8-1-2009

Foreword

Kai Uwe Eckardt

Bertram L. L. Kasiske

Omar Abboud

Ali Abu-Alfa

Nasrulla Abutaleb

See next page for additional authors

Recommended Citation

Eckardt K, Kasiske BL, Abboud O, Abu-Alfa A, Abutaleb N, Acharya V, Adler S, Adragao T, Agarwal A, Akizawa T, Akl A, Al-Rukhaimi M, Andress D, Arici M, Tomas Arriola M, Ashurst I, Badr K, Bakr A, Balogun RA, Becker B, Bellorin-Font E, Bernieh B, Bover J, Branley P, Braun J, Cantor T, Carroll L, Cary S, Chauveau P, Chmielewski C, Coco M, Coen G. Foreword. Kidney International 2009; 76(SUPPL. 113).

Authors

Kai Uwe Eckardt, Bertram L. L. Kasiske, Omar Abboud, Ali Abu-Alfa, Nasrulla Abutaleb, Vidya Acharya, Sharon Adler, Teresa Adragao, Anil Agarwal, Tadao Akizawa, Ahmed Akl, Mona Al-Rukhaimi, Dennis Andress, Mustafa Arici, Mariano Tomas Arriola, Ione Ashurst, Kamal Badr, Ashraf Bakr, Rasheed A. Balogun, Bryan Becker, Ezequiel Bellorin-Font, Bassam Bernieh, Jordi Bover, Pauline Branley, Johann Braun, Tom Cantor, Laurence Carroll, Sue Cary, Philippe Chauveau, Christine Chmielewski, Maria Coco, and Giorgio Coen

Foreword

Kidney International (2009) **76** (Suppl 113), S1–S2; doi:10.1038/ki.2009.188

Clinical practice guidelines serve many purposes. First and foremost, guidelines help clinicians and other caregivers deal with the exponential growth in medical literature. It is impossible for most busy practitioners to read, understand, and apply a rapidly changing knowledge base to daily clinical practice. Guidelines can help fill this important need. Guidelines can also help to expose gaps in our knowledge, and thereby suggest areas where additional research is needed. Only when evidence is sufficiently strong to conclude that additional research is not needed should guidelines be used to mandate specific medical practices with, for example, clinical performance measures.

Methods for developing and implementing clinical practice guidelines are still relatively new and many questions remain unanswered. How should it be determined when a clinical practice guideline is needed? Who should make that determination? Who should develop guidelines? Should specialists develop guidelines for their practice, or should unbiased, independent clinicians and scientists develop guidelines for them? Is it possible to avoid conflicts of interest when most experts in a field conduct research that has been funded by industry (often because no other funding is available)? Should guidelines offer guidance when strong evidence is lacking, should they point out what decisions must be made in the absence of evidence or guidance, or should they just ignore these questions altogether, that is, make no statements or recommendations?

Professional societies throughout the world have decided that there is a need for developing clinical practice guidelines for patients with chronic kidney disease (CKD). Along with this perceived need has come the realization that developing high-quality guidelines requires substantial resources and expertise. An uncoordinated and parallel or repetitive development of guidelines on the same topics reflects a waste of resources. In addition, there is a growing awareness that CKD is an international problem. Therefore, Kidney Disease: Improving Global Outcomes (KDIGO) was established in 2003 as an independent, nonprofit foundation, governed by an international board of directors, with its stated mission to 'improve the care and outcomes of kidney disease patients worldwide through promoting coordination, collaboration, and integration of initiatives to develop and implement clinical practice guidelines.'

To date, KDIGO guideline initiatives have originated in discussions among the KDIGO Executive Committee members and the KDIGO Board of Directors. In some instances, topic areas have been vetted at KDIGO 'Controversies Conferences.' If there is then a consensus that guideline development should go forward, two Work Group chairs are appointed, and with the help of these chairs, other Work Group members are selected. Efforts are made to include a broad and diverse expertise in the Work Group, and to have international representation. Work Groups then meet and work with a trained, professional evidence review team to develop evidence-based guidelines. These guidelines are reviewed by the KDIGO Board of Directors, and a revision is then sent out for public comment. Only then is a final, revised version developed and published.

The mineral and bone disorder of CKD (CKD–MBD) has been an area of intense interest and controversy. In 2005, KDIGO sponsored a controversies conference 'Definition, Evaluation and Classification of Renal Osteodystrophy.' The results of this conference were summarized in a position statement that was published in 2006. The consensus of the attendees at this conference was that a new set of international guideline on CKD–MBD was indeed warranted.

