Recommendations for Kidney Disease Guideline Updating:

A Report by the KDIGO Methods Committee

Katrin Uhlig[1], Jeffrey S. Berns[2], Serena Carville[3], Wiley Chan[4], Michael Cheung[5], Gordon H. Guyatt[6], Allyson Hart[7,8], Sandra Zelman Lewis[9], Marcello Tonelli[10], Angela C. Webster[11,12], Timothy J. Wilt[13,14], Bertram L. Kasiske[7,8]

[1]Tufts Medical Center, Boston, Massachusetts, USA; [2]Perelman School of Medicine at the University of Pennsylvania, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, USA; [3]National Clinical Guideline Centre, Royal College of Physicians, London, UK; [4]Northwest Kaiser Permanente, Portland, Oregon, USA; [5]KDIGO, Brussels, Belgium; [6]Department of Clinical Epidemiology and Biostatistics, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada; [7]Division of Nephrology, Hennepin County Medical Center, Minneapolis, Minnesota, USA; [8]University of Minnesota, Minneapolis, Minnesota, USA; [9]EBQ Consulting, LLC, Northbrook, Illinois, USA; [10]Department of Medicine, University of Calgary, Calgary, Alberta, Canada; [11]Cochrane kidney and transplant and Centre for Transplant and Kidney Research, Westmead Hospital, New South Wales, Australia; [12]Sydney School of Public Health, University of Sydney, New South Wales, Australia; [13]Center for Chronic Diseases Outcomes Research, Minneapolis VA Health Care System, Minneapolis, Minnesota, USA; [14]Minnesota Evidence-Based Practice Center, Minneapolis, Minnesota, USA.

Correspondence:
Katrin Uhlig, MD MS
Tufts Medical Center, 750 Washington St, Boston, MA 02111, USA
Email: kuhlig1@gmail.com

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ABSTRACT

Updating rather than *de novo* guideline development now accounts for the majority of guideline activities for many guideline development organizations including KDIGO (Kidney Disease: Improving Global Outcomes), an international kidney disease guideline development entity that has produced guidelines on kidney disease since 2008. Increasingly, guideline developers are moving away from updating at fixed intervals in favor of more flexible approaches that use periodic expert assessment of guideline currency (with or without an updated systematic review) to determine the need for updating. Determining the need for guideline updating in an efficient, transparent, and timely manner is challenging, and updating of systematic reviews and guidelines is labor intensive. Ideally, guidelines should be updated dynamically when new evidence indicates a need for a substantive change in the guideline based on *a priori* criteria. This dynamic updating (sometimes referred to as a living guideline model) can be facilitated with the use of integrated electronic platforms which allow updating of specific recommendations. This report summarizes consensus-based recommendations from a panel of guideline methodology professionals on how to keep KDIGO guidelines up-to-date.

INTRODUCTION

Kidney Disease: Improving Global Outcomes (KDIGO) is a global organization which aims to improve care and outcomes of kidney disease patients worldwide through the development and implementation of nephrology clinical practice guidelines (CPGs). KDIGO has produced nine comprehensive guidelines since 2008 which cover major areas of kidney disease care. Going forward, updating rather than *de novo* guideline development will constitute the majority of its guideline activities. Clinical practice guidelines need to reflect current evidence to be trustworthy. A critical task for a guideline development initiative is to keep its guidelines up-to-date and to be transparent about the process by which it can assure their currency. The rate at which guideline recommendations become out-of-date varies. Some guidelines may remain the standard of care for years after publication, while others might be obsolete within a few months - for example, if a key trial is invalidated due to subsequent study, scientific misconduct, or if a recommended agent is removed from the market based on post-marketing surveillance.

A number of approaches have been followed for keeping guidelines up-to-date, but it is not clear how to optimize trade-offs between currency, efficiency, quality, and cost. One approach is to update guidelines at fixed intervals, but this does not allow for timely updating of out-of-date recommendations and can waste resources for updates that may not be necessary. This illustrates the value of a flexible approach that uses periodic expert assessment of guideline currency and ongoing surveillance of emerging literature to support decision-making regarding the need for updating.

Deciding whether an update is warranted hinges on the judgment about the potential impact of new evidence on content or strength of existing recommendations. Approaches vary concerning how and by whom this judgment is made. Generally, an in-depth understanding of the quality and quantity of new pertinent evidence (based on updated systematic reviews and meta-analyses) will provide greater certainty when assessing whether an update is required.

