is presented in Appendix 5.

Fourteen handbooks[7-9, 25, 27-35] were assessed. Four of the six quality appraisal criteria were not considered applicable to *The UpPriority Tool*.[28] This is because the primary purpose of *The UpPriority Tool* is to prioritise the clinical questions within a guideline that is undergoing an update process, rather than anything to do with determining whether a guideline should be updated in the first place.

Overall, no handbook addressed all six criteria. Three handbooks[9, 30, 34] addressed four of the criteria, five handbooks addressed three of the criteria,[7, 29, 32, 33, 35] one handbook[26] addressed two of the criteria, and the remaining four handbooks[8, 25, 27, 31] addressed one criterion. Mostly, the handbooks identified in this review did not adequately address the updating criteria outlined in the GIN-McMaster Guideline Development Checklist.[21]

Fourteen handbooks[7-9, 25, 27-35] had a policy, procedure or timeline for routinely monitoring and reviewing whether the guideline needed to be updated.

Nine handbooks[7-9, 26, 28-30, 32-35] outlined who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available.

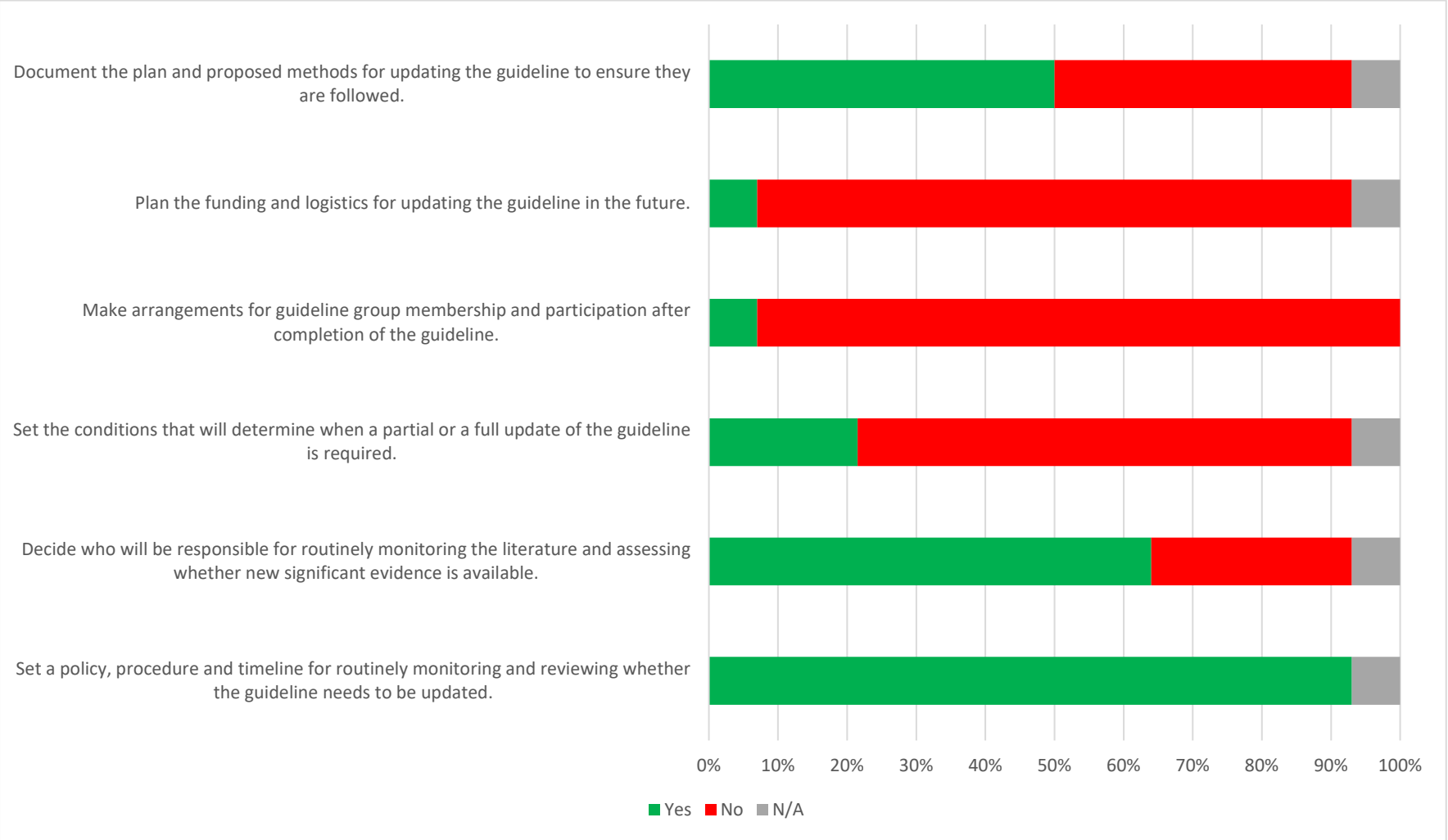
Fourteen handbooks[7-9, 25, 27-35] reported the triggers that indicate the need for an update. However, only three[7, 33, 34] outlined the criteria used to determine the type of update required.

One handbook[28] outlined arrangements for guideline group membership and participation after completion of the guideline, and this was *The UpPriority Tool*.

One handbook, the *Procedure Manual* (UPPSTF),[9] included a plan for the funding and logistics for updating the guideline in the future.

Seven handbooks[7, 9, 29, 30, 32, 34, 35] recommended that researchers document the plan and proposed methods for updating the guideline to ensure they are followed.

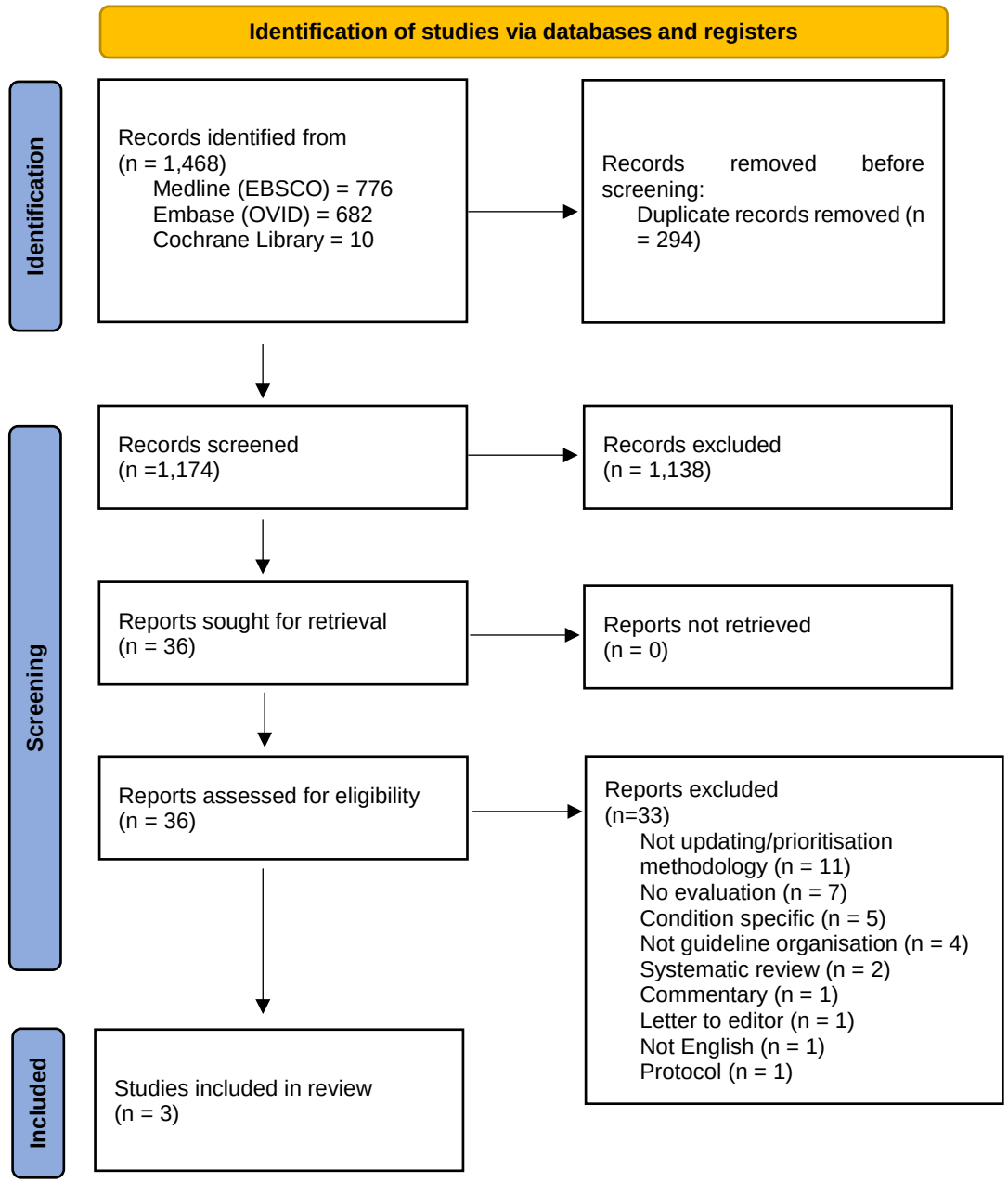
Figure 3 Quality assessment of included handbooks



3.6 Database search results (peer-reviewed articles)

The search of electronic databases (see Appendix 2), from 1 January 2011 to 27 October 2021, identified a total of 1,468 citations. After the removal of duplicates, 1,174 records were screened, with a further 1,138 records excluded based on titles and abstracts. A total of 36 full-text articles were assessed for eligibility according to the inclusion and exclusion criteria; 33 were excluded (see Appendix 3). This resulted in three articles being eligible for inclusion in this review; no additional articles were identified from the index documents. The PRISMA flow chart (outlining the search, screening and selection of studies) is presented in Figure 4.

Figure 4 PRISMA flow diagram of included studies



3.7 Characteristics of included peer-reviewed articles

Of the three peer-reviewed articles eligible for inclusion, one (published in 2020[49]) evaluated additional search techniques employed by NICE. While no associated handbook was identified for this evaluation, the authors state that these additional search techniques are applied routinely by NICE in guideline surveillance when required; this is implied by the methods described in *Developing NICE guidelines: the manual (PMG20)*.[7] The aim of guideline surveillance is to check that guidelines are up to date. This is achieved by identifying any new evidence that may contradict or reinforce recommendations within the existing guideline,

identifying new interventions that may need to be considered and through consideration of changes in context, for example, changes in policy. The other two peer-reviewed articles (published in 2020[50] and 2021[51]) were an evaluation of *The UpPriority Tool*,[28] developed by the GIN. Appendix 6 provides an overview of the characteristics of the included peer-reviewed articles.

3.8 Evaluation of updating processes

The aim of the publication by Casey et al.[49] was to investigate the impact of additional search techniques employed by NICE to determine if they increase precision and reduce the screening burden without impacting on the decision to update or not. The additional search techniques employed were focused subject headings, subheadings, frequency operators and title only searches. Two rounds of testing were conducted on five surveillance reviews;[49] see Appendix 6.1.

Overall, the authors reported that a combination of focused subject headings and frequency operators could improve the precision of surveillance searches; all studies included in the surveillance review were identified and, although some studies from the original search methods were not retrieved for two of the reviews, this would not have affected the surveillance decision on whether to update the review.[49] The authors concluded that these additional search techniques should be considered for surveillance topics where the initial search yields many studies for screening and for rapid reviews, where limited resources prohibit a full systematic review. However, it should be noted that these additional search techniques were only tested on NICE surveillance reviews and these results may not be replicated when used for other guidelines.[49] Moreover, these additional search techniques are not detailed in Developing NICE guidelines: the manual (PMG20).[7]

The aim of the 2020 publication by Sanabria et al.[50] was to develop *The UpPriority Tool* and pilot the tool with one of the NICE CGs. *The UpPriority Tool*[28] was developed to help guideline developers prioritise clinical questions within a CG that has been scheduled for updating. Each clinical question is scored against six priority items as described in Section 3.3.4. After which, clinical questions are categorised as, clinical questions prioritised for updating, clinical questions that could be prioritised for updating or clinical questions not prioritised for updating.[28] The authors piloted *The UpPriority Tool* with the NICE CG, *Meningitis (bacterial) and meningococcal septicemia in under 16s: recognition, diagnosis, and management*.[50] Of the six participants invited to apply the tool independently to the clinical questions within this guideline, three applied the tool (50% response rate). Intraclass correlation coefficient (ICC) and 95% confidence intervals (95% CI) for each item and across items were calculated. As per Landis and Koch,[52] the level of agreement was defined as:

- Poor – 0.00-0.20

- Fair – 0.21-0.40
- Moderate – 0.41-0.60
- Substantial – 0.61-0.80
- Almost perfect – 0.81-1.00

The overall ICC was 0.65 (95%CI 0.36–0.82). There was a substantial degree of agreement for Item 2 (Availability of new relevant evidence), fair degree of agreement for Item 1 (Impact of outdated recommendations on safety), Item 3 (Context relevance of the clinical question) and Item 6 (Impact on access to healthcare) and poor degree of agreement for Item 4 (Methodological applicability of the clinical question) and Item 5 (Users' interest). The overall degree of agreement was considered fair, given the wide confidence intervals observed. Participants took a median of 0.5 hours to complete the priority ratings using the tool;[50] see Appendix 6.2.

The 2021 publication by Sanabria et al.[51] used *The UpPriority Tool*[28] to systematically assess 107 clinical questions from four guidelines developed in the Spanish National Health System. The aim of the study was to use *The UpPriority Tool* to identify which clinical questions within the CGs need to be prioritised for updating and assess the implementation of the tool in a real-world set of CGs.[51] The authors contacted the original GDG members (n=54) and further new members (n=18). Overall, 30 appraisers completed the assessment of the CGs using *The UpPriority Tool*. Each participant spent a mean of 3.8 hours (range 0.5–10 hours) evaluating the clinical questions with the tool. Appraisers highlighted four main areas where the tool was most useful:

- inclusion and assessment of new clinical questions
- improvement of training materials
- guidance for searching new evidence
- management of clinical questions not prioritised for updating

The degree of agreement among the participants was good for the CG on open-angle glaucoma (ICC 0.87 [95%CI 0.80–0.92]), moderate for the CGs on chronic heart failure (ICC 0.62 [95%CI 0.80–0.92]) and inherited retinal dystrophies (ICC 0.63 [95%CI 0.41–0.78]), and poor for the CG on menopause (ICC 0.15 [95%CI -0.63–0.62]).[51]

Following the application of the tool, while no changes were suggested, four areas for consideration were proposed. Firstly, it was acknowledged that members of the UpPriority Implementation Working Group should provide expertise and updated specialist knowledge to the prioritisation process. Secondly, it was suggested that the exemplar prioritisation

reports would be helpful. Thirdly, while *The UpPriority Tool* does not recommend any priority thresholds to decide which clinical questions should be prioritised for updating, it was suggested that each UpPriority Implementation Working Group should agree if a priority threshold is needed and if so, define said threshold. Fourthly, methodological support from the developers of *The UpPriority Tool* (including responding to queries) was deemed to be essential across the whole process;[51] see Appendix 6.2.

3.9 Methodological quality of peer-reviewed articles

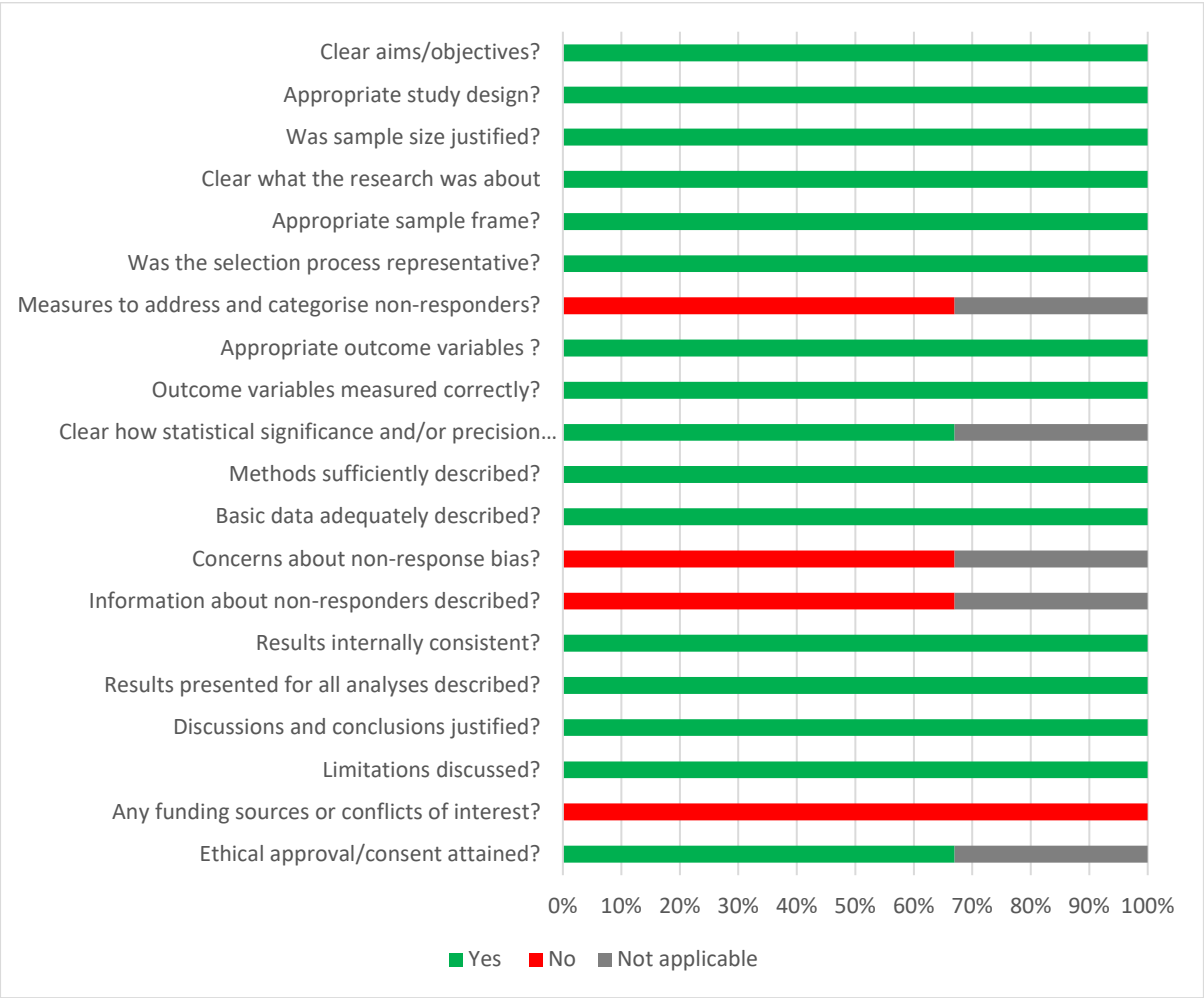
All three included peer-reviewed publications were assessed using the AXIS tool[22] and were of good quality. A summary graph is presented in Figure 5, and the detailed quality assessment of each study is presented in Appendix 7.

In relation to the quality of reporting domains, all studies provided a clear statement of aims and it was clear what the research was about. In all studies, the methods were sufficiently described, as was the basic data and results, and it was clear how statistical significance was determined in the two studies[50, 51] where it was appropriate. Study limitations were also presented in all studies.

In relation to study design quality, all studies employed an appropriate study design with appropriate outcomes and conclusions, which were justified by the results. All studies used convenience samples of guidelines that were representative of the target population, that is, guidelines requiring updating. No conflicts of interest were identified. Both studies had ethical approval.

Concerning the possible introduction of bias domains, the selection of guidelines and appraisers was representative of the target population and outcomes were measured appropriately. Non-response bias was not applicable to Casey et al.[49] as they did not recruit participants. Sanabria et al.[50] had a 50% response rate when piloting *The UpPriority Tool* but all responders remained anonymous so no data on non-responders could be provided. However, all invited participants had similar backgrounds. The evaluation of *The UpPriority Tool* [51] had a response rate of 85.7%; non-response was not considered an issue in this study.

Figure 5 Methodological quality assessment of included studies using modified AXIS tool



4 Discussion

4.1 Summary of findings

We identified 15 methodological handbooks[7-9, 21, 25-35] from ten organisations that provided some guidance on the updating process of CGs and three peer-reviewed articles that evaluated updating processes. While a number of COVID-19 living guidelines were identified in initial searches, these were not eligible for inclusion as they were disease-specific. Moreover, due to the need for rapid guidance in response to the COVID-19 pandemic, the methods used in these living guidelines were not included in organisations' general, non-disease-specific methods guidance.

