

Instructions to authors for the NDT ERBP perspectives

Nephrology, Dialysis and Transplantation (NDT) will now start with a section specifically devoted to papers on guidance: the ERBP perspectives. In 2009, the guideline body of ERA-EDTA, European Renal Best Practice (ERBP) changed its view on how it wanted to provide guidance for the nephrological community[1]. Now, the ERBP perspectives provide a means to publish papers where evidence is assembled in a structured and transparent way, and where guidance is provided for the practicing nephrologist. There is clearly a need for this type of publications, as there is lack of well performed randomized controlled trials, and an ever increasing number of reports of purely observational studies, trials using surrogate outcomes, or suggestions for translation of basic science to the clinical field, making it difficult for the individual general nephrologist to develop a balanced opinion or treatment strategy for specific problems.

To ensure that it will be clear to everyone what exactly is being done, the following terminology will be used regarding the type of publication that can be accepted. This terminology describes *process flow charts of action* for different types of documents that will be published in the "ERBP perspectives" section of NDT.

Systematic review with statements

Proposals for topics for a systematic review can be forwarded by "expert groups" to guidelines@era-edta. An *expert group* is an assembly of people with a common interest in a certain area. The group should be *multi-centric*, and expertise will be evaluated based on publications and international presentations on the topic. The topic should be concise and well-defined, so typically one single clinical question, e.g. "the use of anti-depressive agents in dialysis patients". If the advisory board of ERBP feels that the topic is of interest to our audience, we expect authors to proceed as follows :

- ➔ define the topic
- ➔ establish an expert group (at least two centres)
- ➔ submit application to guidelines@era-edta.org

- ➔ produce PICO (Patient Intervention Comparator Outcome) question(s)
- ➔ produce a search strategy, perform a search
- ➔ review abstracts to select papers for detailed review
- ➔ Review selected papers for relevance and discard non-relevant ones
- ➔ data extraction in a dedicated excel sheet (template provided by ERBP methodology support team) including formal risk of bias assessment
- ➔ Synthesize and grading of the evidence in summary of findings tables (template provided by ERBP methodology support team).
- ➔ produce statements

In the introduction of the paper, the authors should describe the problem investigated in the paper and its relevance. It should be clear what the topic is of the paper: which specific type of Patients are involved (and which are not), what the tested Intervention is, and what the alternative treatment is to which it is compared (Comparator). Lastly, it should be clear which outcomes will be taken into account (Outcome) with distinction between the primary and secondary outcomes reflecting both benefits and harms (PICO methodology). We will also accept systematic reviews of diagnostic test accuracy studies.

In the methods section of the paper, authors should provide a short description of the search strategy, with an extensive search strategy being available online. In the results section, authors should provide the number of papers retrieved, number of papers withheld based on abstract, number of papers withheld after reading the full paper, with an explanation on why some papers have been eliminated; this can be done in a tree presentation. In the methods section, the authors should provide the extraction table, including a formal assessment of the risk of bias of each included study. We expect the authors to adhere to the reporting guidelines for systematic reviews as outlined by the PRISMA statement (<http://www.prisma-statement.org/index.htm>). The body of the text should contain statements, with grading of evidence and recommendation according to GRADE[2], and their rationale. Alternatively, authors can present flow charts of action in diagrams or decision trees, e.g. to present a diagnostic work up for specific problems. In all cases, it should be clear what is the preferred way of action, and what the quality of the evidence is to support that statement. Note that this is essential, as this is the major difference with a narrative review. All

papers will be evaluated and reviewed by 3 members of the ERBP advisory board and 3 independent external reviewers.

Guidelines endorsements and updates, guidelines commentaries and position statements

A multi-centric group of authors can propose to adapt an existing guideline from another guideline issuing body to guidelines@era-edta.org. This adaptation can be done to make it more suitable for the specific area of nephrology, or the European context (cfr the hep C guideline[4]). An update on existing guidelines can also be done if new evidence with substantial impact becomes available (the ERBP paper on "when to start dialysis"[5]). A position statement is a document wherein a group of experts express their view on a topic where there is no strong evidence basis and differing views among experts.

In the introduction of the paper, the authors should clearly state why an update/commentary/adaptation is needed, and what the precise scope of the document is. It should be clearly indicated what the original guideline is, and what the adapted version is (statements with grading). After each statement, a rationale should be provided.

