EEPRU

RESEARCH REPORT

Supporting the routine collection of patient reported outcome measures (PROMs) for the National Clinical Audit
Work Package 2
How should PROMS data be collected?

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RR0038

August 2015

The University Of Sheffield.

UNIVERSITY *of* York

EXECUTIVE SUMMARY

Objectives

Across health care settings, electronic patient reported outcome measures (e-PROMs) can be administered using a range of systems and administration modes (for example web-based, mobile phones or kiosks). The use of e-PROMs is not widespread in the UK and there is no clear guidance regarding the best ways in which to deliver the questionnaires, set up and implement the systems required, or feedback data to clinicians, other health care professionals and patients.

The overall aim of the research described in this report is to understand current practice for the administration and application of e-PROMs in health care settings, to inform the use of these measures in the National Clinical Audit (NCA), and to identify areas where future research would be beneficial. The specific objectives are threefold:

1. Identify and critique the existing evidence on the use of electronic methods for the administration of PROMs for routine use in health care settings and the systems used to deliver them.
2. Review the potential benefits, uses and applications of e-PROMs.
3. Highlight the challenges involved in the collection and implementation of e-PROMs.

Methods

Existing literature and interviews with clinicians and academics working in the field were used to understand the current practice for the administration and application of e-PROMs. To source existing literature, four different approaches were used. The first approach involved searching International Society for Pharmacoeconomics and Outcomes Research and the International Society for Quality of Life Research websites which list publications relating to e-PROMs. The second approach involved searching several conference abstract websites. The third approach involved searches for UK and international guidelines, recommendations and standards. The fourth approach adopted was to ask the interviewees whether they knew of relevant papers and reports (published or unpublished).

The qualitative study was carried out with a selection of clinicians and researchers with experience of developing, applying and using e-PROMs. Potential interviewees were identified from contacts known by the research team. A snowball approach was used to develop a long list of potential

interviewees who were asked to take part. A semi-structured interview guide based on the objectives of the project, the results of key review papers in the area, and the personal experience of the research team were used. Interviews were transcribed verbatim, and analysed using a simple content analysis approach where the interview topic guide was used to code the interviews.

Results and conclusions

A wide range of published articles, reviews and abstracts were sourced. Nine interviews were carried out with academics (n=3) and clinicians (n=6). The data sources provided information regarding: the mode of administration and specifics of collecting e-PROMS, the benefits and impacts of using e-PROMs, engagement of others regarding the use of e-PROMs, and the challenges of implementing and using e-PROMs. The results provide important evidence that can be used to inform the implementation of e-PROMs as part of the NCA, and about potential difficulties in the widespread application of these systems. From this, recommendations for the implementation of e-PROMs can be drawn. These include:

- Using multiple data collection modes to improve response rates. There is some evidence to suggest that there are limited issues of equivalence of using different modes of administration.
- Allowing multiple places of completion (i.e. home and in clinical settings).
- Gaining support from all key stakeholders (i.e. clinicians, IT departments, support staff, patients).
- Using the PROMs data in clinical decision making.
- Developing systems in a collaborative manner.
- Choosing which PROMs to use based on the available evidence and the purpose of the system.

There are a range of limitations of existing e-PROMs systems. The systems do not always have the full support of clinicians and other key stakeholders (such as other staff or managers and commissioners) involved in their implementation. Mixed response rates are also reported. It is unclear how best to maximise response beyond offering as much flexibility as possible.

Future research

The results of this study highlight a number of areas where future research would be informative for the NCA. These include:

- Investigating how to maximise response rates.

- Investigating how to engage clinicians and users.

- Investigating how to present the PROMs data to patients, clinicians, providers and commissioners.

- Evaluating the benefits of collecting PROMs.

- Carrying out usability research into the presentation of the e-PROM systems across different modes of administration.

- Investigating how different clinical pathways would most benefit from e-PROMs.

- Investigating equity issues and the impact of e-PROMs on the application of the systems.

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Acronyms

CMHT	Community Mental Health Team
DH	Department of Health
EEPRU	Policy Research Unit in Economic Evaluation of Health and Care Interventions
e-PROM	Electronic Patient Reported Outcome Measure
ISOQoL	International Society for Quality of Life Research
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IVR	Interactive Voice Recognition
MOD	Measuring Outcomes in Depression
NCA	National Clinical Audit
NHS	National Health Service
PC	Personal Computer
PDA	Personal Digital Assistant

PROM   Patient Reported Outcome Measures
R&D   Research and Development
WP   Work Package

1.   INTRODUCTION

The Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU) was approached by Jason Cox (R&D Division) to prepare a programme of research to support the appropriateness and use of patient reported outcome measures (PROMs) collected for the National Clinical Audit (NCA). The EEPRU programme was informed by a R&D template prepared by Simon Bennett, Steve Fairman and Keith Willett at NHS England.

The purpose of introducing PROMs into the NCA programme is to be able to: 1) compare performance between providers and commissioners in the National Health Service (NHS), 2) compare the cost-effectiveness of alternative providers in delivering the specific services (i.e. linking outcomes and resource use), and 3) assess the cost-effectiveness of alternative interventions and other changes in the NHS. The intention is to introduce PROMs across a range of conditions over the next 3 years commencing with 13 conditions in the 2014/15 NCA programme.

The agreed research programme consists of 3 concurrent work packages (WP) as described in the document submitted to the Department of Health (DH) (8th November 2013). The current document provides details on the objectives, methodology and results for Work Package 2 (WP2): To understand how electronic PROMs (e-PROMs) data could be collected.

2.   BACKGROUND

Across health care settings, e-PROMs are administered using a range of systems and administration modes (for example via the internet, using mobile devices or kiosks in clinics). Traditionally, PROMs have been completed by the patient using pencil and paper methods. However, evidence is growing to suggest that in routine care electronic methods may offer greater advantages than traditional methods. This is because electronic methods can be useful for collecting sensitive data, enable simultaneous data entry, reduce the incidence of missing data and possibly help to reduce the low response rates associated with paper questionnaires.[1;2] They may also be more convenient for the patient and offer flexible timing for data collection as electronic modes of administration allow questionnaires to be completed at the convenience of the patient.[1] Results can also be fed back to clinicians more quickly to inform decision-making.

However, the use of e-PROMs is not widespread in the UK and there is no clear guidance about the best ways in which to deliver the questionnaires, implement the systems required, or to feedback data to clinicians, other health care professionals and patients. There is also scepticism surrounding

the value and completeness of data gathered in this way, particularly outside clinical trials and within the context of routine clinical practice.[3]

3.   OBJECTIVES

The overall aim of WP2 is to understand current practice for the administration and application of electronic PROMs in health care settings, and to identify areas where future research would be beneficial. The specific objectives of the project are to:

1. Identify and critique the existing evidence on the use of electronic methods for the administration and application of e-PROMs for routine use in health care settings, and the systems used to deliver them.

2. Review the potential benefits, uses and applications of e-PROMs.

3. Highlight the challenges involved in the collection and implementation of e-PROMs.

4.   METHODS

4.1   Identification of literature

A focused scoping search was carried out in PubMed on 19th February 2014 to gauge the size and feasibility of conducting a systematic review of reviews of the literature. The PubMed strategy comprised keyword terms for 'technologies', such as 'computer', 'internet', 'online' and 'software', combined with an Oxford PROMs filter (provided by the Oxford PROMs group) and a systematic reviews filter to limit the search by study design.

Following the scoping search, the review team considered that it was necessary to take an iterative and focused search approach (rather than conventional systematic searching) to identify potentially relevant literature for this research. This is because the topic area in question is diffuse, multidisciplinary and largely unpublished due to the relatively short timeframe e-PROMs have been in use, which presents many challenges when searching. The searches were limited to the last 5 years given the growth in the use of e-PROMs in this time period.

Four different approaches were applied as starting points in the search for any relevant reviews, reports and recently completed studies (Figure 1 illustrates the approach taken by the review team). Some approaches were primarily used to retrieve specific document types such as abstracts, guidelines and recommendations.

