

KIDNEY DISEASE: IMPROVING GLOBAL OUTCOMES FOUNDATION

In short: KDIGO Foundation
Foundation in the public interest
Avenue Louise 65, Suite 11
1050 Brussels
Belgium

Enterprise identification number: 0879.785.248 (Register of Legal Entities Brussels)

(hereinafter referred to as the "Foundation")

MINUTES OF THE MEETING OF THE KDIGO TRUSTEES ON OCTOBER 1, 2018

1. BUREAU

The meeting opened under the chairmanship of co-chairs David Wheeler & Wolfgang Winkelmayr.

The co-chairs stated that the Trustees have been validly convened, since according to article 6 of the Articles of Association, all Trustees have been convoked by letter containing the agenda of the meeting of the Trustees no later than 8 days before the meeting and, according to article 14.1 of the Articles of Association and the attached attendance list, at least two thirds of the Trustees are present or represented.

Minutes from the March 2018 meeting were approved.

2. AGENDA

See attachment

3. DISCUSSION

3.1 Methods & Patient Participation

Dr. Marcello Tonelli has been working with KDIGO to create a Methods Manual that will serve as a “Standard Operating Procedure” for all guideline work groups. The manual will outline processes and how best to utilize MAGICapp. KDIGO was one of the first organizations to adopt the GRADE system on which MAGICapp is based.

As an organization, KDIGO recognize that guidelines can become out of date over time. There is a need for easier and quicker processes for updating, including continual surveillance of evidence. This will help keep KDIGO guidelines current.

KDIGO formerly had a Methodology Committee that published a paper on the process. Dr. Tonelli was part of this group. In his new role as Methods Chair he recommended MAGICapp to the Executive Committee. MAGICapp stands for ‘**MA**king **Gr**ade the **I**rrresistible **C**hoice’. KDIGO is currently piloting MAGICapp for the GN Guideline Update.

The platform allows for faster updating of guidelines creating a “Living Guideline”. It also ties the evidence more closely to the recommendation statements, allowing users to see how they are based on evidence. New trials can be added during the guideline development process or after publication. Such new evidence may necessitate a change in the recommendation or their grading. The Work Group would make those decisions.

KDIGO is trying to figure out the best way to engage patients in the Guideline process. The MAGICapp group also provided a proposal on engaging patients, as did SONG. Patients can help prioritize outcomes by defining those issues that matter most to patients. It is important to look at what other organizations are doing to involve patients and gather patient input.

3.2 Hepatitis C Guideline Update

The 2008 Hepatitis C guideline was the first KDIGO guideline to be published. It did not use the GRADE system, but used the terms “weak”, “moderate”, and “strong” for the recommendations. The need to update the guideline was raised back in 2014. As the field moved rapidly, the guideline was slightly delayed in order to wait for important new evidence. The Updated Guideline was published in October 2018.

3.3 Transplant Candidate Guideline

The guideline on Transplant Candidate Selection is the next guideline up for publication. It has 19 chapters and upwards of 120 recommendations. Some recommendations are ungraded but fewer than were found in the Living Donor Guideline.

KDIGO will look to submit it for publication in Q1 of 2019 and publish in Q3 of 2019. The Guideline will be published in *Transplantation*, the journal of The Transplantation Society, which provided financial support to its development.

3.4 GN Guideline Update

The first Work Group meeting was held in Amsterdam in August 2018, and a second meeting might be needed in 2019. During the meeting, there was a clash of clinical insights versus pure evidence-based approach. The guideline process is not far enough along to know the benefits and/or drawbacks of using MAGICapp.

Based on the conference held in Singapore in November 2017, upwards of 90% of the original guideline will need to be revised. Since the guideline spans so many diseases it is difficult to involve 2-3 patients in the guideline development process.

Instead of ungraded recommendation statements, the Work Group will offer “practice points” (e.g. when to do a kidney biopsy). These will be applied to items where guidance is needed but there is little strong evidence. Practice points can be included in MAGICapp, but will not be supported by actual evidence tables. Rationale for issuing the practice point can and should be included.

Quite a few errors and mistakes were found in the ERT tables. The Cochrane Kidney & Transplant review missed certain studies. The Work Group needs to work hand in hand with the ERT to get the evidence tables right. This will be pursued aggressively by KDIGO staff and the Work Group Co-chairs.

3.5 Blood Pressure Guideline Update

The first work group meeting will be held in January 2019 in New Orleans. The ERT aims to provide evidence tables by mid-November. This will give the Work Group ample time to review tables and identify any problems or errors. Then the Work Group will be tasked with drafting 'straw dogs'.

3.6 Diabetes Guideline

The first work group meeting will be held in January 2019 in New Orleans. The ERT will also be Cochrane, so it will be easy to combine this meeting with the Blood Pressure Guideline Update meeting.

3.7 Controversies Conferences

Onco-Nephrology – Co-chaired by Jolanta Malyszko, Poland and Camillo Porta, Italy. This conference continues the KDIGO tradition of bringing disciplines together and will be the first time KDIGO brings nephrologists and oncologists together.

