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## EQ-5D in dialysis units: a PROM with a view

(EQ-5D dans les unités de dialyse : un PROM avec une vue d'ensemble)

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### Summary

Chronic kidney disease (CKD) is a silent worldwide epidemic responsible for a high clinical and socioeconomic burden. Beyond disease-related outcomes, there is an urgent need for clinicians to focus on implementation of validated patient-reported outcome measures (PROMs) in routine care practice. This updated concept of high-quality renal care implies a changing paradigm, with a focus on patient experiences and health-related quality of life (HRQL) measures. This is even more crucial in end-stage renal disease, where adequate dialysis should aim at a multidimensional approach instead of only analytical targets. It is vital to emphasize interventions that positively affect the quality of life of the patient with CKD beyond improving their survival. Although the importance of using HRQL measures is well established, there has been resistance to their use in routine care. There are numerous tools to assess HRQL, but not all are easy to apply. It is essential to overcome these possible barriers and better adequate the HRQL tools to the patients. The shorter and simpler instruments are more appealing, as well as the electronic health questionnaires. The EuroQol-5 Dimensions tool (EQ5D) is a standardized measure of health status, is simple and quick, and provides information that can be used in economic assessments of healthcare. In this era of limited health resources, cost analysis and economic evaluations are becoming increasingly relevant. In dialysis units, sustainability management should include a pathway of integrated care, including home and center dialysis, that values the better adjustment of prescriptions to the individual patient. The authors advocate using the EQ5D to support this pathway of quality in dialysis units toward global health gains. The EQ5D is a PROM with a view centered on patient and sustainable health services.

Key words : CKD,PROM,EQ5D,HRQL, quality of life, dialysis

### Résumé

L'insuffisance rénale chronique (IRC) est une épidémie mondiale silencieuse, responsable d'un lourd fardeau clinique et socio-économique. Au-delà des résultats liés à la maladie, il est urgent que les cliniciens se concentrent sur la mise en œuvre de mesures validées des résultats rapportés par les patients (PROM) dans la pratique des soins de routine. Ce concept actualisé de soins rénaux de haute qualité implique un changement de paradigme, l'accent étant mis sur les expériences des patients et les mesures de la qualité de vie liée à la santé (QVLS). Ceci est encore plus crucial dans l'insuffisance rénale terminale, où une dialyse adéquate doit viser une approche multidimensionnelle au lieu de se limiter à des objectifs analytiques. Il est essentiel de mettre l'accent sur les interventions qui ont un effet positif sur la qualité de vie des patients atteints d'IRC, au-delà de l'amélioration de leur survie. Bien que l'importance de l'utilisation des mesures de la QVLS soit bien établie, il y a eu une résistance à leur utilisation dans les soins de routine. Il existe de nombreux outils pour évaluer la QVLS, mais tous ne sont pas faciles à appliquer. Il est essentiel de surmonter ces barrières et de mieux adapter les outils QVLS aux patients. Les instruments plus courts et plus simples sont plus attrayants, de même que les questionnaires de santé électroniques. L'outil EuroQol-5 Dimensions (EQ5D) est une mesure standardisée de l'état de santé, simple et rapide, et fournit des informations qui peuvent être utilisées dans les évaluations économiques des soins de santé. Dans les unités de dialyse, la gestion de la durabilité devrait inclure un parcours de soins intégrés, incluant la dialyse à domicile et en centre, qui valorise une meilleure adaptation des prescriptions à chaque patient. Les auteurs préconisent l'utilisation de l'EQ5D pour soutenir ce parcours de qualité dans les unités de dialyse vers des gains de santé globale. L'EQ5D est un PROM dont la vision est centrée sur le patient et des services de santé durables.