Figure 1: Approaches applied in the identification of relevant literature
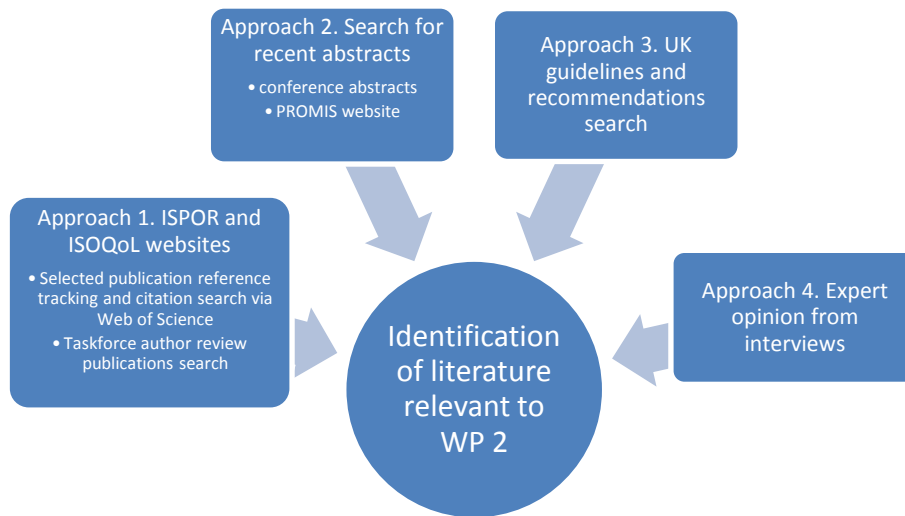
The first approach involved searching the International Society of Pharmacoeconomics and Outcomes research (ISPOR) and the International Society for Quality Of Life research (ISOQoL) websites which list publications relating to e-PROMs. The assumption was that focused e-PROM literature would point to relevant literature for the review via reference follow-up or citation searching of a selected number of publications. As starting points for finding relevant literature, three publications in ISPOR (4-6) and four publications in ISOQoL (6-10) provided 272 references and 89 citations from the Web of Science database.

In addition, searches were carried out for published reviews by authors of the ISPOR ePRO Good Research Practices Task Force. The names of the Chair and Leadership Team were acquired from the ISPOR website (http://www.ispor.org/taskforces/eprotf.asp). Seventeen authors were searched in Scopus (Elsevier) on 14th May 2014. Searches were limited by date (2010 until present) and given the large number of publications produced by all 17 task force members; the results were limited to reviews only.

The second approach involved searching several conference abstract websites on 13th May 2014 using keywords including 'epro', 'electronic patient reported outcomes' or 'data collection' for recent and unpublished abstracts on ePROs since 2010. These included:

- ISOQoL – searched Quality of Life Research journal abstract booklets
- Annual Patient-Reported Outcome (PRO) Consortium - searched within the web sites.
- ISPOR - searched via the Electronic Scientific Presentations Database.
- Medical Informatics Association - searched within the web sites.

In addition, the US Patient Reported Outcome Measurement Information System (PROMIS) website publications listings were searched between 2010 until present for recent and potentially relevant publications.

Searches for UK and international guidelines, recommendations and standards (for example those produced by the NHS, Department of Health and Food and Drug Agency) were carried out on the Google search engine using terms such as 'data collection' or 'electronic' AND 'patient reported outcomes' AND 'clinical practice'.

The fourth approach was to ask the interviewees whether they knew of relevant papers and reports (published or unpublished).

4.2   Interviews with experts
4.2.1   Respondent identification

To understand and explore in more detail the current practice for the administration and application of e-PROMs in health care settings, a qualitative study was carried out with a selection of clinicians and researchers with experience of developing, applying and using e-PROMs. Potential interviewees were identified from contacts known by the research team, and by speaking to key academics and clinicians working in the field. A snowball approach was then used to develop a long list of 24 potential interviewees, both from the UK and abroad, who were contacted by e-mail and asked to take part. The e-mail provided information about the topics included in the interview and a consent form. If they did not respond to the initial invitation one reminder e-mail was sent.

4.2.2   Interview process

A semi-structured interview guide was developed based on the objectives of the project, the results of key review papers in the area, and the personal experience of the research team. The questionnaire was peer-reviewed by all members of the study team prior to use. The majority of questions were phrased as open-ended so that interviewees were able to provide additional related information throughout and at the end of the interview. A copy of the questionnaire is provided in Appendix 1. The respondents were given the option of either a face-to-face or telephone interview. The interview was audio recorded if the respondent agreed to this. Interviews were conducted by two members of the research team (BM and AK).

Firstly, the purpose of the interviews was explained, and any questions about the study or the consent form were answered. Following this, a definition of e-PROMs was provided. The main interview followed the semi-structured interview guide which included sections about the mode of administration and specifics of collecting e-PROMS, the benefits and impacts of using e-PROMs, engagement of others regarding the use of e-PROMs, and the challenges of implementing and using e-PROMs.

4.2.3   Data analysis

All interviews were transcribed verbatim, and the transcripts were read several times by two members of the research team (BM and AK). The data was analysed using a simple content analysis approach. The interview topic guide (Appendix 1) was used to code the interviews, and this was done by one member of the project team (BM). This initial coding was assessed by two other members of the project team (AK and MF), and used to extract the key messages for each section of the interview topic guide. All themes were allocated to the sections of the topic guide, and no other categories were added.

4.2.4   Ethics

The study was reviewed and approved in April 2014 by the Research Ethics Committee at the School of Health and Related Research (ScHARR) via the University of Sheffield Ethics Review Procedure.

5.   RESULTS

5.1   Literature
Authors from the ISPOR task force had published 70 reviews. The majority of the reviews were set in the US. A range of published articles from the UK were identified by interviewees. However, there was still a relative lack of literature from the UK in this area, as a number of the systems identified were recent, and several were still under development.

5.2   Interviewees
Academics (n=3) and clinicians (n=6) involved in or researching the application of e-PROMS in routine clinical practice agreed to be interviewed. Six interviews were conducted by telephone and three face-to-face. Interviewees were involved in a range of areas relating to the use of e-PROMs, including: development (n=6), routine collection or collection as part of a pilot or research study

(n=5), analysis of data (n=3), or use of the results in clinical settings to inform consultations or decision making (n=9). The majority of interviewees (n=7) were based in the UK with one in the US and one in Canada. Their clinical expertise covered a broad spectrum including gynaecology, cancer, mental health and orthopaedics. A summary of each interviewee's involvement, clinical area and country is provided in Table 1. Of the 15 other potential respondents contacted to take part, five were involved in the technological aspect setting up the systems and delivering e-PROMs, three were clinicians or involved in a clinical setting, and seven were academics.

Out of the nine interviews, one was not audio recorded but notes were taken by the interviewer. A total of eight interviews were included in the analysis as a technical failure on one interview meant this could not be transcribed.

Table 1: **Respondent involvement in e-PROMS**

ID	Summary	Clinical area(s)	Country
R1	Clinician involved in the development, research, testing, implementation, and employment of an e-PROM system.	Used in a range of clinical areas including colorectal surgery, urology and gynaecology. Developed for anaesthetics and orthopaedics.	UK
R2	Clinical academic involved in the development of an online system for collecting PROMs data and linking it with medical records.	Cancer	USA
R3	Clinician and PROMs lead and involved in the development of a national registry that includes a PROMs element.	Orthopaedics	UK
R4	Clinical academic using e-PROMs in a large transplant centre.	Heart and lung transplant	Canada
R5	Clinician, developer of UK e-PROMs system.	Initially shoulder and elbow surgery but also used in a range of other clinical areas.	UK
R6	Clinician involved in the routine collection of e-PROMs, also uses system developed by R5.	Mental health	UK
R7	Academic involved in a programme of work about using e-PROMS in clinical practice in primary care. Investigating the use of e-PROMs routinely for helping clinicians make decisions when planning care for long-term conditions.	Conditions in the DH long term conditions programme including asthma, COPD, stroke, heart failure, diabetes and epilepsy.	UK
R8	Academic involved in a range of studies investigating the implementation of e-PROMs in a range of routine cancer settings.	Cancer	UK
R9	Academic involved in a range of studies investigating the implementation of e-PROMs in a range of routine cancer settings.	Cancer	UK

5.3 Results of interviews and literature review

In each section below evidence from the literature review is summarised and the results of the interviews are discussed in narrative form with edited verbatim quotes used to illustrate the key themes. The italicised edits in the quotes are very minor in nature and have been done to facilitate readability. The sections are ordered as follows: Mode of administration, Benefits and impacts of e-PROMs, Engagement, and Challenges.

5.4 Mode of administration and specifics of collecting –PROMs

5.4.1 Collection of e-PROMs

From the literature review it was apparent that there are various means of collecting e-PROMs, and they can be broadly classified by mode of administration within clinical settings or outside clinical settings. Within clinical settings, computerised technologies include traditional personal computers (desktop PC), mobile tablets-PCs, hand-held computers or personal digital assistants (PDAs). The SmartPen technology is a pen-like device that is used to select responses on paper and it uniquely identifies the patient and the assessment. While the SmartPen is a printed paper version, it carries the advantages of electronic data capture.[9]

Findings from the literature suggest that PROMs can also be administered outside the clinical settings, mainly in people's own homes. They include using tablets, desktop PCs with an internet connection, smart phones offering similar features to a PDA (or the use of a PDA in the home if available), and telephone interactive voice recognition (IVR) which is not currently in widespread use.[9;11] There are several examples of prototype websites that are currently being developed. One is the PatientViewpoint which has been developed in the US to collect PROMs in oncology with the view of linking them to electronic medical records.[12] This website can be used both inside and outside clinical settings. The characteristics of various administration modes are summarised in Table 2.