Of the handbooks included, all provided some information on at least one of the criteria of interest to the review. The ACP,[8] AWMF,[33] Estonian Health Insurance Fund[34] and USPSTF,[9] provided the most information on criteria through a combination of the detail outlined in their handbooks as well as through their responses to an email (that was sent to all organisations) seeking further information on identified gaps.

For a number of criteria (namely, evidence synthesis methodologies used, review of updated CGs, approval and or endorsement of CGs, dissemination of CGs), handbooks typically reported the processes used for development of new guidelines without confirming if these same processes are used for updating guidelines.

Like a number of handbooks included in this review, the Irish guidance (*How to develop a national clinical guideline: a manual for guideline developers*),[1] defines different types of update (namely, full, rapid and partial). An update to a CG is triggered when a pre-defined time period lapses; currently, this time period is defined as three years after publication of the CG. This review typically includes an evaluation of the implementation of the CG, consideration of the scope (that is, clinical questions addressed within the CG), a systematic literature search (from the date of the previous literature search if the scope of the guideline and clinical questions remain the same), addition and or removal of clinical questions, consideration of other published NCEC NCGs and, if appropriate, utilisation of the GRADE system and editorial changes. The four possible outcomes following this review are, the CG is fully revised and updated, partially updated with changes to specific recommendations, not updated at all or withdrawn. If the review concludes that the CG is to be updated, the processes for peer-review, endorsement and dissemination are the same as those detailed for a new guideline.

Like other international organisations, the NCEC has produced a set of criteria to prioritise whether a guideline should be developed in the first instance.[53] These criteria are similar to those used by organisations internationally, when determining whether an update to a CG is indicated. These criteria (which are also listed in Section 1.1) are, patient safety, the burden

of the clinical topic, evidence analysis, economic impact, variability in practice, the potential for addressing health issues, clinical guideline implementation. Similarly, when prioritising CGs for updating, the NCEC strongly recommends that CGs scheduled for updating are prioritised according to the same criteria, to optimise the use of available resources.[1] *The UpPriority Tool*,[28] uses a similar process to that outlined, which is applied at the clinical question level as opposed to the CG level.

4.2 Findings in the context of previous research

Updating CGs is a complex process that includes identifying new evidence, assessing whether it impacts the recommendations, assessing whether an update is required (and if so, the type of update indicated), conducting the update and disseminating the updated guideline. Additionally, there is the parallel issue of updating the systematic reviews that often inform updates to a CG. Our review found that, overall, no single handbook contained guidance on all steps of this process. These findings are consistent with previous studies that suggest there is a lack of adequate details for updating of CGs in many handbooks, and more explicit guidance is needed.[14, 54] Moreover, in the majority of handbooks, it was unclear who was responsible for and who should participate in updating the CG.

It has been argued that partial updating often makes more sense than updating the whole CG because topics and recommendations differ in terms of the need for updating.[55] Furthermore, prioritisation of existing CGs is an effective way of ensuring that resources are directed toward the upkeep of CGs that are relevant and of the highest priority.[56] Seven of the included handbooks[8, 9, 25, 28, 32-34] referred to priority-setting procedures. However, only four[8, 9, 32, 34] (two of which confirmed via email communication),[8, 34] provided some detail on the criteria used to prioritise between guidelines and no uniform approach was identified. Approaches included were broadly based on the topic and rate of change of the evidence base, the review-by date of the guideline, clinical burden and public health importance of the topic and opinions of interested parties. The latter could potentially bias the outcome of the prioritisation process.

Rapid guidelines and updates of the same are increasingly being used to communicate guidance in response to new evidence,[27] or in an emergency such as the COVID-19 pandemic. These processes are outlined in handbooks by the WHO,[32] NICE[29] and SIGN.[31] In the Irish context, such emergency guidance is produced by guidance development structures such as the National Standards for Clinical Practice Guidance, rather than the NCEC. Rapid guidelines and rapid updates of the same tend to abbreviate or remove guideline development steps,[27] thus recommendations are less applicable to general guideline development.

The Checklist for the Reporting of Updated Guidelines (CheckUp)[57] is a 16-item reporting guideline to evaluate the completeness of reporting in updated guidelines and to help guideline developers in updating CGs. The authors of CheckUp suggest assessing the quality of CGs using the AGREE II instrument and prioritising the update of high-quality CGs. The updating process could also incorporate improving the methodological quality of the CG.[58] A systematic assessment of the reporting of the updating process in updated CGs using the CheckUp tool found the reporting of the updating process in updated CGs to be suboptimal.[58] Another study found the presentation formats used to indicate the changes in recommendations varied widely across CGs, even within the same guideline organisation.[59]

The UpPriority Tool[28] was developed to inform decision-making as to whether a clinical question within a guideline requires updating; which, in turn, may reduce the burden of updating a CG. The two included studies[50, 51] that tested this tool, highlight its usefulness in identifying which questions within a CG need to be prioritised for update in real-world scenarios. The level of agreement for application of the tool across four CGs ranged from good to poor; which may reflect variation in the GDGs who originally developed the CGs. While feedback from the appraisers in the studies was positive and no changes to the tool were suggested, areas to consider for improvement included the identification of key appraisers, customisation of training materials, establishment of priority thresholds and provision of methodological support.[51]

The recommendations contained within a CG are typically underpinned by a systematic review (or evidence synthesis). In general, the evidence synthesis methodologies used to update CGs, as described in the included handbooks, were the same as those used to develop new guidelines. However, it is acknowledged that there is a need to improve the timeliness and reduce the burden of maintaining the validity of CGs. For example, during the prioritisation process, consideration could be given to newer, more efficient evidence synthesis methodologies. A 2017 qualitative study of systematic review production models currently employed within and outside Cochrane[60] identified six opportunities to improve the production of systematic reviews. These included:

- clarification of roles and expectations of authors
- continuity and consistency of input into reviews
- active coordination of the review process
- centralisation of some aspects of review production
- dividing reviews into smaller steps
- improvement of approaches to capacity building and information sharing.

Machine learning algorithms to support systematic reviewing are rapidly evolving and it is thought that the future of systematic reviewing will involve such algorithms to support searches and screening of titles and abstracts thereby increasing efficiency.[61] Another approach to supporting systematic reviewing is crowdsourcing, whereby a large group of people make small contributions to achieve a large output (that is, completion of the systematic review). However, disparities in individuals' backgrounds, drop-out rate and co-ordination of the project are some challenges associated with this approach.[62]

Updating an existing systematic review to inform an update to a CG, is generally more efficient than starting a new systematic review. However, poor reporting of existing systematic reviews can make this difficult. Moreover, there is a lack of clear guidance on how updates to systematic reviews should be reported.[63] In some instances, search strategies for an update to a CG differ from the original,[64] which raises the issue of whether the updated searches should be applied to original dates instead of the date from when the last search was conducted.[64] This makes the process of updating CGs very onerous. As such, there is a need to develop and evaluate more efficient search strategies.[65] In the included study from Casey et al.,[49] the authors investigated the impact of additional search techniques, employed by NICE, to determine if they increase precision and reduce the screening burden without impacting on surveillance decisions. It was concluded that the search techniques employed should be considered for surveillance topics where the initial search yields a large number of studies for screening and for rapid reviews where limited resources prohibit a full systematic review.[49] Additionally, Martínez García et al.[66] have evaluated the efficiency and feasibility of two approaches to determine if the recommendations within a CG require updating. The authors concluded that the use of restrictive search strategies was a feasible and efficient method through which to identify significant new evidence likely to trigger a recommendation update.

Terminology across the handbooks included in this review was inconsistent. For example, full and partial updates were also referred to as major and minor (or modular) updates, respectively; retiring a guidelines was also referred to as withdrawal or expiration of a guideline. This lack of standard terminology and definitions is one of the challenges identified in updating CGs. To address this, the GIN Updating Guidelines Working Group compiled the Updating Glossary with domains, terms, definitions, and synonyms related to updating of CGs.[67] The authors concluded that use of the updating Glossary could facilitate and improve knowledge translation and enable identification of research gaps.[67]

Methods to develop and implement dynamic or living CGs are still in their infancy, but they have been especially useful throughout the COVID-19 pandemic. For example 'A living WHO guideline on drugs for COVID-19' has been published, drawing on evidence synthesised in two living network meta-analyses.[68] For this review, only two eligible handbooks (*SIGN 50: a guideline developer's handbook*[30] and *AWMF Guidance Manual and Rules for Guideline*

Development)[33] described their universal approach to living guidelines; other living guidelines identified were disease-specific and therefore not eligible for inclusion. As described in Section 3.4, the NHMRC and NICE are in the process of developing their guidance for living guidelines. While it is anticipated that the use of living guidelines will become more common, currently, guidance on routine use of living guidelines is lacking. Living guidelines require living systematic reviews, living evidence to decision frameworks and living prioritisation processes;[69] all of which require significant resources. For example, the Australian National COVID-19 Clinical Evidence Taskforce produced living guidelines for the treatment of people with COVID-19; these were updated weekly. An evaluation of the first five months of the project was undertaken, which noted that while updates were valuable, there were a number of challenges including, workload management and significant stressors placed on staff.[70] As such, the longevity of living guidelines is a major issue. For example, the continuous surveillance and updating of a pregnancy CG was stopped prematurely due to lack of financial resources for maintaining the surveillance strategy.[71] Moreover, platforms for communication and dissemination of updates to living guidelines need to be reactive to ensure that clinicians and decision-makers are using up-to-date recommendations and have confidence in the implementation of CGs.[69]

One approach to overcoming the challenges associated with living guidelines is to increase the resources allocated to the process, or adapt the process itself. Adapting the process could mean focusing the scope or modifying the methodology used, for example not doing a full systematic review. However, the latter could result in a higher risk of bias and resulting recommendations that are less reliable.[47] For the production of living, rapid practice points, Qaseem et al.[46] invested more resources and focused the scope, thus maintaining key methodological steps (such as systematic review) and the rigor of the process.[47] Living guidelines are thought to be most appropriate in a public health emergency (for example, the COVID-19 pandemic),[68] or in situations where there is ongoing research that is likely to influence the recommendations within a CG and as a result, impact the currency of the CG.[15] As such, there is a need to ensure that a rigorous process is in place to identify and prioritise a CG as "living" and the status of a CG as "living" should be reviewed.[47]

4.3 Strengths and limitations of this review

We conducted a systematic and exhaustive search that included main databases, and several organisations' websites. In addition, we contacted all identified organisations to retrieve non-published handbooks and or address gaps in the data extracted; therefore, we believe that we included most of the existing relevant handbooks. However, there are some limitations. It is possible that we did not identify all relevant handbooks because some are not publically available. Moreover, due to resource constraints, we restricted inclusion to English language only and did not search for, or include, disease-specific handbooks. It is possible that we did not identify all potentially eligible peer-reviewed articles from the database search. Finally,

the criteria used to assess the methodological quality of the handbooks included were not validated for this purpose.

4.4 Implications for practice based on review findings

Of the handbooks included in this review, all provided some information on at least one of the criteria of interest to the review; none provided information on all of the criteria of interest. A number of other research gaps were also identified. Firstly, there is a lack of clear guidance on the roles and responsibilities attributed to each stage of the update process. For example, who would be responsible for triggering the update process if the "review by date" criterion is removed? Secondly, there is a need for clarity around how and where updates to a CG should be reported. Thirdly, there is a need for clear guidance on when a full systematic review is required for the update, or if abridged methods can be used; if abridged methods are appropriate what would these consist of? Fourthly, there is a need for more research into improving the efficiency of updating through the use of machine learning and crowdsourcing. The following areas for consideration were noted:

- terminology and definitions used internationally were not standardised
- detail on the resources (time, funding, personnel) required to undertake an update to a CG, and who is responsible for each stage of the updating process, was poorly described
- methods used to determine if an update is indicated, as well as methods to prioritise CGs (and to prioritise clinical questions within a CG) for updating were not standardised
- evidence synthesis methods used to update CGs were generally the same as those used to develop guidelines de novo which are onerous and may represent inefficient use of resources.

4.5 Conclusion

This review identified 15 eligible handbooks from 10 organisations that described update processes and prioritisation methods for CGs; no single handbook contained guidance on all of our pre-defined steps. In general, the most comprehensive information was obtained from the ACP, AWMF, Estonian Health Insurance Fund and USPSTF. Additionally, in terms of prioritisation, only *The UpPriority Tool* was identified; this tool is designed for prioritisation of clinical questions within a CG scheduled for updating, not prioritisation of the CGs themselves. However, the thresholds that the NCEC would accept as indicating the need to prioritise a clinical question for updating would need to be considered. Updating clinical guidelines is resource-intensive and time-consuming. International or national groups who provide

methods guidance for developing and updating CGs should consider providing more comprehensive guidance and standardising the terminology used to facilitate optimal updating of CGs and prioritisation of CGs for updating. These findings may support the NCEC in considering and or modifying its current methodologies for updating clinical guidelines, to optimise the use of available resources. Comprehensive guidance from the NCEC on updating CGs and prioritisation of CGs for updating would be a valuable contribution to the international knowledge base.

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Appendix 1 List of organisations searched

Organisation name	Organisation URL
Agency for Healthcare Research and Quality, USA	https://www.ahrq.gov/
Belgian Health Care Knowledge Centre, Belgium	https://kce.fgov.be/en
Best Practice Advocacy Centre New Zealand, New Zealand	https://bpac.org.nz/guidelines/
Canadian Agency for Drugs and Technologies in Health, Canada	https://www.cadth.ca/
European Network for Health Technology Assessment	https://www.eunethta.eu/
Finnish Institute for Health and Welfare, Finland	https://thl.fi/fi/
Guidelines International Network	https://g-i-n.net/
Institute of Medicine, USA	https://nam.edu/about-the-nam/
McMaster GRADE centre, Canada	https://cebgrade.mcmaster.ca/
National Board of Health and Welfare, Sweden	https://www.socialstyrelsen.se/en/regulations-and-guidelines/national-guidelines/
National Health and Medical Research Council, Australia	https://www.nhmrc.gov.au/
National Institute for Health and Care Excellence, UK	https://www.nice.org.uk/
Public Health Agency of Sweden, Sweden	https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/
Ravijuhend, Estonia	https://www.ravijuhend.ee/
Scottish Intercollegiate Guidelines Network, Scotland	https://www.sign.ac.uk/
World Health Organization	https://www.who.int/

Appendix 2 Search strategy

Database: Medline (EBSCO) **Search date: 27 October 2021**			
#	**Query**	**Limiters/Expanders**	**Results**
1	TI ((updat* or up-to-date or up to date) N8 (guideline* OR guidance OR priorit*)) OR AB ((updat* or up-to-date or up to date) N8 (guideline* OR guidance OR priorit*))	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	12,099
2	TI (methodolog* OR handbook*) OR AB (methodolog* OR handbook*)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	350,978
3	(MH "Guidelines as Topic+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	168,963
4	(MH "Evidence-Based Medicine+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	75,074
5	S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	572,842
6	S1 AND S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	4,913
7	PT guideline OR practice guideline	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	159,011
8	S6 NOT S7	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	1,127
9	S6 NOT S7	Limiters - Date of Publication - 20110101-20211231	833
10	S6 NOT S7	Limiters - Date of Publication - 20110101-20211231 Expanders - Apply equivalent subjects Narrow by Language - English	776
Database: Embase **Search date: 27 October 2021**			
#	**Query**	**Results**	
1	((updat* or up-to-date or up to date) adj8 (guideline* or guidance or priorit*)).ab,ti.	17,644	
2	(methodolog* or	507,558	

	handbook*).ab,ti.	
3	*evidence based practice/	10,010
4	2 or 3	516,891
5	1 and 4	1,258
6	limit 5 to yr="2011 -Current"	1,014
7	limit 6 to (conference abstract or conference paper or "conference review")	300
8	6 not 7	714
9	limit 8 to English language	682
Database: The Cochrane Library Search date: 27 October 2021		
#	**Query**	**Results**
1	(updat* NEAR/8 (guideline* or guidance or priorit*)):ab (Word variations have been searched)	444
2	MeSH descriptor: [Guidelines as Topic] explode all trees	1,928
3	MeSH descriptor: [Practice Guidelines as Topic] explode all trees	1,640
4	MeSH descriptor: [Evidence-Based Medicine] explode all trees	906
5	(methodolog* or handbook*):ab (Word variations have been searched)	22,038
6	#3 OR #4 OR #5	24,384
7	#1 AND #6 with Cochrane Library publication date Between Jan 2011 and Jan 2021, in Cochrane Reviews, Cochrane Protocols, Special Collections	10

Appendix 3 Studies excluded after full text review

	Peer-reviewed article	Reason for exclusion
1	Agbassi C, Messersmith H, McNair S, Brouwers M. Priority-based initiative for updating existing evidence-based clinical practice guidelines: The results of two iterations. Journal of Clinical Epidemiology. 2014;67:1335-42.	Disease-specific
2	Akl EA, Meerpohl JJ, Elliott J, Kahale LA, Schuenemann HJ, Living Systematic Review N. Living systematic reviews: 4. Living guideline recommendations. Journal of Clinical Epidemiology. 2017;91:47-53.	Not guideline organisation
3	Alonso-Coello P, Garcia LM, Gimeno JMC, Sola I, Qureshi S, Burgers JS, et al. The updating of clinical practice guidelines: insights from an international survey. Implementation Science. 2011;6:107.	Not updating/prioritisation methodology
4	Becker M, Neugebauer EAM, Eikermann M. Partial updating of clinical practice guidelines often makes more sense than full updating: A systematic review on methods and the development of an updating procedure. Journal of Clinical Epidemiology. 2014;67:33-45.	Not guideline organisation
5	Bero LA, Hill S, Habicht J, Mathiesen M, Starkopf J. The updated clinical guideline development process in Estonia is an efficient method for developing evidence-based guidelines. Journal of Clinical Epidemiology. 2013;66:132-9.	Not updating/prioritisation methodology
6	Christensen NL, Rasmussen TR, Jekunen A, Heinonen S, Dalton SO. Lung cancer guidelines in Sweden, Denmark, Norway and Finland: a comparison. Acta Oncologica. 2017;56:943-8.	No evaluation
7	Couch KS, Corbett L, Gould L, Girolami S, Bolton L. The International Consolidated Venous Ulcer Guideline Update 2015: Process Improvement, Evidence Analysis, and Future Goals. Ostomy/wound management. 2017;63:42-6.	Not updating/prioritisation methodology
8	El-Harakeh A, Lotfi T, Ahmad A, Morsi RZ, Fadlallah R, Bou-Karroum L, et al. The implementation of prioritization exercises in the development and update of health practice guidelines: A scoping review. Plos One. 2020;20:15.	Systematic review
9	Fog Heen A, Olav Vandvik P, Brandt L. A new generation of reliable clinical practice guidelines through magic. Revista Peruana de Medicina Experimental y Salud Publica. 2014;31:118-26.	Not English
10	Gambito EDV, Zamora MTG, Gonzalez-Suarez CB, Grimmer KA, Valdecanas CM, Dizon JMR, et al. Updating contextualized clinical practice guidelines on stroke rehabilitation and low back pain management using a novel assessment framework that standardizes decisions. BMC research notes. 2015;8:643.	Disease-specific
11	Martínez García L, Pardo-Hernandez H, Niño de Guzman E, et alDevelopment of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol. BMJ Open 2017;7:e017226.	Protocol
12	Gould MK, Cooke CR. A guide to guidelines for pulmonary, sleep, and critical care medicine clinicians. Proceedings of the American Thoracic Society. 2012;9:211-4.	No evaluation
13	Gurgel RK. Updating Clinical Practice Guidelines: How Do We Stay Current? Otolaryngology-Head and Neck Surgery. 2015;153:488-90.	Commentary
14	Hollon SD, Teachman BA. Advantages of developing clinical practice guidelines using international standards. Psychotherapy. 2019;56:340-6.	No evaluation
15	Jin, YH., Yao, XM. & Zeng, XT. Development of rapid advice guideline and standard and continuous updating guideline: experiences and practice. Military Medical Research. 2021;8.	Letter to editor
16	Koduah A, Asare BA, Gavor E, Gyansa-Lutterodt M, Andrews Annan E, Ofei FW. Use of evidence and negotiation in the review of national standard	No evaluation