Once a decision has been made to update a guideline, the process for the actual update will depend on what has been done to assess the need for an update. For example, if systematic reviews of new evidence and how they impact the existing recommendations have already been done, this will reduce the effort for evidence review in the update. If the decision to update rested mainly on expert opinion, then the update will require updating the supporting systematic reviews. Thus, there is a trade-off

between committing resources earlier (to better inform the decision for updating) versus later (when the resources can be focused on the evidence reviews and updated recommendations).

While guideline updates can build on the analytic frameworks of existing guidelines, they also need to consider relevant additions, omissions or alterations to the existing topics, changes to Populations/Interventions/Comparator/Outcomes (PICO) questions, safety information, and changes in practice. Thus, the complexity of keeping guidelines up-to-date should not be underestimated as it requires capacity for ongoing evidence surveillance, expert judgment to identify triggers for updating or necessary changes in guideline scope, and the ability to conduct updates when needed.

Multiple electronic tools can be used to automate labor intensive steps in systematic review and guideline development.[1] Web-based programs support literature searching and screening, data presentation and synthesis for systematic review, evidence grading, formatting and writing of guideline documents. While these electronic tools certainly benefit *de novo* guideline development, they are also critical in facilitating updates. Once a new guideline is created as electronically structured content in a database, it can subsequently be kept up-to-date more efficiently.

KDIGO convened a Methods Committee to advise on a practical and efficient method to keep its guidelines up-to-date. The KDIGO Methods Committee included members with expertise in systematic review and guideline development from KDIGO, Kidney Disease Outcomes Quality Initiative (KDOQI), American College of Chest Physicians (ACCP), National Institute for Health and Care Excellence (NICE), National Clinical Guideline Center (NCGC), Kaiser Permanente, Cochrane Collaboration, Agency for Healthcare Research and Quality, and Grading of Recommendations Assessment, Development and Evaluation (GRADE). The committee held regular conference calls from October 2013 until April 2015 and shared documents and manuscript drafts via email. Given KDIGO's current need to update several of its guidelines, the Methods Committee selected guideline updating and maintenance of guideline currency as important areas on which to advise KDIGO. This included consideration of methodology and technology for developing new guidelines as critical determinants for the methods for updating. The committee reviewed existing guideline updating practices and methods based on a narrative review of literature and input from the committee experts. As KDIGO is committed to following GRADE, the review focused on methods that interface and support GRADE methods steps.[2] The committee also reviewed existing standards on processes and metrics for up-to-date guidelines. Further, it reviewed existing

platforms that support guideline updating and explored partnerships for possible collaboration. Finally, it offered recommendations based on the consensus of the committee members.

KDIGO uses several different processes to determine the need for guideline updates. Its Boards makes decisions about which guidelines to update. Controversies conferences are also used to vet the currency of its guidelines.[3] Past guideline work group co-chairs or members may be asked to monitor for new evidence, PICO questions, and important safety information that may not come from randomized controlled trials (e.g., withdrawal of key treatments from the market due to safety concerns).

The guiding principles for guideline updates are identical to those for new guidelines. Guideline entities need to carefully choose, vet, and approve guideline panel members; incorporate stakeholder input; adhere to an analytic framework; formulate focused questions that are addressed by systematic review; and follow transparent processes for evidence synthesis and grading. These principles have been described in various standards for guideline development including those by the Institute of Medicine (IOM),[4, 5] Guideline International Network (GIN),[6] and the GRADE working group.[7, 8]

The nephrology literature is characterized by a lack of studies that are adequately powered to address clinical endpoints. As a result, systematic reviews of evidence may not offer clear answers, and evidence interpretation and consensus development remain core activities for the nephrology guideline panel. This highlights the importance of adhering to established guideline development standards to guard against potential bias. KDIGO guidelines span many topics and contain graded recommendations as well as ungraded statements. Graded recommendations are based on in-depth evidence reviews for a PICO question while ungraded statements are not. The graded recommendations are the focus of this paper, as their updating requires updating of the evidence review.

While this paper is focused on KDIGO guidelines, updating is a challenge for any guideline entity. Therefore the recommendations in this paper are potentially relevant to all guideline developers.

