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Developing an Intervention to Implement Electronic Patient-Reported Outcomes in Renal Services in the UK

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Abstract. Routinely collecting and using electronic patient-reported outcome (ePRO) data in clinical practice can improve patients' experience and outcomes, but implementing this at scale has proved challenging. As part of the *Optimising routine collection of electronic patient-reported outcome*s (OPT-ePRO) study, we therefore developed an intervention that aimed to facilitate the implementation of ePROs. We are conducting OPT-ePRO in the context of secondary care for people with chronic kidney disease in the UK, with three renal units participating as our study sites. Intervention design was guided by Normalisation Process Theory, and informed by published literature and qualitative research. The intervention consisted of a national infrastructure to securely collect, transfer and display ePRO data, complemented with materials and procedures to support kidney patients and renal unit staff with embedding ePROs in usual care pathways. The next step will be to bring the OPT-ePRO intervention into practice and iteratively refine it.

Keywords. eHealth; Patient-generated health data; Symptom assessment

1. Introduction

Electronic patient-reported outcome (ePRO) data is digitally collected information that reflects the personal impact of illness and treatment as assessed by patients, such as information on symptom burden or quality of life. Studies have shown that routinely collecting and using ePRO data as part of clinical care can improve patients' experiences and outcomes [1], while also informing audits and commissioning of services. The challenge now is to implement ePROs more widely in order to harness these potential benefits.

Despite extensive knowledge on how to successfully implement ePROs [2,3], national initiatives have struggled with low response rates [4,5]. One issue is that patient and staff engagement in the implementation varies widely between groups and

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facilities, and is often limited [4,5]. This may be explained by insufficient support for embedding collection and use of ePROs into usual care pathways. Therefore, we developed an intervention aimed at facilitating implementation of ePROs into clinical practice, with UK renal services as the exemplar context. This formed the first phase of the *Optimising engagement of routine collection of electronic patient-reported outcomes* (OPT-ePRO).

2. Methods

2.1. Theoretical framework

We used Normalisation Process Theory (NPT) as the theoretical framework to guide development of the OPT-ePRO intervention [6]. NPT has been widely used to plan implementations of eHealth interventions in clinical practice [7] and consists of four constructs: coherence (e.g. do users have a shared view of the intervention's purpose); cognitive participation (e.g. do users understand and agree on who will deliver the intervention); collective action (e.g. do existing resources and systems allow the intervention to 'fit'); and reflexive monitoring (e.g. how do users appraise the intervention's value).

2.2. Study setting

Secondary care for people with chronic kidney disease in the UK is provided by over 70 main renal units; three of these acted as our study sites. We selected renal units as our study setting because they are more digitally mature than many other parts of the National Health Service. All renal units have an electronic patient record (EPR) system connected to a national infrastructure. Currently, this infrastructure –commissioned by the Renal Association—enables digital clinical data from renal units' EPRs to flow into a national repository to facilitate: audit by the UK Renal Registry; research; and patients' self-management via a patient portal (https://www.patientview.org/) (see Figure 1). As part of the OPT-ePRO intervention, we aimed to make this infrastructure bidirectional: with ePRO data –in our case: symptom burden and EQ-5D (i.e. quality of life) scores—flowing from the portal through the repository into renal units' EPRs.

2.3. Approach to intervention development

To develop the intervention, we used literature reviews [2,3] and frameworks [8,9] on implementing ePROs in general, complemented with context-specific qualitative data and stakeholder codesign (see below). We recruited participants from our study sites:

- Non-participant observations of workflows: we observed three 4-hour outpatient clinics (total: 12 hours) and eight in-centre haemodialysis sessions of nearly five hours each (total: 39 hours) to gain insight into existing routines and to identify opportunities for collecting and discussing ePROs. We used a data collection template to gather field notes on e.g. patient time and activities; staff presence and activities; and on how patient data was recorded, reviewed and discussed;
- Observations of clinic consultations: to understand if and how symptoms and quality of life were discussed, we audiorecorded and transcribed 11 routine clinic visits (177 minutes in total) in haemodialysis and outpatient settings;

- Participatory co-design workshops; we conducted three workshops with patients and caregivers (total n=25) and two with staff (n=13) to review designs and prototypes of intervention elements; identify potential implementation barriers; and to co-create solutions to overcome these through collaborative synthesis. Each workshop took approximately three hours.

Guided by our theoretical framework, we thematically analysed field notes, consultation transcripts and workshop materials. Using the constant comparative method [10] we synthesised results across sites, settings and data sources. We described intervention elements in line with relevant reporting guidance [11], while mapping them to NPT constructs. To deliver the IT-related intervention elements, we worked closely with study sites' IT departments and the patient portal supplier. We provided them with technical and functional requirements (developed with input from end users and the Renal Association), as well as an end-to-end test plan and data.

The UK Health Research Authority's Research Ethics Service, North West - Greater Manchester West Research Ethics Committee approved the study (ID 245870).

