

# Kidney Disease: Improving Global Outcomes

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**Abstract** | Kidney Disease: Improving Global Outcomes (KDIGO) is an independent organization with the mission to improve care and outcomes of patients with kidney disease worldwide through the development and coordination of clinical practice guidelines. KDIGO has established firm links with other organizations that have previously produced clinical practice guidelines in the field of kidney disease. The first three KDIGO guidelines—treatment of hepatitis C, management of bone and mineral disease, and care of kidney transplant recipients—have been finalized and the next three—acute kidney injury, management of glomerulonephritis, and management of blood pressure in chronic kidney disease—are under development. The ultimate goal is to cover most major aspects of care for patients with kidney disease. Corner stones of KDIGO's guideline development process are independent, multidisciplinary, international work groups, close collaboration with professional methodology experts who perform systematic evidence reviews, and open public review of each guideline. Grades of Recommendation Assessment, Development, and Evaluation (GRADE) methodology is applied for grading the quality of evidence and strength of recommendations. International conferences organized by KDIGO support the coordination of guideline development, assess the suitability of guideline topics and help to establish global consensus on definitions and policies.

Eckardt, K.-U. & Kasiske, B. L. *Nat. Rev. Nephrol.* advance online publication 29 September 2009; doi:10.1038/nrneph.2009.153

## Introduction

Kidney Disease: Improving Global Outcomes (KDIGO) was founded 6 years ago as an independent organization with the explicit 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”.<sup>1</sup> Almost 15 years earlier, the Institute of Medicine had recommended the development of clinical practice guidelines as an important tool of evidence-based medicine.<sup>2</sup> Although the number of clinical trials is far too low to provide solid evidence for most aspects of clinical care, there are still too many trials for clinicians to study in detail. Moreover, the quality of clinical trials is inherently variable and the results are usually complex, which renders interpretation difficult. The aim of guideline development is to subject the results of clinical research to systematic review in order to derive recommendations for diagnosis and therapy (Figure 1). During this process, gaps in available knowledge are identified, which should result in the prioritization of research questions to foster the generation of new knowledge. Both processes have the potential to improve patient care and outcomes.

Although the concept of clinical practice guidelines is attractive, the development of such guidelines is associated with several risks and challenges. The methodology of guideline development must be at least as stringent as the methodology of clinical trials. The systematic review

of published trials, extraction of data from these trials and comparison of study results requires considerable effort and expertise. Moreover, the interpretation of the aggregate study results and extrapolation of the combined findings to clinical practice recommendations require a careful and unbiased analysis. Professional medical societies have frequently considered guideline development as one of their tasks, but have not always been able to establish adequate methodology, transparent rules and policies and to provide sufficient resources for optimal guideline development. Industry has promoted guideline development in areas related to their products, which has frequently resulted in ‘guideline publication bias’, characterized by a redundancy of clinical practice guidelines in commercially attractive areas but a scarcity in other areas that are equally or even more important from a clinical perspective but are less attractive from a commercial point of view. The association of work group members with industry has also created concern about the objectivity of guideline development. Furthermore, there is a risk that performance measures will be inappropriately developed from recommendations made on the basis of limited evidence. For all of these reasons, considerable concern has been raised about the process of guideline development.<sup>3,4</sup> This brief Review outlines the structure, methodology and activities of KDIGO and describes how this organization is trying to meet the many challenges of guideline development in the field of kidney disease.

## The history of kidney disease guidelines

The development of clinical practice guidelines for kidney disease illustrates several of the advantages and

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## Competing interests

The authors declare an association with the following organization: KDIGO. See the article online for full details of the relationship.

## Key points

- Kidney Disease: Improving Global Outcomes (KDIGO) is an independent not-for-profit organization
- KDIGO coordinates and conducts the development of evidence-based clinical practice guidelines in the field of kidney disease
- The KDIGO guidelines are developed by international, interdisciplinary work groups
- KDIGO work groups collaborate with a professional evidence review team for a systematic review of published data in a specific topic area
- KDIGO work groups use the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) approach for grading the quality of the evidence and the strength of the recommendations
- KDIGO guideline drafts are subjected to public review as an integral part of the process

alone has had a tremendous impact on the awareness of chronic kidney disease, related research and public policies.<sup>9</sup> In 1999, the European Renal Association and European Dialysis and Transplant Association (ERA-EDTA) initiated the development of the European Best Practice Guidelines (EBPG). In Canada, Australia and the UK, additional English language guidelines were developed, and in several other countries, clinical practice guidelines were developed in local languages.