Mots clés : IRC, PROM, EQ5D, qualité de vie, QVLS, Dialyse

## UPDATE CONCEPT OF QUALITY IN DIALYSIS UNITS

Globally, an estimated 5-10 million people die every year from chronic kidney disease (CKD) in the world and this silent epidemic, with high clinical and socioeconomic burden needs awareness and plan of actions (1). There has been an effort from the European Kidney Health Alliance to promote innovation and complementary tools in kidney replacement therapy, especially in home-dialysis treatments, to increase patient's autonomy and empowerment (2). However, a paradigm shift will not be possible without policy measures. In Portugal, the incidence and prevalence of CKD have been increasing steadily to the point that it is the second European country with the highest incidence of renal replacement therapy (1, 3, 4). This irreversible illness progressively erodes the patients' health and quality of life (QoL) and it is essential to identify and address patient priorities, values and goals. Ensuring that renal patients have the opportunity to discuss their preferences and have a positive experience of care is vital in a high-quality service (5). Unfortunately, quality statements on patient experience are not usually included in topic-specific quality standards.

Quality parameters in dialysis units are mainly focused on serum levels of hemoglobin, phosphate, Kt/V urea, etc., which are clinically relevant, and should be kept under scrutiny, but lag behind the goals of patient rehabilitation in chronic treatments.

An update concept of adequate dialysis implies a changing paradigm, with focus on patient experiences, and health related quality of life measures (HRQL) in the circuit of CKD, beyond analytical targets. These dimensions of adequacy are increasingly prioritized by the patients and should be taken into account by clinicians and stake holders (6, 7).

Although in the last decade there has been an increasing awareness of patient-centered outcomes and patient-centered wellness, it is urgent to focus on the development and implementation of validated patient-reported outcome measures (PROMs) in routine care to achieve the ultimate goal of living well with kidney disease. Some countries are currently trying to integrate PROMs in daily routine care, like the Edmonton Symptom Assessment System Revised, in Canada (8) or even in France where the French Society of Nephrology, Dialysis and Transplant recommended the use of EQ5D and 12-Item Short Form Health Survey for outcome measures and e-Satis national public system for measuring patient satisfaction (9, 10).

## HRQL MEASURES AND EQ5D

Better QoL is the ultimate goal of treatments and the methods of its measurement have evolved, not only in the clinical field, but also in research and health policy. HRQL measures are commonly used in clinical trials, as it provides useful information for healthcare providers about the added value of a certain treatment. In routine care, we frequently aim for laboratory results to evaluate the effectiveness of our treatment. However, measuring HRQL provides a multi-dimensional (physical, psychological, functional, and social) perspective of patient health status and gives us the real efficiency of the current treatment. This is especially important in chronic diseases, where it is expected that prolonged treatments will have a more impact on the patient's QoL. Besides, the association between lower HRQL and hard outcomes is well-documented. As reported by the Dialysis Outcomes and Practice Patterns Study (DOPPS) study, HRQL is strongly associated

with higher risk of death and hospitalization in dialysis patients, even when considering serum albumin concentration and other risk factors (11). In addition, treatment adherence may also be negatively influenced by a lower HRQL (12).

Several studies of HRQL have been conducted in CKD patients and all showed a poorer QoL when compared to general population (13-15). Moreover, dialysis is associated with a significant decrement in QoL compared to kidney transplantation (16). Regarding different dialysis techniques, the studies comparing HRQL are not unanimous. Some reported that peritoneal dialysis (PD) seems superior to hemodialysis (HD) when considering occupational status, patient satisfaction, and dialysis staff encouragement (17,18); other studies showed no statistically significant differences (19). Nevertheless, a 2020 systematic review and meta-analysis reported better results for PD regarding generic HRQL and even for specific subdomains such physical functioning, limitations due to emotional problems and burden of kidney disease (20).. Interestingly, a study focused on utility-based QoL found that HD had a clinically lower mean utility estimate than PD (21). Within PD patients on automated peritoneal dialysis seem to have a significantly higher mean utility than those on continuous ambulatory peritoneal dialysis (16). These results provide evidence-based utility that could be applied in economic evaluations of renal replacement therapies, useful for policy makers and in individual treatment discussions with CKD patients.