	Peer-reviewed article	Reason for exclusion
	treatment guidelines and essential medicines list: experience from Ghana. Health policy and planning. 2019;34:ii104-ii20.	
17	Lamontagne F, Agoritsas T, Siemieniuk R, Rochwerg B, Bartoszko J, Askie L et al. A living WHO guideline on drugs to prevent covid-19 BMJ 2021; 372:n526.	Disease-specific
18	Liang N, Li H, Wang J, Jiao L, Liu B, Xiong Y, et al. Development of Rapid Advice Guidelines for the Treatment of Coronavirus Disease 2019 with Traditional Chinese Medicine. American Journal of Chinese Medicine. 2020;48:1511-21.	Not updating/prioritisation methodology
19	Martínez García L, Pardo-Hernandez H, Juliana Sanabria A, Alonso-Coello P, Penman K, McFarlane E, et al. Guideline on terminology and definitions of updating clinical guidelines: The Updating Glossary. Journal of Clinical Epidemiology. 2018;95:28-33.	Not updating/prioritisation methodology
20	Martínez García L, Sanabria AJ, Araya I, Lawson J, Sola I, Vernooij RWM, et al. Efficiency of pragmatic search strategies to update clinical guidelines recommendations. BMC Medical Research Methodology. 2015;15.	Not guideline organisation
21	Martínez García L, Sanabria AJ, Pardo-Hernandez H, Alonso-Coello P, Aceituno-Velasco L, Araya I, et al. Continuous surveillance of a pregnancy clinical guideline: An early experience. Systematic Reviews. 2017;6:143.	Not guideline organisation
22	McDonald S, Elliott JH, Green S, Turner T. Towards a new model for producing evidence-based guidelines: A qualitative study of current approaches and opportunities for innovation among Australian guideline developers. F1000Research. 2019;8:956.	Not updating/prioritisation methodology
23	Picon PD, Beltrame A, Banta D. National guidelines for high-cost drugs in brazil: Achievements and constraints of an innovative national evidence-based public health policy. International Journal of Technology Assessment in Health Care. 2013;29:198-206.	Not updating/prioritisation methodology
24	Prabhu M, Eckert LO. Development of World Health Organization (WHO) recommendations for appropriate clinical trial endpoints for next-generation Human Papillomavirus (HPV) vaccines. Papillomavirus research. 2016;2:185-9.	No evaluation
25	Qian Z, Qi W, Liangying H, Qiuyu Y, Xiao C, Qi Z, et al. Dynamic guideline formulation method and case introduction. Chinese Journal of Evidence-Based Medicine, 2021, 21(4) : 491-496	No evaluation
26	Rochwerg B, Agarwal A, Siemieniuk R A, Agoritsas T, Lamontagne F, Askie L et al. A living WHO guideline on drugs for covid-19 BMJ 2020; 370:m3379.	Disease-specific
27	Shimoi T, Nagai SE, Yoshinami T, Takahashi M, Arioka H, Ishihara M, et al. The Japanese Breast Cancer Society Clinical Practice Guidelines for systemic treatment of breast cancer, 2018 edition. Breast Cancer. 2020;27:322-31.	Not updating/prioritisation methodology
28	Vernooij RWM, Martínez García L, Alonso-Coello P, Brouwers M. Reporting Items for Updated Clinical Guidelines: Checklist for the Reporting of Updated Guidelines (CheckUp). PLoS Medicine. 2017;14:e1002207.	Not updating/prioritisation methodology
29	Vernooij RWM, Martínez García L, Hildago Armas L, Florez ID, Poorthuis MHF, Brouwers M, et al. Updated clinical guidelines experience major reporting limitations. Implementation Science. 2017;12:120.	Systematic review
30	Vogel JP, Dowswell T, Lewin S, Bonet M, Hampson L, Kellie F, et al. Developing and applying a 'living guidelines' approach to WHO recommendations on maternal and perinatal health. BMJ Global Health. 2019;4.	Disease-specific
31	Yamauchi C, Yoshimura M, Sekiguchi K, Hamamoto Y, Nakajima N, Oguchi M, et al. The Japanese Breast Cancer Society Clinical Practice Guideline for radiation treatment of breast cancer, 2018 edition. Breast Cancer. 2020;27:9-16.	Not updating/prioritisation methodology

	Peer-reviewed article	Reason for exclusion
32	Yi TW, Donnellan S, Levin A. Evidence-Based Decision Making 4: Clinical Practice Guidelines. Methods in Molecular Biology. 2021;2249:455-466.	Not updating/prioritisation methodology
33	Zhao R, Zhai S, He N, Su S, Lu W, Ye Z, et al. Evidence-based Guideline for Therapeutic Drug Monitoring of Vancomycin: 2020 Update by the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society. Clinical Infectious Diseases. 2020;71:S363-S71.	No evaluation

Appendix 4 Characteristics of included handbooks

Appendix 4.1 Clinical practice guidelines we can trust

Handbook characteristics	
Organisation	Institute of Medicine
Year	2011
Country	USA
URL	https://www.awmf.org/fileadmin/user_upload/Leitlinien/International/IOM_CLINICAL PRACTICE GUIDELINE_lang_2011.pdf
Title of the publication	Clinical practice guidelines we can trust
Description of the update/retirement process	
What types of update exist?	N/R
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	**Recommendations for determining if an update is necessary are:** ▪ The clinical practice guideline publication date, date of pertinent systematic evidence review, and proposed date for future clinical practice guideline review should be documented in the clinical practice guideline. ▪ Literature should be monitored regularly following clinical practice guideline publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the clinical practice guideline. ▪ Clinical practice guidelines should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a clinical practice guideline should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm; that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations. **Role/responsibility:** The Institute of Medicine Committee on the Development of Standards for Systematic Reviews of Comparative Effectiveness Research recommends that all systematic reviews are conducted by research organisations under contract to the Department of Health and Human Services or the Patient-Centered Outcomes Research Institute and that standards set by the Institute of Medicine committee are agreed.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	A priority-setting procedure might be useful to identify clinical practice guidelines that should take precedence for review and existing clinical practice guidelines may be withdrawn from the National Guideline Clearinghouse. Additionally, the IOM recommends that the National Guideline Clearinghouse (online repository for guidelines) should eliminate clinical practice guidelines for which trustworthiness cannot be determined, and identify the trustworthiness of those retained.

	Role/responsibility: National Guideline Clearinghouse. The National Guideline Clearinghouse ceased operations on 16 July 2018, after this guideline was published.
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	A priority-setting procedure might be useful to identify clinical practice guidelines that should take precedence for review. Eventually existing clinical practice guidelines will undergo an update or be withdrawn from the National Guideline Clearinghouse. The updates and new clinical practice guidelines will more likely be developed according to the proposed standards. If the future number of new clinical practice guidelines is smaller, the identification of trustworthy clinical practice guidelines may be less onerous. However, if availability of medical evidence continues to expand and the development of clinical practice guidelines continues to increase, the task will remain large. **Role/responsibility:** N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	Not reported for updated guidelines. Details for methodologies used in the development of new guidelines is below. Trustworthy guidelines should: ▪ be based on a systematic review of the existing evidence ▪ be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups ▪ consider important patient subgroups and patient preferences, as appropriate ▪ be based on an explicit and transparent process that minimises distortions, biases, and conflicts of interest ▪ provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations ▪ be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines. Details for the reviewing of new guidelines is below. **External review** External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical

	experts, organisations (for example, healthcare, specialty societies), agencies (for example, federal government), patients, and representatives of the public. The authorship of external reviews submitted by individuals and or organisations should be kept confidential unless that protection has been waived by the reviewer(s). The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a Clinical Practice Guideline in response to reviewers' comments. A draft of the Clinical Practice Guideline at the external review stage or immediately following it (that is, prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Although the handbook does not explicitly report on the approval and endorsement process, it does state that effective multifaceted implementation strategies, targeting both individuals and healthcare systems, should be employed by those implementing the guideline to promote adherence to trustworthy Clinical Practice Guidelines.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	N/R **Role/responsibility:** National Guideline Clearinghouse and AHRQ. The National Guideline Clearinghouse ceased operations on 16 July 2018, after this guideline was published.
What resources are required to undertake update and who decides this?	N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: AHRQ - Agency for Healthcare Research and Quality; N/A - not applicable; N/R - not reported.

Appendix 4.2 Handbook for Supporting the Development of Health System Guidance

Handbook characteristics	
Organisation	Swiss Centre for International Health
Year	2011
Country	Switzerland
URL	https://www.swisstph.ch/fileadmin/user_upload/WHOHSG_Handbook_v04.pdf
Title of the guideline manual	Handbook for Supporting the Development of Health System Guidance
Description of the update/retirement process	
What types of update exist?	▪ Minor ▪ Major
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	Each published guideline is required to include a due date of the next update. It is advisable to outline updating issues into a guidance update plan and to state in the guidance when minor or major updates are expected to take place (for example, by a statement such as "review by [date]"). An outline of the update plan should be part of the final guidance document. Update of guidance is justified by the fact that new evidence can be made available at any time to fill an evidence gap or to reinforce or to contradict existing evidence. Furthermore, new research in the methods used along the whole guidance development process may well be refined over time (for example, to assess the quality of evidence, to combine quantitative and qualitative evidence); or advances in the understanding of health systems and how interventions operate across all components of the system may occur as well. Criteria for deciding when to update guidance may include: ▪ the date of the most recent evidence: this refers to the date of the systematic review that provided the evidence on the effects of interventions (as opposed to the reviews, if different, that provided evidence on implementation issues). The publication date of the review, the range of years covered by the search strategy of the primary research included in the review and the date of the most recent primary research should all be looked at. A systematic review could have been published in 2010 but the search strategy of the primary research may have reached only up to 2008, and the most recent study included in the review dated from 2006. This guidance would be based on 5 year old evidence ▪ indications that new evidence may be available shortly; for example, the existence of a protocol of a relevant Cochrane review, published in the Cochrane Library; or based on knowledge of ongoing research projects ▪ when developing guidance using rapid methods in this case updating may be especially relevant

	▪ a reasonable timeframe that allows to incorporate recent research findings or lessons learned from similar guidance implementation. It should be considered that not all aspects of guidance may need to be updated at the same time. For example, most typically, evidence profiles (and recommendations based on them) will need to be updated based on new evidence. However, if new methods are available, only certain parts of the guidance will need to be revisited. It is advisable to outline updating issues into a guidance update plan and to state in the guidance when minor or major updates are expected to take place (for example, by a statement such as "review by [date]"). An outline of the update plan should be part of the final guidance document. **Role/responsibility:** N/R
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility	N/R

it is to do this.	
What resources are required to undertake update and who decides this?	N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: N/R - not reported.

Appendix 4.3 Guidelines International Network: Toward International Standards for Clinical Practice Guidelines

Handbook characteristics	
Organisation	Guidelines International Network (Qaseem A et al.)
Year	2012
Country	International
URL	https://www.acpjournals.org/doi/full/10.7326/0003-4819-156-7-201204030-00009
Title of the publication	Guidelines International Network: Toward International Standards for Clinical Practice Guidelines
Description of the update/retirement process	
What types of update exist?	N/R
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	**Guideline Expiration and Updating** To facilitate updating, a guideline should include an expiration date and or describe the process that the guideline groups will use to update recommendations. Guidelines become outdated at different rates depending on the availability of new evidence. Therefore, it is important to identify the expiration date of a guideline, as well as an update process, if planned. Developers should prospectively determine whether and when they will update a guideline or when it should be considered inactive if an update is not performed. **Role/responsibility:** Guideline development group.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process	N/R

different?	
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	N/R
What resources are required to undertake update and who decides this?	N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: N/A - not applicable; N/R - not reported.

Appendix 4.4 AWMF Guidance Manual and Rules for Guideline Development

Handbook characteristics	
Organisation	Association of the Scientific Medical Societies
Year	2013
Country	Germany
URL	https://www.awmf.org/fileadmin/user_upload/Leitlinien/AWMF-Regelwerk/AWMF-Guidance_2013.pdf
Title of the publication	AWMF Guidance Manual and Rules for Guideline Development
Description of the update/retirement process	
What types of update exist?	▪ Complete ▪ Modular ▪ Limited to individual key questions
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	Supplementation and updating should be continuous processes. The AWMF encourage the submission of comments and suggestions when considering when an update is required. The AWMF no longer publishes guidelines on the Internet once their validity has expired. The expiration date is the date indicated by the relevant medical society when the guideline should be re-subjected to regular review. If not indicated by the medical society, the AWMF will classify the guidelines as "out-of-date" at the latest 5 years after issue and remove the guideline from AWMF's publication system. The extent of revision (complete, modular or limited to individual key questions) depends on: ▪ whether the guideline has been updated recently ▪ results of any updated guidelines searches ▪ results of new, relevant research findings from systematic literature searches ▪ judgment of the experts in the guideline development group ▪ obtaining targeted feedback from the field on the successes/problems associated with implementing the guideline ▪ status analyses, needs analyses and prioritising (unclear from the handbook what this includes). **Planning supplements and updates** Key questions that need to be answered when seeking targeted feedback and conducting status analyses, needs analyses and prioritising: ▪ Who shall be responsible for monitoring and initiating the update of our guideline? ▪ What impact has the guideline had? ▪ Which new key questions have emerged? ▪ Has new scientific knowledge emerged that makes it necessary to change the recommendations?

	▪ Do other guidelines (national, international) have recommendations with related contents that can be reviewed and adapted? ▪ Are there key questions requiring systematic search of the literature and synthesising of the evidence? ▪ Which resources are available to the guideline development group? These questions ought to always be re-appraised whenever a guideline needs updating. **Role/responsibility:** The medical society that produced the guideline is responsible for setting the date of expiration.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	**AWMF deletion of guidelines that have not been updated** Guidelines are classified at the latest within 5 years after their creation as "non-updated" and removed from the publishing system by the AWMF or on the specified date for a scheduled review, which is also considered the 'expiry date', if specified by the last GDG at time of authoring. According to the decision of the AWMF Standing Guidelines Commission, guidelines which have expired are no longer published online by the AWMF. The professional associations are encouraged to uphold their update deadlines and to register these update cycles with the AWMF. The AWMF administrative offices will notify the medical societies of the impending expiry of the guidelines with a formal letter about 6 months before the expiration date. If the medical society has not registered any updates or submitted any updated guidelines for publication, the previous guideline file will be deleted after the deadline has expired. It is the responsibility of the medical societies, as authors and publishers of the guidelines, to save and archive the non-updated versions for documentation purposes. The AWMF only publishes the respectively current guidelines and always directs queries on formerly valid guidelines to the medical societies that published those guidelines. These "non-updated" guidelines were previously labelled with a red mark, moved to a separate directory called "non-updated guidelines" and were no longer accounted for in the internal keyword search system for AWMF guidelines. However, they were still available over the Internet and could be found using external search engines. As of October 2008, this directory was completely deleted. **Role/responsibility:** AWMF administrative offices delete any guideline after the deadline for update have expired.
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	The prioritisation lies with the leading medical society – there are no fixed criteria. Most often, amendments are triggered by relevant new evidence and regular updates are triggered by expired validity.

	The handbook reports that the extent of the revision depends on status analyses, needs analyses and prioritising. However, no detail on what this prioritisation process looks like is given. **Role/responsibility:** The medical society that produced the guideline.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	The prioritisation lies with the leading medical society – there are no fixed criteria. Most often, amendments are triggered by relevant new evidence and regular updates are triggered by expired validity. The handbook reports that the extent of the revision depends on status analyses, needs analyses and prioritising. However, no detail on what this prioritisation process looks like is given. **Role/responsibility:** The medical society that produced the guideline.
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	Detail on methodologies are not reported. However, the handbook states that the easiest way to ensure continuous updating is for the original guideline to have been systematically developed. Literature searches and strategies for answering clinically relevant questions can be saved and reused when necessary. When updating a guideline version, the searches may cover only the period after publication of the earlier guideline version. **Role/responsibility:** The medical society that produced the guideline.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, following contact with the organisation it was confirmed that the process of reviewing is the same as that for new guidelines. Details for reviewing of new guidelines is below. **External review** A review process prior to publication of a guideline allows any uncertainties or missing areas to be identified. This is conducted by persons who were not involved in developing the guideline. The group of reviewers should be made up of experts in the medical field, methodologists and, if appropriate, patient advocates or representatives.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, following contact with the organisation it was confirmed that the process of approving and endorsing guidelines is the same as that for new guidelines. Details for approving and endorsing new guidelines is below. **Global adoption** After the structured consensus development process is completed, including any external review and final editing by the coordinators, the overall guideline is adopted by all members of the GDG, usually in an e-mail resolution procedure. The next step is formal adoption by the boards of the participating medical

	societies. This ensures that all parties involved in developing the guideline and the co-editing medical societies bear mutual responsibility for the contents. Any changes desired by the medical societies to passages requiring consensus approval must be re-approved by consensus within the guideline development group and re submitted to the chairpersons of the other participating medical societies.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updated guidelines, following contact with the organisation it was confirmed that dissemination of updated guidelines is the same as that for new guidelines. Updated guidelines are published on the websites of those who produced the updated guideline. There are further dissemination activities which are the responsibility of the guideline group, guideline program or scientific medical society. **Role/responsibility:** Dissemination activities which are the responsibility of the guideline group, guideline program or scientific medical society and the AWMF administration office.
What resources are required to undertake update and who decides this?	Not reported for updated guidelines. Following contact with the organisation it was confirmed that German Guideline Program in Oncology and the Programme for Programme for National Treatment Guidelines provide institutional resources for updating. Other guidelines are updated with resources of the scientific medical societies. **Funding** A funding strategy serves in planning and estimating the costs the guideline will incur. Most members of the GDG do their work on an honorary basis, exceptions might be external moderators or methodologists. The costs for a guideline may vary, depending on the topic to be addressed and the class intended. For this reason, it is advised that a rough financial framework is developed in advance. The AWMF supports the GDGs with basic advice free-of-charge and provides informational materials along with all aids and tools described in the AWMF Guidance Manual. **Role/responsibility:** N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	To keep guidelines continuously up to date, a living guideline approach can be taken, whereby the guideline is updated at least once a year. In the updated guideline, the most important innovations should be set out at the beginning (“what's new?”), the recommendations should be marked with “verified”, “modified” and “new” and dated. The methodological approach is supplemented in the guideline report. A systematic review of the need for revision with the result that no changes are required is also considered to be an update. A criteria-based check and ranking of the content to be updated is helpful, for example, using The UpPriority Tool.

Key: AMWF - Association of the Scientific Medical Societies; N/A - not applicable; N/R - not reported.

