Educating end-stage renal disease patients on dialysis modality selection: a clinical advice from the European Renal Best Practice (ERBP) Advisory Board

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Introduction

Creating and updating evidence-based guidelines in medicine are costly and time-consuming. For that reason, the nephrological community tried to build up a single set of international guidelines under the aegis of Kidney Disease Improving Global Outcomes (KDIGO) [1]. However, this international effort may not be correctly perceived by European nephrologists, who sometimes feel that differences in practice patterns make it difficult to apply guidelines developed outside Europe. On the other hand, the latest versions of the European Best Practice Guidelines (EBPG) may appear outdated in some respects, while not all aspects of nephrological practice are currently covered by KDIGO.

A specially appointed ERA–EDTA Work Group met in Paris to discuss a European guideline planning in early January 2008, and agreed that the Association should continue producing and updating guidelines in collaboration with KDIGO [2]. It also agreed that ERA–EDTA should issue suggestions for clinical practice in areas in which evidence is lacking or weak, which would be published as ‘clinical advice’ rather than ‘clinical guidelines’ [2].

With regard to peritoneal dialysis (PD), the European Renal Best Practice (ERBP) Advisory Board recently decided not to create new or updated guidelines, as there was not enough new evidence to produce a meaningful change in scope from the previous guidance documents published in 2005 by EBPG [3]. Instead, it was felt that advice on three important PD-related topics for everyday clinical use was needed: peritoneal membrane evaluation, modality selection and adequacy. The text on membrane evaluation is currently in press [4].

The present publication comprises the clinical advice on renal replacement therapy (RRT) modality selection for end-stage renal disease (ESRD) patients. These recommendations have been issued by an ERBP Expert Group and approved by the ERBP Advisory Board.

Four areas of interest will be discussed:
(i) Initial dialysis modality selection
(ii) Choice between continuous ambulatory PD (CAPD) and automated PD (APD)
(iii) Transition between RRT modalities
(iv) Assisted PD

1. Initial dialysis modality selection

There is insufficient evidence to support a general preference of HD over PD, or vice versa, for medical reasons. Therefore, the initial modality choice should be made primarily by the well-informed patient.

Clinical advice 1.1:

(i) As a consequence, all RRT centres should try and provide, or support in collaboration with other centres, all available treatment options: PD (including CAPD and APD), HD (including home HD and nocturnal programmes) and transplantation (including cadaveric and non-cadaveric), to make sure that all patients can select the modality that is most suitable for them.

(ii) As a consequence, all patients and their families should receive well-balanced information about the different RRT modalities, by means of a structured education programme. This also applies to late-referred patients and those starting dialysis in an emergency situation, which should receive the information once their condition has stabilized.

Most studies suggest a better survival rate in PD than in HD patients during the first few years after starting therapy.
performing PD requires a minimum of physical skills and mental capacity. It is clear that some physical problems, such as visual impairment and tremor or deformities of the hands, may interfere with PD handling. In the opinion of the ERBP Expert Group, these problems do not a priori preclude the application of PD as an RRT. Several companies and research groups have invested in the development of tools to ease handling of the PD equipment [17,18], and it is the task of the PD team to provide creative solutions to individual problems. Moreover, several centres in the world have gained experience in the so-called ‘assisted PD’ [19–21]. In this setting, it is not the patient him/herself but a nurse or another assisting person that performs the PD treatment. Assisted PD must be considered as an alternative to in-centre HD for non-autonomous patients. Even with the additional cost of the assistance, assisted PD in developed countries has been reported to be cheaper than in-centre HD [22] (for details, see ‘Assisted PD’ section below).

There are an increasing number of elderly patients starting dialysis worldwide. In Europe, in 2008, the population older than 65 years accounted for 17% of the general population [23], and can be expected to continue to grow in the future. When advising elderly patients on modality selection, the following points should be considered [24]. On one hand, elderly patients starting RRT have numerous co-morbidities at dialysis initiation [25]. Older age is frequently associated with loss of physical functions such as strength, dexterity, vision or hearing. Furthermore, elderly patients may present cognitive dysfunction at dialysis start. The initiation of dialysis can be associated with a significant decline in the functional status [26,27], and also cognitive function may deteriorate after dialysis initiation. This implies that assistance may become necessary in self-care patients during the course of their PD treatment. However, caregivers of elderly patients on PD may experience adverse effects on their own quality of life [28], which may, in turn, cause a loss of assistance. On the other hand, PD may present some advantages in the elderly patients with ESRD. Access failure rate is higher in the older HD patients [29]. Elderly patients on dialysis are exposed to arrhythmia and hypotension during the HD sessions. Quality of life is particularly relevant for the elderly patients on dialysis. Travel time to and from the HD centre has a negative impact on patient's quality of life [30,31], whereas home therapy as offered by PD is associated with a better quality of life compared with in-centre HD. In view of all the above, non-dialytic (or so-called conservative) treatment should also be discussed with the patient and his relatives. A projection of expected survival using the