Currently, there are numerous tools to assess HRQL, some are generic like the Karnofsky Index (22) or EQ5D (23); and other are more specific to CKD patients: Kidney Disease Quality of Life Instrument -SF (24,25) or the Kidney Disease Questionnaire (26). Although these are more focused on the CKD population, they could be complex and time-consuming to apply in routine care. Most importantly, we should consider instruments that can be used to inform economic evaluations in healthcare interventions. This is one of the benefits of EQ5D since it facilitates the calculation of quality-adjusted life years (QALY).

The EQ5D is a standardized measure of health status developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic appraisal (27). It is easy and quick to apply compared with other generic tools (28) and it has been used in ESRD patients in different countries (29-30). This instrument consists in a descriptive system questionnaire and a visual analogue scale. It has five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression; and five response levels: no problems, slight problems, moderate problems, severe problems, and unable to /extreme problems. The descriptive system can be represented by a single number (index value) which reflects how good or bad a health state is according to the preferences of the general population. These values can be used to compute QALY in economic evaluations of healthcare.

In the healthcare sector we are constantly confronted with decisions about allocation of resources. Given the limited health resources, cost-utility analysis is increasingly used to inform decisions on whether to adopt new, but expensive health-care interventions (31). HRQL measures allow the generation quality-of-life weights and the calculation of the QALY used in these cost-utility analysis (32). The QALY is a measure that incorporate not only the mortality (gain in quantity of years), but also the morbidity (gain in QoL). If a treatment helps lengthen life or improve QoL, these benefits are comprehensively summed up to calculate how many additional QALY the treatment provides (33).

Of the many HRQL tools available, the EQ5D (34) and the Short Form 6-dimension (SF-6D) (35) are the most widely used. Both have been used in patients ESRD, but as reported by Yang et al, the EQ5D seems to have a more favourable cost-effectiveness profile, leading to more attractive incremental cost-effectiveness ratios when compared to SF-6D (36). Its routine use should occur in stable and ambulatory condition to minimize the confounding bias of acute settings and inter-current acute events. On the other hand, the impact of previous hospital admissions or adverse events on the EQ5D should be explored and evidenced. It is an opportunity of clinically relevant investigation.

In our experience the EQ5D was a very practical tool to use in the PD unit. We conducted a cross-sectional observational study to evaluate the HRQL in our prevalent PD patients and used the EQ-5D-5L questionnaire in a routine hospital visit. A total of 70 PD patients (52.9% male; mean age 55.9 years) were included. Patients with a longer period of PD dialysis had lower EQ5D-index values (i.e., a worse health state). On the other hand, a better nutritional status (higher normalized protein catabolic rate and higher albumin) was associated with a patient perspective of better overall health. Our results are in line with most studies of HRQL, where the main factors of poor HRQL are associated with older age, longer time in dialysis and malnutrition (37). Interestingly, higher dialysis adequacy was not associated with better HRQL. In fact, there is not a proven relation between higher Kt/V and better QoL. This motivated our current project of a prospective evaluation to disguise the triggers of lower HRQL score, whether they are medical complications or psycho-social reasons. We believe that the assessment of HRQL could have an impact on our clinical practice and our treatment decisions. It helps to determine the burden of CKD, but also provides valuable new insights into the relationships between HRQL and risk factors. Facing the high prevalence of aged and illiterate population, and the lack of resources in dialysis units, a simple tool such as the EQ5D is attractive. The use of its index values makes it possible to assess the intrapersonal variability of the patient over time on dialysis. A sustained reduction in the patient's quality of life alerts the nephrologist to a more detailed assessment of factors associated with worse QoL (nutritional status, anemia, socio-psychologic situation). In some cases, the treatment (hemodialysis, peritoneal dialysis) could no longer adequate to patient's life and the burden of the treatment could ultimately support technique transition.

