

KIDNEY DISEASE: IMPROVING GLOBAL OUTCOMES FOUNDATION

In short: KDIGO Foundation
Foundation in the public interest
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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 MARCH 28, 2022

1. BUREAU

The meeting opened under the chairmanship of Co-Chairs Wolfgang Winkelmayr and Michel Jadoul.

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 8.3 of the Articles of Association and the attached attendance list, at least two thirds of the Trustees are present or represented.

Minutes from the September 2021 meeting were approved.

2. AGENDA

See attachment

3. BUSINESS MATTERS

3.1 Call to Order

The Co-Chairs welcomed four new Trustees: Gloria Ashuntantang (Cameroon), Joachim Ix (USA), Irene de Lourdes Noronha (Brazil), and Irma Tchokhonelidze (Georgia). KDIGO strives for a geographic and clinical diversity and gender balance among its volunteers. The Co-Chairs also reminded all Trustees that Trustee meetings should not be discussed with non-members or outside the Trustees.

It was decided that membership of a Guideline Work Group will not be announced publicly, but Guideline Co-Chair names will be released. If Work Group members are giving a talk on a KDIGO Guideline, they will be asked to alert KDIGO. Slides should always be labeled as a draft if the Guideline is not yet published.

3.2 Belgian Regulations

New Trustees have been asked to submit required documentation in order to be recognized by Belgian law as ‘trustees’ of the foundation. The new list of Trustees will be published in the Belgian Gazette.

3.3 Finances

KDIGO uses accrual accounting. The Trustees reviewed an unaudited balance sheet, profit/loss statement and the cashflow statement of YE 2021. Cash and total assets are very healthy at present. Spending will increase in 2022 as meetings go back to being in-person and Evidence Review Teams are hired for upcoming guidelines.

3.4 Recognition and Appreciation for Volunteers

Recognizing volunteers in the usual ways has been difficult over the last two years due to the pandemic. It is important to convey how valuable the volunteers are to KDIGO. Some other ideas for consideration including having a volunteer “featurette” in KDIGO Direct or something like the NKF International Recognition process. KDIGO has previously provided certificates of attendance at certain conferences.

Academic credits are especially valuable to younger volunteers or fellows to help elevate their careers. KDIGO could write formal letters of recognition to be sent to department chairs or deans that include demonstration of impact and collaboration. These would need to spell out the exclusivity of KDIGO event and Work Groups and list the output of the activity. The target audience for these letters would be non-nephrology. May not need to highlight exactly how much time individuals spend on KDIGO activities. KDIGO will need to ask permission before sending any letter or correspondence. Also, KDIGO plaques for the Executive Committee will return in October.

3.5 10 Years of Independence

In October 2022, KDIGO will celebrate 10 years of organizational independence. In celebration of such a momentous occasion, a reception may be held at ASN or ERA to recognize the forefathers and fore thinkers of KDIGO. Similar receptions have been held in the past (ASN – Philadelphia and ERA – Vienna). Both of those receptions were sponsored, but it might be best to avoid having sponsorship for this one. Is it feasible to hold an event in Orlando in November? Orlando is not a very walkable city, so it might not be well attended. Possibly wait until ERA in Milan or the next ASN in Philadelphia.

3.6 Policies & Protocols

Policies must be approved by the Executive Committee whereas protocols are general documents that do not require a vote by the Executive Committee.

3.6a Self-Nomination Policy

KDIGO strives for diversity, but Co-Chairs and staff routinely receive self-nomination emails for conferences and guideline Work Groups. The policy will allow a formal response. Self-nominations after a final controversies conference or guideline Work Group roster has been established will generally not be considered. Motion passed and policy is approved.

3.6b Guideline Liability Disclaimer

After a review by the KDIGO lawyers, the disclaimer language presented at the front of each guideline as been modified. Updated language was reviewed, motion passed, and policy is approved.