Appendix 4.5 WHO handbook for guideline development, 2nd Edition

Handbook characteristics	
Organisation	World Health Organization
Year	2014
Country	International
URL	https://www.who.int/publications/i/item/9789241548960
Title of the publication	WHO handbook for guideline development, 2nd Edition
Description of the update/retirement process	
What types of update exist?	There are 3 types of WHO guidelines, Standard, Consolidated and Interim. While no information is given on the type of update, for example, full, partial, all guidelines are expected to be kept up-to-date. ▪ Standard guidelines generally focus on clinical interventions, health-care system or policy approaches, public health interventions or exposures, diagnostic tests or surveillance and monitoring. Recommendations in a standard guideline are either developed de novo or by updating previous WHO guidelines. ▪ Consolidated guidelines are also known as a compilation of guidelines. They contain recommendations from existing WHO guidelines, or from guidelines produced by other organisations that have followed processes consistent with WHO processes. Producing consolidated guidelines is complex because existing guidelines may need to be updated and new recommendations may have to be added to address important gaps in the existing guidance. In addition, maintaining the document is difficult, since individual recommendations may become outdated at different times. Production times for consolidated guidelines vary widely. During the updating process, all the standard procedures as outlined in the WHO handbook for guideline development should be followed. Existing recommendations must be thoroughly, clearly and explicitly cross-referenced. Consolidated guidelines require review by the GRC if any of the included recommendations were initially published without GRC review; the updating process led to changes in any of the existing recommendations; or new recommendations were developed. A compilation of guidelines that includes recommendations developed by organizations external to WHO must also be reviewed by the GRC. Only consolidated guidelines whose recommendations have all been previously approved by the GRC and have remained unchanged during the updating process do not require review by the GRC. ▪ Interim guidelines are produced when WHO is asked to provide guidance when the available data and information are most certainly incomplete, especially if additional data are anticipated in the near future. Interim guidelines should always clearly indicate when additional evidence affecting the interim recommendation(s) is expected to be reported, and thus when an update is anticipated. ▪ Guidelines in response to an emergency or urgent need include emergency (rapid response) guidelines and rapid advice guidelines.

	o Emergency (rapid response) guidelines: Public health emergencies may necessitate a response from WHO within hours to days. Hence, many of the guideline development processes and methods outlined in the WHO handbook for guideline development are not applicable. It may not be feasible to perform a systematic review of all available evidence. However, only sources of high-quality evidence should be used. It is important that the decision-making process be documented and that the rationale for each recommendation be stated, even if it is based on indirect or very limited evidence or on expert opinion. o Rapid advice guidelines: If a public health event continues for an extended period, the initial emergency (rapid response) guidelines must be reviewed to take into account both the evidence emerging from the event and a systematic review of the relevant evidence. Such rapid advice guidelines will follow WHO processes more closely and must meet the standards for guideline development at WHO. These guidelines are published with a review-by date that indicates when the guidance may become invalid, or when it will be updated or converted to a standard guideline.
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	WHO guidelines should be issued with a "review-by" date to indicate how long the recommendations are expected to remain valid. There is no absolute rule about the length of validity. Occasionally guideline developers may want to update guidelines before the "review-by" date, particularly if new evidence is published. This new evidence should always be seen in the context of the total body of evidence supporting the recommendations and thus should be part of a new or updated systematic review. **Role/responsibility:** Technical units are responsible for keeping their guidelines up to date. As guidelines near their "review-by" date, they should be carefully examined for currency. If there is reason to believe one or more recommendations need updating, plans should be made to start that process. The steering group of the technical unit monitor new information, user needs and requests that inform when an update may be needed. The responsible technical officer within the technical unit and the steering group develop strategies for identifying new information.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	The process of retiring a guideline is not reported. However, the following is reported for recommendations that are no longer valid. If there are concerns that one or more recommendations in a guideline may no longer be valid, the department should make every effort to ensure that the guideline implementers and other stakeholders are aware of the uncertainty and of plans to update the recommendations. Such announcements can be placed on the relevant pages of the WHO website, linked to the online copies of the guideline, circulated directly to the known stakeholders and published in journals. **Role/responsibility:** N/R

Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	In deciding on the date by which a guideline should be reviewed, the rate of change of research on the topic, questions for which no evidence has been found, and the potential need for new advice should be taken into account. **Role/responsibility:** Technical units are responsible for keeping their guidelines up to date.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	Updating guidelines is challenging if evidence has to be retrieved to support a large number of existing recommendations. In this situation it is important to give priority to controversial areas, or those in which new evidence has emerged. If recommendations will be updated incrementally, the planned approach should be discussed with the GRC Secretariat and outlined in the planning proposal. **Role/responsibility:** Technical units are responsible for keeping their guidelines up to date.
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	Not reported for updating guidelines. The text states that recommendations in WHO guidelines should be based on a systematic review of the scientific literature guided by specific key questions about the intervention, exposure or approach under consideration.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines. The process of reviewing new guidelines is below. WHO guidelines must undergo peer review before the draft is finalised for publication. The external review group is primarily responsible for peer review, along with the relevant departments at WHO headquarters and in the regional offices. The final draft guideline with recommendations should be circulated for review before it is submitted into the WHO clearance process and to the GRC. Peer reviewers acting in their individual capacity need to complete a declaration of interests form, while reviewers representing organisations do not need to complete this form. Any update that involves changing recommendations needs to be reviewed by the GRC. Updates that add new evidence without changing the recommendations do not require review, although under certain circumstances, if the topic or new evidence is highly controversial, GRC review may be advisable.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines. The approval process for new guidelines is below. GRC review of final guideline documents occurs as part of the final executive clearance. In headquarters, submission to the GRC is done after approval by the relevant director and before submission to the assistant director-general. Documents should be in a final edited form ready for layout, proofreading and printing when they are submitted for final clearance.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updating guidelines. The dissemination of new guidelines is below. Dissemination involves making guidelines accessible, advertising their availability and distributing them widely. Guideline developers should consult with WHO Press on priced and mandatory free distribution.

	Priced distribution is done by WHO Press through sales agents in all regions and by the WHO bookshop. The extent of mandatory free distribution depends on the type of publication but can include depository libraries, schools of public health, schools of medicine, WHO country offices and missions in Geneva. **Role/responsibility:** WHO Press.
What resources are required to undertake update and who decides this?	N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: GRC - Guideline Review Committee; N/R - not reported.

Appendix 4.6 GIN-McMaster Guideline Development Checklist

Handbook characteristics	
Organisation	GIN-McMaster
Year	2014
Country	International
URL	https://cebgrade.mcmaster.ca/guidelinechecklistprintable.pdf
Title of the publication	GIN-McMaster Guideline Development Checklist
Description of the update/retirement process	
What types of update exist?	▪ Full ▪ Partial
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	Recommendations are provided that relate to updating clinical guidelines: ▪ Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated (for example, update systematic reviews every 3 years to determine if there is any new evidence available). o Under this point the GIN-McMaster guideline refers to the Association of the Scientific Medical Societies in Germany guidelines which have also been data extracted and included in this review. These guidelines outline the following: ***Planning the update*** o *The quality of a guideline depends largely on whether the recommendations are checked for topicality at regular intervals and updated if necessary. A specific date and statements on further periodic and event-related updates with corresponding responsibilities should be noted in the guideline document.* o *The need to continue and update a guideline arises from the availability of new scientific knowledge on the one hand and from the results of the evaluation of the previous application of the guideline on the other. Both serve to identify potential for improvement in the supply.* o *The starting point is accordingly an inventory and needs analysis to identify subject areas in need of revision. The methodological requirements result from the requirements for guidelines according to the Association of the Scientific Medical Societies in Germany set of rules.* o *The update can be carried out partially - only for selected areas - or completely. In the case of a partial update, the guideline group checks the validity of the parts that have not been updated before submission and confirms them for a corresponding period of time.* ▪ Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available (for example, consider involvement of experts not previously involved in the guideline development group to periodically review the guideline).

	▪ Set the conditions that will determine when a partial or a full update of the guideline is required (for example, if only certain recommendation statements need to be updated, or whether many recommendations are out of date making the entire guideline invalid, or when recommendations are necessary for newly available treatments). ▪ Document the plan and proposed methods for updating the guideline to ensure they are followed. **Role/responsibility:** N/R
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	N/R
What resources are required to undertake update and who decides this?	Arrangements should be made for guideline group membership and participation after completion of the guideline (for example, rotating membership every 1-2 years, selection of a new group at time of updating, continuing participation by guideline panel chair).

	Funding and logistics should to be planned for when updating the guideline is conducted in the future (for example, securing ongoing funding, and standing oversight committee to oversee the updating process). **Role/responsibility:** N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: GIN - Guidelines International Network; N/A - not applicable; N/R - not reported.

Appendix 4.7 Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations

Handbook characteristics	
Author	GIN-McMaster (Morgan RL et al.)
Year	2018
Country	International
URL	https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-018-0330-0
Title of the publication	Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations
Description of the update/retirement process	
What types of update exist?	N/R
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	Updating refers to how and when a guideline requires revision because of changes in the evidence or other factors that influence recommendations. When developing an interim guideline, the date for when the Rapid Guideline or full Practice Guideline will be conducted should be defined. If developing a Rapid Guideline, the date for when the full Practice Guideline will be conducted should be defined. As part of outlining a strategy for how and when an update or a guideline revision will be needed, for interim guidance or Rapid Guidelines, a clearly defined timeline and date for when the full Practice Guideline will be conducted should be provided in the document. This recognises that interim guidance and Rapid Guidelines are conducted under an expedited or consolidated process and additional evidence and thorough review may increase the certainty of the recommendation. **Role/responsibility:** N/R
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R

What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	It is acknowledged that rapid guidance or interim guidance are conducted under an expedited or consolidated process and additional evidence and thorough review may increase the certainty of the recommendation. No other reference is made to the review process.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	In an emergent or dangerous situation, Rapid Guideline updates may be disseminated as 'staged releases' in the following order: (1) the first action/release is to protect public health, and respond to the crisis or spill that is heavily weighted to protect against worst-case scenario; and (2) the second release, based on new and additional information will address planned updates and change in values. **Role/responsibility:** N/R
What resources are required to undertake update and who decides this?	N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: N/A - not applicable; N/R - not reported.

Appendix 4.8 The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline

Handbook characteristics	
Organisation	Guidelines International Network Updating Guidelines Working Group and collaborators
Year	2019
Country	International
URL	https://www.jclinepi.com/cms/10.1016/j.jclinepi.2020.06.018/attachment/92a57f7f-a189-478d-aceb-b561ad1c6ffa/mmc2.pdf
Title of the publication	The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline
Description of the update/retirement process	
What types of update exist?	N/A - The UpPriority Tool focuses on within guideline prioritisation of clinical questions, rather than differentiation between update types.
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	The UpPriority Tool focuses on within guideline prioritisation of clinical questions, rather than selecting between guidelines. The UpPriority team suggest: ▪ assessing clinical questions within a clinical guideline using the tool at least every 2 years. ▪ implementing a prioritisation process for updating clinical questions within a clinical guideline, using The UpPriority Tool, before the surveillance process. ▪ that at least 4 appraisers assess each clinical guideline. **Role/responsibility:** The UpPriority team suggest that the original GDG assess the clinical questions within a clinical guideline.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	N/A - The UpPriority Tool focuses on within guideline prioritisation of clinical questions, rather than selecting between guidelines. It does not appear to have a process for retiring clinical questions. **Role/responsibility:** N/A
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	The answer to this domain is step (1) below but no information provided on this step in The UpPriority Tool. The UpPriority team suggest the following sequence in an updating strategy: 1. Prioritisation process for updating clinical guidelines within a clinical guideline portfolio. 2. Prioritisation process for updating clinical questions within a clinical guideline using The UpPriority Tool. 3. Surveillance process: Identifying new relevant evidence, assessing whether the new evidence has an impact on the current clinical questions, and whether updating is required. 4. Updating process: Reviewing and, if necessary, modifying the clinical questions. After every update cycle, all clinical guidelines or clinical questions (prioritised and not-prioritised) need to

	restart the updating strategy. **Role/responsibility:** The UpPriority team suggest that the original GDG assess the clinical questions within a clinical guideline.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	**How to apply The UpPriority Tool?** 1. **Mapping of the clinical guideline:** The clinical guideline should be mapped before applying The UpPriority Tool. This process starts with identifying the clinical questions developed in the original clinical guideline. Each clinical question should then be linked to its respective recommendations and the supporting references. The process should also include the compilation of the original literature search strategies, evidence syntheses, Summary of Findings tables, and Evidence to Decision frameworks, if available. 2. **Developing of the priority survey:** Online software can be used to design the survey and collect responses. The survey should include clinical questions, recommendations, references, and priority items. 3. **Assessing clinical questions according to six priority items:** The UpPriority team suggest assessing clinical questions according to six priority items, described below in the "Rating Priority items" 4. **Calculating and ranking the priority scores:** The UpPriority team suggest different priority scores to support decision-making for updating clinical questions within a clinical guideline, described below in the "Rating Priority items" section. Scores are assigned based on a 7 point likert scale, 1 (strongly disagree) 7 (strongly agree). 5. **Deciding on prioritised clinical questions for updating:** Based on ranking priority scores, The UpPriority team suggest a consensual, contextualised, and justified decision of which clinical questions should be prioritised for updating. 6. **Developing a priority report:** The UpPriority team suggest a presentation format to communicate results of the prioritisation process. **Rating priority items** Each clinical question within a clinical guideline should be assessed using the 6 priority items, and each item should be rated on a 7-point Likert scale (one meaning strongly disagree and seven meaning strongly agree). ▪ **Item 1 – Impact of outdated recommendations on safety:** Evaluate whether potentially outdated recommendations have any implications on safety in the current clinical guideline healthcare context. o 1 – Following a potentially outdated recommendation is unlikely to result in harm to patients. o 4 – Uncertain. o 7 – Following a potentially outdated recommendation is likely to result in harm to patients.

	▪ **Item 2 – Availability of new relevant evidence:** Assess the availability of new relevant evidence related to the clinical question and recommendations. o 1 – There is no new evidence related to the clinical question and/or recommendations, or there is new evidence but it does not have an impact on current recommendations. o 4 – Uncertain. o 7 – There is new evidence that may modify the clinical question and/or recommendations. ▪ **Item 3 – Context relevance of the clinical question:** Review if the clinical question is still supported by factors of interest (burden of disease, variation in clinical practice, or emerging care options) in the current clinical guideline healthcare context. o 1– The clinical question is not relevant to current practice. o 4 – Uncertain. o 7 – The clinical question is still relevant to current practice. ▪ **Item 4 – Methodological applicability of the clinical question:** Review if the clinical question still addresses components of interest (population, intervention, comparison, and outcomes) in the current clinical guideline healthcare context. o 1– There are new populations, interventions, comparisons, or outcomes that are not covered by the current clinical question. o 4 – Uncertain. o 7 – The clinical question still addresses the components of interest (population, intervention, comparison, and outcomes). ▪ **Item 5 – Users' interest:** Estimate the current interest (for example, citations, downloads, news, debate, or website visits) of patients, healthcare providers, healthcare system, or other stakeholders related to the clinical question and recommendations. o 1 – The clinical question and recommendations are not considered an influential topic to current practice. o 4 – Uncertain. o 7 – There is a growing interest on behalf of patients, healthcare providers, or other stakeholders regarding the clinical question and recommendations. ▪ **Item 6 – Impact on access to healthcare:** Evaluate whether the recommendations have any implications on access and coverage in the current clinical guideline healthcare context. o 1 – The recommendations are not legally binding to funding decision and do not have an impact on access and coverage to healthcare. o 4 – Uncertain. o 7 – The recommendations are legally binding to funding decision and may have an impact on access and coverage to healthcare.

	After scoring, clinical questions can be classified into 1 of 3 categories based on the ranking of priority scores (highest to lowest): 1. clinical questions prioritised for updating 2. clinical questions that could be prioritised for updating 3. clinical questions not prioritised for updating No thresholds to classify clinical questions according to their priority for updating (for example, high, medium or low relevance for updating) included in handbook. **Role/responsibility:** The UpPriority team suggest that the original GD assess the clinical questions within a clinical guideline.
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	The methodology described below is that which could be used to inform whether a clinical question should be updated. However, it does not describe the evidence synthesis methodologies used to update the clinical question itself. ▪ **Item 1 – Impact of outdated recommendations on safety:** Evaluate whether potentially outdated recommendations have any implications on safety in the current clinical guideline healthcare context. o Review recommendations and its supporting evidence (benefits and harms section of the clinical question). o Review alerts for medicines and healthcare products published in regulatory agencies. ▪ **Item 2 – Availability of new relevant evidence:** Assess the availability of new relevant evidence related to the clinical question and recommendations. o Review the supporting evidence of the recommendations (for example, number, design, and publication year of included studies). o If aware of new evidence, identify references with a pragmatic literature search. o Assessing the impact of new evidence with a qualitative and/or quantitative approach could be based on methods for updating systematic reviews. ▪ **Item 3 – Context relevance of the clinical question:** Review if the clinical question is still supported by factors of interest (burden of disease, variation in clinical practice, or emerging care options) in the current clinical guideline healthcare context. o Review the scope and purpose of the clinical question and clinical guideline. o Review, if available, how the clinical question was rated in the previous prioritisation process. ▪ **Item 4 – Methodological applicability of the clinical question:** Review if the clinical question still addresses components of interest (population, intervention, comparison, and outcomes) in the current clinical guideline healthcare context.

	○ Review the components (population, intervention, comparison, and outcomes) of the clinical question. ○ If aware of new relevant evidence (item 2), assess its potential to modify the components (population, intervention, comparison, and outcomes) of the clinical question. ▪ **Item 5 – Users' interest:** Estimate the current interest (for example, citations, downloads, news, debate, or website visits) of patients, healthcare providers, healthcare system, or other stakeholders related to the clinical question and recommendations. ○ Reflect on the impact of the clinical guideline in media. ▪ **Item 6 – Impact on access to healthcare:** Evaluate whether the recommendations have any implications on access and coverage in the current clinical guideline healthcare context. ○ Review recommendations and its supporting evidence (resource use, equity, and feasibility). ○ Review the availability of medicines and healthcare products in regulatory agencies, and governmental institutions. An example of an UpPriority report is provided here **Role/responsibility:** N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	N/A - The UpPriority Tool focuses on within guideline prioritisation of clinical questions. It does not appear to have a process for reviewing updated clinical guidelines.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/A - The UpPriority Tool focuses on within guideline prioritisation of clinical questions. It does not appear to have a process for approving/endorsing updated clinical guidelines.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	N/A - The UpPriority Tool focuses on within guideline prioritisation of clinical questions. It does not appear to have a process for disseminating updated clinical guidelines.
What resources are required to undertake update and who decides this?	The UpPriority team suggest that at least 4 appraisers assess each clinical guideline.
Living guidelines	
Does the organisation provide detail on living guidelines?	N/A

Key: N/A - not applicable; N/R - not reported.

Appendix 4.9 Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods

Handbook characteristics	
Organisation	Clinical Guidelines Committee of the American College of Physicians
Year	2019
Country	USA
URL	https://www.acpjournals.org/doi/10.7326/M18-3290?searchresult=1
Title of publication	Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods
Description of the update/retirement process	
What types of update exist?	▪ Full ▪ Partial Not reported in this paper but following contact with the organisation it was confirmed that guidelines may be updated in whole or in part or withdrawn if no update can be done. Partial updates are not published as full papers but instead as a letter whereas full updates are published as a new version with the annotation "version 2", for example.
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	Differentiation between partial and full updates was not evident from this paper. Clinical Policy staff are responsible in selecting clinical guidelines for review and assessment. The criteria for determining if an update is necessary was not reported, neither was how it is determined what type of update is warranted. **Role/responsibility:** Clinical Policy staff.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	All ACP clinical guidelines and guidance statements are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued. Expired documents are available in an inactive clinical guidance section on the ACP website, as well as in the app. **Role/responsibility:** N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	Not reported in this paper but following contact with the organisation it was confirmed that the criteria outlined in the 2010 handbook are used to prioritise both de novo guideline development and updating of guidelines. These criteria are: ▪ effect of the condition on morbidity and mortality ▪ prevalence of the condition ▪ whether effective healthcare is available ▪ areas of uncertainty and evidence that current performance does not meet best practices

	▪ cost of the condition ▪ relevance to internal medicine ▪ likelihood that evidence is available to develop recommendations. **Role/responsibility:** Clinical Guidelines Committee.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	Not reported in this paper but following contact with the author it was confirmed that the key questions should be updated, however it was not clear how key questions are classified as such. **Role/responsibility:** N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	Not reported in this paper but following contact with the organisation it was confirmed that a full systematic review is conducted for updating guidelines. **Role/responsibility:** N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, contact with the organisation confirmed the process is the same as that for new guidelines. Details for reviewing of new guidelines is below. **Clinical Guideline Committee Review** The Clinical Guideline Committee reviews and discusses all clinical guidelines and guidance statements at in-person meetings. The topic subgroup introduces the clinical guideline or guidance statement with a brief presentation summarising the evidence and proposed recommendations. For clinical guidelines, the Clinical Guideline Committee reviews and appraises the evidence reports, accompanying literature contained in those reports, and Evidence to Decision tables to ensure an explicit link between evidence and recommendations. The Clinical Guideline Committee uses a similar process for guidance statements with regard to assessment of the existing guidelines and their accompanying evidence. Although no formal consensus method is used, members discuss recommendations and guidance statements and revise accordingly until they achieve a general consensus on the final version. **Clinical Guideline Committee Voting Policy** Only Clinical Guideline Committee members can participate in voting. Voter eligibility within the Clinical Guideline Committee is determined on the basis of the management of conflicts of interest for the topic. Votes are taken for each recommendation or guidance statement individually. A 75% agreement among eligible voters is required to approve a recommendation or guidance statement. This threshold is the same for both conditional and strong recommendations in clinical guidelines. If the threshold is not met, the recommendation or guidance statement can be discussed further, revised, and voted on again, or removed

	from the paper. Votes cast during Clinical Guideline Committee meetings are blinded during the meeting to avoid bias, and a record of voting results is kept and recorded in the meeting minutes (un-blinded). The Clinical Guideline Committee does not publicly disclose the voting records of individual members. **CGC Public Panel Review** The Clinical Guideline Committee Public Panel reviews and provides feedback on Clinical Guideline Committee clinical guidelines and guidance statements at various stages of development, including key questions, outcome rating (guidelines only), and the Clinical Guideline Committee-approved guidelines or guidance statements. When papers include talking points with patients, the Clinical Guideline Committee Public Panel reviews this section carefully. The Clinical Guideline Committee reviews the comments and takes them into consideration in its decision making and in the final manuscript.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, contact with the organisation confirmed the process is the same as that for new guidelines. Details for approving and endorsing new guidelines is below. **Peer review process** ACP clinical guidelines and guidance statements are posted for review and comments by the ACP Board of Governors, which represents ACP members from all 50 states and territories, other countries, and various subspecialties. The Board of Regents, ACP's highest governing body, provides comments and final approval of the guideline or guidance statement as ACP policy. The Board of Regents votes to approve Clinical Guideline Committee papers with a simple yes-or-no vote and cannot make changes to the recommendations or guidance statements. ACP may send out guidelines for external peer review and feedback by clinical experts before approval by the Board of Regents or for endorsement from other medical societies once the guideline is complete and approved. Clinical guidelines and guidance statements also undergo a thorough peer review on submission to a journal for publication consideration.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updated guidelines, contact with the organisation confirmed the process is the same as that for new guidelines. Details for dissemination of new guidelines is below. **Publication and Dissemination** All ACP clinical guidelines, guidance statements, and evidence reviews are submitted for publication in a high-impact journal wherein each manuscript is independently peer reviewed. All ACP clinical recommendations and guidance statements are considered public documents and are available for free. Links to the papers can be found on ACP's website. In addition to journal publication and website posting, ACP clinical guidelines and guidance statements are presented at ACP's annual meeting, announced in ACP newsletters, published in the free ACP Clinical Guidelines app and covered by national media outlets. Guidelines are submitted to the Guidelines