Table 2: Characteristics of different modes of administration in a clinical setting (adapted from Rose 2009)[9]

	Smart Pen	PDA	Tablet - PC	Desktop PC	IVR
Mobile	++	++	+	-	+
Easy to handle	+	++	++	++	+
Fill out time independent from staff time	++	++	++	+	++
Assessment can be made in the regular waiting room	++	++	++	-	-
Visually impaired patients	-	-	+	+	+
Data entry time	+	++	++	++	++
Timeliness of access to the data/immediate reports	++	++	++	++	++
Assessment at home using same mode	-	-	++	++	++
Development of new questionnaires	-	+	+	+	-
CAT ready	-	+	+	+	+
Hardware investments	-	+	-	-	++
Administrative costs	++	++	++	++	++

CAT: Computer adaptive test; PDA: Personal digital assistant. The ratings indicate if the particular characteristic, use or technical feature is a strength (+), higher strength (++) or (-) weakness.

The experts interviewed reported collecting e-PROMs using a range of administration modes. This includes using online systems developed for this purpose (to enable completion at the convenience of the patient), kiosks in clinics, tablet computers and IPads, and also mobile phones. A range of methods are combined by some interviewees to maximise completion rates as illustrated below.

"So there are two kiosks in outpatients which are touchscreen and so the kids come to clinic and enter the PROMs prospectively straight into the system. We have some tablet PCs which again hopefully they will use to prospectively enter the data. We also do paper based as well." (R3)

"We have a system whereby patients complete [and] recomplete a questionnaire which is electronic online usually at home or if they're able to do so. The patients fill the PROMs in clinic using touchscreens. But the majority of patients use an online facility to do it" (R1)

"All my patients are on the system so we routinely collect outcomes for every single patient…we are inclusive so we collect the PROM through any medium necessary. We first try electronically and if we can't, we have other means…phone them up, face to face when they come in and that's how we maximise the data collection." (R4)

5.4.2 Who completes the e-PROMs?

By definition, PROMs and e-PROMs are completed by the patients. However the literature suggests that there are important factors to consider when assessing the feasibility and acceptability of collecting PROMs. They include the patient's ability to self-report, whether patients require help in certain settings (for example during hospitalisation), and the timing of assessment.[10] When patients are incapable of filling out PROMs themselves (for example young children, those who are too unwell, illiterate or cognitively impaired), it can be acceptable for them to be completed by proxies. However, in such instances it is necessary to accurately document whether proxies have been used because self-report and proxy-report are known to differ, and proxies may provide their own assessment of the patient rather than how the patients would complete the PROM.[10]

The majority of interviewees reported that patients completed the e-PROMs, with the caveat that if the measures are completed at home then it is difficult to know who completed the questions, or if the patient was influenced during completion (for example by their carer). It was reported that many patients who are quite ill or have not used the system before may require support to complete the measures. The support may be provided by carers or a member of staff, depending on where the measures are completed. Some interviewees reported that they record who completes the measures if possible, though this was not consistent.

> *"Usually it's the patient themselves…Occasionally carers will do it or it will be done with somebody with assistance like a translator or a relative, and we document who has done it…It's not done with a clinician present." (R1)*

> *"The patients. Do they get help to complete it and of course the validation techniques all assume that the patients do it themselves electronically obviously they're all doing it themselves, but are they getting help from their son or mother or whatever we just don't know." (R5)*

> *"Recording is done by the clerical staff in the clinical group who administer that and it's the support team support workers you know in the clinic itself who actually check the patients have done it and print off the results and if they haven't done it they'll ask the patients to do it using touchscreen" (R1)*

5.4.3 Time of completion

It is clear from the literature that PROMs can be administered at one or several time points, and the frequency and timing will depend on the purpose of collecting the data. For instance, to measure the impact of treatments, there needs to be at least one baseline and one follow-up measure. In some cases, patients are asked to fill in the PROMs each time they come in contact with the health

services. There is a trade-off between more frequent assessment and patient burden. However, completing PROMs at every visit makes it more routine and habitual. In an outpatient setting, PROMs can be collected at each visit or sometimes in between visits.[10] In summary, the time of completion depends on the pathway. This view was supported by the interviewees and there was an interest in collecting longitudinal data for the patients.

Interviewees reported that follow up completions can be over a range of different frequencies depending on the setting and clinical area. For example, routine collection may occur at a certain time point following an operation (to assess the success of the treatment and improvement in key outcomes), or prior to every clinic visit (to inform consultations). Some e-PROM systems are available for completion by patients on an ad hoc basis, and can act as a trigger for a clinical consultation if the patient scores established cut off points for the measure, indicating a concern (for example in anxiety and depression).

> *"We've used it in several evaluations of use in routine practice so in one study they completed it every two weeks no matter what their visit schedule was and for another study they completed it during the week before their clinic visit so it was tied to the frequency of their clinic visit." (R2)*

> *"Generally we do a pre-op and then six to eight weeks post-op; so we call it the six weeks but it can go up to eight or somewhere in-between, and then it depends a little bit on what procedure they've had done." (R3)*

> *"That is completely dependent on the pathway." (R5)*

> *"If people fill in the PROMs at home then this can act as a trigger if an earlier appointment is needed when the score is above the cut-off." (R6)*

5.4.4   Place of completion

As discussed in the literature, and also in Section 5.4.1, PROMs can be collected either in the clinical setting or outside clinical setting, that is, at home. As shown by the interviews, the place of completion is dependent on the system used. For many of the online systems, patients are asked to complete the e-PROMs at home prior to their consultation. In some cases where this is not done, the PROMs are available to complete at the clinic using, for example, a kiosk, touchscreen or tablet computer. There may be disadvantages associated with filling PROMs in waiting rooms. One disadvantage is that patients may be anxious about their visit in which case the data from PROMs may reflect a mixture of their health and the feelings associated with the visit. Oncology would be an

example where this could happen. There are also occasions where patients arrive late and may not have adequate time before their appointment to complete their PROMs. Therefore, encouraging patients to complete their PROMs at home using the web-based systems may be preferable.[12]

> *"They complete online before they arrive." (R1)*

> *"Again it's a mixture. We're trying to obtain a home email address and encourage people through an email to complete the PROM at home but it is often [completed] in clinic. There are a handful of surgeons and they've got a bank of touchscreen computers in their outpatients and the patients all log on as they arrive. Then as I say we have paper based forms in the clinic. So at the moment it's certainly more than 50% are administered in clinic but the number of completions from home is growing." (R3)*

5.4.5   How are patients invited to fill in the e-PROMs?

The literature demonstrates that patients can be notified to complete PROMs using either automatic or manual means. The formats can range from email, telephone, text messages, verbal or paper. In a survey of e-PROM systems in oncology, email was the most popular means, used in 14 out of 35 systems.[13] In some cases, patients may be invited by medical or administrative staff when they arrive for appointments.[14] In addition to the first invitation to complete the PROM, several electronic systems are also programmed to send automatic reminders to patients.[13;15] This is mainly applicable when PROMs are being administered outside clinical settings.

In the interviews, respondents reported using e-mail and postal methods to invite patients to complete the measures, as well as asking patients during or prior to their consultation. For example, details of how to access a system may be sent out with an appointment letter. Clinicians and other staff are involved in inviting patients to complete the measures with varying levels of success. If the e-PROMs were collected in a research setting, research assistants or nurses were asked to speak to patients following a study protocol. E-mail reminders are also used, as are incentive systems (such as vouchers for completion). The content of the invite is a key factor in increasing participation, and it is seen as important to inform the patient of why completing the measure is valuable to both them and to the clinical team.

> *"Yes the invite goes by post…with their appointment details" (R1)*

> *"The nurse in the clinic is the one that says have you completed your measures. I would say the nurse is the one that keeps an eye on it. But you know they're familiar with it now. At the beginning…we had a research assistant. But once it was implemented then the patients were contacted and they knew about it…" (R5)*

"Does not work with receptionists and the only way this can get done is with the clinicians."
(R6)

5.4.6   e-PROM system development

PROMIS is an initiative by the National Institutes of Health Roadmap in the US to create a database of outcome measures for clinical research and practice.[11] The database consists of items banks covering physical, mental, and chronic conditions. The PROMs can be administered in several ways and forms making the system very flexible.

