

Electronic Patient-Reported Outcomes in Hemodialysis

Subjects: **Others**

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The success of hemodialysis (HD) treatments has been evaluated using objective measures of analytical parameters, or machine-measured parameters, despite having available validated instruments that assess patient perspective. Patient-reported outcomes (PROMs) and patient-reported experience measures (PREMs) collectively referred to as PROs (patient-related outcomes). Electronic patient-reported outcomes (ePROs) encompass the use of digital technology to provide answers to standardized PRO questionnaires.

hemodialysis

ePRO

PROMs

PREMs

1. Patient-Related Outcomes (PROs) (PROMs and PREMs)

PROMs are self-report tools used to obtain assessments of health benefits, illness or medical treatment from the patient's perspective in the form of a quality-of-life questionnaire or symptom questionnaire. In clinical practice, they have the potential to highlight relevant symptoms and symptom changes and to promote patient participation in their treatment. Their approach is strictly individualized and can only be used to improve outcomes specifically for that patient [1][2].

PREMs incorporate information about the patient's experience of care as perceived by the patient. In routine clinical practice, they provide useful information about care management that can be used to improve the quality of clinical services in general, which will be of common benefit to all patients [1][2][3].

PROs (PROMs and PREMs), unlike anamneses, are provided directly by the patient and are not interpreted by healthcare professionals [1]. PROs allow us to determine whether our actions and treatment decisions improve the outcomes that matter most to patients and to enhance their experiences.

The routine use in clinical practice of PRO data increase quality of care. However, they may have no impact on the process or outcomes of patient care, which may be related to the lack of knowledge about the appropriate use of PROs and their application in different settings, especially in nephrology. Since they pose a burden on the patient, if they are not used for decision making, they may lose the justification for performing them. This knowledge is necessary to develop strategies to guide the optimal use of PRO data [2].

In recent decades, drug regulatory authorities are paying more attention to PROMs data when making decisions on new drug approvals [4]. Even in the development of medical devices, the importance of PROMs is also beginning to

be recognized, and evidence of this is that the United States Food and Drug Administration (FDA) has produced a document outlining a proposed conceptual framework to advance the development of rigorous and meaningful PROMs that can be used in clinical trials focused on the creation of innovative renal replacement therapy monitors [5].

2. Type of PROs

There are several generic PROMs that can be filled out by patients with a variety of diseases (SF-36, WHOQOL, WHOQOL-BREF, MQOLand, PHQ-9, etc.) and specific PROMs for renal diseases (KDQOL-SF, KDQOL-36, ESAS-r, KDQ, CHEQ, etc.) [1]. In nephrology, there is no consensus on which specific questionnaires should be used for routine evaluation of patients with advanced CKD. The Dialysis Symptom Index (DSI) has been considered the most relevant, comprehensive and simple symptom questionnaire [6]. Regarding the preference for recording PROMs data of renal patients in Europe, an expert consensus selected the Kidney Disease Quality of Life-36 (KDQOL™-36), as it shows both generic and disease-specific outcomes. Regarding PREMs instruments, there is no consensus for renal registries, as more studies are needed. It is recommended to include all patients on renal replacement therapy in the PROMs/PREMs questionnaire program, whose data should be collected at least once per year [3] (Table 1).

Table 1. Main current patient-reported outcomes measures developed for adults with chronic kidney disease (CKD).

STUDY Ref.	Assessments	Item Number	Burden Rating Scale	Population/Validation	Recall
CKD-SBI [7]	Prevalence, severity and frequency of symptoms	33	11 point Likert scale	CKD/ESRD	4 weeks
CHEQ [8]	Health perception, physical, social, physical role, emotional role, pain, mental compound, vitality, cognitive and sexual disorder, sleep, job, recreation, travel, finances, general QoL, diet, body image, dialysis access, symptoms	80	2–7 point Likert scale	ESRD/CKD	4 weeks/3 months/in general
DSI [9]	Physical symptom burden, symptom severity	30	5 point Likert scale	ESRD/CKD	1 week
KDQOL-SF [10]	Symptoms, burden of kidney disease, work situation, cognitive	82	2–10 point	ESRD/CKD	4 weeks

STUDY Ref.	Assessments	Item Number	Burden Rating Scale	Population/Validation	Recall
	impairment, social aspects, sexual disorder, sleep, social support, patient satisfaction, physical functioning, role physical, pain, general health perceptions, emotional well-being, emotional state, social function, energy		Likert scale		
KDQOL-36 [11]	Includes the SF-12 as generic core plus the burden, symptoms/problems, and effects of kidney disease scales from the KDQOL-SF™v1.3.	36	5 point Likert scale	ESRD/CKD	4 weeks/in general

Failure. *Nephrol. Nurs. J.* 2020, 47, 465–474.