EMPIRICAL EVIDENCE ON DURABILITY OF GUIDELINE RECOMMENDATIONS

Empirical studies have found that the durability of guideline recommendations varies. An analysis of NICE clinical guideline recommendations showed that 14% were no longer up-to-date by three years after publication, increasing to approximately 50% after 5 years.[9] A study of class I cardiology recommendations by the American College of Cardiology/American Heart Association found that the time from initial publication to an updated guideline ranged from 4 to 10 years.[10] Class I recommendations are strong, definitive recommendations that something should be done. In the updated guideline, 80.0% of class I recommendations were retained in the subsequent version; 8.9% were downgraded, 0.3% were reversed, and 10.8% were omitted. The probability for downgrade, reversal, or omission was higher for recommendations that were based on lower quality evidence compared to higher quality evidence (i.e., from multiple randomized studies). Other factors indicating that a guideline may be out-of-date are newly available diagnostic or therapeutic options, adoption of a new standard of care, safety alerts, and new research insights into the meaning of different endpoints.[11]

EXISTING STANDARDS FOR UP-TO-DATE GUIDELINES

Several groups have developed standards for guideline methods and commented on how to assess the currency of guidelines and keep guidelines up-to-date. The IOM recommends that the CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.[4] Further, literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG. Finally, CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. The IOM report provides some scenarios that indicate a need for updating, i.e., when new evidence shows that a recommended intervention causes substantial harm; when a new intervention is better than a previously recommended intervention, either in terms of efficacy or harms; or when a recommendation can be applied to new populations. The IOM acknowledges that even without new evidence from research studies, guidelines may need to be updated (e.g., if the standard of care has evolved).

The National Guideline Clearinghouse stipulates in its 2013 criteria for inclusion of clinical practice guidelines that "the guideline must have been developed, reviewed, or revised within the past five years, as evidenced by appropriate documentation (e.g., the systematic review or detailed description of methodology)." [12] Another point of reference for guideline methods is the Appraisal of Guidelines for REsearch & Evaluation Instrument (AGREE II).[13] It specifies that a procedure for updating the guideline should be provided. GIN recommends that a guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.[6]

A recent review shows that the most commonly periods proposed for updating are two to three years, although guidelines become outdated at different rates.[14] Generally, the process for updating CPGs is poorly described in guideline handbooks. In particular, guidance on the literature search, evidence selection, assessment, synthesis and external review of the updating process is often lacking. A survey of CPG institutions also showed a lack of standardization and rigor in updating methods.[15]

CURRENT PRACTICES TO KEEP GUIDELINES CURRENT AND UP-TO-DATE

Current guideline developers' methods for updating fall broadly into those that are based on flexible updates based on identified need (e.g., triggered by ongoing evidence surveillance), those that review the decision to update at defined intervals with updates following as needed, and those that update after a fixed interval. An example of the shift to flexible updating is ACCP's "living guideline model" where targeted recommendations are updated continually in the face of new information that warrants a substantial change to practice.[5, 16]

Other organizations use a variable schedule for updates; Kaiser Permanente undertakes reviews at least every two years (or annually),[17] and NICE have implemented an adaptive review process alternating between a limited and a more thorough surveillance every two years.[18] The decision-making process for when an update is needed also varies. These differences are explored in more detail in the following section.

Identifying the need to update

Use of explicit criteria as triggers for updating increases the transparency of decision-making around guideline updating. Shekelle *et al*. identified six situations that might require a guideline to be

updated.[5, 11, 19] They include 1) changes in available interventions, 2) changes in evidence on the benefits and harms of existing interventions, 3) changes in outcomes that are considered to be important, 4) changes in evidence that current practice is optimal, 5) changes in values placed on outcomes, and 6) changes in resources available for health care (Table 1). Shekelle emphasized the importance of the first four criteria, which relate to identifying when new information on interventions, outcomes and performance justify changing a guideline. Changes in the values placed on outcomes (criterion 5) occur as societal norms change. Measuring these values and how they change over time is usually too complex to consider explicitly when determining the need for updating. Changes in availability of resources for healthcare or the costs of interventions (criterion 6) may be considered in the context of guidelines for a specific jurisdiction, but can usually not be assessed for international guidelines, such as those by KDIGO, since policymakers and payers in disparate health care systems outside of the guideline group need to consider additional factors when deciding whether services remain affordable.[19]