Jensen et al. reviewed 33 systems in oncology using e-PROMs and out of the 33 systems identified, they gathered detailed information on 27 systems, with 70% in the US.[13] One third of the systems were implemented in one single academic institution. Twelve out of 27 were directly integrated with the electronic health records system. PatientViewpoint, developed in the US, is a prototype website to collect PROMs in an outpatient setting in oncology.[12] The PROMs data are linked to the electronic medical records. Following piloting of the prototype, the conclusion was that PatientViewpoint was a system that was acceptable to both clinicians and patients.[16] Wu et al. listed a selection of 10 commercial electronic systems integrated with electronic health records and patient portals that have acquired considerable market in the US.[17]

The interview data found that systems were developed via a range of collaborations between clinical groups, researchers and software developers, and also as the result of research projects. Some systems are linked securely with other sources of information such as the Patient Information System.

"It's been developed here...with collaboration with medical physics...commercial colleagues...a software house...and with [academic] colleagues." (R1)

"It's a registry held securely NHS level security in a central store. It was setup that way because we thought the technology was at the level that would allow that...so we finally bit the bullet and went down the internet route rather than on the computers in hospitals....so it's web based you log in with a secure password and then it's basically a standard database whereby it asks you to, there's millions of fields, and it's very complex as in you can record all sorts of weird and wonderful data.... so you can log on a smartphone, iPad, PC..." (R3).

5.4.7   e-PROM system management

From the literature, it is clear that a "supportive environment" is very important to facilitate the machinery of e-PROMs data collection. This can be summed up as having the right technical support, support for the patients, and support for the provider.[9] These are discussed in more detail in Section 5.6.2.

In the interviews, respondents reported that for the successful management of an e-PROM system it is important to have support from the whole team including clinicians and other medical, administrative and support staff. This is achieved by embedding the system into the clinical practice process, and informing the whole team of the importance of collecting outcomes data from the patient perspective.

> *"So actually with a well-designed system what we find is the clerical staff and the admin and clinic and support workers and nursing staff will facilitate the like err collation of the actual questionnaire in terms of printing them off and making sure patients have done them err and process and that. And that seems to work quite well; it's embedded if you like in the routine clinical process." (R1)*

> *"It's the team really so we have a system, because of the electronic database, now we have a system by the secretaries will populate the system with the patients name and we have a Specialist Spinal Nurse who collects some of the clinical scores…Physiotherapists, the junior team, and the consultants, so we all have little roles to play in the system." (R3)*

5.4.8   What PROMs are used?

From the literature, Synder et al. list a number of considerations in selecting a PROM: generic versus condition specific, profile versus preference based, single item versus multiple item and static versus dynamic.[10] In selecting a PROM, it is clear that there are advantages and disadvantages associated with each type, and consideration of the reasons for collecting PROMs and the way in which the data are to be used could determine which of these aspects are important. Both condition specific and generic measures relevant to the clinical area are included in the e-PROMs system.[18] This includes electronic adaptations of well-established measures, and also new measures developed by the teams. Item banks from the PROMIS databank are an example of the dynamic measures which have been used in the United States and are starting to be adapted internationally.[11;19]

The interviewees referred to a broad range of measures including both condition specific and generic measures, specific questions used to elicit particular information, newly constructed measures and a mixture or compilation from various sources. In addition to PROMs, some systems

also include patient experience questionnaires, and clinician report instruments. Some systems have adapted the measures they include over time, and an advantage of electronic systems is that it can be easy to implement this with minimal cost implication. The measures were chosen based on a range of factors including relevance to the condition and available information about their psychometric validity.

> *"They are condition specific e-PROMs that we've developed ourselves, condition specific PROMs that others have developed and we also use generic PROMs." (R1)*

> *"…mainly cancer general cancer PROs but the system is designed to administer any type of PRO and so we've also used PROMIS measures [an item bank system]…we've used the needs assessment, we've used disease specific things…clinicians can select which questionnaires they want which patients to complete." (R2)*

> *"It's in primary care for people with multiple conditions and we will use individualised measures which in principle should be not necessarily generic but you know specifically if you want alongside EQ-5D and a number of condition specific measures." (R7)*

> *So the clinicians come to me and I present the ones that are available and I tell them where they can go and find others and then we have we have a meeting and we discuss it…we select the measures…at team clinical level. And then we get like a pilot study where we get the patients. And patients complete the questions and we ask the patients what you think about it. Which one do you think makes more sense to you? (R4)*

> *"You look at the signs that's already out there, you look at what instruments have been validated, most of the time all you have to do is ask the clinician and they will know so then you go and do your background work on that particular instrument and make sure there is good literature showing the validation. In my practice it's not really changed. All the pathways are using exactly the same instruments that they started with." (R5)*

5.5 Benefits and impacts of e-PROMS

5.5.1 How PROMs data are used

PROMs were originally designed for use in clinical trials and studies. More recently there has been an increasing interest in using them in the provision and delivery of health services. As shown in Figure 2, PROMs data can be used in the care of individual patients (individual patient level), at provider level in assessing the provision of care (group level) and finally at national/regional level in assessing all the providers. In the UK, the use of data at national level has gained momentum with the collection of PROMs in four surgical areas.[20-24]

Figure 2: Uses of PROMs
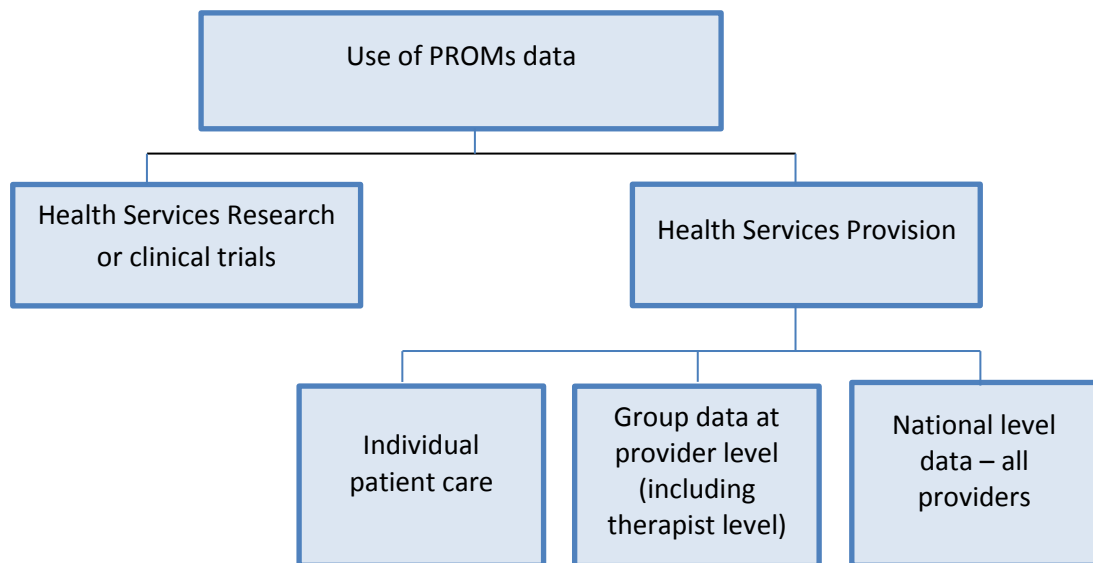
At group level, data from PROMs are aggregated and summaries are provided to clinical directors, managers, team leaders. These can be used to monitor teams, or compare outcomes at hospital levels.[25] In the literature reviewed for this report, the vast majority focussed on the use of individual patient level data in clinical practice. At patient level, there are options to present current scores only (with or without benchmarking or cut-offs), or to present the scores over time.

The literature suggests that one of the major advantages of e-PROMs is that they can be collected and fed back in real-time. In developing a PROMs scores reporting system, a number of steps are involved. These include: determining when and how to present the results; whether they will be discussed with patients and, if so, how; whether it is part of the clinical workflow or not; who will receive the results (clinician in charge of care or others); when to address the PROMs results (part of a visit) and finally the formatting of the PROMs scores.[10]

The literature identifies 'Making sense of the data' as one of the key barriers or facilitators in the use of PROMs.[26] A systematic review of qualitative evidence of experiences of professionals using PROMs, 13 out of 16 studies reported the use of feedback. Graphical representation of results is preferred but professionals wanted ways to be able to identify clinically important change. This concern was also identified by Synder et al. who suggested that the information is complemented by providing cut-off scores for different levels of severity, notwithstanding that these cut-offs would only be useful if they are sensitive and specific to the population for which PROMs are being collected.[10]

From the interviews, respondents reported using the data in a range of ways, including informing clinical consultations and benchmarking. In some cases, data were presented to both the clinician and patient. This information can be used to track change over time, and highlight areas of concern. Data are presented in a number of ways in existing systems, including providing scores across domains and presenting key information graphically. In some systems, the data are available instantly to patients. Systems to flag any anomalies or low scores that could indicate concern may be used in some cases. PROM scores can also be used to inform whether a patient needs a consultation, for example if their scores on a measure of mental health indicate a risk of self-harm or suicide. If this happens an e-mail to the consultant can be triggered to inform them to take further action.

