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Considerable research and investment has focused on the use of electronic patient reported outcomes (ePROs) in nephrology. However, systematic collection of ePROs to inform the care of patients with chronic kidney disease remains sporadic. A change in culture is needed to encourage their wider adoption in clinical practice.

Patients with chronic kidney disease (CKD) often report a high symptom burden that has a considerable negative impact on their health-related quality of life (HRQoL) (1). Information on symptoms and HRQoL can be obtained from patients using validated, psychometrically robust questionnaires. Responses have traditionally been collected on paper, but there is increasing interest in the digital collection and real-time use of electronic patient reported outcomes (ePROs). Data on ePROs offer unique insights; in clinical trials they can provide valuable evidence on the efficacy and tolerability of treatments and in routine clinical care they can be used to deliver personalised care and to assist auditing and benchmarking to improve services (2). Increasing evidence from specialities such as oncology indicates that use of ePROs in routine care is a cost-effective method of improving clinician–patient communication, enhancing symptom management, reducing hospitalisations and improving HRQoL and overall survival (3, 4). Yet, despite some prioritisation at a national policy level, routine collection of ePROs to inform kidney care is limited.

Current use and evidence of benefit

The majority of healthcare systems do not report routine collection of ePROs for patients with CKD. However, in Denmark, a generic web-administered ePRO system known as Ambuflex is used to manage kidney outpatient follow-up (5). Key areas of ePRO research in nephrology include outcome selection aligned to core outcome sets (a list of minimum outcomes which key stakeholders have recommended should be measured and reported in research and/or routine care), the development of outcome measures including assessment

of their reliability, validity and ability to detect change, and the feasibility and acceptability of ePRO use for patients (1). However, a lack of empirical evidence on the efficacy of use of ePROs in kidney care has been highlighted by clinicians as a reason for slow adoption into routine practice (6).

Several studies are exploring the effectiveness of ePROs in kidney care. For example, the Australian Symptom Monitoring with Feedback Trial (SWIFT) is a registry-based, cluster randomised controlled trial (RCT) that is investigating the effect of undertaking 3 monthly ePRO symptom monitoring with clinician feedback over 12 months on HRQoL; secondary outcomes are overall survival, symptom severity (including haemodialysis-associated fatigue), healthcare utilisation and cost-effectiveness (7). In Canada, the Evaluation of routinely Measured PATient reported outcomes in HemodialYsis care (EMPATHY) trial is a pragmatic multi-centre cluster RCT that will implement and evaluate the use of disease-specific and generic ePRO monitoring with linked symptom guidelines for clinicians and patient information handouts (8). The primary outcome of this study is patient-provider communication assessed using a communication assessment tool. Both SWIFT and EMPATHY are focusing on in-centre haemodialysis populations.

In the UK, the Optimising routine collection of electronic patient-reported outcomes (OPT-ePRO) study developed an intervention that utilises existing infrastructure to securely collect, transfer and display ePRO data across all stages of CKD and treatment modalities (9). An evaluation of this intervention in routine practice is planned. The renal ePROM (RePROM) pilot trial demonstrated the feasibility of a RCT of ePRO symptom monitoring in patients with advanced CKD (10). The intervention comprised real-time integration of ePRO symptom data into the electronic health record with automated alerting of the clinical team when participants reported severe symptoms. The preliminary findings suggest that healthcare utilisation was lower in the ePRO group than in the control group. These data will inform a future RCT aimed at exploring the efficacy and cost-effectiveness of the ePROs intervention.

Real-world implementation

A return on the research investment in ePROs could be seen through implementation in real-world settings. Context is key to successful implementation, which requires a clear understanding of the patient population, the purpose of ePRO collection and pathways for clinical responses Although RCTs provide valuable evidence, contextual factors that can subvert implementation efforts in real-world settings must be considered.

Barriers to collection and use of ePROs include poor clinician ‘buy in’, which is associated with difficulty in integrating ePROs into existing digital systems, impact on workflow, anxiety about interpretation and inability to effectively deal with responses (6). Commonly reported facilitators of ePRO use include ‘champions’ who have the time and knowledge to explain the potential importance of ePROs to colleagues and patients (6). The complexity of

decisions involved in treating kidney disease highlights the importance of shared decision making in nephrology and ePROs can support this model of care. Within a high-pressure clinical environment, clinicians could potentially act as gatekeepers to ePRO use controlling access to systems and review of data; a change in culture is required to address this issue. A systematic case needs to be made that ePROs can enhance workflow efficiency and improve patient care. Support from international and national professional societies and integration of ePROs into clinical service specifications is required to facilitate their widespread adoption.

Potential unintended consequences of use of ePROs include worsening of existing healthcare inequalities due to a lack of access to digital devices, single language systems and the poor health literacy of some patients. Care must also be taken to communicate directly with patients about what their results mean for them rather than over-digitizing the patient experience by acting on raw scores alone. Effective patient and public involvement at all stages of ePROs implementation from measure selection to system evaluation can mitigate some of these issues.