Overall, a combination of multidisciplinary expert assessment and evidence surveillance is required for a comprehensive assessment of guideline currency.[11] Decision-making can be facilitated through use of an explicit grading system. KDIGO follows the GRADE system which provides a systematic and transparent approach to assessing quality of evidence, and linking evidence to recommendations. Grading evidence and recommendations is usually conducted after literature surveillance and appraisal. However, GRADE also allows a guideline panel to agree on criteria that would warrant an update based on impact on clinical decision-making, such as changes in quality of evidence, effect-estimates and the strength and direction of recommendations.

Use of literature review to inform the decision for updating

Several reputable guideline producers base the need to update on systematic literature searches that focus on some or all PICO questions from the original guideline. The initial searches may be restricted to high-impact or key journals, and pertinent systematic reviews. For example, Kaiser Permanente conducts annual systematic literature searches for each key PICO question -- looking for all systematic reviews, and for original studies in high-impact journals. The decision to update is based on the priority of the PICO question especially if multiple questions suggest the need for an update. Other developers undertake focused searches on all review questions, but include additional input to inform the decision.

Use of stakeholder input to inform the decision for updating

Several producers have mechanisms in place to incorporate input from external stakeholders. Stakeholders may be invited to submit evidence, notify changes in the evidence base, or alert developers to sentinel events such as US Food and Drug Administration warnings or removal of a product from the market that impact the guideline.

One method used by NICE involves sending a questionnaire to the original guideline development group at the same time as a high level literature search it is undertaken. The combined information gathered from the original guideline developers along with the new evidence is used to determine whether any aspects of the guideline need to be updated. This process follows an adaptive surveillance cycle, with more thorough approach and stakeholder input every 4 years. At the 4-year surveillance, stakeholders are invited to comment on the proposed update decision during a consultation phase. All stakeholder comments are considered by the surveillance team and responses to such feedback are publicly available once the final decision to update or not has been made.

Role of the Guideline Review Panel

In many guideline programs, a review panel is assigned the role for determining whether or not a guideline update should go ahead, and what the scope of the proposed update should be. Information gathered from literature searches and stakeholder opinion is presented to an internal team or panel. The panel may have the authority to make the final decision (e.g., NICE) or it may refer the decision to another committee (e.g., American College of Physicians proposes topic to the Agency for Healthcare Research and Quality's for a new evidence report). The ACCP considers areas in which frontline clinicians and patients (internal or external to the panels) identify a need for guidance while defining the new scope and PICO questions. Processes to address sentinel events or escalate important triggers can differ between organizations; some include this within their standard update review, whereas others (e.g., NICE) have an expedited procedure for rapid updates in exceptional circumstances that require an urgent change to recommendations.

Decision-making regarding need for update

Ultimately, the decision on whether or not to update a guideline relies upon the subjective judgment of a review panel. Decision-making can be facilitated through use of an explicit grading system. KDIGO follows the GRADE system which provides a systematic and transparent approach to assessing quality of

evidence, and linking evidence to recommendations. GRADE allows the guideline panel to agree on criteria that would warrant a guideline update based on impact on clinical decision-making, such as changes in quality of evidence, effect-estimates and the strength and direction of recommendations. An example of current NICE criteria for this decision is shown in Supplementary Table S1; NICE publishes their assessments once completed. Similar considerations apply across different organizations. Input from a larger stakeholder and expert group may reduce the element of subjectivity (as discussed above).

TECHNOLOGICAL PLATFORMS TO SUPPORT *DE NOVO* GUIDELINE DEVELOPMENT AND UPDATING

As for other major guideline producers, the emphasis and reward for KDIGO has been on new guideline development, and resource constraints often result in delayed updating. Electronic tools that support the repetitive and fatiguing activities in guideline development and updating therefore hold great promise for facilitating dynamic updating. Applications, programs and electronic platforms can support various steps of systematic review and guideline development, such as literature searches, literature monitoring, screening, record keeping, data extraction, data presentation and table generation, meta-analysis, writing and editing of guideline text, and publishing. A selection of such tools is shown in Supplementary Table S2.[1]

Some tools deserve to be described in more detail as they are customized for guideline development and fulfill core requirements for efficient updating. Guideline updating can proceed with great efficiency if it can seamlessly build upon previous work. Therefore, a key requirement for electronic guideline update tools is a centralized database with content organized as structured information components for each recommendation. Each structured information component should include a clinical question of interest in the PICO format, evidence profiles with effect estimates and recommendations. One platform that provides content in this format is MAGICapp.

