

Editorial Review

European best practice quo vadis? From European best practice guidelines (EBPG) to European renal best practice (ERBP)

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present publication reviews the arguments based on which this decision was taken.

Summary

Although medical guidelines generally are graded according to their evidence level, low evidence ‘judgement’ are generally perceived as much as absolute truth by the medical community as high evidence ‘guidelines’ are. Being aware of this bias, a workgroup appointed by the European Renal Association–European Dialysis and Transplantation Association (ERA-EDTA), the members of which are the authors of the current publication, decided that European nephrology guidelines issued by the Association should be published only as ‘guidelines’ in the case of high-level evidence; otherwise they should be named ‘recommendations’ or ‘position statements’ and be published in a different format. Acknowledging that in nephrology, high levels of evidence are often lacking, it was also decided to rename the responsible body from European Best Practice Guidelines (EBPG) to European Renal Best Practice (ERBP). The

Guidelines and Scientific Societies

Over the past two decades clinical guidelines (CPG) have become a common element of medical practice in nephrology. Several major nephrology societies have issued and periodically updated CPGs to assist renal physicians in everyday clinical practice. The European Renal Association/European Dialysis and Transplantation Association started producing CPGs ~10 years ago. The Kidney Disease Global Outcomes Improvement (KDIGO) initiative represents the latest and most ambitious project for producing and disseminating CPGs related to various aspects of kidney diseases worldwide [1].

Various organizations, public policy makers and health-care authorities now consider evidence-based guidelines as an essential mechanism to improve healthcare. The need for CPGs has been driven by the fact that there is a wide variation in clinical practice not only in general medicine but also in almost every medical specialty or subspecialty. Systematic application of CPGs may counter such a variability and there is a consensus that the use of well-chosen, rigorously constructed CPGs represent a good option for increasing the quality of care [2].

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The production of CPGs is considered as an ethical and professional duty by several major scientific societies. In 1983 the International Society of Hypertension (ISH) became one of the first medical associations to develop CPGs that subsequently have been disseminated worldwide among specialists and general practitioners. Their quality and wide dissemination attracted the attention of the World Health Organization [3] that endorsed them and began a collaboration with them.

Guideline generation by scientific societies has, however, been criticized because of methodological flaws [4]. There have been recent concerns that certain nephrology CPGs could have been unduly influenced by particular interests of the guideline-setting committees [5]. Some experts therefore maintain that CPGs should be mainly produced by technology assessment agencies [such as the Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES) in France, the Agency for Health Care Policy and Research (AHCPR) in the USA or the National Institute for Health and Clinical Excellence (NICE) in Great Britain] rather than by speciality societies.

The quality of recommendations in clinical nephrology guidelines

Variability in nephrological practice has been documented repeatedly [6,7] and addressing this problem is perceived as a public health priority by opinion leaders and renal epidemiologists [8] alike. Developing clinical policies based on the results of rigorous clinical studies is a sound method of optimizing the translation of valuable scientific knowledge into patient care. CPG-driven medical practice has now many supporters within the medical profession, among health policy makers and health authorities. Clinical performance measures, i.e. CPG-derived indicators of clinical practice, are viewed as standards for judging the quality of clinical care and are increasingly used to provide cost-effective healthcare. Audits based on these indicators are increasingly performed at national, regional and local levels. The Dialysis Outcomes and Practice Patterns Study (DOPPS) perhaps provides the best example of how auditing a large set of clinical indicators that can ultimately provoke differences in clinical outcomes may improve renal care [9]. Various renal registries provide feedback to nephrologists on core indicators of disease severity and quality of treatment. In the USA, reimbursement is linked to the achievement of predefined quality goals and a similar system is developing in Germany. In the UK general practitioners are awarded points for their achievement of specific goals according to the quality of their detection and treatment of chronic kidney disease (CKD) and payment is received in line with the number of points obtained.