3.6c Protocol on Guideline Authorship and Conference Reports

Guideline updates need to acknowledge the original work group (e.g., Hep C GL). This will prove to be tricky with new chapters and inclusion of untouched original chapters. Plan to include bios and disclosures for new members only, no need to include updated bios in guideline updates. Plan to list the previous Work Group members separately if they were not involved in the update. Could original authors challenge the content of an update? Possibly but unlikely if it is noted that they did not work on the update. Do we include the ERT in the authorship of a Guideline? Other organizations allow the ERT to publish an accompanying document but do not typically include the ERT as authors since the ERT is paid. KDIGO does include them as authors on the Executive Summary.

Conference report authorship usually includes the Conference Co-Chairs and Steering Committee. Conference participants are usually listed as contributors / collaborators and listed in PubMed. KDIGO has maintained this approach for 40-50 conferences. Recently KDIGO has received some complaints. For Genetics in CKD, they did not want authorship to be disincentive. If KDIGO is more transparent about the authorship and sets expectations upfront, then everyone will know the authorship structure when they accept their role. A tiered solution based on responsibility seems to work.

3.7 Methods Committee

Unfortunately, MAGICapp did not deliver as a working platform and did not work out in practice for the KDIGO meta-guidelines, so KDIGO has decided not to renew that contract. There is still room to expand and improve the Methods Committee. Ethan Balk has stepped aside to help lead an ERT and will be replaced and the committee expanded by 2 members. Since each Guideline Work Group includes a member of the methods committee, this expansion will provide enough members for each guideline. Methods Committee members will need to rotate off if they are selected as the ERT. KDIGO is planning a face-to-face meeting in May, with the Methods Manual being ready by October.

In the Methods Manual, the section on the disclosure of interest has been rewritten. The new form is based on the ICJME form. KDIGO asks all Work Group Co-Chairs and Work Group members to complete this form when they join the Work Group, before each Work Group meeting, and at the time of publication. KDIGO Co-Chairs will screen Work Group Co-Chairs and WG Co-Chairs will screen all WG member forms for potential conflict and decide what is relevant. KDIGO staff could screen for conflicts but perhaps best to defer to the chairs for the final decision. Standard policy of full disclosure.

Management of competing interests for WG members will be overseen by the WG Co-Chairs. Trialists can participate on a WG but may not be allowed part of the decision-making process for certain topics (e.g., Anemia in CKD). It is difficult to exclude trialists or have a WG that is fully

non-conflicted. Complete recusal may be difficult. Transparency is key. Definitely some subjectivity as the “Devil is in the detail”. WG members can still ask trialists or others any questions. More people with generic skill on the WG that can still access the experts with specific questions. Ideally, experts can contribute their expertise without impacting decision-making. WG Chairs can seek advice from the KDIGO Co-Chairs and Methods Committee as needed. Financial conflict is more straightforward vs non-financial. This process will continue to evolve over time. In general, the form is acceptable with some minor revisions [edits to the Competing Interests table (shift specific / non-specific to first column)].

The Methods Committee’s working plan is to finish methods manual, continue refining the disclosure of interest form, prioritize future GL updates, address how to do focused recommendations, and address how to incorporate patient preferences. Broad representation of patients is key. Patient preferences vary across the globe, and it is important to balance representation, perspectives, and fluency of the English language. Is there such a person that is a “typical” patient? Allison Tong previously submitted a proposal to KDIGO to help collect patient preferences, but KDIGO currently may not have the bandwidth to focus on this right now. May be time to consider an online patient portal.

4. CONSIDERATION OF AND DECISIONS ON IMPORTANT ISSUES

4.1 Evidence Review Team Process

KDIGO has used five different Evidence Review Teams (ERT) for its recent guidelines. KDIGO would like to make its Request for Proposal for an ERT more efficient, and is considering a few different options:

- Option 1: Standing ERT for ~5 years
 - Could change from a positive to negative experience over the course of the contract if ERT members change / leave, etc.
 - Are ERTs interested in such a long contract?
 - Tufts was the permanent ERT when KDIGO was still part of NKF
 - More difficult to budget and costs rose dramatically by the 3rd or 4th year
- Option 2: Rotate among 3 ERTs
 - ERTs can work together and share information
 - Learn from each other, a little healthy competition
- Option 3: “In-House” KDIGO ERT
 - Academic independence is crucial to the KDIGO mission
 - In-house ERT could also work on other guidelines for other groups?