> *"So the patient sees the score report right away and then the score report is also available to the clinician if they log on to the web system and then a simpler and plainer version of the score report was imported into the electronic medical record system that we had at the time." (R2)*

> *"A copy of a graphical representation of the results [is used]. So they know what the level of pain is and you know how far they can walk and what their condition level is. The physicians have the same results and this is an interaction that happens at the time of the visit." (R4)*

> *"If patients reveal any risks of committing suicide, this is flagged up in the system and we get an urgent message…If there is deterioration in scores, this triggers an email and then I can call them to ask if they needed an earlier appointment." (R6)*

5.5.2   The potential benefits of e-PROMs

The feedback of PROMs results to clinicians and patients is a relatively new development and Greenhalgh and Meadows suggest that theories of change can be used to appreciate the mechanisms by which PROMs can lead to changes in practice.[25] The usefulness of PROMs feedback can be assessed by disentangling their impacts on decisions pertaining to: ordering investigative or diagnostic tests, referrals to other professionals, changes in prescriptions, better understanding of the condition, and impact on management. While these are changes in processes, they could positively influence outcomes and improve patient experience.

Santana & Feeny developed a conceptual framework describing the potential benefits of the use of PROMs.[27] While the paper is focussed on chronic care management, it is applicable to other areas of health. As shown in Figure 3, PROMs can be a vehicle to facilitate communication at different levels: clinician-clinician, patient-clinician, patient-relative, and clinician-relative. Improved communication can lead to increased patient engagement and activation which in turn can lead to

patient adherence, and both patient and clinician satisfaction. This is also conducive to shared-decision making which can result in better management of conditions.

Figure 3: Impacts of PROMs on communication, engagement and outcomes
Source: Reproduced with minor adaptation from Santana and Feeny (2014), with the authors' permission.[27]
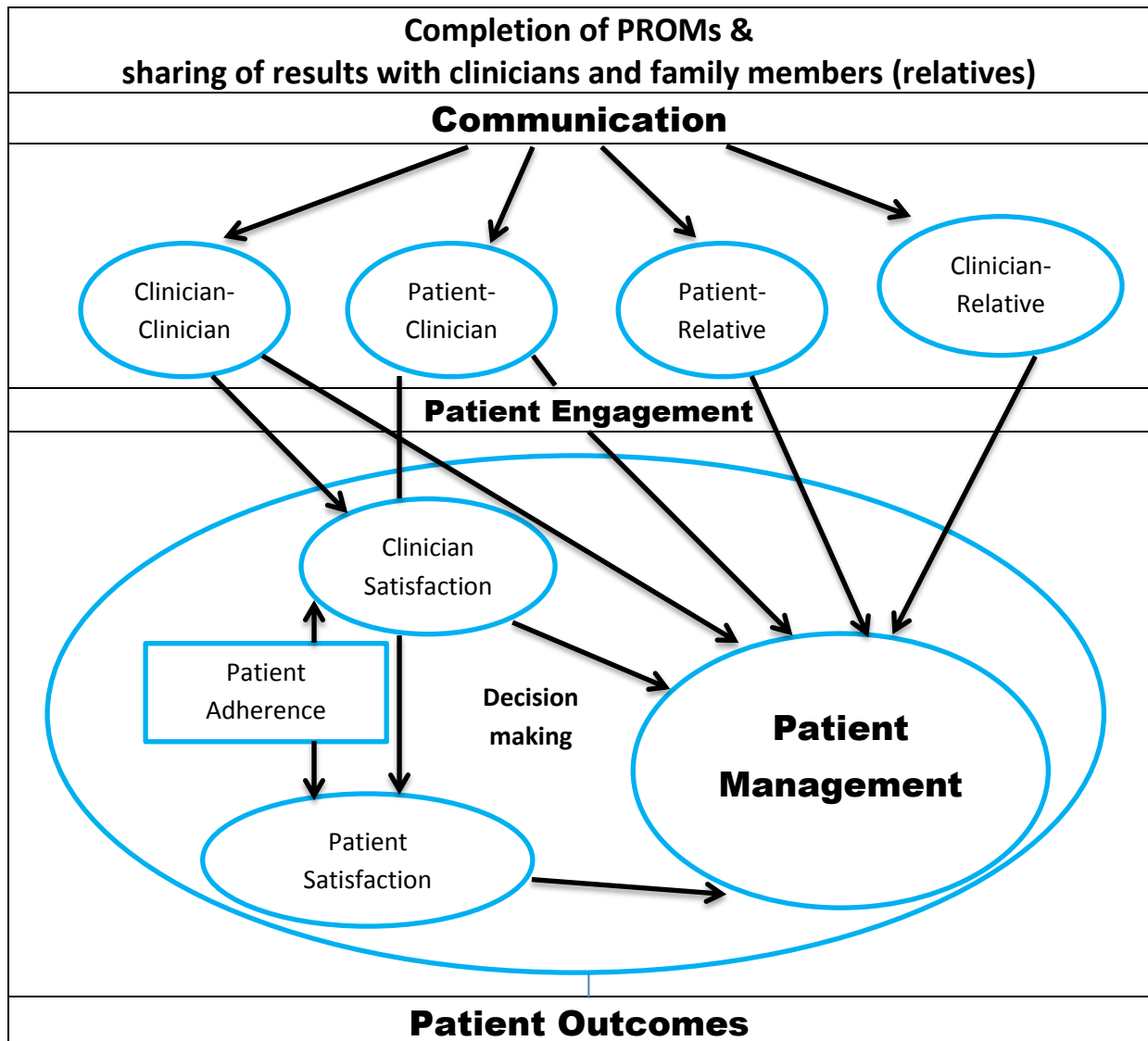
As shown in Figure 3, the use of PROMs can lead to better processes and so better outcomes. Other authors have also highlighted the potential of PROMs in enhancing the process of care by improving communication, increasing patient education and supporting shared-decision making.[26;28] There is some evidence to support this from a small study with 28 oncology patients in Leeds who were asked to fill in the European Organisation of Research and Treatment Core Quality of Life Questionnaire (EORTC QLQ-30) and Hospital Anxiety and Depression Scale (HADS).[29] The authors

found that doctor-patient interactions improved mainly because additional areas for discussion arose during consultations. The results of this study are to be interpreted with caution because of the small sample size but Velikova et al. referred to similar findings in the literature.[29] Several authors reported that clinicians were able to identify issues that might have otherwise remained unnoticed in the absence of the collection of PROMs.[16;28] In some cases clinicians added that the PROMs did not necessarily provide any information that they did not already know.[16]

In the interviews, a range of the benefits of using e-PROMs were acknowledged. These included clinicians understanding more about conditions from each individual's perspective, and identifying issues that might otherwise not be considered (for example patient preferences for interventions). Instant use of the data is a major benefit of e-PROMs, and can help to structure the patient consultation, save the patient attending an appointment if there is no sign of risk, or inform early discharge. The e-PROM scores can also help clinicians assess their own and other's performance.

> *"It's about identifying issues that might otherwise go unaddressed. It talks about helping to structure the visit; it talks about patient activation and about obtaining information that's already known." (R2)*

> *"e-PROMs allows you to look at what the patient has said, in black and white if you like, what the patient's said about their condition…Their opinion their feelings about their condition, which is actually very empowering because then you understand you've got a good insight from their perspective. Because the danger we all know is a clinician's view of a patient's condition is often different from the patient's perspective of their condition." (R1)*

> *"e-PROMs allow instant analysis and processing the data then to present these symptom scores in a meaningful way that would then enable or enhance clinical communication." (R2)*

> *"Benefit to me I know my quality of work, benefit to the patient they don't have to come back to clinic unnecessarily, benefit to the system which has a theme for service provide from two aspects, the quality and also the economics side of it, is it improving patients' lives and is it doing it in a resource careful manner so those are the two questions really, the two aspects." (R5)*

5.5.3   Evidence of impacts of e-PROMs

PROMs can positively impact the quality of improvement in the provision of care.[26] Patients are provided with the opportunity of highlighting what matters to them in the context of their conditions and as a result, the clinician can directly address these issues. As discussed in Section 5.5.2, there is some evidence in the literature that the use and feedback of PROMs may lead to improvements in communication. However, there is little empirical evidence for improved patient outcomes as a result of collecting and using PROMs. Based on a review of seven studies, the effects

of providing any type of PROMs feedback were very limited.[25] An additional 17 papers which were reviewed reported the results from randomised control trials where the intervention was feeding back the PROMs results and the control was not providing any feedback. The impacts of feeding back information to clinicians revealed that the effects were positive in only one study in an outpatient setting.[25] On the whole, they concluded that the impact of PROMs feedback compared to not providing feedback on patients' outcomes was very weak. Despite the lack of empirical evidence on the impact of providing feedback from PROMs collected, there are many systems that provide feedback in the literature and in the interviews carried out. Seven papers in a review of 16 studies identified the possibility that collecting PROMs could improve the confidence of patients in their clinicians' competence, which in turn, could be used to manage patients' expectation and their ability to take responsibility for their treatment where appropriate.[26]

Interviewees reported that the availability and use of e-PROMs data had led to changes in practice in some settings by, for example, improving the patient management process due to an increased depth of knowledge about patients.