2. Schick-Makaroff, K.; Thummappol, O.; Thompson, S.; Flynn, R.; Karimi-Dehkordi, M.; Klarenbach, CKD: chronic kidney disease; CKD-SB: Chronic Kidney Disease-Symptom Burden Index; CHEQ: CHOICE Health S.; Sawatzky, R.; Gresham, J. Strategies for incorporating patient-reported outcomes in the Experience Questionnaire; CKD QOL: Chronic Kidney Disease Quality of Life; DSI: Dialysis Symptom Index: care of people with chronic kidney disease (PRO kidney): A protocol for a realist synthesis. *Syst. Rev.* 2019, 8, 20.

References [7][8][9][10][11] are included.

3. Breckenridge, K.; Bekker, H.L.; Gibbons, E.; van der Veer, S.N.; Abbott, D.; Briançon, S.; Cullen, R.; Garneata, L.; Jager, K.J.; Lønning, K.; et al. NDT Perspectives How to routinely collect data on patient-reported outcome and experience measures in renal registries in Europe: An expert

consensus meeting. *Nephrol. Dial. Transplant.* 2015, 30, 1605–1614.

Electronic patient-reported outcomes systems (ePROs) encompass the use of electronic technology (such as computers, tablets, phones, apps) to provide responses to standardized instruments or PRO questionnaires [1].

4. Alayebi, O.L. Key methodological considerations for usability testing of electronic patient-reported outcome (ePRO) systems. *Qual. Life Res.* 2020, 29, 325–333.

They provide rapid access to this information for the healthcare team and are increasingly used in clinical trials and studies to evaluate the efficacy and safety of interventions from the patient's perspective [12].

5. Flythe, J.E.; Hilliard, T.S.; Ikeler, K.; Keller, S.; Gipson, D.S.; Grandinetti, A.C.; Nordyke, R.J.; Perrone, R.D.; Roy-Chaudhury, P.; Unruh, M.; et al. Toward patient-centered innovation: a conceptual framework for patient-reported outcome measures for transformative kidney replacement devices. *Clin. J. Am. Soc. Nephrol.* 2020, 15, 1522–1530.

The use of ePROs instead of paper formats in clinical trials could improve the feasibility of PROMs assessment in routine clinical practice, as it eliminates the need for subsequent data entry and storage of questionnaires, as well as increasing the security of data protection. It makes data analysis and reporting easier by enabling data to be made available in reportable formats with fewer errors and less missing data. It is more cost-effective in routine evaluation and has the potential for immediate scoring and presentation of results. It also has the potential to link PROMs to electronic medical record data, thus improving communication in multidisciplinary care and facilitating PROM assessment [1][12][13].

6. Van der Velde, E.M.; Meuleman, T.; Plantier, K.; van Rijn, C.; Bos, W.J.W.; van Heeswijk, P.J.; Bann, H.A.; Hemmeler, M.P.; Dekker, F.W. Patient reported outcome measures: Selection of a valid questionnaire for routine symptom assessment in patients with advanced chronic kidney disease.

A four-phase mixed methods study. *BMC Nephrol.* 2019, 20, 1–11.

account; the need to have an internet connection, a smartphone, computer or tablet, a certain degree of digital literacy or to have the support of a family member or healthcare personnel to carry out the digital survey in the dialysis symptom index for chronic kidney disease stages four and five. *BMC Nephrol.* 2015, 16,

event that the patient has a physical impediment or does not know how to deal with new technologies.

36.

Physical Activity, Quality of Life, and Health-Related Quality of Life in End-Stage Renal Disease: The CHOICE Health Experience Questionnaire. *Am. J. Kidney Dis.* 2001, **37**, 11–21.

on the previous response, it reduces the total number of responses and therefore the burden on the patient and 9. Welsbord, S.D.; Fried, L.F.; Arnold, R.M.; Rotondi, A.J.; Fine, M.J.; Levenson, D.J.; Switzer, G.E. their acceptance [4]. It also facilitates the use of this data at different healthcare levels: directly to the patient care Development of a Symptom assessment instrument for chronic hemodialysis patients: The department, extending to the level of healthcare facility management and administration, and even to the level of dialysis symptom index. *J. Pain Symptom. Manage.* 2004, **27**, 226–240. healthcare policy makers [1][14].