3. Results

The extended national infrastructure as outlined in Figure 1 encompassed all IT elements of our OPT-ePRO intervention. It enabled patients to enter ePRO data at home or in clinic via the existing patient portal, which they could access on any PC or mobile device. Many patients already had access to the portal, but only some were actively using it. Before each clinic consultation, staff would invite a patient to enter their ePRO data. Within 2-3 minutes, results were sent to the national data repository, and then pushed into the renal unit's EPR system for clinical staff to review and discuss with the patient. An overview screen in the EPR displayed current and previous ePRO results in tabular format, with colour coding linked to symptom severity. When

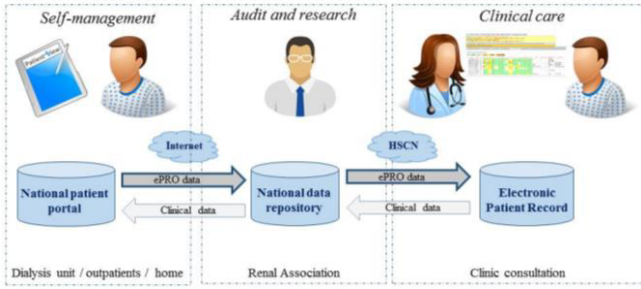

Figure 1 National infrastructure for capturing, storing, transferring and displaying ePRO data for people with kidney disease in the UK. HSCN refers to the NHS' secure Health and Social Care Network

discussing results with patients, clinicians could generate pop-up screens to graphically display scores for individual ePRO items. There was a review functionality in the portal for patients to access their own ePRO results.

We identified relevant intervention components relating to values and roles, presented in Table 1 under the NPT constructs of coherence and cognitive participation. Components relating to service organisation and delivery are presented under collective action. We will explore reflexive monitoring –the process by which users adapt to and collectively assess the impact of the intervention—in future work evaluating the intervention in practice. Materials and procedures for each element left room for individual sites to organise the ePRO implementation in a way that fitted their local

context. All staff materials were combined into a handbook that contained information on how different aspects of the ePRO implementation would work. Patient materials were mostly delivered as flyers with concise messages, handed out in clinic or included in patient letters. Local champions were involved in delivering several parts of the intervention, and were usually a nurse manager and a consultant nephrologist.

Table 1. Overview and description of OPT-ePRO intervention elements, organised by NPT construct

Element name	Materials and procedures (what)	Delivery (how, by whom, where)
	COHERENCE & COGNITIVE PARTICIPATION	
Implementation initiation and engagement	• Initiating the implementation process and driving it until the local champion and other staff were ready to take this over • Building relationships with and across all those involved, including patients, clinical staff, IT staff, management, volunteers, etc.	F2F, email and phone conversations by study facilitator
Patient outreach	• Explaining the implementation to patients; present potential benefits of ePROs; demonstrate ePRO module in patient portal	F2F conversations with individual patients in clinic by staff and volunteers
	• Flyer announcing the implementation and listing potential benefits of ePROs	Handed out in clinic or included in outpatient letters by staff
Staff outreach	• Planning implementation with local champion	Study facilitator
	• Explaining the implementation to staff; present potential benefits of ePROs	F2F during team meetings by local champions and study facilitator
	• Overview of the implementation process and of potential benefits of ePROs	Included in the handbook (on paper at nursing station and in electronic format)
Assigning key staff roles	• Identifying staff members or volunteers for key roles in collecting and discussing ePROs	F2F conversations with individuals candidates by local champions
	• Checklist of implementation responsibilities, and the capabilities required to fulfill them	Included in the handbook (on paper at nursing station and in electronic format)
	COLLECTIVE ACTION	
ePRO data entry & transfer	• Providing patients access to the patient portal, i.e. registering new users and resetting passwords of non-active users	F2F conversations with individual patients in clinic by staff or volunteers; information included in outpatient letters by staff
	• ePRO data entry & transfer functionality for patients	Screen accessible online by patients via the portal in clinic or from home; data transfer via the national infrastructure (Fig 1)
	• Patient materials, such as patient portal user guidance, password reminder cards, and a list of frequently asked questions regarding ePRO data collection and use	Mostly on paper, handed out by staff in clinic; the list of frequently asked questions was accessible online by patients via the portal
Review of ePRO results	• ePRO review functionality for patients	Screen accessible online by patients via the portal in clinic or from home
	• ePRO review functionality for staff	Screens accessible by staff via the renal unit EPR system in clinic
	• Discussing ePRO results with patients	F2F consultations with individual patients by staff in clinic
Staff training and support	• Instructing key staff on how to fulfill their role in the ePRO implementation, including how to access and interpret ePRO results	F2F sessions with individual staff members in clinic by study facilitator and local champions
	• Training materials that outline the information provided during the F2F instruction sessions	Included in the handbook (on paper at nursing station and in electronic format)

Abbreviations: EPR, electronic patient record; ePROs, electronic patient-reported outcomes; F2F, face-to-face

4. Discussion and conclusion

We developed a theory-informed and co-designed intervention to facilitate implementation of ePROs into UK renal services by supporting patients and staff with

embedding collection and use of this data into usual care pathways. Previous studies explored the feasibility of using tablets in renal settings to support ePRO collection locally [12,13], but our study is the first to deliver an infrastructure that is nationally scalable. In addition, we proposed a strategy to optimise use of ePROs in these settings, thereby addressing an acknowledged gap in the literature [14].

In the next phase of the OPT-ePRO study, we will evaluate the intervention in practice. When sites deploy the intervention, we will monitor for low ePRO response rates and conduct qualitative research to identify implementation barriers and to explore ways to address them. The qualitative research will also give us insight into how patients and staff understand and experience the intervention. This will inform iterative modifications of the intervention, mapped to the reflexive monitoring construct of our theoretical framework. Once all major barriers have been addressed, we expect the intervention to be suitable for deployment by other renal units, thereby enabling national implementation of ePROs in UK renal services and contributing to harnessing their potential benefits for patients and healthcare services.

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