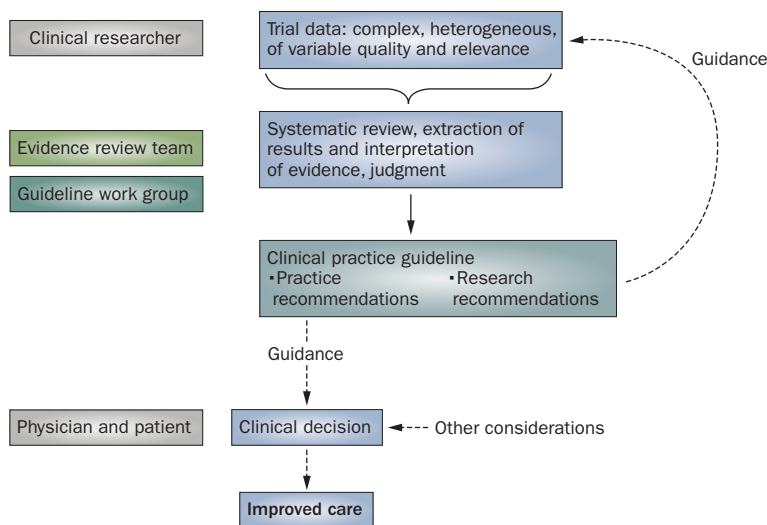
Disease manifestation, health-care resources, health-care systems and regulations vary in different parts of the world, so practice recommendations must be adapted to local circumstances. On the other hand, the evidence on which such recommendations are based is usually universal, and their applicability is not limited to specific regions. However, an uncoordinated approach to guideline development, together with direct funding of guideline projects by commercial sponsors, has resulted in a redundancy of guidelines in some areas. For example, between 1998 and 2008 more than 10 clinical practice guidelines on the management of anemia in patients with chronic kidney disease were published in the English language.<sup>10–20</sup> On the other hand, during the same time period few guidelines were developed on the management of kidney diseases with a specific etiology.

KDIGO was founded in 2003 to fundamentally change this haphazard process, to develop more clinical practice guidelines and to coordinate the development of clinical practice guidelines by different international organizations in the field of kidney disease. The organization reflects an attempt to improve the process of guideline development, make the best use of available resources and expand the spectrum of fields for which clinical practice guidelines are available.

## KDIGO

### Structure and management

KDIGO is a not-for-profit organization incorporated under Belgium law and is independent of established professional medical associations. The organization is led by an international board of directors (Figure 2). Most of the approximately 50 board members are practicing nephrologists from all parts of the world, but patient representatives and medical experts from overlapping disciplines also participate.<sup>1</sup> The board of directors elects an executive committee, which plans and oversees KDIGO's activities and is chaired by two KDIGO board members, who are elected to serve as co-chairs of KDIGO. All positions are rotated and a nominating committee proposes new members of the board, the executive committee and the co-chairs. Former board members form a board of councilors, which advises and makes recommendations for KDIGO activities. For all administrative issues, KDIGO has appointed the US NKF as its management organization because of the considerable expertise and professionalism that the NKF has gained in guideline development during the DOQI and KDOQI process. KDIGO collaborates with professional medical



**Figure 1** | The development of clinical practice guidelines. Clinical practice recommendations derived from the evidence review provide guidance to physicians and patients to make informed clinical decisions. In addition, identification of the gaps in available knowledge and formulation of research questions by the work group can guide clinical researchers and funding bodies to increase the evidence by further research. The final goal of this iterative process is the improvement of patient care and outcomes.