KDIGO recognizes that no option is perfect but will work to identify three ERTs for a rotating model. Also, KDIGO should perform exit interviews with each outgoing ERT to see what KDIGO can do better as the contracting organization.

As KDIGO does more guideline updates, should the original ERT work on the update? Or should a new ERT be hired and be made to review the previous ERTs work? If a new ERT is

brought on at the update stage, there should be a policy or protocol in place to make sure they check the work of the previous ERT.

4.2 Current & Upcoming Guidelines

The finishing touches are being applied to the update of the 2018 Hepatitis C Guideline with plans for a Q2 submission. Similarly, the update of the 2020 Diabetes in CKD Guideline, which finished its public review last week, will also be submitted for publication in Q2 of this year. The de novo guideline on ADPKD will hold its first Work Group meeting on June 18-20 in Berlin. For the update to the 2012 CKD Guideline, comments are currently being collated after the Scope of Work public review period. The Scope of Work for the update to the 2012 Anemia Guideline was reviewed earlier this year, and KDIGO will begin its search for an ERT. Finally, the Glomerular Diseases (GD) Guideline, which was published last October, will already begin its first update. In order to keep this guideline current, the update process will occur at the chapter level. The first chapters to be updated are Lupus and ANCA-Associated Vasculitis. KDIGO has begun searching for an ERT to perform these chapter updates.

Other guidelines that have been previously approved by the Trustees, but which still need a start date, are an update to the 2012 AKI Guideline and 2-4 other chapters from the GD Guideline. All of these updates will most likely begin in 2023.

4.3 Publication of Guidelines

The KDIGO Guideline Development Process is an extremely long and detailed process from the Work Group Co-Chair appointments to publication. Two large pieces of the timeline are the evidence review and the publication process. Time to publication once submitted can take up to six months, which seems like a long time to keep the guidance from reaching the audience. Ideally, future guidelines will be more “modular” with standalone chapters, so the updating process would be smoother and minimizing the need for changes to other chapters. However, KDIGO received a bit of pushback from the publisher since each chapter would need to be its own individualized citation and DOI number. Also, the publisher was unable to make any concessions (e.g., using the previously typeset chapters, having to resubmit all unchanged items, etc.) on the production schedule for updates.

One solution to this process would be for KDIGO to self-publish the full-text guideline on the website and only publish the Executive Summary in the journal. Having the guideline as an HTML publication would allow for easier and quicker updates. Potential drawbacks to this idea include impact to author’s H Index, only having one citation for the guideline, not having the full-text version published in a peer-reviewed journal, and not having a galley proof stage to catch errors.

Questions for consideration: Does this impact the author’s H Index? Can online guidelines be indexed? Does publishing in a peer-reviewed journal add more “weight” / validity to the guideline? Does this affect the journal impact factor?

Current guidelines go out for a one-month period for public review and reviewers are acknowledged in the guideline as such. Then the journal also does a peer-review. This review is more superficial and looks only for factual errors or areas needing clarity. Could KDIGO do its

own KDIGO-invited peer review rather than relying on the journal? Could the journal review take place during the open public review to save time?

Need to remember the audience is practicing clinicians who need the guidance as soon as possible. Guidelines do not produce new or novel data but rather distill the existing evidence into actionable terms. Clinicians often look to the full guideline for rationale and the evidence base. Could KDIGO leave the original Public Review version up on the website with clear disclaimers / watermarks? A draft version would likely be downloaded and used even if it had watermarks. Would the journal be ok with this or consider it pre-publication? Current process is to embargo the document until publication as significant changes are often made during the galley proofs. Often guidelines are out of date by the time they are published, so KDIGO needs to adapt. How does KDIGO want the guidelines to be used? Users may not read the entire guideline but could delve into a specific chapter. KDIGO should think about shortening the full guideline, streamlining, and focusing on implementation.