Another key requirement is the availability of structured data on evidence retrieval (search strategies, screening, citations), access to relevant full-text publications and the systematic reviews underlying recommendations. Covidence is one platform that allows storage of information on duplicate screening, data extraction, while Doctor Evidence provides digitized data from primary studies. These platforms can be integrated with platforms such as MAGICapp to provide end-to-end support from question formulation to guideline publishing and updating, and the synergistic benefits are shown in Table 2.[20]

In addition, their literature surveillance systems can search many more databases than ever before; search filters and PICO can be readily adjusted to accommodate variable thresholds for the literature monitoring (e.g., screen only high-impact journals with a minimum population size or follow-up duration).

Many guideline producers including KDIGO rely on print publications to disseminate their guidelines. This is time-consuming, and yields a rigid format which is not conducive to dynamic updating. Online guideline authoring tools and publication platforms may facilitate guideline updates and enhance uptake at point of care while maintaining methodological rigor and transparency. MAGICapp links its structured guideline content to electronic medical records and includes decision aids to inform decision making.[20] In the future, tools like MAGICapp will enable guidelines to cross reference with various ontologies (e.g., ICD, SnoMed, MeSH) for enhanced integration with electronic medical records or textbooks.

Before selecting a tool, a guideline organization needs to determine the scope of its updating activities and whether it aims to move to dynamic updating. The choice of tool should also consider the needs of the guideline producer (e.g., capabilities, preference for outsourcing, capacity for pilot testing or customization,) and weigh the potential benefits of automation against added costs and effort for process change and maintenance. Some programs (e.g., Doctor Evidence) offer services by research analysts for data extraction, review or quality, functions for which a producer may otherwise rely on volunteers or its own evidence review team. Guideline developers should also consider the support that will be available for implementing the new tool, as well as compatibility and interoperability of the new tool with other tools that they may use now or in the future. Given the rapidly evolving nature of these tools, guideline developers should ensure that their data are stored in a structured format that allows exporting and importing across platforms.

COLLABORATION WITH GUIDELINE DEVELOPMENT ENTITIES IN THE NEPHROLOGY DOMAIN

Collaboration across guideline entities is critical to enhance efficiency and economy in guideline updating. Guideline producers with similar goals should join in setting priorities and ensuring coverage and currency of important guideline topics. Collaboration can not only avoid unnecessary duplication of effort but also inconsistency across recommendations by different organizations.

For KDIGO, the activities of Cochrane Kidney and Transplant (CKT, previously known as the Cochrane Renal Group) have particular relevance. The CKT produces and disseminates systematic reviews relevant to patients with kidney disease which are published in the Cochrane Database of Systematic Reviews

(CDSR) part of *The Cochrane Library*. The CKT also maintains a specialized register of controlled clinical trials . which is updated daily through systematic searches of citation databases, clinical trial registers, and conference proceedings. CKTs strengths include established processes for evidence surveillance and embedded early warning systems; established systems for classifying evidence and organizing study reports; and a growing number of relevant, high quality, up-to-date systematic reviews which are mapped to any clinical practice guidelines they have informed.

The CKT has a strong track record of collaboration with other guideline developers where its support ranges from basic evidence retrieval, to training guideline support staff in question formulation, evidence sorting, appraisal and summary. CKT has also prioritized review updates and new reviews in line with known guideline group activities, and routinely incorporate GRADE where possible. CKT guideline partners have included the Caring for Australasians with Renal Impairment guideline group, the European Renal Best Practice group (ERBP, formerly European Best Practice Guidelines). CKT has also provided more indirect support to individuals and groups working on guidelines, including NICE clinical guidelines and National Institute for Health Research evaluation, trials and studies programs. Given these established links, involving the CKT may also enhance information flow between KDIGO and other entities.