risks associated with the development of guidelines in general. In 1997, the National Kidney Foundation (NKF) in the US started the Dialysis Outcome Quality Initiative (DOQI) by developing clinical practice guidelines in four areas: hemodialysis adequacy, peritoneal dialysis adequacy, vascular access and management of anemia.<sup>5–8</sup> Subsequently, guideline development was extended to the management of non-dialysis-dependent kidney disease, and the name of the program was changed to Kidney Disease Outcomes Quality Initiative (KDOQI). These initiatives have undoubtedly had a significant impact on nephrology as a discipline; they have encouraged intense debate about optimal treatment for patients with kidney disease, almost certainly reduced heterogeneity in practice and laid the groundwork for future research by providing definitions and benchmarks. The guideline on the Definition and Staging of Chronic Kidney Disease



judgment can and should be used to complement limited evidence. When faced with very limited evidence (generally an absence of clinical trials) the choice is either to 'say nothing' or to make a recommendation based on whatever limited evidence is available, while clearly indicating that such a recommendation is predominantly based on opinion and not evidence. Although methodological purists may prefer to restrict guidelines to recommendations based on only high-level evidence, the provision of useful guidance to clinicians inevitably requires the inclusion of recommendations for areas in which the evidence is weak or virtually absent. To say nothing frequently leads caregivers to ask what an expert in this area would do. Making a recommendation explicitly based on limited evidence and expert opinion may also help to frame the clinical questions that are of highest priority for future clinical trials. Although the dilemma of evidence and judgment affects all areas of guideline development, it is of particular relevance for the care of patients with kidney disease, as the number of randomized, controlled trials in nephrology lags behind that in other medical disciplines.<sup>24</sup>

Almost since its inception KDIGO has researched, consulted, discussed and debated the best approach to making recommendations on the basis of limited evidence. As a result of this process, the KDIGO board of directors decided, given the purpose of the organization to provide the best possible guidance, that it is unavoidable to include recommendations primarily based on expert judgment. However, the quality of the available evidence and gaps in our knowledge must be very transparent.

In order to achieve such transparency, KDIGO uses Grades of Recommendation Assessment, Development, and Evaluation (GRADE) methodology, which is increasingly used by other organizations as well.<sup>25</sup> GRADE enables an important distinction to be made between the quality of the evidence and the strength of the recommendation.<sup>26</sup> In the modified GRADE approach used by KDIGO, four different levels are used to characterize the quality of evidence as either high (A), moderate (B), low (C) or very low (D) and two different levels (1 or 2) are used to characterize the strength of a recommendation.<sup>27,28</sup> A level 1 grading implies that a recommendation should almost always be followed. By contrast, a level 2 recommendation should be applied for the majority of circumstances, but always requires weighing of the risks and benefits for each specific situation, taking into account the patient's preferences and values.<sup>27,28</sup> Although under specific circumstances a level 1 recommendation can form the basis for a clinical performance measure by defining an expected standard of care, level 2 recommendations are definitely unsuitable for transformation into a clinical performance measure, given the degree of uncertainty that following the recommendation will improve patient outcome. Moreover, a level 1 recommendation is considered to be unlikely to change with the results of future research, and as such, the

necessity of further trials in that particular area requires very careful consideration. On the other hand, a level 2 recommendation clearly indicates that further research to test alternative methods of patient care may be useful. Although the higher the quality of the evidence the higher the likelihood of a strong recommendation being derived, no direct algorithm exists that links the strength of a recommendation to the quality of evidence.

The combination of the four different levels of evidence quality and the two strengths of recommendation already allows for considerable granularity. In addition, work groups can choose to make an ungraded statement, particularly in areas that are not suitable for systematic evidence review or if the work group decides not to perform such a review. This may occur, for example, when the anticipated outcome of an extensive literature search is highly unlikely to yield high quality evidence and, therefore, the result does not justify the efforts.

In the KDIGO guideline document, each set of recommendations related to a specific question or topic is followed by a 'rationale' section, which explains the background, summarizes the evidence and the reasoning for each recommendation, and explains why specific wording was chosen. Evidence review tables provide details of the design and results of clinical trials that were considered to be relevant for a specific topic.