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Guideline

A "guideline" refers to an extensive document ("the book") with statements on a specific topic, irrespective of the strength of the recommendations, or the quality of the evidence. In view of the strict methodological requirements, the huge workload and the associated commitment in terms of financial, intellectual and labor aspects, this type of publication can only be initiated by the advisory board of ERBP, or by one of the ERA-EDTA associated working groups (Eureca-m, Eudial, Immunology, WGIKD, Eutox) in collaboration with ERBP. Other societies can make proposals for topics on subjects relating to nephrology, or to make guidelines on how to deal with a certain topic in patients with CKD.

In each of these 3 types of documents, statements should be made and graded according to the GRADE classification system[2]. When a statement is based on a structured, transparent and exhaustive research of the available literature, and is funded on *high quality science* (i.e. at least one RCT of sufficient quality), this statement will be graded as *evidence level A or B*. In terms of strength of evidence, it means that we are, based on the available evidence, confident that it is unlikely that new studies will change our view substantially in the future. The *level of recommendation* depends upon the clinical relevance or desirability (for the individual patient, the society, the funding body) of the intervention. A *level 1 recommendation* means that most patients would like to have the treatment, and that the intervention/statement can be considered to be an acceptable policy; a *level 2 recommendation* means that some, or even most, of patients might not like to follow the recommendation, as they see no advantage in it. Accordingly, the intervention/statement cannot be seen as a general policy, despite evidence of its validity. E.g. presume there is evidence from two well performed large RCT's that antiviral medication "A" can reduce the mean duration of a flu from 7 to 6 days, but that one bottle "A" costs 10000 euro. This will be an evidence level A (as the evidence is of high scientific quality) but the recommendation will be level2, because we believe that the cost/benefit is not favorable (so the statement will most likely start with the words "*we do not recommend.*"). It has to be understood that not only financial costs, but also "costs" in terms of quality of life, side-effects etc have to be taken into account.

When the statement is based on a structured, transparent and exhaustive research of the available literature, and is funded on the best *available* evidence, this will be evidence *level C or D*. Although the difference with a level A or B might appear as purely semantic, it is not: it implies that no high level quality science is available to support the statement, but, taking all the lower quality evidence into account, the experts agree that the stated strategy is the preferred one. This mostly refers to problems where only observational trials are available, where RCTs only deal with surrogate outcomes, or where the translation of underlying biological processes makes it plausible that the

stated strategy is the most optimal. However, it cannot be excluded that future randomized controlled trials will change our views and the statement profoundly. Note that despite the evidence level being low, the *strength of the recommendation can be strong or weak* also for evidence level C or D statements.

When the statement is based on a structured, transparent and exhaustive research of the available literature, but by lack of any available evidence, has to be based on the opinion and expertise of an expert panel, this called an *ungraded statement*. Of note, an ungraded statement can also be used in areas where no or only limited evidence of sufficient quality is available in the literature, but where great (sometimes unpublished) expertise and knowledge is present in the author group, e.g. for rare renal diseases. As such, although the methodological value of an ungraded statement is low, the clinical relevance can be quite high. An example is the position statement on evaluation of peritoneal membrane characteristics[6].

1. Zoccali, C., et al., *European best practice quo vadis? From European Best Practice Guidelines (EBPG) to European Renal Best Practice (ERBP)*. *Nephrol Dial Transplant*, 2008. **23**(7): p. 2162-6.
2. Atkins, D., et al., *Grading quality of evidence and strength of recommendations*. *BMJ*, 2004. **328**(7454): p. 1490.
3. Vanholder, R., et al., *Catheter-related blood stream infections (CRBSI): a European view*. *Nephrol Dial Transplant*, 2010. **25**(6): p. 1753-6.
4. Covic, A., et al., *Endorsement of the Kidney Disease Improving Global Outcomes (KDIGO) hepatitis C guidelines: a European Renal Best Practice (ERBP) position statement*. *Nephrol Dial Transplant*, 2009. **24**(3): p. 719-27.
5. Tattersall, J., et al., *When to start dialysis: updated guidance following publication of the Initiating Dialysis Early and Late (IDEAL) study*. *Nephrol Dial Transplant*, 2011. **26**(7): p. 2082-6.
6. van Biesen, W., et al., *Evaluation of peritoneal membrane characteristics: clinical advice for prescription management by the ERBP working group*. *Nephrol Dial Transplant*, 2010. **25**(7): p. 2052-62.