Is there any use in moving to another journal? Moving to another journal does not guarantee a reduced or shorten timeline. Does ISN have any influence? Should give the journal a chance to respond. KDIGO hopes to meet with them at ERA to discuss next steps.

Next steps will be for KDIGO to collect more information:

- Meet with journal and publisher again
- Survey both end users and Work Group members.
- Pull statistics on downloads, pageviews, etc.
- Explore other journal options

For the Hepatitis C Guideline Update and the Diabetes Guideline Update, which will both be submitted in Q2, KDIGO will publish them as E-publications only. There will not be a print copy.

4.4 Controversies Conference Reports

After each Controversies Conference, KDIGO aims to submit the conference report to the journal within six months. Since these papers are written by volunteers and the allotted word count from KI is 4400, sticking to this timeline can prove tricky. In efforts to streamline the process, KDIGO has begun providing detailed timelines to the Steering Committee and since 2016 has brought in Jennifer King, a science writer, to help write the first draft and shepherd the report to completion. Unfortunately, Jennifer is not able to make it to every conference, so if any Trustee know of a trustworthy science writer, please make the KDIGO staff aware. Currently the relationship with *Kidney International* remains strong.

4.5 Future Topics

For guideline consideration:

- Cardio-Kidney Issues
- Dialysis
 - Might be hard to do in a guideline due to the global audience of KDIGO

For conferences:

- Innovation and Wearable Technology (sweat sodium monitoring)
- Advocacy
- CKD in Children
 - Growth hormones
 - Too young for PD?
 - Transplant among pediatric patients
- Transition from Pediatrics to Adult Care in CKD
 - “Special Considerations” for pediatrics could be included in guidelines similar to considerations for female vs male patients
- Cystatin-C
- Women and CKD

Other topics on the list need to be defined more clearly including Dialysis Innovation, Precision Medicine & AI, Green Nephrology, and Telemedicine. Dialysis Innovation could focus on affordable dialysis, which may be a better topic in a few years. Could consider a conference on Dialysis/Nephrology in Emergency/Disaster Situations (e.g., Covid-19, floods, earthquakes, etc.).

Funding and sponsorship are always taken into consideration; however, certain conferences that would not generate much revenue are worthwhile (e.g., HIV Conference in Cameroon). KDIGO can afford 1-2 such topics every few years. Women and CKD might be such a topic but should be considered for early 2023. This conference could cover immunosuppressive treatment, fertility issues, pregnancy in solid organ transplant recipients, neonatal care, and breastfeeding and drug interactions.

5. REPORTS

5.1 Implementation

The pandemic forced KDIGO to take on more virtual activities including webinars and podcasts, which have received impressive numbers. Participation in international congresses continues to grow as well as dedicated sessions at upcoming congresses. Furthermore, KDIGO has seen an impressive increase in social media interactions. Thank you to the Trustees who have participated in and/or reviewed material for these activities. KDIGO is always open to suggestions on potential medical illustrators or assistance by junior faculty.

Each guideline now is being released with a suite of materials at the time of publication, including Top Ten Key Takeaways, Central Illustration, and a slide set. KDIGO is also working with the ADA to publish a Consensus report showcasing the similarities in our guidelines. KDIGO also lead a Joint Statement on Blood Pressure Management with 13 other organizations including ACC/AHA, ESH, ISH, ESC, etc. Both collaborations are an impressive indication of KDIGO reach.

5.2 Future Meeting

The next Trustee Meeting will be on Monday, September 19, 2022.

The Co-Chairs adjourned the meeting.

Signatures:

Michel Jadoul
Co-Chair

Wolfgang Winkelmayr
Co-Chair

Annex:

1: Agenda

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