In the two most recent KDIGO guidelines, which used the modified GRADE approach described above, 16–20% of the recommendations were level 1, 61–64% were level 2, and 19–20% were ungraded statements.<sup>29,30</sup> Although a higher proportion of stronger recommendations would certainly have been desirable, KDIGO believes that the transparency and clarity of its approach in outlining the limitations of the evidence base is essential. The honest description of the limited evidence also provides the best possible impetus for improving the evidence base through further research. Work groups are also asked to issue research recommendations on the basis of the evidence review and to suggest priorities for the testing of relevant clinical questions.

#### Open public review of KDIGO guidelines

An integral part of KDIGO's guideline development process is an open, public review. Once the extraction of data from relevant publications by the evidence review team is complete the KDIGO work group prepares an advanced draft of a guideline. This draft is first reviewed by the KDIGO board of directors, and is usually discussed in detail at the annual board meeting. The questions and comments derived from this review are then integrated into the next version of the draft guideline, which is subsequently submitted to external review. Although KDIGO invites individuals to participate in this review on the basis of their documented expertise and previous commitment to guideline development, any interested individual can volunteer to participate after registration through the KDIGO website. Comments from industry representatives are welcome, provided

that they are clearly identified as such. The review form given to external reviewers includes questions about the reviewers' agreement with the recommendations and provides unlimited space for general and specific comments. This feedback has been invaluable, with more than one hundred individuals in addition to the board members reviewing each guideline. All comments are forwarded to each work group member, both in a tabulated and text form. Taking these comments into account, the work group then develops the final version of the guideline. Each single recommendation is formally voted on by work group members and in cases for which a majority vote rather than a unanimous vote supports the recommendation, the different positions are explicitly outlined in the rationale section. The final version of the guideline is then submitted for publication.

### Topic selection

The selection of topics for guideline development is a critical component of the process. Although KDIGO is able to build on a set of guidelines previously developed by other organizations, the organization attempts to coordinate the updating of these guidelines and aims to expand the scope of available guidelines. Input into this process has been solicited from colleagues worldwide through the distribution of questionnaires at international conferences. The board of directors has subsequently vetted topics and defined priorities. A guideline coordination task force that comprises representatives of other organizations that develop clinical practice guidelines for nephrology in the English language meets annually to exchange the guideline development plans of each organization in order to avoid duplication of efforts.

KDIGO has also successfully hosted several international Controversies Conferences to summarize the available knowledge in a specific topic area, to discuss what kind of recommendations can be derived from available knowledge and to assess what needs to be undertaken in the future to improve the evidence base for clinical management (Table 1). In some instances, these conferences have helped to decide whether sufficient evidence is available for the development of a clinical practice guideline in a specific area, and when the optimal timing for that might be. For example, a Controversies Conference in 2005 led to a new concept of bone and mineral disease in chronic kidney disease, and laid the groundwork for the KDIGO guideline published in 2009.<sup>29,31</sup> A conference on the care of kidney transplant recipients was also followed by a guideline in this area.<sup>30,32</sup> Another conference held in 2007 concluded that redundancy of guidelines in the field of anemia management should be avoided and that the next update of an anemia guideline should be performed by KDIGO when sufficient new data are available.<sup>33</sup> Two conferences have addressed the global challenges of chronic kidney disease,<sup>34,35</sup> and a Controversies Conference in 2009 will examine the current definition and classification system

**Table 1** | Previous and planned KDIGO conferences

Conference topic	Year
Definition and classification of CKD <sup>22*</sup>	2004
Definition, evaluation and classification of renal osteodystrophy <sup>19*</sup>	2005
Care of the transplant recipient <sup>20*</sup>	2006
CKD as a global public health problem <sup>22*</sup>	2006
Coordination of clinical practice guidelines for anemia in CKD <sup>21*</sup>	2007
Clinical practice guidelines: methodology and transparency	2007
Blood pressure in patients on dialysis	2009
Classification and prognosis of patients with CKD <sup>24*</sup>	2009
Drug dosing in patients with acute and chronic kidney disease	2010
Prevention of CVD events in CKD patients	2010
Controversies in living kidney donation	2011
Dialysis—back to the future	2011

\*References indicate publications with reports, clinical updates and position statements related to the specific conference. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease.