> *"I think it's enabled me and my colleagues who use it to have a better understanding of patients and their condition and our feedback we've had from patients using [a patient face validity assessment questionnaire]. And these questionnaires have been very positive and anecdotally as well as from observational data we've found patients do think it helps communicate, they do engage well with it, and they think it's a useful exercise" (R1)*

> *"Yes again as I showed you the where is it the virtual clinic approach [providing direct contact to named Consultants by email or telephone], the virtual clinic has started based on this and we don't see patients unnecessarily now so we only see patients who need to be seen." (R5)*

> *"If we find that our treatments are not making any difference at all, we can discharge service users." (R6)*

5.5.4   Potential harms of e-PROMs

A systematic review carried out by Boyce et al. on the qualitative evidence of professionals on the use of PROMs revealed that PROMs could have some unintended effects on patients.[26] Firstly, completing PROMs and using the data in consultation could be construed as an invasion of privacy of patients in potentially asking questions on aspects of their lives that they did not want to disclose. Secondly, the use of PROMs could narrow the scope of the consultation by focusing on issues which were on the completed questionnaires. Thirdly, professionals thought that patients could find certain questions distressing, which could jeopardise the clinician-patient relationship. However, it

needs to be stressed that the latter three points reflect the opinions of professionals and not patients. This concern was also expressed by a study assessing the feasibility of collecting PROMs in secondary care mental health.[30] The authors highlighted the possibility that requesting the patient to complete a PROM at the first visit may act as a barrier for the clinician to successfully engage with the patient. While e-PROMs have the ability to improve care, the "humanity of the interaction" should be preserved.[31] Wolpert suggests that there is no evidence of harm caused by PROMs but there is some evidence for increasing anxiety.[32]

Interviewees reported that the harms of e-PROMs include the potential for gaming, where patients who understand the process may complete the measures to determine whether they obtain treatment or not. There may be the potential for clinicians to have to provide "bad news" based on the self-reported results provided by patients which may not always be accurate based on the questions used.

> *"So you know, the physician sometimes says I'm not sure if I want to know all that...Bringing bad news to the patient and the relatives, we can see that has a harm" (R4)*

> *"The only harm I can think of is risk. We have not done enough to look at whether gaming is a potential risk. I think if patients get in their head that the way they fill this in determine whether they get treatment, then it might happen" (R6)*

> *"…implementation didn't work very well, the technology worked but there were problems with implementation and I think I couldn't say that the problems damaged people or not because I have no idea at all." (R8)*

5.6   Engagement

5.6.1   Reasons for starting using e-PROMs

At the national level, DH introduced a policy to try and promote the use of PROMs to improve patient-level care and communication between the patient and clinician, as well as evaluate the quality of services delivered by the NHS.[33] This has been reiterated in various NHS Outcomes Frameworks.[34-36] In the US, the National Institutes for Health (NIH) have directly called for the use of electronic systems to record PROMs,[37] and have since developed PROMIS as a method of collecting e-PROMs.[9;11]

However, none of the interviewees referred to the development at the national level as a catalyst for their involvement in the collecting e-PROMs. A range of reasons were provided for getting involved in the use of e-PROMs. For example, e-PROM use was starting to reduce the burden of

collecting paper based PROMs and the subsequent data entry required. E-PROMs were also introduced to allow views of patients relating to their condition to be instantly taken into account.

> *"The eureka moment was, if you like, when I was entering the data into the database and thinking well if we could get the patient to do this for us then we could it would add a lot of value to it." (R1)*

> *"In healthcare the decisions are taken higher up and I thought that having the questionnaires if … the patients thought that was a good idea. It would help provide … like a prompt to enhance communication and help that kind of dialogue and involvement of the patient." (R4)*

> *"I thought naively collecting PROMs electronically would be a much better way of collecting all the data without having to do it face to face." (R5)*

5.6.2   Engaging others to use e-PROMs

From the literature, one of the ways of engaging others to use PROMs is to convince professionals the value of collecting PROMs.[26] To be able to use PROMs effectively, professionals need the right supportive environment which can be divided as the following: technical support, patient support and provider support.[9] Technical support is needed irrespective of the mode of administration. In the case of e-PROMs, setting up the computerised system and supporting staff to use it is important. Similarly in administering PROMs by pen and paper, adequate support ought to be provided in preparing questionnaires, ensuring that the materials are appropriately presented, reducing the burden associated with data entry etc. At the patient level support, while the patients fill in the PROMs themselves, some introduction on PROMs and their use is deemed necessary. There is some evidence that patients prefer e-PROMs over paper.[9] Finally at the level of provider support, the main barrier in introducing and using PROMs is people's attitudes.[9;14;32] One of the main concerns is that the process of collecting PROMs and using them is time consuming.[9;14] Realistically, the process can be made as convenient as possible, addressing issues such as how the collection of PROMs is integrated in the workflow. However, a large amount of effort needs to take place prior to introducing a system to ensure that healthcare professionals are knowledgeable about how to access the data and interpret them.[32]

In the literature, governance issues surrounding the collection of PROMs need to be adequately addressed for staff to engage.[38] Upon trying to standardise procedures, a system may lose its flexibility. However, there ought to be clear policy guidelines, mainly from the information governance side, on collecting PROMs, using PROMs and connecting them to the rest of the information system.

From the interviews, engagement was increased by providing full training and evidence supporting the approach, and encouraging senior staff to successfully engage more junior staff responsible for overseeing the data collection. Explaining the benefit for patients was also seen as important to increase engagement in the process from their perspective.

> *"Personally I did the following: a. Found colleagues who were willing to go out of their way to get involved in this; b. Personally convinced others that this was a good idea and explained the potential benefits" (R6)*

> *"So unless you incentivise the clinician in a way they understand and appreciate and the only way to do that is to understand the clinical pathway and intervene in the right places you're never going to succeed." (R5)*

> *"I suppose it's just speaking at meetings and sort of you know talking to friends and colleagues and so forth." (R1)*

5.6.3 Completion rates for both baseline and follow-up

An observational study was carried out to evaluate the feasibility and usefulness of the PatientViewpoint system mentioned in section 5.4.6.[16] Based on 52 patients in the study, out of 224 baseline and two weeks follow-up questionnaires expected, 190 were completed, that is a completion rate of 85%. However this is a small study and therefore the completion rates need to be interpreted with caution. In a study in Germany, 523 patients were recruited at 14 GP practices to complete e-PROMs (St Georges Respiratory Questionnaire and EORTC QLQ-30) over a one-year period.[14] Out of these patients, 413 completed only one assessment and 110 completed two or more. Therefore, one follow-up or more was only available for 21% of the patients in the study. The completion rate for follow-up was mainly due to short consultation time. This study was also a pilot but highlights the potential barriers in obtaining follow-up questionnaires.

Interviewees report that completion rates vary from system to system, and also between research studies and routine collection settings. There is also evidence to suggest that completion rates differ across different demographic groups, and reduce at follow up. It was reported that overall completion rates are higher when PROMs are collected using a range of administration modes.

> *"About 70% of patients complete the PROM before they come to clinic and the other 30% will be offered the opportunity to do it when they arrive..... It varies; at times it doesn't work as well and you get practically no patients who complete the PROMs at home because the details that they need to access the system haven't been issued or the patients haven't had enough time.... And other times it seems like we're doing very well and we might get 90% or*

100% sometimes…we've looked at age and demographic issues…It's the younger patients who are generally more connecting and generally better…But the older patients again can be resourceful and have friends and family who will help them so you know it varies a bit…I think the completions at follow-up are more 50/50." (R1)

"…it seems that generally email compliance hovers between about 25 and 40% depending on the population group…paper compliance I've got as high as 50% with significant nagging by myself, my staff and my patients…So it can be much higher if you do nag; if you sell it properly; and it's how you phrase the email it's what you address it so it doesn't got into the spam folder. You know there are lots of issues to get around. And not making it too bulky, you know if you get 25 questionnaires they're going to stop half way through." (R3)

"I get my own data about ninety percent complete but that's because it's so inclusive we have so many different ways of getting it." (R6)

5.6.4   Encouraging the ongoing collection of e-PROMs
From the literature, to encourage the ongoing collection of e-PROMs, one needs to ensure that clinicians and other professionals understand the value of PROMs and feel comfortable in administering them, as well as interpret and use the data correctly.[10;32] As discussed in Section 5.6.2, it is important to have a supportive environment.[9]

From the patient and clinician perspective, encouraging ongoing collection was linked to the importance of understanding the condition. More practically, interviewees reported that it was important to build e-PROM collection into the overall care process. The extent to which the incentives actually increase or maintain completion rates is unclear. However, it is should be stressed that the use of incentives to sustain the collection of PROMs is unsustainable with pressing demands on health care resources.