	International Network library, where they are accompanied by a checklist of guideline standards. **Role/responsibility:** N/R
What resources are required to undertake update and who decides this?	Not reported for updated guidelines, contact with the organisation confirmed the process is the same as that for new guidelines. Details for resourcing of new guidelines is below. Financial support for the development of ACP clinical guidelines and guidance statements and for evidence reviews commissioned by ACP comes exclusively from the ACP operating budget. **Role/responsibility:** N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	The Clinical Guidelines Committee is working toward creating living systematic reviews and clinical guidelines and a core set of topics to ensure that certain topics do not expire. The ACP have produced guidance for the development of living, rapid practice points (that is, provision of interim, time-sensitive answers, based on the best available evidence, to pressing questions related to individual and public health). Although not clinical guidelines, the principles underpinning the development of rapid practice points are the same as those for clinical guideline development. **Living, Rapid Practice Points Updating: Process, Periodicity, and Versions** The Clinical Policy team maintains ongoing communication with the evidence review team, and the SMPC monitors all surveillance notices, reports, or updates from the evidence review team. If the evidence review team issues a surveillance notice indicating that no new studies were identified, the SMPC publishes a comment on the most recent version of the practice points that indicates the date of the last search and that no new studies were identified. When new studies are identified, the SMPC reviews the evidence review team's assessment (surveillance report or plan for full update). The SMPC considers quantitative and qualitative factors such as, but not limited to, the certainty of the evidence, balance between benefits and harms, and contextual considerations when assessing if the new evidence leads to meaningful changes to its previous practice points. After this assessment, the SMPC takes one of the following actions: **1. Reaffirm the practice points** If the new evidence or contextual considerations do not lead to meaningful changes in the practice points, the SMPC will publish an update alert that reaffirms the current practice points. The SMPC may also use

	update alerts to modify the language rather than intent of the practice points, such as to improve readability. **2. Revise and modify the practice points** If the new evidence or contextual considerations lead to meaningful changes in the practice points, the SMPC will develop a new version of the practice points. The Clinical Policy team will work with the SMPC subgroup to revise the practice points following the same development and approval process as described earlier. The new version, titled version 2, version 3, and so on, references all preceding practice points versions and update alerts. Update alerts and new versions will indicate the date of the last search, provide a summary of the new evidence, and update the existing rationale and evidence tables to incorporate the new evidence as well as relevant contextual considerations. All update alerts and practice points versions are indexed on ACP's website. **Retirement From Living Status** At any time, as a result of the living searching, surveillance, and updating process, the SMPC may determine that a topic does not require further updates and, therefore, decide to retire the publication from living status. This may happen when the topic is no longer considered a priority for decision making, when there is confidence that the conclusions are not likely to change with the emergence of new evidence or affect the practice, or when it is unlikely that new evidence will emerge. On retirement of a topic from living status, the SMPC will publish an update alert in the journal reporting the change in status along with a brief rationale. **Publication and Dissemination** All ACP practice points are submitted for publication in a high-impact, peer-reviewed journal. Links to the articles can be found on ACP's website. In addition to journal publication and website posting, the practice points may be presented at ACP's annual meeting, announced in ACP newsletters, and covered by national media stories. The ACP practice points are also submitted to the Guidelines International Network library. **Financial Support** Financial support for the development of ACP practice points comes exclusively from ACP's operating budget. ACP staff and consultants who author the practice points receive no additional compensation for the development of the articles, apart from their wages or salary, which comes out of the ACP operating budget. No industry funding is accepted for any stage of development. Members of the SMPC do not receive any honoraria except for reimbursement for travel-related costs for any in-person work, which

	comes out of ACP's operating budget. The accompanying rapid systematic reviews are typically funded by a public entity (for example, the Agency for Healthcare Research and Quality or Veterans Administration).

Key: ACP - American College of Physicians; N/A - not applicable; N/R - not reported; SMPC, Scientific Medical Policy Committee.

Appendix 4.10 SIGN 50: a guideline developer's handbook

Handbook characteristics	
Organisation	Scottish Intercollegiate Guidelines Network
Year	2019
Country	Scotland
URL	https://www.sign.ac.uk/media/1050/sign50_2019.pdf
Title of the publication	SIGN 50: a guideline developer's handbook
Description of the update/retirement process	
What types of update exist?	▪ Update ▪ Minor revision
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	The currency of guidelines is categorised in a traffic light system on the SIGN website in the following way: ▪ current (within 3 years of publication or over 3 years old and revalidated) ▪ over 3 years old and not revalidated ▪ over 7 years old and not revalidated. A full review of a guideline after a fixed time period is not always appropriate as new evidence is published at different rates in different fields. It also imposes a workload for future years that may not be achievable in practice. **Scoping for the need to update** SIGN considers whether or not published guidelines need to be reviewed after a period of 3 years and all SIGN guidelines carry a statement indicating that they will be considered for review 3 years after publication. A literature review is carried out to establish if there are previous or ongoing projects in Healthcare Improvement Scotland on the same topic. Searches also cover other UK guidelines, the Cochrane Library for systematic reviews, the National Institute for Health Research for Health Technology Assessments and Emergency Care Research Institute for evidence reports. A report is prepared, supplemented by comments received since publication of the guideline, outlining the potential impact of any new evidence on the recommendations in the guideline. During consultation, the group responsible for developing the guideline, or a wider group of healthcare professionals, is asked to consider the potential impact of the new evidence on the guideline. The report and recommendations on the need to update the guideline is made available to Guideline Programme Advisory Group which is a subgroup of SIGN Council. The outcome of the report will be 1 of 4 options:

	▪ Revalidate if no evidence was identified that would change recommendations and an update is not required. ▪ Update if there is new evidence that would change recommendations in some areas of the guideline. ▪ Request a proposal for a new guideline if the new evidence would change many of the existing guideline's recommendations. ▪ Withdraw the guideline if the new evidence renders it unsafe or obsolete. **Requests for a change to a published guideline** The Guideline Programme Advisory Group considers proposals for small changes to published guidelines on a rolling basis and guidelines will be updated if a proposal meets the following criteria: ▪ new evidence substantially changes a small number of recommendations in the guideline (corresponding to no more than two related key questions) OR ▪ a specific issue such as a new drug therapy or national issue such as a new government policy will give rise to a new key question AND ▪ the nature of the update may not warrant assembling a multidisciplinary group. **Role/responsibility:** Guideline Programme Advisory Group review the report and recommendations on the need to update the guideline.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	From time to time it is necessary to consider withdrawing guidelines which are outdated or no longer relevant. Proposals to withdraw guidelines are submitted initially to Guideline Programme Advisory Group and if it agrees with the proposal it is submitted to SIGN Council for final approval. Once it has been agreed to withdraw a guideline, all versions of the text and any associated material will be removed from the SIGN website. The list of published guidelines will be amended to show the guideline as withdrawn, with a note of the reason for withdrawal. Guidelines may be withdrawn for any of the following reasons: ▪ superseded by a more recent or more comprehensive guideline ▪ evidence that the guideline is fully complied with by NHS Scotland, and has become accepted practice ▪ emergence of new treatments or preventive measures that render the guideline irrelevant ▪ the guideline is over 10 years old. **Role/responsibility:** Guideline Programme Advisory Group review proposals for withdrawal of guidelines and if it agree with the proposal this is submitted to the SIGN Council for final approval.
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	The handbook provides information on prioritisation of topics, although this is not specific to updating. **Criteria for selection of topics** There is a lack of evidence to guide choice of criteria and methods for prioritising topics, although the

	criteria used by guideline development organisations are broadly similar. Guideline topics selected for inclusion in the SIGN programme are chosen on the basis of the burden of disease, the existence of variation in practice and health outcomes, and the potential to improve outcome. The following criteria are considered by SIGN in selecting and prioritising topics for guideline development: ▪ clinical priority areas for NHS Scotland ▪ areas of clinical uncertainty as evidenced by wide variation in practice or outcomes ▪ conditions where effective treatment is proven and where mortality or morbidity can be reduced ▪ iatrogenic diseases or interventions carrying significant risks ▪ the perceived need for the guideline, as indicated by a network of relevant stakeholders. **Role/responsibility:** Guideline Programme Advisory Group and the SIGN Council.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	Updates can apply either to sections of guidelines, or in some circumstances to individual recommendations. Processes have to be in place to address all of these possible options, no further detail provided. **Role/responsibility:** N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	**Updating a guideline** If the scoping process carried out 3 years after publication confirms the need for an update, the process for carrying out the update is largely the same as that described elsewhere in this manual. The principal difference is that the update will focus on those sections of the original guideline that have been identified, through the scoping, as being in need of updating. The same methodological principles apply, although the nature of the sections being reviewed may necessitate a slightly different composition from the original guideline group. For example, if a section on surgical interventions is a major part of an update, the guideline group is likely to include more surgeons and theatre staff than say pharmacists or allied health professionals. The guideline group must decide whether or not the proposed changes are sufficiently far reaching as to justify the need for a national meeting. If a national meeting is not held, the first draft of the guideline is published on the SIGN website for a fixed period, during which time potentially interested parties will be alerted to its presence and invited to submit comments. **Making a small change to a guideline** When the Guideline Programme Advisory Group decides that a guideline is in need of a small change, the process for this is largely the same as that described for updating a guideline, although the scope of the update is much narrower and the timescale shorter. The level of involvement of a guideline development group and extent of consultation will depend on the nature of the changes to the guideline.

	Role/responsibility: SIGN team.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	For updates to existing guidelines, national open meetings are only held if the content of the guideline has significantly changed. Otherwise, the guideline is made available for open consultation on the SIGN website for one month. No consultation meeting is held for published guidelines that are undergoing a small change. In this case the revised section of the guideline is sent directly to appropriate expert reviewers.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	SIGN guidelines in general do not have an approval or endorsement process beyond that described above.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updated guidelines, presumably the process is the same as that for new guidelines. Details for dissemination of new guidelines is below. **Publishing the guideline** All SIGN guidelines are available free of charge on the SIGN website. Updates including any corrections are made to the electronic version of the guideline, which is the definitive version at all times. The search strategy and register of interests declared by the guideline development group, and consultation report are published alongside the guideline. A report of any updates is also available. Other supporting material may include: ▪ implementation resources, for example, patient pathways, costing tools ▪ patient resources, for example, booklets, sample leaflets ▪ learning resources, for example, slide sets, on-line tutorials. **Role/responsibility:** Dissemination of SIGN guidelines in NHS Scotland is organised within each NHS board by local distribution co-ordinators, who are responsible for disseminating guidelines across their board. The distribution co-ordinators are notified of all new guidelines and updates to published guidelines and given an opportunity to order Quick Reference Guides to distribute within their board.
What resources are required to undertake update and who decides this?	Not reported for updated guidelines. Details for resourcing of new guidelines is below. **SIGN team** The SIGN Programme Manager assigned to each guideline helps the Chair to identify potential barriers to successful group work, to plan and progress the guideline development project, and acts as facilitator at group meetings. The SIGN team supporting each guideline development must ensure that clinical knowledge and expertise is appropriately applied to the interpretation of the evidence base and that all group members have the opportunity to actively contribute when the drafting of guideline recommendations is being undertaken.

	Guideline development group members GDG members in turn must make a full commitment to the group and the tasks involved in guideline development, and are responsible for indicating areas of concern to the Chair. GDG members should also bear in mind that they represent both a geographical region and a specialty or professional group, and must be prepared to consult with colleagues to ensure that the widest possible range of views are considered, whilst maintaining confidentiality around the content of discussions undertaken within the group. The approximate life span of each GDG varies depending on whether it is a new project (around 29 months), an update (around 15 months) or a minor revision (3–6 months). For a full guideline project, groups meet on average once every 2 to 3 months, although subgroups may meet more frequently. **Role/responsibility:** N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	As with an update to a guideline, the process for updating a living guideline is largely the same as that described elsewhere in the SIGN 50 handbook. The main difference is that a living guideline is developed on a rolling programme of regular updates. The frequency of updating will depend on the rate at which new evidence is emerging, but will normally be annual or biennial. Each update focuses on those areas of the current guideline where new evidence has been identified. The same methodological principles apply and literature searches are based on a series of existing key questions. They seek to update and build on the evidence base used in the original guideline and subsequent updates. The only new questions that may be addressed are any arising from the patient issues search, or that arise from new developments identified during the process of scoping the update. Once searches are completed, if new evidence has been identified to change a recommendation or to add a new topic, the text and recommendations of the guideline are revised. The updates are summarised in the published guideline. The other processes used will be the same as those used for a new guideline. A possible exception is, as with an update, the need for a national meeting.

Key: N/A - not applicable; N/R - not reported; SIGN - Scottish Intercollegiate Guidelines Network.

Appendix 4.11 Developing NICE guidelines: the manual (PMG20)

Handbook characteristics	
Organisation	National Institute for Health and Care Excellence
Year	2020
Country	UK
URL	https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-the-manual-pdf-72286708700869
Title of the publication	Developing NICE guidelines: the manual (PMG20)
Description of the update/retirement process	
What types of update exist?	▪ Full update ▪ Partial update (of a discrete section or recommendation and or series of recommendations)
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	NICE's surveillance team check whether recommendations in guidelines remain up to date by following this following process: ▪ Feedback from topic experts via a questionnaire ▪ A search for new or updated Cochrane reviews and national policy ▪ Consideration of evidence from previous surveillance ▪ Examining related NICE guidance and quality standards and NIHR signals ▪ A search for ongoing research ▪ Examining the NICE event tracker for relevant ongoing and published events ▪ Literature searches to identify relevant evidence ▪ Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline ▪ Consulting on the proposal with stakeholders. **Reacting to events using an event tracker** Some topic areas are fast moving and this increases the risk of guidelines having out-of-date recommendations. Therefore, NICE maintains an event tracker containing information on key events, such as ongoing studies, that are judged to be relevant to the guideline content. Ongoing studies are identified for the event tracker through the standard check and also through NICE's engagement with the National Institute for Health Research. The event tracker means that NICE can react quickly to changes in the evidence base, by initiating a check of the guideline as soon as the event has occurred. A check does not necessarily mean that the guideline will be updated. 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/Commission on Human Medicines. This list is not exhaustive and individual events are considered on a case-by-case basis. Events are identified through constant intelligence gathering, for example, the standard check, the guideline development process and stakeholder correspondence, as well as enquiries sent to NICE. **Process for reacting to events** The NICE surveillance team considers how an event could affect a guideline. If an event is likely to affect guideline recommendations a check is performed before the next scheduled standard check. This involves considering the impact of the event on the guideline recommendations and incorporating feedback from topic experts in the area. The check may include intelligence gathering and literature searches, if needed, involving the same approach as for the standard check. Checks in response to events do not undergo stakeholder consultation because they focus only on an important event and potentially a small section of a guideline. However, the decisions are communicated on the NICE website. If NICE's Guidance Executive decides that an update of the guideline is needed after this type of check, registered stakeholders are informed of the planned approach. **The standard check** All NICE guidelines are checked every 5 years. **Topic expert engagement** Topic experts including members of NICE's Expert Advisers Panel are invited to participate in surveillance and provide views about the continued relevance of recommendations. If their response is limited or further specialist input is needed, NICE may seek input from other experts, such as government bodies or representatives from a Quality Standards Advisory Committee. **Intelligence gathering**

	Topic experts are surveyed for their views on the continued relevance of the published guideline and recommendations, and their knowledge of recent developments in the topic area and any important new evidence since publication of the guideline. Feedback is also sought from internal teams within NICE who have expertise in the topic area under surveillance (for example, where there is a social care or medicines focus in the guideline). NICE may also ask stakeholders for their views, including organisations representing the interests of patients, people using services, carers and the public. Additional intelligence might include: ▪ external queries and comments received since publication of the guideline (these are collated in an issues log for consideration during surveillance) ▪ related NICE guidance and quality standards (including placeholder statements in NICE quality standards) developed since the guideline was published ▪ information about guideline implementation, including evidence derived from analysis of primary data on the uptake of recommendations ▪ information about important ongoing studies in the area covered by the guideline (identified through searches of trial databases) ▪ changes in licensing status of medicines ▪ updated or new national policy. **Literature searching** Published evidence is identified through searching a range of bibliographic databases relevant to the topic, which are generally based on those searched for the published guideline. Sources searched may vary depending on the topic. In general, MEDLINE, MEDLINE in Process, Embase, Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials would be considered. **Search approaches** The search approach will vary between topics and may depend on priority areas highlighted through topic expert engagement and intelligence gathering. The following search approaches can be used: ▪ population or population/intervention search as needed for the guideline scope with: o RCTs and systematic reviews as a default o if RCTs are not appropriate because of the topic or guideline (for example, purely diagnostic), then other study types will be considered ▪ focused search(es) for a specific question or a new question, meaning that the study type searched for (RCTs or observational studies) should reflect the type expected to address the question. ▪ citation search forward/back (this option is supplemented with either a restrictive full scope search or focused searches).

	Other considerations It may be appropriate to consider setting limits for the searches, which could include, but are not limited to: ▪ study design using appropriate search filter(s) ▪ date ▪ location ▪ population(s)/subpopulation(s) ▪ intervention ▪ service delivery aspect ▪ prognostic factors. **Search period** The search period will start at the: ▪ end of the search for the last update of the guideline ▪ end of the search for the last standard check. The search date ends on the date the search is conducted. **Decision-making** Proposals on the need to update a guideline include an element of judgement and are based on an assessment of the relevant evidence published since guideline publication (abstracts of primary or secondary evidence), information obtained through intelligence gathering and feedback from stakeholder consultation. The update proposal will be based on the following options: ▪ no update (check again in 5 years) ▪ no update at present but date of next check should be brought forward or pushed back (this decision would be made exceptionally, for example where it is clear that new evidence critical to this decision is due to be published) ▪ full update (develop replacement guideline) ▪ partial update (update defined sections of the guideline) ▪ transferring the guideline to the static list ▪ refreshing the guideline (this can occur when a decision has been made not to update the guideline and instead small changes that do not require topic expert input are made) ▪ withdrawing some recommendations or the whole guideline. When a guideline is being updated, the original scope may be used (unchanged), the original scope may be modified (for example, where new areas have been identified that require an extension to the scope) or a new scope may be developed.

	Static list check Guidelines are considered static when the recommendations are still current and should continue to be implemented, but are unlikely to change in the foreseeable future (because the evidence base or practice is unlikely to change). Guidelines are only considered static after consultation with stakeholders, and providing the following criteria are met: ▪ there is a decision not to update following a standard check and no major ongoing research expected to publish before the next standard check or ▪ the guideline is not intervention-based (for example, it focuses on commissioning or implementation) and no major changes to commissioning or service configurations have occurred since guideline publication, or are expected. Following stakeholder consultation, a proposal to add the guideline to the static list may no longer be appropriate if stakeholders have made NICE aware of: ▪ relevant research or ▪ pertinent issues that need to be monitored or ▪ information that would impact on the 'no update' proposal. Any ongoing research is added to the event tracker to feed into a guideline check process. **Process** Static guidelines are looked at 5 years after they go on the static list and then every 5 years to determine whether they should undergo a standard check. This preliminary check is similar to the standard check but no literature searches are done. Topic experts are asked to supply information on any new published evidence that could affect the recommendations. Information is also gathered from the event tracker. This is likely to highlight the main events that could trigger a standard check and a possible update of the guideline. This process is applied consistently across static list guidelines with key decisions recorded as part of an audit trail. Guidelines are removed from the static list when the preliminary check suggests new evidence may affect the recommendation. They then undergo the standard check as described in the section on the standard check. **Scheduling updates** When scheduling updates of guidelines, NICE prioritises topics according to need for both new and updated guidelines. **Role/responsibility:** NICE surveillance team.