of chronic kidney disease and discuss the need for a revision of the current guideline on the basis of evidence that links chronic kidney disease staging to outcomes.<sup>36</sup>

Although the panel of topics for which the development of clinical practice guidelines seems worthwhile will no doubt continue to increase with the expansion of medical evidence, approximately 20 areas currently seem to qualify for guideline updates or the development of new guidelines related to the care of patients with kidney disease (Table 2). Although this number seems manageable, the need for regular updates of so many guidelines creates considerable challenges, which can only be met in close collaboration with other organizations. For example, KDOQI has decided to not develop new guidelines in upcoming years. Rather, KDOQI will perform systematic literature reviews in the field of management of cardiovascular complications in chronic kidney disease, and KDIGO will use these reviews to prioritize clinical practice guideline updates and to simplify the evidence review process for these updates. The EBPg initiative has now been converted into a new initiative called European Renal Best Practice (ERBP), which will focus on literature reviews and the development of position statements rather than clinical practice guidelines, in order to compliment KDIGO.<sup>37</sup>

### Funding

Members of the KDIGO work groups, conference program committees, the KDIGO board of directors, and co-chairs all volunteer their time and effort. The administrative management and the professional evidence review are provided by paid staff and these costs, together with costs for communication, travel, meetings and publications make up the KDIGO expenses. The majority of these costs are covered by corporate sponsors, including pharmaceutical companies and health-care equipment providers. However, companies can only make unrestricted donations and cannot sponsor a

**Table 2** | Scope of guideline topics in the field of kidney disease

Guideline topics	Publication year		
	DOQI/KDOQI*	EBPG*	KDIGO
<b>Syndromes</b>			
CKD evaluation, classification and stratification	2002	—	2011 <sup>†</sup>
Acute kidney injury	—	—	2010 <sup>§</sup>
<b>Specific disease</b>			
Chronic glomerulonephritis	—	—	2010 <sup>§</sup>
<b>Renal replacement therapy</b>			
Hemodialysis	1997, 2006	2002, 2007	—
Vascular access	1997, 2006	2007	—
Peritoneal dialysis	1997, 2006	2005	—
Care of the kidney transplant recipient	—	2000, 2002	2009
<b>Comorbidities, specific treatment aspects</b>			
Anemia	1997, 2001, 2006, 2007	1999, 2004	2012
Bone and mineral metabolism	2003	—	2009
Bone and mineral metabolism in children	2005	—	—
Hypertension and antihypertensive agents	2004	—	2011 <sup>§</sup>
Cardiovascular disease	2005	—	—
Hemodynamic instability on hemodialysis	—	2007	—
Dyslipidemia	2003	—	2012 <sup>†</sup>
Nutrition	2000	2007	—
Nutrition in children	2008	—	—
Diabetes	2007	—	—
Hepatitis C	—	—	2008

This list is recognized to be somewhat arbitrary and needs to be continuously updated with topics and updates added depending on available evidence. \*For simplification only previous guidelines by DOQI and/or KDOQI in the US and EBPG in Europe are included in addition to KDIGO guidelines. †Guideline development planned. ‡Ongoing guideline development. Abbreviations: CKD, chronic kidney disease; EBPG, European Best Practice Guidelines; DOQI/KDOQI, Dialysis Outcome Quality Initiative and Kidney Disease Outcomes Quality Initiative; KDIGO, Kidney Disease: Improving Global Outcomes.

specific KDIGO guideline. The KDIGO board of directors decides exactly how the budget is spent. Private donations have also contributed to KDIGO’s budget, but unfortunately these are not sufficient to cover all expenses. Although KDIGO realizes that complete independence from industry sponsorship would be ideal, this is currently not achievable; fulfilling requests for complete avoidance of industry support<sup>22</sup> would effectively end KDIGO guideline development.