Blood Pressure in Dialysis – Co-chaired by Jenny Flythe, USA and Kevan Polkinghorne, AU. To be held in February 2019.

Acute Kidney Injury – Co-chaired by John Kellum, USA and Marlies Ostermann, UK. Dr Kellum was the co-chair of the AKI Guideline. This conference will help launch the update of the AKI Guideline.

Nomenclature – Co-chaired by Andy Levey, USA and Kai Uwe Eckardt. This will be a unique conference focusing on consensus of terminology used to discuss kidney disease. The attendees will be made up of nephrology journal editors and editors of related disciplines.

Cardio-Renal Conference Series – The conference report on Heart Failure is still under review by the European Heart Journal. The EHJ accepted the Arrhythmias paper. The Coronary Artery & Valvular Diseases Conference was held in Vienna in June. The co-chairs decided that two papers will be published from that conference, splitting the topic. Co-chair Tom Marwick has a relationship with JACC and is interested in submitting there.

3.8 Topic Prioritization

Anemia: The KDIGO guideline was published in 2012 and a Controversies Conference was held on Iron Management in 2014. The guideline does require updating, but there is a lot of activity in this space at the moment. The activity includes large phase 3 studies on HIF stabilizers, an in-press Cochrane Iron Review, and the PIVOTAL trial. Possibly separate recommendations based on treatment (HIF vs ESA). KDIGO will need to carefully time any update based on the new data coming out.

KDIGO plans to hold two separate Controversies Conferences on Anemia issues. The first primarily on Iron Treatments and the next to emphasize HIFs and traditional ESAs. KDIGO will aim to hold the first conference at the end of 2019. Topics to be discussed will depend on the new trials and evidence available. Co-Chairs will be carefully identified, taking into account conflicts of interest.

Early Identification & Intervention in CKD: This conference will focus on what do to when CKD is diagnosed. There will be an emphasis on determining the impact of decreased kidney

function on standard treatment for conditions like diabetes and hypertension. Depending on the population (elderly, living donors, etc.), different approaches may need to be considered.

The discussion would be highly relevant to healthcare systems where some tests are not readily available and treatment of ESRD is not common, as well as identifying the problems of over-diagnosis and diagnosing without clear follow up treatment. The goal will be to advise on reducing CVD risk in this population and dealing with progression of kidney disease.

One of the co-chairs could be a primary care physician. This conference is not about screening or how to screen, but identifying at risk populations for targeted screening and preventing progression in early stage CKD. This is important in developing countries.

Care of the Transplant Recipient: The original guideline was published in 2009. Since then there have been some advances in immunosuppression. It is a potentially large subject that touches upon a very high number of topics. Some parts of the guideline are out of date, some are not. There are questions around procurement and organ usage. Just updating the immunosuppression section may not be a good use of our time. There has been some significant change with induction. The use of generics in transplant medicine could be a controversial area.

May be prudent to start a Transplant Conference Series. Potential topics could include:

- Selecting specific controversies
- Transplant and diabetes
- Malignancy
- Treatment of individuals with failing transplants
 - Transition back to dialysis
 - Do you remove the failing graft?

Transplanting Kidneys from Deceased Donors: This topic could cover a global discussion on the use of high-risk kidneys (e.g. cancer, infection, etc.), biopsies, retrieval and procurement, and the discard rate. The discard rate is upwards of 20% in certain parts of the US and around 3% in Australia. A review of the global variances, differences in approach, and who is ultimately responsible for discarded organs (e.g. nephrologists, surgeons?). This has a potential huge impact for patients.

ADPKD: KDIGO held a Controversies Conference on ADKPD in 2014. At the time, there was not enough evidence to embark on a guideline. There have been a number of significant developments since the meeting. The Trustees voted to proceed with a guideline but not to include Alport's or any other genetic diseases.

Electrolyte Imbalance Series: The Potassium Management Controversies Conference will take place October 4-7, 2018. The next conference in the series could look at magnesium or sodium (Dialysate or Hyponatremia). Then possibly look at Acid Base Balance. Questions were raised about how robust these topics are. The topic of calcium might be too much of an overlap with CKD-MBD. The BiCARB study should be wrapping up soon. This study looks at whether oral sodium bicarbonate therapy improves function and quality of life in older patients with CKD and low-grade acidosis. The next conference should include basic science and nutrition.

Kidney Disease of Unknown Origin: This topic is already a controversial area with a great deal of interest. It is global in nature, as it is an international epidemic. Could potentially be an important Controversies Conference topic. KDIGO would have to approach this differently than other organizations, as there are many groups involved in the topic. Currently there is not even basic research available. KDIGO will monitor the topic as a potential Controversies Conference.

Cardio-Kidney Conference Series: Potential to start a “volume” of guidelines on this topic including a library of individual recommendation statements that could be rapidly updated. Maybe start with diagnostics. Not a lot of guideline support from the co-chairs of the three conferences held to date (Arrhythmias, Heart Failure, Coronary Artery).