If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	Proposals on the need to update a guideline, which could include withdrawal of a guideline include an element of judgement and are based on an assessment of the relevant evidence published since guideline publication (abstracts of primary or secondary evidence), information obtained through intelligence gathering and feedback from stakeholder consultation. Additionally, when a full update is published the old guideline is withdrawn. The NICE Pathway is revised in line with the new recommendations. **Role/responsibility:** N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	The handbook provides information on prioritisation of topics, although this is not specific to updating. **Choice of guideline topics** NICE guidelines are a key source for the development of NICE quality standards and therefore new guidelines developed by NICE are usually chosen from a library of topics for quality standards and then agreed with the relevant commissioning body (NHS England or the Department of Health and Social Care). Decisions on which library topics to develop guidelines on, and in what order, are based on factors such as: ▪ whether there is existing NICE-accredited guidance on which to base a quality standard that encompasses the whole of the topic ▪ the priority given to the topic by commissioners and professional organisations, and organisations for people using services, their families and carers ▪ the health and care burden, and the potential to improve outcomes and quality of life. A topic selection oversight group at NICE considers topics for guideline development, taking these factors into account. NICE then discusses topics identified in this way with NHS England, the Department of Health and Social Care, and Public Health England, and a prioritised list is agreed by these 3 bodies. Topics are then formally referred to NICE and scheduled into NICE's guideline development plans. **Role/responsibility:** N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R

What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	**Full update** The guideline is developed using the same methods and process as for a new guideline. If a full update of a guideline is needed either: ▪ a new scope is prepared, following the process for new guideline development or ▪ the scope of the published guideline is used and registered stakeholders are informed. Sometimes an existing topic-specific committee is asked to update a guideline in their topic area. Sometimes a new topic-specific committee is set up for the update. Where possible, the developer informs all members of the topic-specific committee, or topic-expert members of the standing committee, for the published guideline if a new committee is being recruited. The composition of the committee should be tailored to new requirements if a new scope has been developed. **Partial update** The guideline is developed using the same methods and process as for a new guideline. If only part of a guideline needs to be updated, either: ▪ a new scope is prepared, following the process for new guideline development or ▪ parts of the scope of the published guideline are used (as determined by the check of the need for an update), and registered stakeholders are informed. In both cases, the scope is clear about exactly which sections of the guideline are being updated and which are not, including any sections that may be withdrawn (for example, if they are now covered in another guideline). Recommendations that are outside the scope of an update may be refreshed. Partial updates using the scope of the published guideline use the review questions and review protocols already defined by the existing guideline. However, if the review questions and/or protocols are unavailable, need refinement, or if there is ambiguity in the published guideline, the developer may approach the committee members with topic expertise for advice before starting the evidence review. Partial updates of guidelines are subject to the same level of scrutiny as full updates and new guidelines. The underlying principles of transparency of process and methodological rigour continue to hold. **Refreshing a guideline**

	Refreshing a guideline allows NICE to improve the usability of recommendations without changing the intent and therefore without the need for an evidence review or committee input. All refreshing changes are signed off by NICE's Guidance Executive. Refreshing changes can be made to guideline recommendations even when the surveillance decision is not to update the guideline. All changes to recommendations made as part of the surveillance process should be agreed by the NICE surveillance team. When a partial update has been agreed, the publishing team also identifies recommendations that may need refreshing to feed into the scoping process. Occasionally during development of partial updates, additional recommendations that are not part of the update may be identified for refreshing by the committee or the publishing team. Refreshing might involve: ▪ amending or adding cross references to other NICE guidance or hyperlinks to other NICE endorsed tools or resources ▪ adding or amending a footnote to reflect changes to a medicine's marketing authorisation, to reflect changes in service configuration (for example, a change from primary care trusts to clinical commissioning groups) or a change to an organisation's name ▪ ensuring recommendations take into account the latest government policy or guidelines, for example, on alcohol consumption ▪ amending recommendations to reflect the current practice context, for example, removing references to tools or resources that no longer exist ▪ bringing recommendations in line with NICE's current policy on wording without affecting the intent, for example: o reflecting the involvement of people in decisions about their care o using person-centred language. Refreshing changes that are made during scoping and guideline development should be agreed with NICE staff with responsibility for quality assurance. **Role/responsibility:** Topic-specific committee.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	**1. PARTIAL UPDATES** **Preparing a partial update for consultation** Consultation usually lasts for 4-6 weeks. Before consultation on a partial update, the developer should check the following: ▪ All sections have been updated as agreed.

	▪ It is clear which sections have been updated and are open for comment during consultation. ▪ Recommendations from sections which have not been updated have been checked to determine whether any changes are essential (for example, if a medicine is no longer available). ▪ Refreshing changes (see the section on refreshing the guideline) to recommendations in sections that have not been updated are kept to a minimum (for example, changing from the passive voice to direct instructions). ▪ A summary of changes to recommendations is included. ▪ The status of any guidance incorporated in the previous version of the guideline has been confirmed with NICE. For example, has the other guidance been updated by the guideline update? ▪ All recommendations (new, updated and unchanged) have been assessed with respect to NICE's equality duties. **Preparing the final version of a partial update for publication** The developer should check the following: ▪ It is clear which sections have been updated, and whether the recommendations have been updated or amended. ▪ The summary of changes to recommendations has been revised in line with the final recommendations. The NICE Pathway is also updated, and resources to support implementation are checked for current relevance. **2. FULL UPDATE** Full updates are subject to the same consultation process as new guidelines developed. This process is described below. **Commenting on the draft guideline** The draft version of the guideline (recommendations, rationales, committee discussions, evidence reviews and methods) is posted on the NICE website for consultation with registered stakeholders. Stakeholders can register at any point during guideline development. NICE informs registered stakeholders that the draft is available, via email and through its promotional channels, and invites them to comment by the deadline. Questions for stakeholders are posted with the draft guideline. The purpose of these questions is to seek stakeholder views on factors such as the potential equality impact. NICE also asks stakeholders to comment on recommendations identified as likely to substantially increase costs, and their justification, and to consider whether any other draft recommendations are expected to add substantial costs. Questions related to implementation may also be included to identify practitioners who are already implementing the draft recommendations, or resources that could be fed into the NICE endorsement scheme.

	NICE is unable to accept: ▪ more than 1 set of comments from each registered stakeholder organisation ▪ comments that are not presented correctly on the form provided ▪ comments with attachments such as research articles, letters or leaflets. In these cases, NICE will invite a registered stakeholder to resubmit a single set of comments with no attachments before the consultation deadline. NICE is unable to accept any comments received after the deadline. Comments should be constructed as reasoned argument and be submitted for the purpose of improving the draft guideline. NICE reserves the right not to respond to comments that are hostile or inappropriate. Stakeholders should make sure that any confidential information or information that the owner would not wish to be made public is clearly underlined and highlighted. Confidential information should be kept to a minimum. Stakeholders should explain why the information is confidential and if and when it will become publicly available. Where views on the guideline are shared by more than 1 stakeholder organisation, NICE encourages these organisations to work together to produce a joint response. This should be submitted by 1 registered stakeholder; other stakeholders supporting the joint response should respond to the consultation noting their endorsement. When registering, and when commenting on the draft scope and draft guideline, stakeholders are asked to disclose whether their organisation has any direct or indirect links to, or receives or has ever received funding from, the tobacco industry. This is in line with NICE's obligation under Article 5.3 of the WHO Framework Convention on Tobacco Control to protect public health policies from the commercial and other vested interests of the tobacco industry. Tobacco companies and those who speak for them or are funded by them (collectively referred to as 'tobacco organisations') cannot register as stakeholders. Tobacco organisations are simply referred to as 'respondents' and any comments received during consultation are reviewed for factual inaccuracy claims and are made public along with any responses. **External expert review** Although NICE does not routinely commission peer review from external experts, members of NICE staff with a quality assurance role, or the developer, may occasionally consider arranging additional external expert review of part or all of a guideline, or an evidence review, executable model or economic analysis. For example, review by external experts may be valuable if novel methods have been used in developing an evidence review.

	External expert reviewers may include practitioners, those commissioning care, academics (for example, with expertise in economic or meta-analysis), or people with a lay perspective. Experts are selected on the basis of their experience in the particular issue under review. External expert review may take place during guideline development or during consultation on the draft guideline. If it occurs during development the comments are not published, but the reviewer(s) should be named in the guideline. Comments from external expert reviewers during the development of the guideline should be discussed by the committee. If the reviewers also comment during consultation, their comments are responded to in the same way as comments from registered stakeholders and are published in the guideline consultation table on the NICE website under 'external expert reviewers'. All external expert reviewers are required to complete a declaration of interests form. **Principles of responding to stakeholder comments** After consultation the committee discusses the comments received during consultation, proposes any changes needed to the guideline, and agrees the final wording of the recommendations. Developers must take the following key points into account when responding to comments from registered stakeholders: ▪ Each comment must be acknowledged and answered as directly, fully and with as much information as possible. ▪ For a draft guideline, the committee must consider whether changes to the guideline are needed as a result of consultation comments; any changes to the guideline must be agreed by the committee before publication. ▪ If changes are made to a guideline as a result of a consultation comment, this must be made clear in the response to the comment. If no changes have been made, it should be clear from the response why not. ▪ Developers should maintain an audit trail of any changes made to the guideline. Registered stakeholders who have commented on the draft guideline are sent the final guideline, and comments and responses, in confidence 2 weeks before publication. Comments and responses are made available on the NICE website when the final guideline is published. NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, if they consider the comments are too long, or publication would be unlawful or otherwise inappropriate. Comments received from non-registered stakeholders and individuals are reviewed by the committee. A formal response is not given and these comments are not made available on the NICE website. Comments received from 'respondents' are reviewed for factual inaccuracy claims and are made public along with any

	responses. Comments received after the deadline are not considered and are not responded to; in such cases the sender will be informed. When evidence is highlighted by stakeholders during consultation, this should be considered for inclusion in the guideline. The developer will take the evidence into account: ▪ if it meets all of the inclusion criteria for the relevant review (as set out in the review protocol), and should have been identified in the guideline searches/screening ▪ if it falls within the timeframe for the guideline search parameters. Any effects on the guideline of including new evidence will be considered, and any further action agreed between the developer and NICE staff with a quality assurance role. If the new evidence falls outside of the timeframe for the guideline searches, the impact on the guideline will still need to be considered, and any further action agreed between the developer and NICE staff with a quality assurance role. **When a second consultation may be needed** In exceptional circumstances, NICE may consider the need for a further 4-week stakeholder consultation after the first consultation. This additional consultation may be needed if either: ▪ information or data that would significantly alter the guideline were omitted from the first draft or ▪ evidence was misinterpreted in the first draft and the amended interpretation significantly alters the draft recommendations. NICE staff with responsibility for guideline quality assurance make the final decision on whether to hold a second consultation.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, presumably the process is the same as that for new guidelines. Details for approving and endorsing new guidelines is below. **Quality assurance of the guideline** After changes agreed by the committee have been made to the guideline in response to consultation comments from registered stakeholders, the guideline is reviewed by NICE staff with responsibility for guideline quality assurance. They check that the changes made to the guideline are appropriate and that the developer has responded appropriately to the registered stakeholders' comments. Further changes to the guideline may be needed; the developer continues to maintain an audit trail of all the changes. The NICE Pathway (everything NICE says on a topic in an interactive flowchart) and any supporting resources are amended in line with any changes to the guideline. These also undergo quality assurance and are signed off within NICE. **Equality impact assessment**

	Before the guideline is signed off for publication, the equality impact assessment is updated by the developer and the committee chair to show whether any additional equality issues have been identified during consultation, and how these have been addressed. The equality impact assessment is published on the NICE website with the final guideline. **Signing off the guideline** NICE's Guidance Executive considers and approves guidelines for publication on behalf of the NICE Board. The Guidance Executive is made up of NICE executive directors, centre directors and the communications director. When considering a guideline for publication, the Guidance Executive reviews a report from NICE staff with responsibility for guideline quality assurance. The report details whether the guideline: ▪ addresses all the issues identified in the scope ▪ is consistent with the evidence quoted ▪ was developed using the agreed process and methods ▪ was developed with due regard to the need to eliminate discrimination, advance equality and foster good relations ▪ will lead to a resource impact when implemented. If any major issue is identified by the Guidance Executive it may be necessary for the committee to meet again to address the problem. The Guidance Executive does not usually comment at other stages during the development of the guideline.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updated guidelines. Details for dissemination of new guidelines is below. **Releasing an advance copy to stakeholders** Registered stakeholders who have commented on the draft guideline and agreed to conditions of confidentiality, are sent the final guideline, the evidence reviews and a copy of the responses to stakeholder consultation comments 2 weeks before publication. This information is confidential until the guideline is published. This step allows registered stakeholders to highlight to NICE any substantive errors, and to prepare for publication and implementation. It is not an opportunity to comment further on the guideline. NICE should be notified of any substantive errors at least 1 week before publication of the guideline. **Publication** The guideline, including evidence reviews, methods, NICE Pathway, key messages for the public and most support tools are published on the NICE website at the same time. **Launching and promoting the guideline**

	The developer and committee work with NICE's media relations team and, if implementation support projects are planned, the implementation lead to disseminate and promote awareness of the guideline at the time of publication and afterwards. It is useful to consider at an early stage of guideline development how the guideline and its support tools will be promoted. Members from the NICE media relations team discuss with the developer and the committee opportunities for promoting the guideline. Committee members may be asked to take part in such activities. NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: ▪ notifying registered stakeholders of publication ▪ publicising the guideline through NICE's newsletter and alerts ▪ issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE. NICE may also use other means of raising awareness of the guideline – for example, training programmes, conferences, implementation workshops, NICE field team support and other speaking engagements. Some of these may be suggested by committee members (particularly members affiliated to organisations for people using services and carer organisations). Each guideline is different and activities for raising awareness will vary depending on the type and content of the guideline. **Press launches** The media relations team may set up interviews or filming with committee members ahead of the guideline launch or on the day itself. NICE can make good use of case studies or experts to illustrate or explain the guideline recommendations. They help to give context to the guideline, explain why the work has been carried out and can illustrate where recommendations have already been put in place or where lessons have been learned. Information may be provided to the media under embargo until the launch date for the guideline. Committee members should ensure that NICE is made aware of any press enquiries they receive before the guideline is launched, and should not answer them without involvement of the media relations team. A guideline launch is usually accompanied by activity on social media which may include graphics, animations, videos and quotes from key committee members or NICE directors. In most cases, this work will be prepared ahead of the launch.

	Committee members may also wish to arrange separate events at which practitioners, providers, commissioners and people using services and the public can learn more about the guideline. Developers should inform committee members that in such cases, the NICE's media relations team should be notified at the earliest possible opportunity. Any materials developed from guideline content by committee members should be submitted to NICE staff with a quality assurance role. Committee members who wish to publish their materials for a UK audience only may do so under the NICE UK Open Content Licence. When there is likely to be substantial media interest, NICE may hold a press conference before publication of the guideline. This form of briefing allows for a more structured and considered exchange of information between NICE and the media, during which any potentially controversial aspects of the guideline can be explained and set in context. It also gives journalists an opportunity to interview people involved in developing the guideline and other contributors – including people with experiences related to the guideline or representatives from charities and other stakeholders who are supportive of the work. The following information was also provided via email: NICE does not directly inform health and social care professionals about the publication of new or updated guidelines, but health professionals are encouraged to subscribe to receive NICE newsletters and alerts about topics that may be of interest to them. There is an expectation that all health professionals keep up-to-date with developments and new guidance relevant to their setting as part of their continuing professional development. In addition, NICE publish news articles and blogs on their website and social media. They issue press releases and updates to a wide range of media outlets, including TV and radio, about new guidance; the decision on whether to feature them is taken by the editors at the respective organisations. **Role/responsibility:** NICE media relations team.
What resources are required to undertake update and who decides this?	Not reported for updated guidelines. Details for resources required to develop new guidelines is below. **Who is involved** ▪ **The committee** The committee is the independent advisory group that considers the evidence and develops the recommendations, taking into account the views of stakeholders. It may be a standing committee working on many guideline topics, or a topic-specific committee put together to work on a specific guideline or multiple guidelines within a topic area. Committee members include practitioners (both specialists in the topic and generalists), service or care providers or commissioners, and others working in the area covered by the guideline. In addition, at least 2 members of every committee are people using services, their family members or carers, or members of the public and community or voluntary

	sector with relevant experience (lay members). If needed for a topic, the committee can co-opt members with specific expertise to contribute to developing some of the recommendations. ▪ **Registered stakeholders** Registered stakeholders are organisations that have registered with NICE because they have an interest in the guideline topic, or they represent people whose practice or care may be directly affected by the guideline. They play an important role in developing and advocating for, or implementing, NICE guidelines. During guideline development NICE keeps registered stakeholders informed of progress by email. NICE also adds information on progress to the guideline page on the NICE website. Registered stakeholders comment on the draft scope and draft guideline, and they may be invited to provide evidence during guideline development. NICE formally responds to comments from registered stakeholders, and these responses are published on the NICE website. Stakeholders support implementation of the guideline once it is published. ▪ **NICE staff and contractors who work with the committee** The committees are assisted by teams whose work covers guideline development, evidence review and support, and quality assurance. These teams are represented at committee meetings and contribute to discussions. They are not committee members, do not contribute to the quorum of the committee or the development of recommendations during meetings, and do not hold voting rights. **Quality assurance by NICE** NICE staff carry out quality assurance of the guideline to ensure that processes have been followed appropriately, and that the methods are clear and transparent. This includes ensuring that the reviews of the evidence and any economic analysis are up-to-date, credible, robust and relevant. They also check that there is a valid link between the evidence and the recommendations. These staff may also be responsible for commissioning the developer. Staff with responsibility for quality assurance must declare any interests, which are managed in line with NICE's policy on declaring and managing interests for board members and employees. Quality assurance takes place throughout development and during checks of the guideline after publication (surveillance). The responsibilities of NICE staff involved in guideline quality assurance are summarised below: ▪ The NICE centre director is responsible for ensuring that the guideline is produced in accordance with this manual. The centre director is also responsible for appointing the committee chair and committee members. ▪ The NICE guideline lead is responsible for the development and quality assurance of the guideline (including the scope), and has delegated responsibility for approving the consultation draft and the final guideline, before approval by NICE's Guidance Executive. The guideline lead also advises the committee chair and the developer on matters of method and process. Guideline commissioning managers help them with this.