- CKT can support KDIGO guideline development with a range of services. On a basic level, CKT can conduct evidence surveillance and retrieval for specific clinical questions and guideline topics and periodically send unfiltered new evidence and 'early warning' markers of new evidence from trial registrations or conference abstracts. KDIGO would have to sort and decide whether new evidence was relevant or worthy of triggering an update.
- Alternatively, CKT can perform the first filter and only forward relevant evidence with potential to trigger review update, while withholding lower level evidence, or evidence related but not central to the guideline.
- CKT can further perform some tasks associated with guideline generation, such as sorting, organizing and appraising new evidence, and adding to or creating new evidence tables.

Further economies of effort and reduction of redundancy are likely to be possible through more strategic collaboration with other organizations producing guidelines on topics that overlap with the scope of KDIGO. Collaboration could involve planning guideline updates such that related topics are

updated simultaneously by different entities, or if there is cross-representation from different entities on update panels. If KDIGO were to endorse or adapt new guidelines from other producers, this would also increase guideline coverage and currency of KDIGO topic areas. This model is used by Kidney Health Australia-Caring for Australians with Renal Insufficiency (KHA-CARI).

Major guideline entities concentrating on nephrology are the Canadian Society of Nephrology (CSN), ERBP, KHA-CARI, KDOQI, Sociedad Latinoamericana de Nefrología e Hipertensión (SLANH) and United Kingdom Renal Association (UK-RA). The approaches of all these groups to guideline development have recently been described with a view to developing a more collaborative approach.[21] There are also other guideline entities with overlapping interests (e.g., hypertension, diabetes, cardiovascular disease) that may permit either joint guidelines, or harmonisation of recommendations.

METHODOLOGICAL MODERNIZATION AND ONGOING QUALITY IMPROVEMENT

Any methodological modernization requires leadership, vision, and decision-making beyond day-to-day business. A commitment to keeping guidelines up-to-date needs to build on an iterative evaluation of workflow and quality improvement. To keep pace with new developments requires the ability to pilot new approaches, and adopt and apply innovations that are cascaded down by program developers. Thus a guideline initiative needs to invest in ongoing quality improvement and methods adoption. Oversight by methods experts may also be required for assessing new technologies regarding the value added.

RECOMMENDATIONS FOR KDIGO

Based on the above review of current standards, processes and empirical studies and tools, the Methods Committee recommends that KDIGO move to dynamic updating of recommendations when warranted by new research evidence or other pertinent considerations. Table 3 contains recommendations for keeping KDIGO guidelines up-to-date by orchestrating a 'living guideline' updating effort. In summary, similar to other guideline producers, KDIGO is shifting its focus from developing new guidelines to keeping its existing guidelines up-to-date. The escalating demand for quality and efficiency in guideline updates requires a high level of institutional commitment in resources, infrastructure, technology and governance. The recommendations in this article provide a roadmap towards this goal.

DISCLOSURE

JSB declared having served on clinical trial Executive Committee for Amgen; he is presently President of the National Kidney Foundation (NKF) and former NKF Vice-Chair for Clinical Practice Guidelines and Commentaries. SC acknowledged that NCGC receives funding from NICE to develop NICE clinical guidelines and reported no additional relevant financial disclosures. WC was formerly Director, Guidelines & Evidence-Based Medicine and internal medicine physician at Northwest Kaiser Permanente, and reported no additional relevant financial disclosures. SZL is Chief Guidelines Officer at Doctor Evidence. MT is Chair of the Canadian Task Force on Preventive Health Care and reported no additional relevant financial disclosures. TJW declared having receiving funding from Kidney Disease: Improving Global Outcomes (KDIGO) to conduct an evidence synthesis report in support of a clinical practice guideline related to living kidney donation. BLK is currently a KDIGO Co-Chair and reported no additional relevant financial disclosures. KU, MC, GHG, AH, and ACW reported no relevant disclosures.

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SUPPLEMENTARY MATERIAL

Table S1. National Institute for Health and Care Excellence (NICE) criteria for deciding whether to update a guideline

Table S2. Selected electronic applications to support systematic review and guideline development and updating tasks

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TITLES AND LEGENDS

Table 1. Criteria to determine the need for guideline updating

Adapted with permission from Shekelle P, et al.[5, 11, 19]

Table 2. Benefits of end-to-end electronic platforms or combinations of complementary tools for guideline development and updating

Table 3. Recommendations for keeping KDIGO guidelines up-to-date