Therefore, KDIGO invited Sharon Moe, MD, and Tilman Drüeke, MD, to co-chair a Work Group to develop a CKD–MBD guideline. The Work Group was supported by the Evidence Review Team at the Tufts Center for Kidney Disease Guideline Development and Implementation at Tufts Medical Center, Boston, MA, with Katrin Uhlig, MD, MS, as the Evidence Review Team's Project Director. The Work Group met on five separate occasions over a period of 2 years, reviewing evidence and drafting guideline recommendations. The KDIGO Board reviewed a preliminary draft, and ultimately the final document. Importantly, the guideline was also subjected to public review and comment.

During the development of the CKD–MBD guideline, KDIGO continued to develop a system for rating the strength of recommendations and the overall quality of evidence supporting those recommendations. A task force had been formed that ultimately made recommendations to the KDIGO Board. After extensive discussion and debate, the KDIGO Board of Directors in 2008 unanimously approved a modification of the Grading of Recommendations Assessment, Development, and Evaluation system. The system that was adopted allows provision of guidance even if the evidence base is weak, but makes the quality of the available evidence transparent and explicit. It is described in detail in the present CKD–MBD guideline (Chapter 2).

The strength of each recommendation is rated 1 or 2, with 1 being a 'We recommend …' statement implying that most patients should receive the course of action, and 2 being a 'We suggest …' statement implying that different choices will be appropriate for different patients with the suggested course of action being a reasonable choice. In addition, each

statement is assigned an overall grade for the quality of evidence, A (high), B (moderate), C (low), or D (very low). The grade of each recommendation depends on the quality of the evidence, and also on additional considerations.

A key issue is whether to include guideline statements on topics that cannot be subjected to a systematic evidence review. KDIGO has decided to meet this need by including some statements that are not graded. Typically, ungraded statements provide guidance that is based on common sense, for example, reminders of the obvious and/or recommendations that are not sufficiently specific enough to allow the application of evidence. Examples include the frequency of laboratory testing and the provision of routine medical care.

The CKD–MBD guideline encompasses many aspects of care for which there is little or no evidence to inform recommendations. Indeed, there are only three recommendations in the CKD–MBD guideline for which the overall quality of evidence was graded 'A,' whereas 12 were graded 'B,' 23 were graded 'C,' and 11 were graded 'D.' Although there are reasons other than quality of evidence to make a grade 1 or 2 recommendation, in general, there is a correlation between the quality of overall evidence and the strength of the recommendation. Thus, there are 10 recommendations graded '1' and 39 graded '2.' There were two recommendations graded '1A,' five were '1B,' three were '1C,' and none were '1D.' There was one graded '2A,' seven were '2B,' 20 were '2C,' and 11 were '2D.' There were 12 statements that were not graded.

The grades should be taken seriously. The lack of recommendations that are graded '1A' suggests that there are few opportunities for developing clinical performance measures from this guideline. The preponderance of '2' recommendations suggests that patient preferences and other circumstances should be strongly considered when implementing most recommendations. The lack of 'A' and 'B' grades of overall quality of evidence is a result of the lack of patient-centered outcomes as end points in the majority of trials in this field, and thus suggests strongly that additional research is needed in CKD–MBD. Indeed, the extensive review that led to this guideline often exposed significant gaps in our knowledge. The Work Group made a number of specific recommendations for future research needs. This will hopefully be of interest to future investigators and funding agencies.

All of us working with KDIGO hope that the guidelines developed by KDIGO will in some small way help to fulfill its mission to improve the care and outcomes of patients with kidney disease. We understand that these guidelines are far from perfect, but we are confident that they are an important step in the right direction. A tremendous amount of work has gone into the development of the KDIGO CKD–MBD guideline. We sincerely thank Sharon Moe, MD, and Tilman Drüeke, MD, the Work Group chairs, for the tremendous amount of time and effort that they put into this challenging, but important, guideline project. They did an outstanding job. We also thank the Work Group members, the Evidence Review Team, and the KDIGO staff for their tireless efforts. Finally, we owe a special debt of gratitude to the founding KDIGO Co-Chairs, Norbert Lameire, MD, and especially Garabed Eknoyan, MD, for making all of this possible.

Kai-Uwe Eckardt, MD
Co-Chair, KDIGO

Bertram L Kasiske, MD
Co-Chair, KDIGO