 Clinical advice 1.2:

The following conditions should not be considered as contraindications to PD:

(i) Physical or mental inability to perform PD
(ii) Older age

(iii) Poor adherence/non-compliance to therapy
(iv) Obesity
(v) Congestive heart failure
(vi) Polycystic kidney disease
(vii) Diverticulosis
(viii) Abdominal hernias
(ix) Portal hypertension
(x) Liver transplantation

The only randomized controlled trial on this subject supports this idea [5]. However, after 2 or 3 years, outcome on PD becomes equal to HD, or worse [6–9], depending upon the study. These differences in outcome seem to be attributable to differences in statistical approach, patient mix and experience with the different modalities. Indeed, outcomes on RRT, both in absolute terms and in relative terms (PD vs HD), appear to be strongly influenced by country and centre experience. Based on these findings, the ERBP Expert Group suggests that the ‘PD first’ approach should be presented to the patient as the most logical choice [10]. However, it also feels that there is not enough hard evidence to consider starting with PD as compulsory. Therefore, the patient’s preference should be taken into account as the primary factor, since patient satisfaction, compliance with therapy and quality of life are better if the patient has been given the opportunity to make his/her own informed choice. Actually, in many European Countries and also at EU level, it is compulsory by law to inform patients of all treatment modalities [11,12].

There is now accumulating evidence that the outcome of patients treated in centres where only one modality is available, or where experience with alternative dialysis strategies is limited, is jeopardized [13]. This seems reasonable as it implies that, in those centres, patients are forced to the only available RRT option, or are treated suboptimally by lack of experience. All centres should make sure they provide, or at least support in collaboration with another centre, all available modalities, including home HD. Although, for obvious reasons, no data on randomized controlled trials are available on this topic, some recent well-conceived cohort studies have indicated that outcome of home (daily) HD is superior to conventional in-centre dialysis, and even equal to cadaveric transplantation, when differences in case mix are taken into account [14]. Meanwhile for logistical reasons, it may not be feasible for all centres to develop their own freestanding home HD programme, and it is strongly advised that centres organize such a programme jointly. In such an agreement, care should be taken for a fair distribution of duties and benefits between centres, to avoid eventual economical bias hampering free patient selection for home HD.

Also, the option of renal transplantation, both cadaveric and non-cadaveric, should be discussed with the medically suitable patients, as the outcomes of those patients appear to be better after transplantation as compared to standard haemodialysis [15]. However, for the elderly and for patients with multiple co-morbidities, this benefit is less clear [16]. It should also not be neglected that there is shortage of organs, and that it might be preferable, from a socio-ethical viewpoint, to allocate organs to those patients who are expected to benefit the most from kidney transplantation.

(i) Physical or mental inability to perform PD
(ii) Older age
algorithm developed by Couchoud et al. [32] can be of help to visualize the concept and consequences of dialytic versus non-dialytic treatment. The ERBP Expert Group also endorses the active use of advanced care directions, especially in the frail and elderly patients.

Presumed or real non-adherence to the prescribed PD regimen can be a challenge to the PD team. Nevertheless, it is unlikely that non-adherent PD patients will become compliant HD patients. It is important for the caregiver, particularly if there is a sudden change in adherence of the patient, to try and find out why this happened. It is especially important to find out whether the non-compliance is related to the PD therapy itself or whether it is a general attitude of the patient. In some cases, the cause of non-compliance is a condition that requires attention from the caregiver, such as denial of disease, depression, social problems (like divorce or death of a beloved person), intercurrent illness and cognitive deterioration. Some of these conditions are only temporary and/or can be treated adequately. Some of the adherence problems may be solved by the implementation of assisted PD [21].