An extensive use of CPG-derived performance measures in quality improvement programmes demands, however, that the knowledge on which the recommendations are based is sound and that the nuances of the guideline statements are correctly interpreted.

Therefore, recommendations should be appropriately calibrated to reflect the strength of underlying evidence. Grading of evidence and recommendations is indeed a fun-

damental step in the formulation of clinical CPGs. In this respect, the establishment of a work group by the Kidney Diseases Improving Global Outcomes (KDIGO) initiative aiming at defining an appropriate grading system was a timely and well-considered decision. GRADE is an example of a clear, transparent and comprehensive grading system that gives explicit consideration to the benefit/harm balance and is applicable to a large range of clinical topics and types of evidence [10]. It has now been approved by several nephrology associations, including Caring for Australasians with Renal Impairment (CARI), the UK Renal Association (UKRA), the European Renal Association–European Dialysis and Transplantation Association (ERA-EDTA), the Canadian Society of Nephrology (CSN) and the Kidney Disease Outcomes Quality Initiative (K/DOQI) in the USA.

The problem of recommendation framing and the risk of recommendation drifting

As CPGs diffuse into medicine and into society at large, it is important to ponder how they are perceived by those outside the inner circle of experts, i.e. the majority of physicians, policy makers and the general public. During the past century, up until the 1990's, clinicians considered CPGs with much circumspection since they were seen as a threat to clinical freedom or even as an imposition that might disrupt rather than strengthen the quality of care. CPGs have long been tainted with the definition of 'cookbook medicine' and, in a subtler form and just in a minority of cases, this attitude still persists today [11]. After many years of resistance by doctors, the use of CPGs has now gained momentum. A number of factors have contributed to the ascendancy of clinical CPGs to the rank of an almost ideal, but sometimes too much idealized, instrument for making health care more efficient and consistent. They comprise (1) rising healthcare costs driven by an expanding demand and an ageing population; (2) variations in the quality of service delivery among public and private health care; (3) variations in the quality of service delivery among for-profit and not-for-profit healthcare providers and (4) the demand by patients and patient associations for the best care possible. Doctors increasingly use CPGs as a basis for their daily practice and patients increasingly demand the care they receive be fully consistent with clinical CPGs.

Guideline funding. Unfortunately, the production of CPGs is costly. The CPG industry offers unconditional grants for CPG activities because these are perceived as meritorious both by doctors and patient organizations, thus, producing a good return in terms of public appreciation of the funding body. This system has been perceived as a considerable source of bias [12]. Some societies have been successful in shielding specific CPG production from specific industry interests, but the reality is that in most cases, including the European Best Practice Guidelines, specific funding by industry with a clear interest in the CPG topic has existed. To improve this situation both ERA-EDTA and

