Guideline development

As the guidelines were based on literature reviews, the first step for each author was to accomplish an as broad and objective collection of literature data as possible. To avoid a potential influence of his/her own bias, each author undertook a literature search, with as research tool the Internet Literature Search Program, available in Reference Manager 9. Once this literature search had been accomplished, the author could add extra references from his/her own experience or database. Each individual literature search obligatorily contained a set of reference words related to haemodialysis strategies (h(a)emodialysis or h(a)emofiltration or h(a)emodiafiltration or dialysis or biofiltration). The second set of words was related to the specific topic of the guideline paper. In the case of biocompatibility, for instance, these reference words were: (bio(in) compatibility or bio(in)compatible or h(a)emo(in) compatibility or h(a)emo(in)compatible or amyloidosis or amyloid). The two resulting databases, which usually contained several hundreds of papers, were then combined to each other with the term ‘and’ as connecting word.

The group decided not to consider matters related to dialyzer reprocessing and cost-benefit. The author then started with a first selection process, whereby irrelevant papers were excluded; e.g. papers not related to chronic hemodialysis but to PD, acute renal failure, plasma exchange, heart–lung machine, continuous dialysis strategies, liver support. Also, papers to be covered in other guidelines were excluded; for the biocompatibility guideline these were for instance papers on coagulation, dialysate quality, and vascular access. Further excluded were: papers which were neither clinical nor biochemical, case papers which did not report an original statement or finding; reports without an English abstract. Once this first selection process was finished, the authors set out to classify the papers according to their level of evidence, as: (A) randomized controlled trial or meta-analysis of several randomized controlled trials; (B) controlled trial without randomization, comparative study, correlation study, experimental study, case study; (C) expert report, opinion, or clinical experience of respected authorities. Evidence level (C) was also withheld if a given statement was obvious, but if no study or reference was available. All selected papers together with their evidence level were then classified in an Excel database, to be screened together with their abstracts by the other commissioners. To this aim, three groups of two to three commissioners were composed. All members of the group had to go through each others paper selection, to indicate whether they considered a paper relevant enough to be entered into the guidelines, and to state the evidence level which corresponded, according to them, to that paper. The final decision was based on the choice of the majority, i.e. if two of the group of three were considering a paper irrelevant, then the paper should not be introduced in the guidelines; if two of the three commissioners decided about an evidence level (B), whereas the other one preferred a level (A), even if the latter was the author of the guideline, then a level (B) was accepted. In the case of a group of two commissioners, the final decision came to the author of the guidelines. The possibility was also accepted that members of each group who were not the authors, suggested papers and/or topics to the author. In this way it was decided which papers should be entered into the guidelines, and all accepted papers were to be cited at least once. The responsible authors classified then all papers according to their content, and a critical analysis was made of the quality of the studies and of the applied methodology. This was condensed into a number of statements, which were classified according to specific general topics, and which were considered to become the backbone of the text. Based on these statements, a number of guidelines were formulated. The guidelines were to be: (i) as condensed as possible; (ii) as specific as possible; (iii) limited in number. Within this context, it was avoided to spread one single specific problem over more than one guideline.

Each guideline was accompanied by its evidence level, which was considered as the evidence level of the majority of the papers that covered this guideline. In the reference list that followed the papers, the evidence level of each cited paper was cited. This backbone text together with the guidelines was then submitted a first time to the entire group. Comments could be given first in writing, then at a common meeting where all committee members were present or, alternatively, at a common teleconference call. This critical analysis was repeated for each text at least three times. Texts, which had been finalized before 01/02/01, were submitted to a literature update at that moment. After 01/02/01 new references were only added if a paper published in the meanwhile contained essential information, but no further systematic literature searches were performed. The texts were then to be finalized within a delay of 5 months (end of June). These final drafts were then

© 2002 European Renal Association–European Dialysis and Transplant Association
submitted to the remarks of peer reviewers designated by the National Societies of Nephrology, whereby each Society had to indicate one reviewer per text. They were also reviewed by the President of the ERA-EDTA, Professor Alex Davison. This review process was concluded within 2 months, after which the texts were submitted for publication to *Nephrology Dialysis Transplantation*. 