There is currently not enough evidence to contraindicate PD to obese individuals. However, several comments on this issue are necessary. Obese patients, especially if diabetic, were shown to have increased risk of death after starting on PD compared to HD [33,34]; however, such evidence is scarce. Furthermore, most studies in PD patients have found similar (if not better) survival in those who are obese versus those with normal body mass index [35,36]. Obese patients may need larger dialysate volumes, usually provided by APD, to achieve adequate Kt/V, although the increase in body mass is not associated with a proportional increase in body water volume [37–39]. However, PD may not be the preferred dialysis modality or is relatively contraindicated in patients with morbid obesity [39,40], in which there may be difficulties in peritoneal catheter placement and tunnel healing process, increased risk of pericatheter leak and infection, possible further weight gain due to increased caloric absorption from the dialysate, as well as risk for abdominal pain or discomfort, and aggravation of dyspnoea, gastro-oesophageal reflux, abdominal hernias or vertebral disease, because of increased intra-abdominal volume and pressure [38,39]. Use of icodextrin solution may be considered for obese patients as the body weight and fat mass in prospective studies have been shown to be relative stable in patients using one exchange of icodextrin-based solution, compared to patients using glucose-based solutions only [41–43].

Congestive heart failure (CHF) is increasingly common in patients with ESRD. It is often associated with low blood pressure, in spite of fluid overload, and it is one of the frequent causes of haemodynamic instability during ultrafiltration to dry weight in HD patients. As such, PD, with its more subtle and gentle capacity for ultrafiltration, might be a better and more comfortable alternative. The only large registry study comparing the outcome of patients with CHF on PD vs HD was undertaken in the USA and found a higher mortality risk in PD patients [7]. However, according to the ERBP Expert Group, the results of this study cannot be extrapolated to European patients, because of the different case mix and characteristics of the US population, and since no icodextrin was available to help maintain fluid balance in PD patients. In addition, and maybe even more important, that study had a methodological bias as it included only prevalent patients who survived the first 90 days on dialysis, a strategy possibly inducing lead time bias in favour of HD. In addition, potential selection bias could not be accounted for in this study. Many single-centre reports indicate that PD can improve quality of life and New York Heart Association (NYHA) classification in patients with CHF [44–46]. Based on the existing information, it is difficult to either support or discard PD as a method of choice in CHF patients. One particular subgroup, however, could be that of anuric PD patients with CHF, in which maintaining adequate dry weight is quite difficult. Furthermore, clinically unapparent overhydration could be present and significant for the diminished cardiac reserve, and use of additional objective measures for dry weight assessment (like bioimpedance, biomarkers or imagistic tools) is recommended. Careful patient monitoring, control of water and salt intake, efforts to preserve peritoneal and renal function and, in many cases, use of APD and icodextrin-based PD solutions are critical for the management of these patients [47]. However, if maintaining correct dry weight is still impossible to achieve, patients should be promptly transferred to HD, preferably using slow-ultrafiltration, long-hours techniques. The ERBP group acknowledges that this is an important area for future research, in view of the increasing frequency of these conditions, and the lack of well-conceived trials on this topic.

2. Choice between CAPD and APD

Clinical advice 2.1:

There is as such no reason to prefer CAPD or APD, as long as the dwell time of the patient is matched to his/her peritoneal transport type. As outcomes on both modalities have been found to be equal, choice should be guided by patient preference.

Several studies [48–50] have observed that outcomes on CAPD and APD are equal. However, it is important to maintain the appropriate dwell time for the appropriate patient: short dwells for fast transporters, to avoid glucose absorption and negative ultrafiltration, and long dwells for slow transporters, to avoid sodium sieving [4]. Failing to do so might lead to fluid overload and inadequate solute removal. It is conceivable that short dwells can more easily be obtained with the use of a cycler, whereas long dwells seem to be more appropriate for CAPD. As a consequence, it is not surprising to see that outcome of fast transporters has been reported to be superior on APD, whereas outcome of slow transporters was better on CAPD [51]. It should be stressed, however, that, even with CAPD, short dwells can be performed, and the APD treatment can be expanded with an extra day exchange to achieve longer dwell times. PD teams should try to accommodate the patient’s lifestyle issues with the underlying membrane char-
acteristics, using the complete available armamentarium, their experience and creativity.

