

Recommendations for kidney disease guideline updating: a report by the KDIGO Methods Committee



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Updating rather than *de novo* guideline development now accounts for the majority of guideline activities for many guideline development organizations, including Kidney Disease: Improving Global Outcomes (KDIGO), an international kidney disease guideline development entity that has produced guidelines on kidney diseases 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 that 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.

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Kidney Disease: Improving Global Outcomes (KDIGO) is a global organization that 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 9 comprehensive guidelines since 2008 that cover major areas of kidney disease care. Going forward, updating rather than *de novo* guideline development will constitute the majority of its guideline activities. CPGs 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 The rate at which guideline recommendations become out of date varies.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 or scientific misconduct, or if a recommended treatment is removed from the market based on postmarketing 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 it impacts 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 whether and what to update) versus later (when the resources can be focused on the evidence reviews and recommendations chosen to update).

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 population, intervention, comparator, and 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, and 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, the Kidney Disease Outcomes Quality Initiative (KDOQI), the American College of Chest Physicians, the National Institute for Health and Care Excellence (NICE), the National Clinical Guideline Center, Kaiser Permanente, the Cochrane Collaboration, the Agency for Healthcare Research and Quality, and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group. The committee held regular conference calls from October 2013 through April 2015 and shared documents and manuscript drafts via e-mail. 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 Executive Board 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,^{4,5} Guideline International Network,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 end points. 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 3 years after publication, increasing to approximately 50% after 5 years.⁹ A study of class I cardiology recommendations by the American College of

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