10. Hays, R.D.; Kallich, J.D.; Mapes, D.L.; Coons, S.J.; Amin, N.; Carter, W.B.; Kamberg, C. Kidney Disease Quality of Life Short-Form (KDQOL-SF™): Version 1.0: A Manual for Use and Scoring; RAND: Santa Monica, CA, USA; All 1997; pp. 38.

Patient outcomes such as quality of life and survival rates [4].

11. Peipert, J.D.; Bentler, P.M.; Klicko, K.; Hays, R.D. Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States. *Am. J. Kidney Dis.* 2018, **71**, 461–468.

4. ePROs in Hemodialysis

12. Schick-Makaroff, K.; Tate, K.; Molzahn, A. Use of Electronic Patient Reported Outcomes in Clinical Nephrology Practice: A Qualitative Pilot Study. *Can. J. Kidney Heal. Dis.* 2019, **6**, 2054358119879451.

Few studies have been conducted focusing on the development of PROM questionnaires specifically for HD patients and to assess the usefulness and acceptability of ePROs.

13. Wong, D.; Cao, S.; Ford, H.; Richardson, C.; Belenko, D.; Tang, E.; Ugenti, L.; Warsmann, E.; Sissons, A.; Kulandavelu, Y.; et al. Exploring the use of tablet computer-based electronic data capture system to assess patient reported measures among patients with chronic kidney disease: A pilot study. *BMC Nephrol.* 2017, **18**, 356.

A study conducted on HD patients in the US, describing the process and preliminary qualitative development of a new symptom-based PROM intended to assess physical symptoms related to HD treatment. laid the groundwork for the process of developing HD-specific PROMs. Forty-two patients were interviewed for symptom-related concepts, and patient-reported concepts were used to generate a preliminary 13-item symptom PROM. Three 14. Sayah, F.A.; Lahtinen, M.; Bonsel, G.J.; Ohinmaa, A.; Johnson, J.A. A multi-level approach for the use of routinely collected patient - reported outcome measures (PROMs) data in healthcare systems. *J. Patient Rep. Outcomes* 2021, **5**, 1–6.

rounds of cognitive interviews were then conducted with fifty-two patients to assess symptom relevance, item interpretability, and draft item structure, on the basis of an iterative refinement of the PROM. Responses and comments from participants during the cognitive interviews resulted in changes to the symptom descriptions, splitting the single item “nausea/vomiting” into two distinct items, removing the interference with daily activity items, and adding instructions among others [16].

15. Schick-Makaroff, K.; Levay, A.; Thompson, S.; Flynn, R.; Sawatzky, R.; Thummappai, D.; Karenbaeh, S.; Karmi, D.; Ford, M.; Greenhalgh, J. An Evidence-Based Theory About PRO Use in Kidney Care: A Realist Synthesis. *Patient-Patient-Cent. Outcomes Res.* 2021, **15**, 21–38.

In the study by Schick-Makaroff et al. [12] involving ninety-nine patients on both peritoneal dialysis (PD) and home HD who completed via tablets two ePROs, the ESAS™ and the KDQOL™-36, the data were used to discuss Development and content validity of a hemodialysis symptom patient-reported outcome measure specific issues such as pruritus, appetite, insomnia, tiredness and dyspnea, as well as general health and the effects of CKD on daily life. Problems leading to a change in the care plan, referral to another professional or reassessment were pruritus, depression, fatigue, insomnia, anxiety and interference of the disease with daily life.

16. Flythe, J.F.; Dorough, A.; Narendra, J.H.; Wingard, R.L.; Dalrymple, J.S.; DeWalt, D.A. *Qual. Life Res.* 2019, **28**, 253–265.

The use of ePROs was found to be useful in the care of patients with home dialysis techniques. The same author also demonstrated that there is general satisfaction with the ePROs registry among patients receiving home hemodialysis [17].

17. Schick-Makaroff, K.; Molzahn, A.E. Evaluation of real time use of electronic patient reported outcome data by nurses with patients in home dialysis clinics. *BMC Health Serv. Res.* 2017, **17**, 1–11.