	▪ The NICE clinical, public health or social care adviser is responsible for providing advice during all stages of guideline development. ▪ The NICE technical lead is responsible for ensuring the technical quality of the non-economic evidence reviews. ▪ The NICE economic lead is responsible for ensuring the technical quality of the economic evidence and any economic analysis. Quality assurance of guideline surveillance reflects quality assurance of guideline development. The NICE associate director is responsible for ensuring that processes are followed and that decisions to update or not update guidelines are robust and fit for approval by NICE's Guidance Executive. The NICE technical adviser ensures the technical quality of the surveillance review, and the NICE clinical, public health or social care adviser provides advice at all stages. **Development** ▪ The developer may be a team within NICE, or in an organisation contracted by NICE to develop guidelines. The developer is responsible for scoping the guideline, supporting the committee and documenting the recommendations, committee discussions and decisions, evidence reviews and methods. ▪ Administrators, coordinators and project managers provide administrative and management support to the committee, planning and scheduling the work, arranging meetings, liaising with stakeholders and all individuals and organisations contributing to the development of guidelines. ▪ The evidence review team (comprising an information specialist, systematic reviewer and for most guidelines an economist) identifies, reviews and summarises the evidence, and undertakes economic analyses. Sometimes developers may commission other organisations to review the evidence. ▪ The information specialist identifies relevant literature to answer the review questions (see the chapter on identifying the evidence: literature searching and evidence submission), creates databases to manage the search results and keeps a log of search results and strategies. ▪ The systematic reviewer critically appraises the evidence, distils it into evidence tables and writes brief summaries (including GRADE tables, GRADE-CERQual or evidence statements, if used) for presentation to the committee (see the chapter on reviewing research evidence). The reviewer also summarises the main issues with the evidence for the committee and contributes to their discussions. ▪ For most guidelines, an economist identifies potential economic issues in discussion with the committee, summarises the published economic evidence and performs additional economic analyses as needed. **Support**

	Staff from other NICE teams work on the guidelines at different stages. They may attend committee meetings and comment on the guideline during consultation and at other times. ▪ **NICE media relations team** The media relations team supports committee members, the developer, and NICE staff with responsibility for quality assurance, on all aspects of communications, including contacts with the media and managing any issues, throughout guideline development and after publication. ▪ **NICE resource impact assessment team** The resource impact assessment team works with the committee, and NICE staff carrying out quality assurance, to provide information on the resource impact (costs and savings) of recommendations. Final cost estimates are available to support the implementation of the guideline. ▪ **NICE adoption and impact team** The adoption and impact team produces tools and signposts to other support that can help organisations put guideline recommendations into practice. The implementation support team works with external organisations on selected priority areas, which depend on the interests of our partner organisations and resources. ▪ **NICE system engagement team** The system engagement team includes the field team who work with regional and local organisations to promote the guideline and help to put it into practice. The NICE endorsement and shared learning programmes also support implementation with external resources and implementation case study examples. ▪ **NICE public involvement programme** The public involvement programme advises on ways to effectively involve people who use health and care services, family members, carers and the public, and supports their participation in guideline development. The public involvement programme encourages organisations representing service user, carer and community interests to register as stakeholders. It also advertises for people using services, carers and the public to apply to join committees and supports them in their roles as committee members. ▪ **NICE publishing team** Editors from the publishing team work with the committee, the developer and NICE staff with responsibility for guideline quality assurance. They ensure that the guideline and related products are written and presented in a way that is clear and accessible to a range of different audiences. They develop the NICE Pathway (which brings together everything NICE says on a topic in an interactive flowchart) and for some topics may produce a visual summary of the recommendations. **Role/responsibility:** N/R
Living guidelines	

Does the organisation provide detail on living guidelines?	N/R

Key: GRADE - Grading of Recommendations, Assessment, Development and Evaluations; GRADE-CERQual - Confidence in the Evidence from Reviews of Qualitative research; N/A - not applicable; NICE - National Institute for Health and Care Excellence; N/R - not reported; RCT - randomised controlled trials.

Appendix 4.12 Interim process and methods for guidelines developed in response to health and social care emergencies

Handbook characteristics	
Organisation	National Institute for Health and Care Excellence
Year	2020
Country	UK
URL	https://www.nice.org.uk/process/pmg20/resources/appendix-l-interim-process-and-methods-for-guidelines-developed-in-response-to-health-and-social-care-emergencies-pdf-11378590459333
Title of the publication	Interim process and methods for guidelines developed in response to health and social care emergencies
Description of the update/retirement process	
What types of update exist?	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
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	▪ **Rapid update of the guideline** – this may or may not involve formal evidence reviews. A rapid update may be required 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 and the referring body, without a formal evidence review. For example, adding or amending recommendations. A rapid update may also be required when 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. For example, 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. ▪ **Refresh the guideline** – NICE state that a guideline can be refreshed even when the decision has been made not to update the guideline. Refreshing a guideline is 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. **Role/responsibility:** NICE surveillance team.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	Withdrawal of a guideline occurs if the guideline is no longer needed or is redundant because service delivery has changed or the recommendations are likely to have limited relevance for the service beyond the health and social care emergency. This may also occur if there are safety issues or there is duplication of

	recommendations if the guideline content or some of its recommendations are merged with another guideline within the suite. There will be no public consultation for a surveillance decision to refresh or withdraw the guideline. **Role/responsibility:** Topic experts will be asked to validate the surveillance decision instead.
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	▪ Literature searching Update searches will be conducted using targeted literature searches employed when drafting the interim guideline itself. Additional searching of ongoing reviews will be conducted through existing collaborative links with established national or international networks and repositories, where available. 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 there unless it is likely to add value to the decision-making process. When no relevant, high-quality systematic reviews are identified (either published or in development): o Opportunities will be explored for progressing relevant reviews and event tracking through existing collaborative links (for example, Cochrane). o Rapid evidence reviews will be undertaken and published by NICE. 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 update independent advisory expert panel decision-making 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: o labelling all recommendations to make it clear that they have been developed using a different approach to standard NICE guidelines o categorising updated recommendations

	○ 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). Due to 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. **Role/responsibility:** 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.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	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. 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. Thematic responses to stakeholder comments will be made available on the NICE website.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	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 or healthcare context and relevance, and safety implications. NICE's Guidance Executive will be asked to approve and sign off the rapid update before publication.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for rapid updates to interim guidelines but presumably this is the same as standard NICE guideline (see Appendix 6.4.13 for more details). The following information was also provided via email: NICE does not directly inform health and social care professionals about the publication of new or updated guidelines, but health professionals are encouraged to subscribe to receive NICE newsletters and alerts about topics that may be of interest to them. There is an expectation that all health professionals keep up-to-date with developments and new guidance relevant to their setting as part of their continuing professional development. In addition, NICE publish news articles and blogs on their website and social

	media. They issue press releases and updates to a wide range of media outlets, including TV and radio, about new guidance; the decision on whether to feature them is taken by the editors at the respective organisations.
What resources are required to undertake update and who decides this?	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. 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. 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. 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. 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, 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. 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. 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. **Role/responsibility:** N/R
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: AGREE II - Appraisal of Guidelines for Research and Evaluation version 2; N/A - not applicable; NICE - National Institute for Health and Care Excellence; N/R - not reported; PROSPERO - International prospective register of systematic reviews.

Appendix 4.13 Estonian Handbook for Guidelines Development 2020

Handbook characteristics	
Organisation	Estonian Health Insurance Fund
Year	2020
Country	Estonia
URL	https://ravijuhend.ee/uploads/userifles/Estonian_Handbook_for_Guidelines_Development_2020_copy.pdf
Title of the publication	Estonian Handbook for Guidelines Development 2020
Description of the update/retirement process	
What types of update exist?	▪ Full ▪ Partial ▪ Individual questions
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	**Updating guidelines** When new knowledge, skills, and possibilities become available, the approved guidelines should be reviewed periodically to assess the extent of the need to update them. This need will arise if new evidence suggests any substantial change in the content of the current recommendations is needed; any organisational changes to the health-care system occur; or if assessing the implementation of the guidelines indicates a review of the recommendations is necessary. The process of updating guidelines should start no later than four years after their initial approval. **Role/responsibility:** Guideline Advisory Board
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	Retired guidelines are stored in an online repository, (www.ravijuhend.ee) managed by the Estonian Health Insurance Fund, until the new updated guideline is approved. **Role/responsibility:** A retired guideline is signed off from the website after a new updated guideline has been approved by the Guideline Advisory Board.
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	Review of the prepared guidelines is arranged by the Guideline Unit by requesting – at the latest during the fourth year after a guideline's approval – an expert opinion from the Chair and or the members of the Panel that prepared the existing guideline. The Guideline Unit, on the basis of expert opinions, provides the Guideline Advisory Board annually with an overview of approved guidelines that need to be updated, together with proposals for the content and volume of the updates. In addition, the Guideline Advisory Board considers the need to update the guidelines on the basis of the results of relevant statistics, audits or applied research, or based on feedback from interested parties.

	Communication from organisation: There are no criteria for prioritising which guideline to update first. Prioritisation can be guided by any external information, such as new research evidence that changes the management of patients with a certain disease or important changes in the healthcare system that would mean any recommendation(s) in the guideline do not align with these changes, for example, inclusion of additional target groups in a guideline. The starting time of the updating process may be affected by the current financial and human resource restrictions or any additional factors that would likely affect the updating process, for example, results of a clinical audit. **Role/responsibility:** The Guideline Unit and Guideline Panel that prepared the existing guideline provide the necessary information to the Guideline Advisory Board.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	The expert opinion distinguishes between the guideline's health questions that would require the evidence to be updated, and other questions that have arisen in the meantime and which require further response. Updating the guidelines may mean supplementing or modifying the scope. In addition to changing health questions, this also includes selecting essential outcomes, if they differ from those of the current guideline. Communication from organisation: The number of clinical questions to be updated depends of the current guideline and, typically, only selected questions and recommendations are reviewed. A general assessment as to whether a guideline needs to be updated is made by Chair and or the members of the Panel that prepared the existing guideline. **Role/responsibility:** The Guideline Panel.
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	The process of updating guidelines is based on the same principles and methodology as preparing a new guideline and should similarly be based on existing Evidence to Decision frameworks. In order to facilitate the updating procedure, the Guideline Unit must ensure at time of publication of original guideline the archiving and availability of key documents used (including evidence summaries and scientific literature used to develop the approved guidelines). **Role/responsibility:** The Guideline Unit.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, however, following contact with the organisation it was confirmed that reviewing processes are the same as those for guidelines developed de novo. Details for review of new guidelines is below. **Review** When the guideline is close to being finalised, the Guideline Advisory Board initiates a review by three reviewers (ideally a general practitioner, a content expert and one Guideline Advisory Board member). The Chair of the Panel submits the final draft (approved by the Panel) to the Guideline Unit, who forwards it to

	the approved reviewers, as well as for consultation by other relevant parties. A Panel member reviews the received feedback and comments, together with the Guideline Unit, and suggests any required changes to the guideline to be made by the Secretariat. Substantive changes will have to be approved by the Panel based on recommendation by the Chair; justifications for any amendments should be provided.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Not reported for updated guidelines, however, following contact with the organisation it was confirmed that approval processes are the same as those for guidelines developed de novo. Details for approving and endorsing new guidelines is below. **Approval by the Guideline Advisory Board** In order for the Guideline Advisory Board to approve the guideline, including its implementation plan and other relevant material, it has to evaluate whether the guideline has been developed according to the principles and methodology set out in this handbook, and whether the necessary processes have been followed and documented. The focus of the evaluation and subsequent discussion in the Guideline Advisory Board is not the content of the guideline, but the rigor of its development. In general, this evaluation should follow the principles highlighted in the GIN-McMaster checklist, developed in collaboration with Estonia, as well as the AGREE II tool and RIGHT statement. The key questions that would signal to the Guideline Advisory Board the quality, clarity and consistency of a guideline include those listed here. ▪ Did the Panel and the Secretariat report using the RIGHT (and, if an adaptation, RIGHT ADAPT) reporting checklist(s)? ▪ Did the recommendations appropriately describe the population, intervention and comparator (if necessary) and include the rating of the strength and quality/certainty of the evidence? ▪ Is there a link between the evidence and the recommendations? ▪ Are the reasons for the Evidence to Decision judgements clear? ▪ Did the guideline working group only make strong recommendations when justified? (The rationale for all strong recommendations should be checked). ▪ Was Conflict of Interest appropriately managed and addressed? (The meeting minutes should be checked). ▪ Are the results of the public consultation available? ▪ How does the guideline score on the AGREE II items?
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Not reported for updated guidelines, however, following contact with the organisation it was confirmed that dissemination is the same as that for guidelines developed de novo. Details for dissemination of new guidelines is below.

	Dissemination of the guideline recommendations The reliability of guidelines is ensured by maximum transparency of the development process. To enable this, the procedure for preparing the guideline must be carefully documented and all documents involved should be stored electronically in order to be publicly disclosed and used again in future. All topic proposals and scopes approved by the Guideline Advisory Board, along with the minutes of the meetings of the Guideline Advisory Board are publicly available on the website. Recommendations that have been completed and approved by the Panel during the guideline development process are also published on the guidelines' website. During the guideline development process, implementation plans are prepared for the dissemination and use of the information contained in the guidelines by the various target groups. The evaluation metrics for implementing the guidelines are also provided. Once the guideline development process reaches the final stage, all assessments, comments, and reviews of interested parties are made publicly available, in addition to the working copy of the guideline, the summaries of the evidence gathered by the team and the protocols of the Panel meeting. Following approval of the guideline, the following items are also made available on the website: ▪ recommendations ▪ the guideline in full ▪ algorithm(s) illustrating the choices and recommendations given in the guideline (if created) ▪ a short version (executive summary) of the guideline if necessary (1–2 pages) ▪ patient recommendations and patients versions (if applicable) ▪ the implementation plan ▪ the final scope of the guideline ▪ summaries of the evidence/findings and Evidence to Decision summaries ▪ minutes of the Panel meetings ▪ an overview of any DOI of the guideline developers, listing their names and professions. **Role/responsibility:** N/R
What resources are required to undertake update and who decides this?	Following contact with the author it was confirmed that updating of guidelines is financed according to the contract between the University of Tartu and Estonian Health Insurance Fund. Updating and composing guidelines is funded solely by the Estonian Health Insurance Fund. **Role/responsibility:** N/R
Living guidelines	

Does the organisation provide detail on living guidelines?	**Small informative recommendation units** Small informative recommendation units, which are recommendations only, can be published online in advanced of full authorisation of guidelines. The number of recommendations in a small informative recommendation unit is typically 1 to 4. This approach allows for rapid feedback by patients, health professionals and policy-makers. It also supports maintaining small informative recommendation units in a live or updated format, where required. These recommendations can be published on the website sooner after approval than full documents. They will require the same approval processes, but the review will take less time because the amount of information is reduced.

Key: ADAPT - adapting evidence informed interventions for implementation in new contexts; AGREE II - Appraisal of Guidelines for Research and Evaluation version 2; DOI - digital object identifier; GIN - Guidelines International Network; N/A - not applicable; N/R - not reported; PICO - population, intervention, comparator, outcome; RIGHT - Essential Reporting Items for Practice Guidelines in Healthcare statement.

Appendix 4.14 Rapid guideline methodology

Handbook characteristics	
Organisation	Scottish Intercollegiate Guidelines Network
Year	2021
Country	Scotland
URL	https://www.sign.ac.uk/media/1836/20210408-rapid-guideline-manual-10.pdf
Title of the publication	Rapid guideline methodology
Description of the update/retirement process	
What types of update exist?	N/R
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	A flexible approach to updating is used to ensure rapidly emerging evidence can be incorporated. The frequency of update is agreed and stated at publication. The option to withdraw the guideline is considered. Rapid guidelines are completed within a 1- to 3- month timeframe to provide guidance in response to an emergency, urgent need or new evidence. **Scoping for the need to update a rapid guideline** Timescales for review and updating are agreed at the time of publication and clearly stated in the rapid guideline. All comments received on published rapid guidelines, or information on important new evidence in the field, or safety alerts, or evidence of impacts on equality groups are considered, either for immediate response or for more detailed consideration on review of the guideline. **Criteria for updating a rapid guideline** New evidence, data or information: ▪ that would significantly change a recommendation; either strengthen, for example from conditional to strong recommendation, or reverse it ▪ that would warrant a new key question to cover new interventions, for example add another treatment option ▪ about patient safety, for example side effects from real-time data ▪ about patient preferences or equity. New research that adds to the body of evidence supporting a recommendation without changing it would not warrant an update. **Role/responsibility:** N/R
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to	**Withdrawing a rapid guideline** From time to time it is necessary to consider withdrawing guidelines which are outdated or no longer

sign-off retired guideline?	relevant. This is especially important for rapid guidelines developed under emergency or rapidly-changing conditions, or when there is an evolving or rapidly-emerging evidence base. **Criteria for withdrawing a guideline** Guidelines may be withdrawn for any of the following reasons: ▪ contextual changes render the guideline unnecessary ▪ superseded by a more recent or more comprehensive guideline ▪ evidence that the guideline is complied with by NHS Scotland, and has become accepted practice ▪ emergence of new treatments or preventive measures that render the guideline irrelevant. **Role/responsibility:** N/R
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	N/R
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	N/R
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	N/R
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	N/R
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	N/R
What resources are required to undertake update and who decides this?	N/R

Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: N/A - not applicable; N/R - not reported; SIGN - Scottish Intercollegiate Guidelines Network.

Appendix 4.15 Procedure Manual

Handbook characteristics	
Organisation	US Preventive Services Task Force
Year	2021
Country	USA
URL	https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual-2021_0.pdf
Title of the guideline manual	Procedure Manual
Description of the update/retirement process	
What types of update exist?	▪ Full update (update all the key questions) ▪ Targeted update (update a limited set of the key questions) ▪ Reaffirmation (topics kept current by the Task Force because they are well-established, evidence-based standards of practice in current primary care practice)
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	The ultimate goal is to balance the annual portfolio of topics by population, type of service (screening, counselling, preventive medication), type of disease (for example, cancer, endocrine disease), and size of project (for example, update vs. new topic). The Task Force aims to update topics every 5 years in order to keep its library of recommendations current. **Role/responsibility:** Task Force Topic Prioritisation Workgroup drafts a prioritised list of topics.
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	Inactive topics are topics the Task Force has decided to inactivate for one or more of the following reasons: 1. Topic is no longer relevant to clinical practice because of changes in technology, new understanding of disease etiology/natural history, or evolving natural history of the disease. 2. Topic is not relevant to primary care because the service is not implemented in a primary care setting or not referable by a primary care provider. 3. Topic has a low public health burden. 4. Topic is otherwise outside of the Task Force's scope. Previously inactivated topics are also eligible as new topic nominations, if appropriate, along with other new topic suggestions. If a topic is inactivated the status on the Task Force Web site continues to be listed as "active" for a minimum of 5 years from the date of the original recommendation, unless considerations arise beforehand to change the status. After this period, the status changes to "inactive." **Role/responsibility:** text refers to Task Force but no reference to specific individuals/groups.

Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	The Topic Prioritisation Workgroup begins prioritisation of an active group of topics approximately 3 years after their previous publication. **Step 1.** A brief background paper on the topic is produced that includes the following information: previous recommendation statement, estimate of disease burden, relevance to prevention and primary care, recommendations of other guideline developers, existing controversy or gap between evidence and practice, and summary of a brief literature search for new evidence. **Step 2.** The Topic Prioritisation Workgroup reviews and discusses the background paper and places each topic into either the active or inactive category. Topics that are retained as active are considered for referral to other organisations. **Step 3.** A request for feedback on all active topics and potential new topics, is sent to Task Force members and partner organisations. Respondents are asked to categorize each proposed topic as high-, moderate-, or low-priority for review in the next 12 to 18 months, based on the following criteria: 1. Public health importance (that is, burden of suffering and expected effectiveness of the preventive service to reduce that burden) 2. Potential for a Task Force recommendation to affect clinical practice (based on existing controversy or the belief that a gap exists between evidence and practice) 3. New evidence (for example, new studies or new analyses of previous data) that has the potential to change the prior recommendation 4. Need for a balanced portfolio of topics **Step 4.** The feedback from Task Force members and partner organisations is considered by the Topic Prioritisation Workgroup, along with the background paper, in assigning a tentative priority category for active topics. The four criteria listed in Step 3, along with resource requirements for the review, are used to recommend priority (low, moderate, or high). **Step 5.** The topic categorisation (active, inactive, refer) and prioritisation (high, moderate, low) becomes final after a vote of the full Task Force membership. **Role/responsibility:** Task Force's Topic Prioritisation Workgroup recommends selection and prioritisation of new topics to the entire Task Force. AHRQ staff develop the work queue for the next 12- to 18-month cycle as per the topics selected and prioritised by the Task Force's Topic Prioritisation Workgroup.
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	The update may encompass all key questions on a topic (full update) or only a limited set of the key questions in the analytic framework (targeted update). While some detail on this process is reported, detail on the criteria used to prioritise between clinical questions within a guideline scheduled for updating are not reported. ▪ When a topic moves forward for update, a new research plan to guide the evidence review is created. The research plan includes the key questions to be systematically reviewed, an analytic framework, and

	inclusion/exclusion criteria to be applied to the review. The previous research plan used for the topic is reviewed and considered in formulating the new research plan; the new research plan may be the same or similar to the previous one, or may be revised and include new or additional key questions to be systematically, reviewed, new or additional contextual questions (which are reviewed, but not necessarily systematically) or new/revised inclusion/exclusion criteria. ▪ When a topic moves forward for a reaffirmation update, the scope of the review focuses on identification of substantial, new evidence that may change the overall recommendation grade (called a limited systematic review update). ▪ A draft research plan is posted on the USPSTF website for 4 weeks for public comment. All public comments received are reviewed and considered by the topic team to revise the research plan. The USPSTF leads approve the revised, final research plan before it is finalised (and it is again posted on the USPSTF website for transparency). **Role/responsibility:** Research plans are scoped by a topic team that is appointed for each prioritised topic. A topic team consists of USPSTF leads (including one of the USPSTF Chairs), at least one AHRQ Medical Officer and the EPC review team. *EPCs are scientific research centres who are contracted by AHRQ to conduct systematic evidence reviews that serve as the foundation for USPSTF recommendations.
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	The specific evidence synthesis methodologies used to update topic reviews vary depending on what is appropriate for the specific topic and type of review (full systematic review or limited systematic review). ▪ Development of a “new recommendation”, an “updated recommendation” and a “reaffirmed recommendation” all include an evidence assessment by the USPSTF, and a vote by the full USPSTF to either issue a “new” or “updated” draft recommendation statement (may or may not be the same recommendation grade as previously) or “reaffirm” a pre-existing A or D grade recommendation. o Grade A recommendation – Strongly Recommended: The USPSTF strongly recommends that clinicians provide (the service) to eligible patients. The USPSTF found good evidence that (the service) improves important health outcomes and concludes that benefits substantially outweigh harms. o Grade D recommendations – Not Recommended: The USPSTF recommends against routinely providing (the service) to asymptomatic patients. The USPSTF found at least fair evidence that (the service) is ineffective or that harms outweigh benefits. ▪ The “evidence assessment” and “vote” are also called the “deliberation process”. “New,” “updated,” and “reaffirmed” recommendation statements are all posted as draft on the USPSTF website for public comment, and all public comments are reviewed and considered prior to finalisation of the

	recommendation statements. The final recommendation statement must also be voted on again, and ratified by two thirds of the USPSTF in order to become final. ▪ The Task Force values consistency in its process for determining grades. Changes in the grade when updating a previously published recommendation should have a strong rationale that stems directly from the USPSTF process of determining grades (i.e., there is a difference in certainty or magnitude that warrants a change in grade). ▪ A grade may result in a change from a previous Task Force recommendation because of one or more of the following: o A change in methods and/or analytic framework since the last recommendation statement. o A change in the definition of a grade. o Evidence has increased or decreased and results in a change in the certainty or magnitude of net benefit, or has made the issuance of a grade less relevant. This may occur when there is a change in understanding about the applicability of older evidence or international evidence. o New methods and/or new evidence regarding subpopulations. ▪ Grade changes may also result from changes in context (clinical context, societal values for specific outcomes, and context of intervention and treatment). In this case, while the analytic framework is largely similar to the prior framework, something has changed in the contextual issues. ▪ It is important that the Task Force communicate in its recommendation statement how the changes in the above factors or context affects its rating of certainty and magnitude and why this results in a grade that is different than a previously published grade. ▪ A "reaffirmation update" may be based on a limited systematic review update rather than a full systematic evidence review. ▪ The focus of the limited systematic review update is to identify new and substantial evidence that would be sufficient enough to change the recommendation. ▪ In a "reaffirmation deliberation process," the USPSTF assesses the new evidence to see if it is substantial enough to change its prior assessment of certainty and magnitude of net benefit on which the prior "A" or "D" grade was based, rather than determining an updated assessment of certainty of evidence and magnitude of net benefit (as is done in an "update"). ▪ The remaining steps of the recommendation development process after the "reaffirmation deliberation" remain the same as for recommendation "updates" and "new" recommendations (that is, posting of draft recommendation, review and consideration of public comments, revisions to recommendation statement, vote on final recommendation by full USPSTF and ratification by at least two thirds, and posting of final recommendation statement).