Nevertheless, barriers to introduce this quality measure as patient-reported outcomes should be anticipated. One of the main barriers pointed out in the use of HRQL measures is the time required for their application, as well as the patient's ability to understand. In these cases, family and carriers may be involved in evaluation of the disease experience. The shorter and simple instruments can be easier to apply and less time consuming. There is also a growing interest for electronic health (eHealth) tools (38) and patients generally found these more convenient and useful in improving communication with health care providers (39). The EQ5D is an example of HRQL tool with a digital version and available in numerous languages.

The other challenge for the healthcare professionals is how to clinically use data obtained from measurements of HRQL. Some therapy interventions may improve patient QoL while others not. For instance, in the ADEMEX trial improving small molecule clearances in chronic PD patients did not result in an improvement in HRQL scores (40). In fact, evidence-based interventions that positively affect the QoL of CKD patients are still scarce. On the other hand, studies of relationship between anemia and HRQL seem to conclude that erythropoietin therapy resulted in significant improvement in various HRQL domains (41). Multiple comorbidities (diabetes,

vascular disease, congestive heart failure, obesity) are also associated with lower HRQL (42). A better control of cardiovascular factors and the prevention of these diseases is also a way to assuring better QoL for CKD patients. In dialysis, malnutrition has been pointed out was determinant factor of poor HRQL (29, 42). To mitigate this problem, the integration of nutritionists in the dialysis units is crucial. We should focus on interventions that positively affect the QoL of the patient with CKD, beyond improving their survival.

### EQ5D AND DIALYSIS SUSTAINABILITY

Dialysis offer is grounded on its high economic burden justified by its social value as a life-saving therapy, and the influence of reimbursement Policies on Dialysis Modality Distribution is acknowledged (43, 44). To make adequate investment decisions in Health, it is crucial to make cost-utility analysis. We aim to apply in CKD management the approach of value-based health-care already used in oncology field, for example: if a treatment is more expensive but has a higher cost-utility in terms of HRQL and QALY this supports the decision to invest with innovative therapies and/or allocation of resources. Consequently, the investment permits a further accessibility of innovation and individualization to a larger number of patients. In dialysis port-folium such approach would support a higher use of home dialysis.

Regimens of bundled payment in dialysis units in Portugal (reimbursed for the comprehensive treatment provided to patients) implied to fulfil a list of quality parameters, resulting in health gains. However, such fixed payment model did not evolve with the current quality standards and the need for higher harmonization of modalities of renal replacement therapies, with more use of home therapies. The present model also overlooked important dimensions of adequacy that science showed to be obligatory in CKD management such as: the quality of transition process to dialysis, quality of the dialysis access, patient-related outcomes, and QoL. Pain management, in elderly dialyzed patients, may be as important or even more important than a KT/V urea strict target. So EQ5D is not substitutive but complementary in a panel of adequacy targets.

On the other hand a modality that offers better outcomes, as measured by EQ5D, deserves strategic investment. It is a pathway of value-based health care and reimbursement. A sustainability management should include a pathway of integrated care in dialysis units, including home and center dialysis, that values the better adjustment of prescription to the individual patient, protecting his life journey.

The authors advocate to use EQ5D to support this pathway of Quality in Dialysis Units towards global health gains. Therefore, the chosen title is justified. We need to include a PROM such as EQ5D in order to make better allocation of resources in dialysis units. In this way EQ5D is a PROM with a view centred on patient and sustainable health services.

In summary, assessing HRQL in patients with CKD is increasingly useful and it is a challenge that needs to be address by the nephrologist and all the stakeholders. The incorporation of EQ5D as a HRQL measure in our clinical practice will provide a better consciousness about the interventions that have a positive impact on QoL.

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#### **Ethical approval**

This is a systematic review so none.

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