3. Transition between modalities

While the first two sections of this publication deal with the choice of RRT modality when a patient approaches ESRD, the present item focuses on transition from one modality to another once the procurement of maintenance RRT has been started. Three types of transition should be considered: HD to PD, PD to HD, and failed renal transplantation to either HD or PD.

One single modality may not procure adequate treatment over an entire lifespan; therefore, nephrologists sometimes have to recommend switching modalities during the clinical course of ESRD patients. At any moment, the consequences of each decision should be evaluated, to estimate benefits or threats not only in the short term, but also in the long term. Patients with chronic kidney disease should be informed, before the start of their RRT, about the possibility of being switched to an alternative modality later on during the course of their RRT. For that reason, unless there are absolute contraindications for a particular modality, pre-dialysis information provided to patients should cover all possible therapies, without marking options as ‘impossible’ or ‘bad’.

In the opinion of the ERBP Work Group, the patient’s informed choice of treatment modality should be respected, as long as his/her clinical conditions allow doing so. If a chosen RRT modality later becomes inadequate, transition to another therapy should be proposed, and the underlying reasoning should be explained to the patient. Even in these circumstances, the choice of the well-informed patient should be respected. When patients decide not to follow medical advice, despite obvious treatment failure, it should be recorded that the change in treatment has been recommended without success. The latter situation cannot be considered as inappropriate adherence to the original modality by the treating physician.

3.1. Transition from HD to PD

In what follows, the ERBP Work Group describes some conditions where the option of PD should be explained to the patient as a potential alternative for HD, as this treatment might be for some reason suboptimal.

Clinical advice 3.1:

Patients on HD should be informed about the option of PD when they suffer from any of the following clinical conditions:

(i) Incapacity to maintain fluid balance
(ii) Relapsing or persistent peritonitis
(iii) Incapacity to control uraemic symptoms or to maintain a good nutritional state
(iv) Changes in lifestyle circumstances
(v) Declining residual renal function
(vi) Intra-abdominal surgery
(vii) Sclerosing peritonitis

The rationale for considering PD in case of irremediable haemodynamic intolerance of HD or incapacitating muscle cramps is obvious [52–57]. In contrast to HD, PD is a continuous therapy that is not characterized by large volume shifts or sudden changes in serum electrolytes like potassium or calcium. Alternatively, short daily or nocturnal HD, preferably performed at home, may also be considered, in order to improve haemodynamic stability.

Pre-dialysis counselling should include the information to the patient on the importance of vascular access for HD, the need for preservation of arm veins for placement of vascular access and the notion that starting with PD is a means of preserving the vascular potential. In HD patients, where creation of a well-functioning native vascular access is not possible, PD should be proposed as a better alternative than the use of permanent central vein catheters, which are associated with substantial morbidity and mortality. Infection risk on PD is comparable to that of HD patients with a native fistula, whereas the infection risk of a tunnelled HD catheter is twice as high.

Ascites may be due to heart failure, hepatic failure or peritoneal metastases. While ultrafiltration during HD may be able to remove fluid from the body and sometimes alleviate the abdominal distension due to ascites, it will often fail to do so. PD may be a better alternative, since fluid can be evacuated through the PD catheter [58,59]. The theoretical concerns of excessive loss of albumin or higher infectious risk seem clinically irrelevant [59].

It has been demonstrated that the outcome of patients transferred from HD is similar to that achieved in patients who are kept on PD from the start of RRT on [60].

3.2. Transition from PD to HD

Clinical advice 3.2:

Patients on PD should be informed about the option of HD when they suffer from any of the following clinical conditions:

(i) Incapacity to maintain fluid balance
(ii) Relapsing or persistent peritonitis
(iii) Incapacity to control uraemic symptoms or to maintain a good nutritional state
(iv) Changes in lifestyle circumstances
(v) Declining residual renal function
(vi) Intra-abdominal surgery
(vii) Sclerosing peritonitis

Euvolaemia is an important predictor of outcome in PD patients [61–63]. Volume overload is related to cardiac dysfunction [64,65] and mortality [66]. Guidance on how to achieve and maintain euvolaemia in individual PD patients is hampered by two factors: (i) the absence of a convenient and accurate device with which to measure volume status; (ii) lack of insight in the prevalence of and factors associated with volume overload. Volume overload in PD can have several causes, which can be
even present together in the same patient at the same time. The most common causes are inadequate dietary intake of salt and/or water, and ultrafiltration failure. Enhanced peritoneal transport via small pores with rapid dissipation of the osmotic gradient (fast-transporter status) is a common cause, which can be readily diagnosed by performing a validated membrane permeability test, and therapy can be adapted accordingly, as described in the EBPG guidelines on this issue [67]. Other causes of ultrafiltration failure, such as decreased osmotic conductance, enhanced fluid absorption or increased intra-abdominal pressure can be diagnosed by studying sodium sieving, disappearance rate of dextrans from the peritoneal cavity, or intra-abdominal pressure measurement, respectively [68].