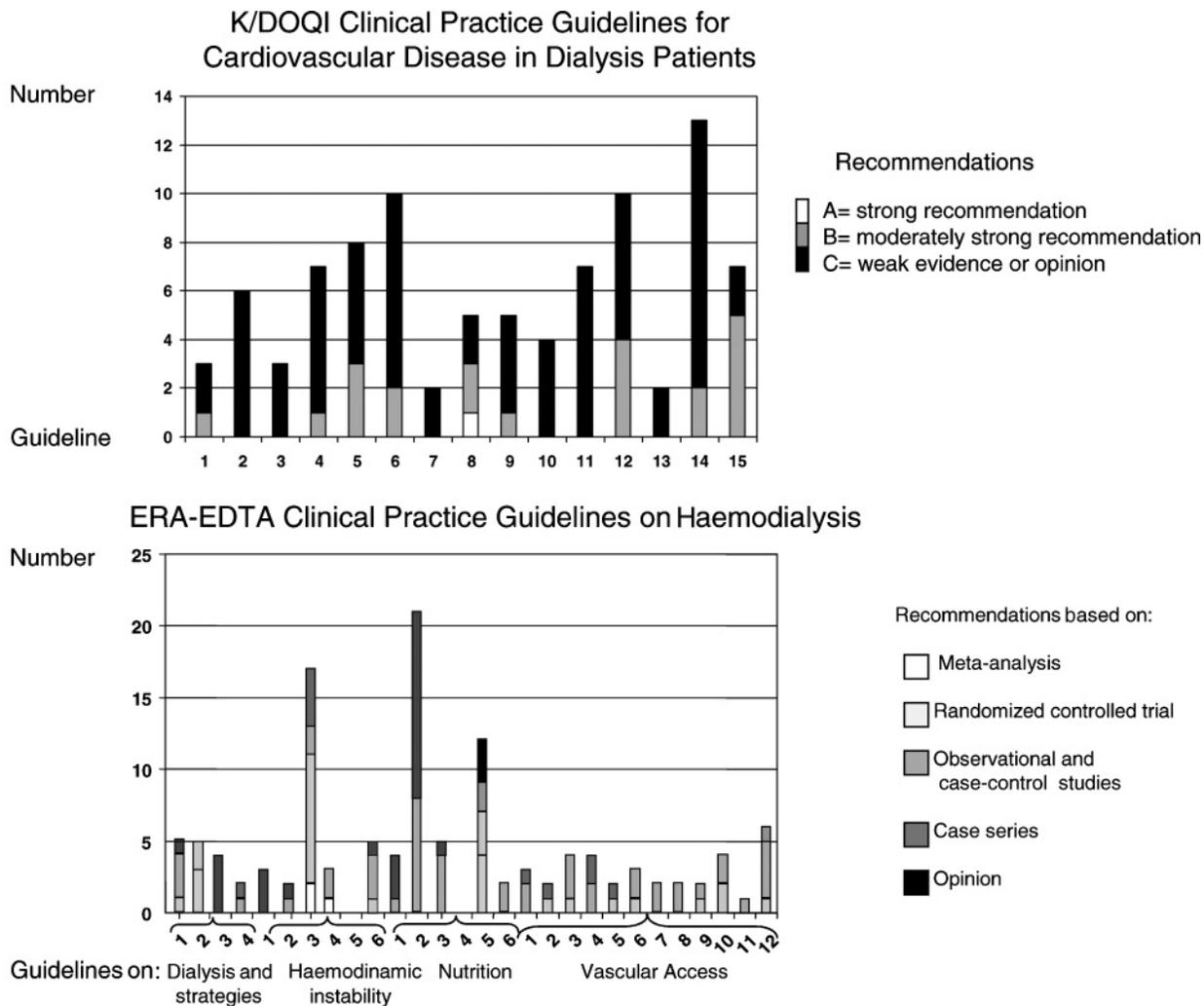


Fig. 1. Summary of strength of evidence of recommendations for the K/DOQI guidelines on cardio-vascular disease in dialysis (upper panel) and evidence base for the latest second wave European Best Practice Guidelines on Haemodialysis (lower panel).

KDIGO have recently adopted a policy that will only allow corporate funding of the guideline development initiative, avoiding in this way the sponsorship of specific guidelines by directly interested industries.

Strength of evidence. A specific concern in nephrology is the limited availability of high-quality clinical studies; for this reason, nephrological CPGs are often built on a weak evidence base. This problem is not only related to the fact that randomized controlled trials (RCTs) until recently have rarely been conducted in nephrology [13] but also because of the frequent exclusion of patients with impaired renal function from large RCTs in the general population [14]. In Figure 1 we summarize the strength of recommendations by two frequently consulted and quoted CPGs (the second wave of haemodialysis CPGs of the ERA-EDTA [15,16,17,18] and the K/DOQI CPGs on cardiovascular disease in dialysis patients [19]). Overall, both CPGs include, alongside recommendations resting on a high level of evidence, a substantial number of recommendations based on weak evidence or on judgement. Such a combined presen-

tation is a cause for concern because it may engender misunderstanding and erroneous interpretations of the strength of CPG recommendations. The appeal of junk food can be increased by presenting it together with gourmet delicacies in the same display. This effect is well known to psychologists and marketing experts. In other words, the risk exists that recommendations based on judgement rather than on evidence may surreptitiously be used to drive changes in clinical practice or to confirm consolidated practices. The process is not an innocent one and recommendations on interventions supported by weak evidence or judgement may be perceived by prescribers and users as compelling recommendations. This may eventually pose the risk of damaging public policies. The application of costly interventions based on low-quality evidence may displace limited resources that are needed for valid interventions and/or research into expensive but hardly evidenced therapeutic strategies.