**Ongoing and future projects**

The first clinical practice guideline developed by KDIGO dealt with the treatment of hepatitis C in patients with chronic kidney disease (Table 2).<sup>38</sup> This topic was intentionally chosen to demonstrate the organization’s plans to extend the development of clinical practice guidelines into areas that have so far not been covered by other organizations and to address needs that are

truly international. The second KDIGO clinical practice guidelines in the field of bone and mineral disease in patients with chronic kidney disease provides an example of the application of KDIGO methodology to areas previously dealt with by other organizations.<sup>29</sup> The third KDIGO clinical practice guideline deals with the care of kidney transplant recipients.<sup>30</sup> Given the central role of kidney transplantation for renal replacement therapy on a worldwide scale, this guideline paid particular attention to the provision of recommendations that are applicable to different situations of health-care resources. Work groups are currently developing guidelines for the management of acute kidney injury, glomerulonephritis and hypertension in patients with chronic kidney disease (Table 2).

**Guideline dissemination and implementation**

The development of a clinical practice guideline is only the first step in the process to improve patient care. Although the evidence on which the guideline is based is usually globally valid, the practical consequences that can and should be derived from the guideline depend to a large extent on regional circumstances of health care. For dissemination and implementation of its guidelines, therefore, KDIGO relies heavily on cooperation with other societies and associations. All complete clinical practice guidelines as well as so-called ‘executive summaries’, which contain all recommendations without the evidence tables and rationale sections are available on the KDIGO webpage.<sup>1</sup> Translations of the recommendations are prepared by work group members and members of the board of directors and the board of councilors and are also available through the website. In addition, KDIGO welcomes complete translations of a whole guideline document into different languages. Professional societies are invited to comment on KDIGO guidelines and to specifically address how different recommendations may apply in different regions around the world and how they should be prioritized under conditions of restricted resources. Plans to explore a more formal process of guideline adaptation, such as the one developed by the ADAPTE collaboration,<sup>39</sup> also exist. Moreover, the KDIGO executive committee has decided to appoint an Implementation Task Force, which will consist of six members representing different regions of the world. Task Force members will coordinate the work of national and regional representatives of the organization to facilitate the presentation and discussion of KDIGO guidelines at national and regional meetings and encourage the publication of translated versions of KDIGO guidelines. While dissemination is an important first step in guideline implementation, the ultimate goal of improving patient outcomes through guideline implementation requires that health-care providers are prepared to adjust their practice and that practice according to the guideline recommendations proves feasible. Testing both aspects of this implementation process would certainly provide important feedback for guideline updates, but

unfortunately, the available KDIGO resources have not yet allowed expansion into this area.

Finally, it is also important to recognize that KDIGO clinical practice guidelines are intended to provide 'guidance' rather than 'rules'. Although the purpose of the recommendations is to assist in decision making, the responsibility of an individual physician to follow or not to follow a specific recommendation in the context of an individual patient's situation should not be replaced.<sup>40</sup>

## Conclusions

Despite the high prevalence of kidney disease and its diverse consequences, clinical research in nephrology has unfortunately lagged behind that of other medical fields. In particular, the number of randomized, controlled trials is lower than in other medical subspecialties. This paucity of clinical data imposes considerable challenges for the development of clinical practice guidelines for patients with kidney disease. By founding KDIGO, the nephrology community has established a unique structure that may serve as a model for international

guideline development. There is still a long way to go from single guideline projects to an ongoing review of relevant new data from all important fields of nephrology with regular updates of clinical practice guidelines, covering the management of specific kidney diseases and their diverse consequences. This process should not only include a critical appraisal of published data, but should also clearly define unresolved questions, and thereby stimulate and prioritize future research. Undoubtedly, the KDIGO organization, structure, agenda and its methodologies will need to evolve in order to achieve these ambitious goals. We believe, however, that a solid basis for this development has been established in a short period of time.

### Review criteria

The information in this Review is based on the experience of the authors and literature accumulated over their years working with KDIGO. No specific database searches were performed.

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### Acknowledgments

The authors are the current co-chairs of KDIGO. They gratefully acknowledge the tremendous support provided to KDIGO by many volunteers, the ground-laying efforts by KDIGO's founding co-chairs, Garabed Eknoyan and Norbert Lameire, the stimulating collaboration with the executive committee, the expertise and dedication of KDIGO staff and members of the evidence review teams, and the financial support of KDIGO's sponsors.