Limited-Scope Conferences & Other Topics: Other topics considered include Alport’s, Analysis of Renal Tubular Function, and Uremic Toxins. The fourth Dialysis Conference will look at novel dialysis innovations. Uremic toxins might fit into this conference or it might be more of a pre-dialysis issue. It will look at wearable / implantable dialyzers and low-water dialysis machines.

Drug Dosing with Declining Kidney Functions: The main focus of this topic is on harms (e.g. Lactic acidosis on Metformin). This will also be addressed in the Onco-Nephrology Conference.

Pregnancy & CKD: This topic will be used to educate obstetricians and needs to involve pediatricians.

Dialysis Complications: This was intended to be the 2nd Dialysis Conference. It will cover the patient-perspective of dialysis and their complications (e.g. itch, restless leg, etc.).

Lifestyle and CKD: This topic would cover changing lifestyle in order to prevent progression. It might be more of an implementation subject.

Nutrition & CKD: Scant evidence for a guideline.

HIV & CKD: Not a lot of evidence at this time for a guideline, mostly expert opinion. Some ongoing studies may lend themselves to guideline development in the future.

3.9 KDIGO Clinical Practice Conferences & Presence in China

Clinical Practice Conferences were just held in Xian and Gui-Yang, China. KDIGO has substantially increased its presence in China in recent years and received a lot of interest from companies looking to gain a foothold in the Chinese market. It is still sometimes difficult to procure funding to send speakers to these meetings, and Transplant topics are still somewhat controversial.

Other Clinical Practice Conferences will be held in Shanghai in 2018 and Seoul in 2019. Dates and locations for Russia, Kenya, Brazil, and others need to be finalized.

4.0 Implementation Summits

KDIGO's first Implementation Summit was held in April 2018 in Tokyo and focused on the CKD-MBD environment in Asia. The next Summit is scheduled for May/June in Hong Kong and will explore Hep C in the Asian region. The meetings are smaller than Controversies Conferences, at about approximately 30 participants or less. They focus on local adaptations of specific topics, with a publication as an output. These summits could be a viable funding stream.

KDIGO is always asked for measures on impact of its guidelines. Currently, KDIGO tracks citations, website traffic, increases in impact factor of a journal, and dissemination of speaker guides and tool kits, but has not actively measured changes in practice or changes in patient outcomes.

4.1 Implementation Tools & Activities

KDIGO provides implementation sessions on many local nephrology society programs. KDIGO could also provide country-specific tools for distribution during these sessions, KDIGO also must try to increase awareness of the brand and its published guidelines in general. Budget constraints are certainly a factor in limiting implementation efforts.

4.2 KDIGO Future Plans

KDIGO is looking for more help on the science side for KDIGO staff. More than just a medical writer, this person will need to know the landscape and be able to thoughtfully comment on the content. This person will report to Michael Cheung, Chief Scientific Officer.

4.3 Upcoming Executive Committee Meetings

- 2019 Executive Committee Meetings
 - March 25 – Prague
 - October 21 – Vancouver

4.4 Financial Report

KDIGO is in roughly in the same position as the end of last year. KDIGO does not have any significant investment revenue, which is an important point for future discussion. Any future surplus may be moved into a money market account. A higher risk account would not be ideal for KDIGO. This should be explored if there is an excess of €1,500,000 to invest. KDIGO will have to research in what currency to make this investment. The US dollar returns may be higher than the Euro; but CHF, GBP, USD are all options. Money market fund should have outside management and not be managed by KDIGO. KDIGO would not invest in pharmaceutical companies.

The 2019 financial projection is healthy. There are two large ERT payments to be made by the end of 2018; ERT payments in the future will be substantially less. Ernest & Young conduct an outside audit every year.

The Trustees unanimously approved the Annual End of Year Report and Financial Audit.

4.5 Fundraising

It is extremely helpful to have introductions for KDIGO volunteers to industry partners. Having a direct introduction to a company contact gives KDIGO credibility. Some of the

largest companies are the most difficult to secure funding from, since they are hindered by bureaucracy and diffuse decision-making.

4.6 Report from the Nominating Committee

The Nominating Committee recommends the following four members to serve on the Executive Committee starting January 1, 2019. The trustees voted and approved the appointment of the following:

- Mustafa Arici, Turkey
- Fan Fan Hou, China
- Jolanta Malyszko, Poland
- Laura Sola, Uruguay

KDIGO also recognized with gratitude the four members whose term will expire on December 31, 2018. They are Ali Abu-Alfa, Lebanon; Jürgen Floege, Germany; Zhi-Hong Liu, China; and Ziad Massy, France.

Michel Jadoul was elected as KDIGO's new Co-chair. He has been involved with KDIGO for many years and looks forward to working with the Executive Committee and the entire KDIGO organization.

4.7 Future Meetings and Other Business

The next Executive Committee Meeting will be held on Monday, March 25, 2019, at the Marriott Prague.

The co-chairs adjourned the meeting.

Signatures:

David Wheeler
Co-Chair

Wolfgang Winkelmayr
Co-Chair

Annex:

1: Agenda

2: Attendance list signed by the Trustees present and confirmed by a co-chair.