Most episodes of peritonitis, exit-site infection or tunnel infection can be treated successfully with intraperitoneal antibiotics and should not be a reason to transfer patients to HD. There are some exceptions to this general rule, however. Exit-site or tunnel infections progressing to or accompanied by peritonitis (i.e. catheter-related peritonitis) with the same organism often require catheter removal. Refractory peritonitis (defined as failure to clear the peritoneal effluent from infectious organisms after more than 5 days of appropriate antibiotics) and relapsing peritonitis (defined as a new peritonitis episode with same organism within 4 weeks from the previous episode) commonly require catheter removal in order to resolve the problems. Also, catheter removal is needed in fungal peritonitis and in unresponsive cases of peritonitis with mycobacteria or multiple enteric microorganisms [69]. Catheter removal in these cases requires a period of peritoneal rest before insertion of a new catheter (2 weeks at least, 6 weeks in case of mycobacterial peritonitis). This, of course, requires temporary transition to HD, unless residual renal function is still satisfactory. Peritoneal adhesions or changes in membrane characteristics may be a consequence of persistent peritonitis and impede further continuation of PD. Since it is difficult to predict their occurrence and implications, the ERBP Work Group feels that insertion of a new PD catheter and resuming PD treatment should be considered if the patient desires to stay on PD. It should also be kept in mind that persisting or relapsing peritonitis could be a hallmark of poor peritoneal membrane condition, making maintenance of PD risky. Patients should be warned that, in these circumstances, successful PD continuation is uncertain, and that transfer to HD might still be needed some time later [70]. Reinsertion of a new catheter should preferably be done under laparoscopy, in order to visualize and—if necessary—treat adhesions.

The importance of residual renal function (RRF) as a determinant of PD patients’ outcome has been demonstrated by numerous studies [71–73]. The PD community started focusing on this finding since some of the larger trials on PD adequacy failed to show further improvement of outcome by increasing peritoneal small solute clearances [74,75]. The benefits of RRF have been attributed to its role in the maintenance of fluid balance, its association with lower inflammation and better nutritional status, its endocrine functions (erythropoietin production and alpha-hydroxylation of vitamin D) and its contribution to the removal of toxic substances [76–82]. Based on these data, some have argued that PD patients should be switched to HD in case of a complete loss of RRF; however, it is quite likely that, also in HD patients, RRF is an important predictor of outcome. In addition, several observational studies have demonstrated that PD in anuric patients is feasible, with acceptable outcomes [61,75,83]. Special attention has to be paid, however, to the volume status of these patients. Given the importance of RRF for outcome, maximum efforts should be done to preserve it, by avoiding nephrotoxic insults. The use of angiotensin-converting enzyme (ACE) inhibitors [84] and angiotensin receptor blockers [85] has been shown to have a protective impact on RRF.

Surgical procedures can disturb the integrity of the peritoneal membrane, leading to leakage or insufficient remaining surface area. However, some surgical procedures (e.g. nephrectomy or removal of a non-functional renal graft) can be performed without disrupting the peritoneal membrane. It is recommended to inform the surgeons about the importance of preserving peritoneal membrane integrity, and to carefully consider surgical indications to avoid iatrogenic disruption of the peritoneal membrane.

Some nephrologists advocate ‘pre-emptive’ switching of PD patients to HD after 2 or 3 years from PD start, even when every aspect of the treatment is going well. This recommendation is based on the findings that, after a few years, outcome on PD starts to get worse than on HD [6–9], and on the concepts that PD may become inadequate with declining RRF and/or that the incidence of sclerosing peritonitis starts to rise with time spent on PD. The ERBP Expert Group endorses here the recommendation of the International Society for Peritoneal Dialysis that time on PD alone should not be a decisive factor in itself for transferring patients from PD to HD [86]. However, with an increasing vintage on PD, physicians should be increasingly aware of the potential pitfalls of the technique, and discuss these and the possible alternatives with the patient.