	Role/responsibility: The evidence reviews are conducted by the EPC that is contracted by AHRQ in support of the USPSTF. The EPC provides the USPSTF with an evidence report and presents the evidence to the USPSTF.
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	Following communication from the organisation, it was confirmed that the review processes for updated (and reaffirmed guidelines) are the same as that for new guidelines. The process of reviewing new guidelines is below. To increase the clarity, transparency, and utility of its recommendation statements to primary care providers and the public, the Task Force shares drafts of its research plans, evidence reviews, and recommendation statements for public comment. The comments are considered in finalising the documents. All comments received through the public comment process are shared with the topic leads for their review and consideration before finalising the document. All Task Force members have access to the full text of all comments; a disposition table summarising the comment themes and the proposed Task Force response; and the revised research plan, evidence review, or recommendation statement. A draft reaffirmation statement is prepared for consideration that includes a summary statement of the recommendation and evidence, the rationale, updated clinical considerations, and a brief summary of the systematic review or evidence update, with references to both the current evidence update and the previous systematic review. The draft reaffirmation statement is posted for public comment following the usual process.
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	Following communication from the organisation it was confirmed that the process of approving and endorsing new guidelines (and reaffirmed guidelines) is the same as that for new guidelines. The process of approving and endorsing new guidelines is below. After consideration of public comments, the topic leads puts forward a new motion for consideration by the full Task Force for the final recommendation. If the final recommendation statement is similar to the posted draft, debate is limited, and the full Task Force votes via email. A “yes” vote from two thirds of the current Task Force membership is needed to pass the motion and ratify the final recommendation. If, as a result of the comment process or new evidence identified during the public comment period, any member of the Task Force believes that a change in the recommendation grade is warranted, they can request that the topic leads make a motion to the Task Force. At that point, any new evidence is reviewed by the topic leads with help from AHRQ and the appropriate EPC staff. The AHRQ Medical Officer and Scientific Director facilitate this process. The topic leads present their motion and any important new evidence to the full Task Force (most often via

	conference call or Webinar), followed by time for discussion. The Chair then calls for a vote on the motion (which may take place via email after several days of reflection and discussion). This approach recognises that the vote on the final recommendation is a different motion than the vote on the draft (hence two separate motions and votes). A "yes" vote from two thirds of the current Task Force membership is needed to pass the motion and ratify the final recommendation.
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	Following communication with the organisation it was confirmed that dissemination processes are the same as those for new guidelines. The process of disseminating new guidelines (and reaffirmed guidelines) is below. The Dissemination and Implementation Workgroup helps the Task Force better communicate with clinicians and members of the public about its recommendations, and also writes the Task Force's annual report to Congress. The Task Force disseminates its research plans, methods, evidence reviews, and recommendation statements through: ▪ USPSTF website ▪ Prevention Task Force app ▪ Journal of record (currently the Journal of the American Medical Association) ▪ Dissemination and Implementation Partners. **Reaffirmation review process** The newly dated reaffirmation statement, a link to the previous evidence review and recommendation statement, and the summary of the evidence are made available on the USPSTF Web site following usual processes. **Role/responsibility:** The Dissemination and Implementation Workgroup disseminates the update and recommendations.
What resources are required to undertake update and who decides this?	The 1998 Public Health Service Act and the 2010 Patient Protection and Affordable Care Act authorise and require the AHRQ to convene the USPSTF and to provide scientific, administrative, and dissemination support to the USPSTF. The AHRQ is an agency within the U.S. Department of Health and Human Services whose mission is to produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. To support the Task Force, the USPSTF program staff: ▪ assists with day-to-day operations ▪ coordinates the development of comprehensive evidence reports

	▪ supports the Task Force in the consistent and transparent application of its methods ▪ provides assistance with the promotion and dissemination of Task Force materials and recommendations. **Role/responsibility:** The 1998 Public Health Service Act and the 2010 Patient Protection and Affordable Care Act.
Living guidelines	
Does the organisation provide detail on living guidelines?	N/R

Key: AHRQ - Agency for Healthcare Research and Quality; EPC - Evidence-based Practice Center; N/A - not applicable; N/R - not reported; USPSTF - US Preventive Services Task Force.

Appendix 5 Quality assessment of included handbooks

	GIN-McMaster Checklist (Updating criteria)					
	1. Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated.	**2. Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available.**	**3. Set the conditions that will determine when a partial or a full update of the guideline is required.**	**4. Make arrangements for guideline group membership and participation after completion of the guideline.**	**5. Plan the funding and logistics for updating the guideline in the future.**	**6. Document the plan and proposed methods for updating the guideline to ensure they are followed.**
Clinical practice guidelines we can trust (2011) ***IOM***	Y	N	N	N	N	N
Handbook for Supporting the Development of Health System Guidance (2011) ***Swiss Centre for International Health***	Y	Y	N	N	N	Y
GIN: Toward International Standards for Clinical Practice Guidelines (2012) ***GIN (Qaseem A et al.)***	Y	Y	N	N	N	N
AWMF Guidance Manual and Rules for Guideline Development (2013) ***AWMF***	Y	Y	Y	N	N	N
WHO handbook for guideline development, 2nd Edition (2014) ***WHO***	Y	Y	N	N	N	Y
Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations (2018) ***GIN-McMaster (Morgan RL et al.)***	Y	N	N	N	N	N
The UpPriority Tool: a prioritisation tool for updating clinical questions within a guideline (2019) ***GIN Updating Guidelines Working Group and collaborators***	N/A	N/A	N/A	Y	N/A	N/A

	GIN-McMaster Checklist (Updating criteria)					
	1. Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated.	**2. Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available.**	**3. Set the conditions that will determine when a partial or a full update of the guideline is required.**	**4. Make arrangements for guideline group membership and participation after completion of the guideline.**	**5. Plan the funding and logistics for updating the guideline in the future.**	**6. Document the plan and proposed methods for updating the guideline to ensure they are followed.**
Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods (2019) ***Clinical Guidelines Committee of the ACP***	Y	N	N	N	N	N
SIGN 50: a guideline developer's handbook (2019) ***SIGN***	Y	Y	Y	N	N	Y
Developing NICE guidelines: the manual (PMG20) (2020) ***NICE***	Y	Y	N	N	N	Y
Interim process and methods for guidelines developed in response to health and social care emergencies (2020) ***NICE***	Y	Y	N	N	N	Y
Estonian Handbook for Guidelines Development 2020 (2020) ***Estonian Health Insurance Fund***	Y	Y	Y	N	N	Y
Rapid guideline methodology (2021) ***SIGN***	Y	N	N	N	N	N
Procedure Manual (2021) ***USPSTF***	Y	Y	N	N	Y	Y

Key: ACP - American College of Physicians; AWMF - Association of the Scientific Medical Societies; CG - clinical guideline; CQ - clinical question; GIN - Guidelines International Network; IOM - Institute of Medicine; N - no; N/A - not applicable; NICE - National Institute for Health and Care Excellence; N/R - not reported; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventative Services Task Force; WHO - World Health Organization; Y - yes.

Appendix 6 Characteristics of included peer-reviewed articles

Appendix 6.1 Evaluation of additional search techniques for surveillance reviews

Publication identification	Publication description	Evaluation (as reported by authors)
Authors (year): Casey (2020) *Organisation:* NICE *Country:* UK *DOI:* 10.1002/jrsm.1461	*Design:* A retrospective analysis on 5 surveillance reviews with less than 2% of the studies included after screening. *Objective:* To investigate the impact of additional search techniques to determine if they increase precision and reduce screening burden without impacting on surveillance decisions (i.e. decision to update or not). *Search techniques:* focused subject headings, subheadings, frequency operators and title only searches *Databases searched:* MEDLINE, Embase and PsycINFO *Outcome measures:* ▪ Total number retrieved: total number of results retrieved by a search strategy. ▪ Number of includes found: number of studies included in the original surveillance decision document that were found by a search strategy. ▪ Search precision: number of included studies contained in the search results retrieved by the search/the total number of studies in the results set (%) ▪ Number Needed to Read: number of publications that needs to be screened in order to identify one relevant publication. NNR is calculated as 1/precision × 100.16	*Outcomes:* **Round 1 testing** *Focused subject headings* ▪ Retrieval: MEDLINE, 1/69 not retrieved, Embase 3/78 not retrieved. ▪ NNR: MEDLINE mean reduction = 11+/−14, Embase mean reduction = 85+/−74 *Frequency operators* ▪ Retrieval: MEDLINE, 4 not retrieved, Embase 3 not retrieved. ▪ NNR: MEDLINE mean reduction = 29+/−25, Embase mean reduction = 32+/−28 *MeSH, Emtree, PsychINFO subheadings* ▪ Retrieval: MEDLINE, 3 not retrieved. ▪ NNR: MEDLINE mean reduction = 8+/−14, Embase mean reduction = 71 +/−72, PsychINFO reduction for CG155 (from 53 to 29) and for CG142 (NNR from 30 to 27). *Title only and the combination of title only and focused subject headings techniques* ▪ Retrieval: MEDLINE, 18 not retrieved, Embase 28 not retrieved. **Round 2 testing:** *Combined searches using focused subject headings and frequency operators compared with baseline* ▪ Precision: 0.5% for baseline, 1.08% for combined (CG141) ▪ NNR: 199 for baseline, 93 for combined (CG141) ▪ Precision: 1.97% for baseline, 2.17% for combined (CG142) ▪ NNR: 51 for baseline, 46 for combined (CG142)

		▪ Precision: 1.20% for baseline, 2.73% for combined (CG149) ▪ NNR: 84 for baseline, 37 for combined (CG149) ▪ Precision: 0.68% for baseline, 0.97% for combined (CG155) ▪ NNR: 148 for baseline, 103 for combined (CG155) ▪ Precision: 1.57% for baseline, 3.33% for combined (CG160) ▪ NNR: 64 for baseline, 30 for combined (CG160) *Usability/critique:* ▪ Improving the precision of surveillance searches did not have a detrimental impact on the decision to update the guideline. The results of this study indicate that the use of these additional search techniques is a viable option to consider for surveillance topics where the initial search yields a large number of studies for screening. These techniques could also be of potential value in other rapid review contexts, where limited resources preclude a full systematic review. ▪ Focus of the study was on searches conducted for NICE guideline surveillance, meaning the results may not be applicable to systematic reviews or guideline development where precision of evidence searches may be less desirable as the risk of missing relevant studies is greater. *Timeliness:* ▪ Frequency operators and focused subject headings (individually or in combination) could be used to improve the precision of surveillance searches. ▪ This could reduce the NNR for individual surveillance topics, reducing the screening burden and the time needed to review abstracts. ▪ However, no comparison of time taken to screen was carried out in this surveillance study.

Key: NICE - National Institute for Health and Care Excellence; NNR - numbers needed to read.

Appendix 6.2 Evaluation of The UpPriority Tool

Publication identification	Publication description	Evaluation (as reported by authors)
Authors (year): Sanabria (2020) *Organisation:* GIN *Country:* International *DOI:* 10.1016/j.jclinepi.2020.06.018	*Design:* The development of this tool consisted of the following: a) establishment of the working group; b) generation of the initial version; c) optimisation of the tool (including an initial feasibility test, semi-structured interviews, Delphi consensus survey, second feasibility test, external review, and pilot test); d) approval of the final version. *Objective:* To develop a pragmatic tool to prioritise clinical guideline questions for updating, The UpPriority Tool.	*Usability/critique:* ▪ A pilot test of the tool was conducted with the NICE clinical guideline meningitis (bacterial) and meningococcal septicemia in under 16s: recognition, diagnosis, and management. ▪ A total of 3 participants from the 6 invited (50% response rate) independently applied the tool. All of them chose to remain anonymous. ▪ Participants took a median of 0.5 hours (range 0.5–2.0) to complete assessments using the tool. The overall ICC was 0.65 (95% CI 0.36–0.82). ▪ Item 2 received a substantial degree of agreement; items 1, 3, and 6 received fair degree of agreement; and items 4 and 5 received poor degree of agreement. ▪ The overall degree of agreement was considered fair, given the wide confidence intervals observed. ▪ No changes were made to the tool at this stage. *Timeliness:* N/R
Authors (year): Sanabria (2021) *Organisation:* GIN *Country:* International *DOI:* 10.1016/j.jclinepi.2021.07.022	*Design:* 30 appraisers systematically assessed 107 clinical questions from 4 guidelines developed in the Spanish National Health System clinical guideline program. Objective: to 1) use The UpPriority Tool to identify which clinical questions within the clinical guidelines need to be prioritised for updating and 2) assess the implementation of the tool in a real-world set of clinical guidelines.	*Usability/critique:* ▪ Appraisers' experience when using The UpPriority Tool The mean time each participant spent evaluating the all clinical questions with the tool was 3.8 hours (range 0.5 to 10 hours). The time varied among the clinical guidelines assessed. Most of the participants considered that the clinical questions needed to be prioritised for updating every 2 years or more (18/30, 60.0%). Appraisers highlighted that the tool was useful and provided positive feedback about the tool. Their comments related to 4 main areas: 1) inclusion and assessment of new clinical questions, 2) improvement of training materials, 3) guidance

Publication identification	Publication description	Evaluation (as reported by authors)
		for searching new evidence, and 4) management of clinical questions not prioritised for updating. ▪ Inter-observer reliability of the tool The degree of agreement among the participants was good for the clinical guideline on open-angle glaucoma (ICC 0.87; 95% CI 0.80–0.92), moderate for the clinical guidelines on chronic heart failure and inherited retinal dystrophies (ICC 0.62; 95% CI 0.80–0.92 and ICC 0.63; 95% CI 0.41–0.78, respectively), and poor for the clinical guideline on menopause (ICC 0.15; 95% CI -0.63 to 0.62). ▪ Suggestions to improve The UpPriority Tool As reported by the authors, after successfully applying the tool and considering the appraisers' feedback, no changes in the tool were proposed. However, some areas for consideration when using the tool, included: 1. identification of key appraisers, 2. customisation of training materials, 3. establishment of priority thresholds, 4. provision of methodological support. ▪ Identification of key appraisers Members of the UpPriority Implementation Working Group should be topic experts that provide expertise and updated specialist knowledge to the prioritisation process. Although the original GDG is a useful source to identify Working Group members, they are not an essential part of it. ▪ Customisation of the training materials Appraisers highlighted the need to include specific examples from the clinical guideline to be assessed. This would require a customisation of the training materials for each clinical guideline assessed (for example, making a specific video and

Publication identification	Publication description	Evaluation (as reported by authors)
		selecting and developing a suitable example[s]). ▪ Establishment of priority thresholds The UpPriority Tool does not recommend any priority thresholds to decide which clinical questions should be prioritised for updating. This study defined an alert threshold of ≥30 for priority score and ≥5 for item scores. Taking into account the thresholds and specific considerations from the appraisers, clinical questions were classified into clinical questions prioritised for updating (high priority for updating), clinical questions that could be prioritised for updating (medium priority for updating), and clinical questions not prioritised for updating (low priority for updating). Depending on the context, each UpPriority Implementation Working Group needs to agree if a priority threshold is needed and if so, be explicit on the criteria used. The priority thresholds described above could be a starting point for other working groups considering using the tool. ▪ Provision of methodological support Some of the concerns raised by the appraisers are already considered in The UpPriority Tool (for example, the assessment and inclusion of new clinical questions, guidance for searching new evidence, and management of clinical questions not prioritised for updating). For this reason, it is crucial to provide methodological support across the whole process and respond promptly to any queries on the prioritisation process for updating. *Timeliness:* N/R

Key: CI - confidence intervals; GIN - Guidelines International Network; ICC - intra-class correlation coefficient; N/R - not reported.

Appendix 7 Quality assessment of included peer-reviewed articles

	Casey 2020	Sanabria 2020	Sanabria 2021
Introduction			
1. Were the aims/objectives of the study clear?	Y	Y	Y
Methods			
2. Was the study design appropriate for the stated aim(s)?	Y	Y	Y
3. Was the sample size (i.e. the number of guidelines/clinical questions selected for updating) justified?	Y	Y	Y
4. Was it clear what the research was about? (Is it clear who the research was about?)	Y	Y	Y
5. Was the sample frame (i.e. the guidelines/clinical questions selected for updating) taken from an appropriate population base (i.e. guidelines that required updating) so that it closely represented the target/reference population under investigation?	Y	Y	Y
6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	Y	Y
7. Were measures undertaken to address and categorise non-responders?	N/A	N	N
8. Were the outcome variables measured appropriate to the aims of the study?	Y	Y	Y
9. Were the outcome variables measured correctly?	Y	Y	Y
10. Is it clear what was used to determined statistical significance and/or precision estimates? (e.g. p-values, confidence intervals)	N/A	Y	Y
11. Were the methods sufficiently described to enable them to be repeated?	Y	Y	Y
Results			
12. Were the basic data adequately described?	Y	Y	Y
13. Does the response rate raise concerns about non-response bias?	N/A	N	N
14. If appropriate, was information about non-responders described?	N/A	N	N
15. Were the results internally consistent?	Y	Y	Y
16. Were the results presented for all the analyses described in the methods?	Y	Y	Y
Discussion			
17. Were the authors' discussions and conclusions justified by the results?	Y	Y	Y
18. Were the limitations of the study discussed?	Y	Y	Y
Other			
19. Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	N	N
20. Was ethical approval or consent of participants attained?	N/A	Y	Y

Key: N - no; N/A - not applicable; Y - yes.
Questions related to quality of reporting: 1, 4, 10, 11, 12, 16, 18.
Questions related to study design quality: 2, 3, 5, 8, 17, 19, 20.
Questions related to the possible introduction of biases: 6, 7, 9, 13, 14, 15.

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