18. Verberne, W.R.; van den Wittenboer, I.D.; Voorend, C.G.; Abrahams, A.C.; van Buren, M.; Dekker, F.W.; van Jaarsveld, B.C.; van Loon, I.N.; Mooijaart, S.P.; Ocak, G.; et al. Health-related quality of life and symptoms of conservative care versus dialysis in patients with end-stage kidney disease: A systematic review. *Nephrol. Dial. Transpl.* 2021, **36**, 1418–1433.

Regarding quality of life and its association with the choice of conservative care (CC) on dialysis or without dialysis, a systematic review of eleven studies with 1718 patients was carried out comparing health-related quality of life (HQOL) and symptoms. These are important findings for patients and physicians when deciding on the choice of

19. Staibano, P. et al. **Performance-based randomized Davis, J.A.; Finn, S.; Gassner, M.; Stevenson, M.;** studies, patients. **Saideh, E. *et al.* Patient-Centred Outcomes in Acute and Chronic Disease: A Systematic Review. *Am J Kidney Dis* 2020, 74, 84.** studies, patients. **opted for dialysis.** *Am J Kidney Dis* 2020, 74, 84.

20. Schick-Makaroff, K.; Wozniak, L.A.; Short, H.; Davison, S.N.; Klarenbach, S.; Buzinski, R.; Walsh, M.; Johnson, J.A. **Burden of mental health symptoms and perceptions of their management in in-dialysis. Mental health outcomes were similar among patients who chose CC or dialysis, even before and after centre hemodialysis care: A mixed methods study.** *J. Patient-Rep. Outcomes* 2021, 5, 111.

21. Jacobson, J.; Yu, A.; Baumgart, A.; Hurth, M.; O'Donoghue, D.; Ohradov, G.; Craig, J.C. **Increased after dialysis initiation. The available data, although heterogeneous, suggest that, in selected older patients, CC has the potential to achieve similar HRQOL and symptoms compared with the choice of dialysis. There is a need for high-quality prospective studies to confirm these results.** *Am J Kidney Dis.* 2019, 74, 179–192.

Despite the scarce literature on PROs applied to HD, it is useful to provide a more personalized and multidimensional approach to patient treatment and to make better clinical decisions (**Table 2**).

Association between Satisfaction with Dialysis Treatment and Quality of Life: A Cross-Sectional Study. *Blood Purif.* 2021, 50, 188–195.

Table 2. Summary of the evidence of PROM in hemodialysis and its contribution.

23. Fotheringham, J.; Vilar, E.; Bansal, T.; Laboi, P.; Davenport, A.; Dunn, L.; Hole, A.R. **Patient**

Author	Ref	Year	Contribution
Flythe et al.		2019	Laid the foundations of the methodology for developing dialysis-specific PROM questionnaires.
Schick-Makaroff, K. et al.		2019	Proved that the use of ePROs is useful in home dialysis techniques.
Staibano, P. et al.		2020	Proposed the standardization of research methods and the reporting of PROMs in HD.
Schick-Makaroff, K. et al.		2017	Demonstrated that there is general satisfaction with the ePROs registry among patients receiving HD at home.
Schick-Makaroff, K. et al.		2021	Suggested that PROM questionnaires (ESAS-r: Renal/EQ-5D-5L) can quickly identify mental health problems.
Jacobson, J. et al.		2019	Proved that PROMs in clinical and research settings can improve the detection and treatment of fatigue in HD.
Verberne, W.R. et al.		2021	Advanced that the use of PROMs in selected patients has the potential to reach a similar QoL in patients on CC or dialysis.
Cirillo, L. et al.		2021	Proved the relationship between satisfaction with care and QoL, highlighting the central role of nephrologist-patient communication in the QoL of dialysis patients.
Fotheringham, J. et al.		2021	Demonstrated the importance of the patient preferences in the selection of more frequent or longer HD or regimens.
Quinn, R.R. et al.		2008	Proved that information on catheter and fistula care decreases the number of complications and increase patient satisfaction with their vascular access.

5. Conclusions

The use of ePROs is useful in the care of hemodialysis patients related to different aspects, including quality of life and their relationship with different potential problems and complications such as anemia, vascular access, and individualization of dialysis parameters or chronic fatigue, as well as aspects related to mental and psychological health such as anxiety or depression. In addition, these tools will make it possible to assess aspects related to patient satisfaction and preferences, which are crucial factors for a holistic optimization of dialysis therapy.

The incorporation of ePROs into clinical practice will have the potential to provide deep insight into a person's disease experience, make clinical trials more effective, transform initiatives into health policy, and individualize high-quality care for patients with chronic kidney disease, especially on hemodialysis.