Non-context specific facilitators of ePRO use include access to resources to guide their use, such as those collated by the PROTEUS consortium (patient reported outcomes tools: engaging users and stakeholders), which was formed to optimise the use of PROs in research studies and clinical practice.

Future directions

Use of new technologies, such as computer adaptive testing, which generates specific questionnaires for each individual based on their previous responses, could reduce the burden of ePRO collection for patients (6). In addition, application programming interfaces that enable secure exchange of data can be used to facilitate linkage and aggregation of ePROs data across platforms, potentially including electronic health records and registries.

CKD is heterogeneous and subtype-specific outcome measures may be required. However, in our opinion, ePROs methodology should concentrate on standardisation of domains and items in questionnaires to enable effective comparison and multiple usage of the collected data, with further investigation of the psychometric properties of existing measures to improve their interpretation, rather than the development of new questionnaires. Better understanding of individual ePRO scores and changes over time, including minimal clinically important differences, will assist clinical decision making. Trust in the ability of ePROs to enhance risk stratification when used alongside other data, will increase uptake and improve shared decision making, particularly when used to inform choice of treatment.

In addition to general guidance on score interpretation, understanding of the true meaning of ePROs can only be undertaken through discussion with patients. To facilitate such conversations, data must be presented in a clear and informative way The increasing use of

clinical dashboards, sometimes termed 'atlases of variation and improvement', and the addition of ePROs to other forms of data within these dashboards can augment patient–provider communication.

The COVID-19 pandemic has led to a huge increase in the use of telemedicine. It is important to design ePRO systems that can support sustainable healthcare programmes, making best use of resources including time and infrastructure. Studies are needed to investigate the cost effectiveness of use of ePROs in kidney care and to calculate their other impacts, including the potential carbon savings associated with reduced on-site clinic visits, transport and healthcare utilisation as a result of use of ePROs to manage and triage outpatient activity.

Optimized use of ePROs can strengthen the patient voice in routine kidney care, but their effective implementation requires more than research efforts and interest from the nephrology community. A willingness to change culture and to consider ePRO data to be equal in value and complimentary to other forms of health data, including clinical outcomes, is required to deliver truly patient-centred care.

Related Links

Proteus Consortium **https://theproteusconsortium.org/**

References

1. Fletcher BR, Damery S, Aiyegbusi OL, Anderson N, Calvert M, Cockwell P, et al. Symptom burden and health-related quality of life in chronic kidney disease: A global systematic review and meta-analysis. PLoS Med. 2022;19(4):e1003954.
2. Schick-Makaroff K, Levay AV, Thompson S, Flynn R, Sawatzky R, Thummapol O, et al. An Evidence-Based Theory About PRO Use in Kidney Care: A Realist Synthesis. The Patient - Patient-Centered Outcomes Research. 2021;15:21-38.
3. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA. 2017;318(2):197-8.
4. Lizée TB, Ethan ; Trémolières, Pierre ; Voog, Eric ; Domont, Julien ; Peyraga, Guillaume ; Urban, Thierry ; Bennouna, Jaafar ; Septans, Anne-Lise ; Balavoine, Magali ; Detournay, Bruno ; Denis, Fabrice. Cost-Effectiveness of Web-Based Patient-Reported Outcome Surveillance in Patients With Lung Cancer. Journal of Thoracic Oncology. 2019;14(6):1012-21.
5. Schougaard LMV, Larsen LP, Jessen AMK, Sidenius P, Dørflinger L, de Thurah A, et al. AmbuFlex: tele-patient-reported outcomes (telePRO) as the basis for follow-up in chronic and malignant diseases. Quality of Life Research. 2015;25:525 - 34.
6. Anderson NE, McMullan C, Calvert M, Dutton M, Cockwell P, Aiyegbusi OL, et al. Using patient-reported outcome measures during the management of patients with end-stage kidney disease requiring treatment with haemodialysis (PROM-HD): a qualitative study. BMJ Open. 2021;11(8):e052629.
7. Greenham L, Bennett PN, Dansie K, Viecelli AK, Jesudason S, Mister R, et al. The Symptom Monitoring with Feedback Trial (SWIFT): protocol for a registry-based cluster randomised controlled trial in haemodialysis. Trials. 2022;23(1):419.

8. Johnson JA, Al Sayah F, Buzinski R, Corradetti B, Davison SN, Elliott MJ, et al. A cluster randomized controlled trial for the Evaluation of routinely Measured PATient reported outcomes in HemodialYsis care (EMPATHY): a study protocol. BMC Health Services Research. 2020;20(1):1-14.
9. Van Der Veer SN, Ercia A, Caskey FJ, Farrington K, Jury F, Rees M, et al. Developing an Intervention to Implement Electronic Patient-Reported Outcomes in Renal Services in the UK. Studies in Health Technology & Informatics. 2020;270:936-40.
10. Kyte D, Anderson N, Bishop J, Bissell A, Brettell E, Calvert M, et al. Results of a pilot feasibility randomised controlled trial exploring the use of an electronic patient-reported outcome measure in the management of UK patients with advanced chronic kidney disease. BMJ Open. 2022;12(3):e050610.

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