In addition, in view of the high and increasing costs of large trials, almost all of the scarce studies are generated by the pharmaceutical industry with focus on new,

expensive drugs, whereas older, less costly drugs or interventions rarely are addressed by such RCTs.

On the other hand, we should realize that many aspects of everyday clinical practice, such as anticoagulation in haemodialysis by heparin or derivatives of heparin or even the haemodialysis procedure *per se*, are not evidence based and are unlikely to ever be tested in RCTs. Nevertheless, also in these areas, physicians need suggestions in order to deal with these problems, and it is especially in such controversial areas that demand from the medical society are sometimes high.

A remedy to the drifting of recommendations: evidence bordering

In early January 2008 a specially appointed ERA-EDTA work group (WG) convened in Paris to discuss European CPG planning. After 2 days of interaction and thorough discussion, the WG agreed that the Association should keep producing and updating CPGs but felt that these should focus only on clinical questions that can be answered on the basis of evidence. Nephrology is an area with a paucity of clinical trials [20]. Position statements, experts' judgement and opinion represent the lowest level of evidence; they still are valuable for the development of continuous quality improvement programmes, and there is a broad demand for guidance by many in the medical community. However, *evidence bordering*, i.e. clearly and explicitly separating statements based on evidence physically from those based on judgement and presenting them in separated documents is one possible option. For this reason, the WG agreed that the ERA-EDTA should provide guidance for clinical practice also in areas where there is lacking or weak evidence. Panellists particularly felt that a special effort should be made to appropriately recognize and emphasize the inherent limitation of giving advice in areas where there is little knowledge base. The WG has formulated the proposal that guidance based on judgement and/or very little evidence be labelled as 'ERA-EDTA position statements' and that these statements be presented in publications issued and distributed separately from true Clinical Guidelines.

To correctly describe the conceptual evolution of its mission, the WG felt that the initiative needed a new name. After considering various options, it was decided that 'European Renal Best Practice' (ERBP) is the name that most optimally conveys the aim of providing the European renal community with independent and fully transparent guidance for clinical practice. Thus, from now on, recommendations that are truly evidence based will be named Guidelines. Guidance based on weak evidence will be separately published in specific Position Statements. European Renal Best Practice is the name of the initiative that will comprise both new Guidelines (or new editions of previous guidelines) and new Position Statements. To prevent equivocation on the strength of the recommendations derived from these two forms of support to clinical practice, ERA-EDTA position statements will be constructed differently and they will be published separately from CPGs.

Furthermore, to avoid duplication of guidelines, one of the aspects stressed from the very beginning of the discussion was that this initiative would be developed in collaboration and complementarity with the global KDIGO initiative.

Conclusion

Efforts aimed at improving the quality of clinical care are a meritorious, useful activity developed by scientific societies. However, guidelines produced by these societies have entered into a critical phase. On one hand, they have gained status among policy makers, health authorities and the public in general. On the other hand, they are currently under scrutiny by experts, professionals and patients' associations because they are perceived as not sufficiently independent and, at least in some cases, as an opaque means surreptitiously addressing industrial interests. Bordering evidence-based information and recommendations from other types of information and clinical guidance may help to set the needed balance and to improve the quality of communication in such a fundamental activity by medical societies. This is the attitude that will be followed by ERBP, the body installed by the ERA-EDTA to take care of, from now on, the European guidance in the field of kidney disease.

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