"We emphasise the importance of understanding the patient's condition and it's then in their interest to engage with that…because it informs the consultation. If you're asking them to do it post consultation they're doing it for our benefit rather than theirs." (R1)

"I make it part of my junior's job because I think collecting PROMs is valuable and has to be done." (R2)

"I think you can't encourage PROMS collection. You can't tell a patient what to do. A lot of techniques have been tried: rewards, financial rewards, nothing works. It is a big incentive if by collecting e-PROMs, it might mean that patients do not have to come back to clinic but even then it's only thirty percent maximum who fill in the PROMs. You can't…, you just have to have inclusive systems to get as much data as possible." (R5)

5.6.5   Important characteristics of e-PROMS

From the literature, it is clear that utility of PROMs both to patients and clinicians is primary to ensuring that PROMs are completed. The PROMs need to be relevant clinically.[10;10;13;32;32;39]

From the interviews the method of approach, the actual PROM used and providing information from the results of the PROMs to patients were seen as important characteristics that encouraged completion and engagement.

> *"…the EQ-5D and the Oswestry generally work well for back pain…" (R3)*

> *"And on this uptake across age and other demographic groups it's more to do with the method of approach rather than the individual…So giving them enough time, explaining in the letter that goes out to them why it's important." (R1)*

> *"…that could be at the individual patient level so when they see a printout of the score, well not a printout but on the screen you know changes I think changes the score over time, probably it's just as important or probably more important than the absolute score. I think training them on how to interpret the scores is very very important for individual patient care…" (R8)*

5.7   Challenges

5.7.1   Costs of the process

No details were identified in the literature on the costs of e-PROM systems and costs of collecting e-PROMs.

Interviewees reported that the costs of implementing and maintaining e-PROM systems varies depending on the scope of the system, the range of stakeholders involved, and also whether it is used commercially or within the NHS.

> *"We reckon the unit cost of is around [£1.20] per questionnaire per patient. I mean our annual license fee that we pay…and it's for about fifteen hundred patients a year I think, it's gone up gradually. The license fee of £2,000 covers the support and hosting and so forth…there's cost of admin staff, things like printers, touchscreens and all that side of things, which difficult to measure independently. But also there's a potential benefit and a dividend in terms of clinic time. So for example, individuals have used the PROMs system to shorten consultation times…" (R1)*

> *"…basically charging in the region of £1,000 pounds a month for surgeons who are in private practice who want to collect outcomes…" (R3)*

"The way we set it up it was it was interesting because we started with a research project. We had a grant and funds for launching it. And then implement was easier right? It was already in place. Now that we're doing it in different clinics and it's not going to start as a research project it will start as the actual implementation." (R4)

"Yes I think to make this effective you've got to show cost benefits and that's again coming back to the clinical pathway and you need to understand how much the clinical pathway is costing. To give you my example I know how much a clinic visit costs so if I can save one clinic visit I know how much money that makes. Today and in future what will not work is bringing innovations of technology which cost a lot of money purely for quality gains. That is difficult to sell. If you have quality gains as well as cost saving that's when it works. So I think within the clinical pathway you need to find ways to get the money that you can spend on PROMs collection and so far we've been successful in every clinical pathway that we've tried to do that. Mental health is one of these we use it to do this. So it's about looking into the clinical pathway and finding out this is where there is some resource that we can save, be it clinical time, direct money in whatever shape or form. There is a cost associated with running the system. It's very difficult but typically I talk about £10 per patient, cost per year. That's just to run the system…it's very hard to find definite figures for it." (R5)

5.7.2   The main barriers to the implementation of e-PROMs

From the literature, the barriers to the collection of e-PROMs are numerous. The barriers can be best classified using 3 of the 4 themes from feedback from professionals: practical considerations, valuing the data, and methodological considerations.[26] The barriers under each of these themes are presented below. Fourteen of the 16 studies reviewed reported practical difficulties. The collection of PROMs imposes burden and time constraints on workload. The difficulty of administering PROMs was also highlighted as a barrier. There is also a lack of clear guidelines on the data collection process that would include clear and simple instructions on patient eligibility, timing, frequency and location of administration.[26;39] Lack of training was also identified as a barrier.[9;10;26;32] The professionals highlighted that the use of technology can be a barrier if it slows down the process rather than facilitating the collection of PROMs. Secondly in the theme of valuing the data, the main barrier identified by 11 of the studies pertained to attitude problems arising from the lack of appreciation for the purposes of collecting PROMs. Professionals questioned the motives behind collecting PROMs and mistrusted others in relation to how such data might be used. Some professionals are uneasy about obtaining feedback on how their patients are doing. The third theme on 'making sense of the data' highlighted the lack of sophistication in the way the data are fed back, making their interpretation difficult and challenging. There is of course a trade-off between presenting sophisticated data and keeping it simple enough to be understood. There are also concerns about the validity and responsiveness of the PROMs used.

Interviewees reported a range of barriers to the implementation and application of e-PROMs. These included clinician resistance, problems with governance, infrastructure and subsequently getting the system up and running. It was also seen as important to combine efforts across settings to encourage joint working. From a patient's perspective, computer literacy, the burden of completing many questionnaires and the fear of what the measurement will be used for were seen as issues, and it was seen as important that the interpretation of the information could be understood by all parties. The issue of whether e-PROMs should be used alone or alongside other data collection methods to increase response rates was also raised.

"Time and all the rest of it. For the provider it's a different equation because most trusts are paid by outpatient visits and the tariff associated with not coming to clinic as opposed to having a telephone conference is different so the trust might lose money unless they can make it more efficient." (R1)

"…there are huge numbers of barriers some of which are easier to deal with than others. I suppose information governance, IT, hosting, and changes in technological landscape, you know new developments in computer technology hardware software like programming. There's all these things changing, and we're in an evolving situation. The other thing is that there is a natural resistance in the NHS to innovation and change…" (R1)

"I think it's the infrastructure to build the system and get it running and training the clinicians on how to use the system and how to interpret the findings…" (R2)

"It's a balance between getting data and questionnaire fatigue because everybody's doing it and patients get bombarded…and you don't want to over burden them because then the results get down and it makes things they just tick and not read and so it's important to try and get the balance and the quality." (R3)

"What will happen with the cancer project is that we've seen that there is a problem with literacy so not only health literacy but then they don't know how to use computers." (R4)

"Yes but I would guess for example someone who wants to monitor like the decision because they now have realised that these PROMs are used for decision making. They could somehow manage it like that in the sense you know well I'm not completing it now because I'm not well and I want to go on vacation and the doctor's not going to let me go on vacation. (R4)

I think you shouldn't pursue something called e-PROMs that's just wrong. You should pursue PROMs and they should be inclusive. How you collect it should be…e-PROMs is fashionable talking about electronic is fashionable that's all it is having a nice little app to collect something is fashionable but unless you have inclusive methods you won't really capture the whole population. (R5)

"I think that there is evidence that PHQ-9 as part of the Quality and Outcomes Framework (QOF), quality and outcomes framework. Clinicians were not happy with the idea and felt the instruments were intrusive whereas patients actually saw them as a validation of their own problems so I think actually it will work the other way round. By using them we will be able to increase patient engagement rather than the instrument itself needing specific interventions increasing engagement." (R7)

5.7.3 How the use of e-PROMS will or should evolve

There is increasing interest from policy-makers to underpin their policies based on evidence. There is an indication that PROMs will be increasingly used as a tool to measure performance at group level.[20;25] The availability of PROMs data at national level has resulted into a new impetus in research on the use of PROMs which will open completely new ways in which PROMs data can be used.[21;40;41]

The use of various outcome indicators in the NHS Outcomes Frameworks,[42] and the Payment by Results Guidance in mental health,[43] support this trend towards the use of PROMs to measure performance and conduct comparative effectiveness research.[38] Santana and Feeny also highlight the future use of PROMs at 'system level'.[27] They refer to the concept of 'learning health care system', where data can be used to identify best practice, areas for improvements and evaluation of interventions. Wu et al. also advocate that standardisation is important and there is a need to harmonize and address questions around clinical and health care research methods, implementation, governance and PROMs and the rest of the electronic records systems.[17;38] However, Wolpert underscores the need to explicitly separate the two aims of collecting PROMs to both inform research and audit as well as to support clinical decision-making.[32]