3.3. Choice of dialysis modality for patients with failed renal transplantation

Clinical advice 3.3:

In patients with failed renal transplantation who return to dialysis, there is no proven difference in survival between HD and PD. Therefore, the choice of dialysis modality for these patients should be based on the same principles as those applying to the initial modality choice.

There is little data available on the impact of dialysis modality on the outcome of patients with failed kidney transplant. However, PD seems to be underused in this setting, for several probable reasons: (i) in most dialysis centres, HD is predominant over PD; (ii) the start of dialysis in emergency situations also favours HD; (iii) the fear of increased peritonitis rate or of rapid loss of RRF in patients transferred to PD [87].
Assisted PD can be defined as a PD modality performed at the patient’s home with the assistance of a health-care technician, a community nurse, a family member or a partner. Additional funding is necessary when patients are assisted by a nurse or by a health-care assistant. Therefore, when using the term ‘assisted PD’, information regarding the type of assistance must be provided. There are two modalities of assisted PD: assisted APD and assisted CAPD. Assisted PD must be considered as an alternative to in-centre HD for non-autonomous patients.

4.2. The assisted PD programme

Even with the additional cost of the assistance, assisted PD in developed countries is reported to be cheaper than in-centre HD [22], although costs may vary between countries. Assisted PD enables nephrologists to increase the use of PD in incident dialysis patients [93]. Community-based nurses must be trained by nurses from the PD centre to perform the connection and the exit-site dressing, and to set up the cycler in case of assisted APD. A 24-h ‘hot line’ to provide medical or nursing counselling to those involved in the patient’s care is needed. The PD centre must deal with organizing the patient follow-up in the PD clinic and hospitalization in the nephrology unit whenever necessary. For assisted APD, only two interventions at the patient’s home are necessary [94,95], whereas patients on assisted CAPD need four visits daily. In countries where assisted PD is fully covered by the health-care insurance, most of the patients on assisted PD are treated by assisted CAPD [96,97]; patients’ cognitive dysfunction and/or anxiety linked to the cycler therapy may explain this preference. In order to decrease the time spent by nurses at the patient’s home, a non-disconnectable device with ultraviolet flash can be used. Patients on assisted PD must be reassessed regularly to see whether or not they have become competent to perform self-care PD. For patients on assisted APD, family assistance is associated with a lower peritonitis risks compared with nurse assistance [98]. However, the results are equivalent when centres send one of their PD nurses for a visit at the patient’s home on a regular basis; this emphasizes the fact that nurses in charge of assisted PD patients must be trained and re-trained by the nurses from the PD centre. In elderly patients, assisted CAPD is not associated with greater peritonitis risk compared with the family-assisted CAPD [99].

4.3. Indications of assisted PD

Nurse- or health-care technician-assisted PD is indicated for ESRD patients who choose PD as RRT modality or in whom HD is contraindicated, who have no contraindication to PD, but are incapable to perform PD exchanges by themselves, and whose family members’ quality of life is affected by the burden of caregiving.

Assisted PD can be indicated in incident dialysis patients or in previously self-care PD patients who have lost their autonomy.

4.4. Assisted PD for the unplanned dialysis starter

The unplanned dialysis starter can be defined as a patient who starts dialysis without any vascular access or PD catheter. These patients usually start HD through a venous catheter. Recently, strategies to use PD for unplanned dialysis starters were implemented [21,100,101]. Assisted PD can be used for a short period of time pending patient education [21,101].

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Disclaimer. The present text is based upon the information available to the work group at the moment of the preparation of this publication. It has been designed to provide information and assist decision making, but is not intended to define a standard of care or to improve an exclusive course of diagnosis, prevention or treatment. Individual decision making is essential in the approach to any disease. Variations in practice are inevitable when physicians take into account individual patient needs, available resources, and limitations specific for a geographic area, country, institution or type of practice. In addition, evidence may change over time.
as new information becomes available, so that practice may be modified subsequently. Every practitioner using this text is responsible for its application to any particular clinical situation. The work group members involved in the development of the present text have disclosed all actual and potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional or business interest. The results presented in this paper have not been published previously in whole or part.

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