Based on the sheer volume of literature on e-PROMs, it can be assumed that electronic means of collecting PROMs are becoming increasingly popular. Consequently, it is possible that there will be a clear preference for e-PROMs over PROMs collected by paper.[18] Synder et al. acknowledged the need to keep updating the ISOQoL User's Guide on the collection of PROMs (1) because this is an area that is evolving rapidly which will inevitably lead to change in practices.[10] Patient portals are currently being evaluated and there are mixed views as to whether they will gain popularity.[15] There is still little evidence to support their positive impacts,[15] but there is some emerging evidence surrounding their use.[16] However, for patient portals to evolve, ways need to be found to overcome racial, ethnic and literacy barriers.[15]

Interviewees indicated that they thought e-PROMs would become more widespread and in turn become more connected with the clinical process. They will also be used to improve the collection

and accuracy of data, and to influence clinical decisions in more settings. The use of electronic systems means that more innovative methods of outcome measurement, such as item banks (which are large sets of items calibrated on the same underlying scoring scale, where patients complete a small number of items based on their previous responses to arrive at an overall score), may become more widespread in the UK, but further work is required before this becomes a reality.

> *"That's going to improve dramatically the collection and the accuracy of data but it's just a leg work phenomenon." (R3)*

> *"I think efficiencies associated with this sort of technology in delivering healthcare will become more apparent and I think there will be increasing demand for it. And the other thing is it's no longer going to be optional to monitor your outcomes." (R1)*

> *"I think that it needs to be incremental in the sense that although we are aware that from a measurement perspective there may be tools that may be much more powerful and efficient such as item banks. I don't think that the clinical environment is prepared for the culture it's not there yet. So it will be probably best to start by using, making best use of tools that clinicians may be more familiar with and do not change what they know. Once they become more familiar with the items then they can go back to the responses of the individual patients if need be to familiarise themselves and to get a better understanding and interpretation of the scores. In the long term we should clearly be looking more towards putting measurement based item banks but I am very sceptical that this can be done if we do not succeed here in implementing much simpler tools into practice." (R7)*

5.7.4   Knowledge gaps

Based on the barriers identified in Section 5.7.2, a number of knowledge gaps have been identified in the literature. Several papers have identified the lack of guidelines for those directly involved in collecting PROMs. While ISOQoL has produced a user guide,[1;10] this needs to be updated and also each provider needs to adapt the guide to suit their particular area so that it is more practical for professionals. Several authors have highlighted the need for further research to make the interpretation of PROMs more meaningful, including methodologies ways to analyse PROMs data.[10;32]

A range of areas where further knowledge would help with the acceptance of e-PROMs were reported. These included addressing differences in PROM scoring and interpretation to make the measures and the interpretation of the measures more accessible to clinicians and patients. More work is also required to understand the value of PROMs to patients, and how to communicate this to them. Ways of motivating clinicians and getting support by understanding the best ways of

demonstrating the benefits of e-PROMs was also discussed, as was making PROMs and the interpretation of PROMs data part of clinical training.

> *"well I think that one of the major barriers is the way the PROM questionnaires are scored differently and scaled differently and presented differently and that makes it hard for people who aren't PROM researchers to understand…my colleagues and I have a project related to that to try and address it but you know I think that's a real barrier." (R2)*

> *"We haven't worked out as a as a specialty what the value of PROMs is to the patient. It has a value but it can have a danger as well …This is why research needs to be done into what you should collect, when you collect, and then what you should do with it, rather than just a tool to beat surgeons and sack surgeons which is unfortunately how it gets used." (R2)*

> *"I think that it's quite rudimentary, the knowledge of outcomes is not a part of clinical training in medicine seen anywhere routinely it's beginning to change very slowly…" (R5)*

> *"Knowledge plenty – problem with people's attitude. How do we motivate clinicians?" (R6)*

> *"We need to have clinicians see the benefits. I think the evidence base including literature that there are benefits of using PROMS in clinical practice although this evidence we must acknowledge has not made a very strong case yet…" (R7)*

6 DISCUSSION

6.1 Summary and key points

The results of the literature review and interviews described in this report provide important evidence that can be used to inform the implementation of e-PROMs within the NCA. The results also provide information about potential difficulties in the widespread application of these systems. From this, recommendations for the implementation of e-PROMs can be drawn (see Table 3).

Table 3: Recommendations for the implementation of e-PROMs

Recommendation	Benefits and issues to consider
Use multiple data collection modes.	May improve response rates. Gives greater flexibility to completion and ability to complete. If data is instantly fed back (in summary, for example as charts) to inform decision making then paper and pencil methods may not be useful.
Allow multiple places of completion (i.e. home and in clinical settings).	May improve completion rates, and maximise the usefulness of the systems and the data produced.
Gain support from all key stakeholders (i.e. clinicians, support staff, patients).	Ensures that systems are embedded in the clinical pathway, with the support of all those involved in its implementation. For patients it is important that the systems are easy to use, and the PROMs are easy to complete and relevant. For clinicians it is important that the measures are relevant to those interpreting the data (who must understand the key features of each PROM and the scores produced), and that the data is presented in an easy to understand way. Engagement is key to ensure that PROMs are collected. The value of collecting PROMs should be understood, and any fears about the use of the data (for example for performance management) dealt with.
Use the PROMs data in clinical decision making.	Allows decisions to be informed by the patient's perspective on their condition. Can present the data in meaningful ways to both patients and clinicians based on the results of validated PROMs.
Develop the system in collaboration.	Allows academics, clinicians and those involved in the technological aspects to work together to create a system that is useful in a clinical setting, and also easy to use.
Choose the PROMs included based on available evidence, and the purpose of the system.	Involves all key parties so that the most relevant measures are used based on the PROMs available and the psychometric evidence (are the PROMs valid for the context in which they are being used?). This can impact on the level of completion. Also, it is important that the right version of the measure is validated and used (for example for proxy completion).

6.2 Limitations of e-PROMs systems

The literature review and interviews also provide useful information about the limitations of e-PROMs systems. For example, the systems do not always have the full support of clinicians and other key stakeholders (such as other staff or managers and commissioners) involved in their implementation. This is due to a range of issues including scepticism of the motivation of collecting the data, increased workload, and a lack of understanding of the potential usefulness of the information collected.[9;26;32] A lot of work is done by separate groups who are not always aware of all the other initiatives in the area, and therefore sharing information about best practice more

widely could be important. There are also mixed response rates reported.[14] It is unclear how best to maximise response beyond offering as much flexibility as possible.

6.3   Limitations of this study

There are a range of limitations to this study. Firstly, despite contacting a number of clinicians and researchers involved in this area, we were only able to talk to a relatively small sample of interviewees who were involved in a limited number of clinical areas. Secondly, we identified interviewees via contacts and others involved in the area, but we do not know about the systems we were unable to identify, and what other information might have been provided about these. Thirdly, we were unable to interview managers who use group level PROMs data and those involved in the technological implementation of the systems. The majority of our interviewees were supporters of at least some aspects of the use of e-PROMs, and this means that the sample may not be representative of all e-PROMs users, who may have a different point of view about some of the topics discussed. Finally, due to the time constraint, we were only able to carry out a non-systematic literature review, and source literature identified by the experts that were interviewed.

6.4   Other considerations

While the issue of equivalence was beyond the remit of this research, it is one that should not be ignored. In other words, do the results of the PROMs vary according to the mode of administration? A meta-analysis of more than 65 studies suggests that there is strong evidence for equivalence between paper and computer means of administering self-completed PROMs.[18] The literature in this area has been growing with the number of new electronic means emerging, for example different screen sizes for mobile phones or tablet computers. In both the literature and the interviews, there was some consensus that while electronic means are preferable, other modes of administration can be used alongside electronic methods to maximise the response rate.[11] While there are limited concerns on the issue of equivalence, it is an area that needs to be monitored as new modes and platforms (for example different screen sizes, types of tablets etc) for collecting e-PROMs are being developed.

In the US- based literature, there is an emphasis on adding PROMs to the electronic health records for use in comparative effectiveness research. According to Wu et al, this has been made possible partly because "the science of patient-reported outcome measurement has matured sufficiently".[38] In the UK, the routine administration of PROMs has been tested in a range of settings, including the Improving Access to Psychological Therapies (IAPT) programme, and the Department of Health surgical and long term condition programmes. However the use of e-PROMs is less widespread in the UK relative to paper PROMs, and as a result there are more immediate

practical challenges in administering e-PROMs. As revealed by the interviews, the administration of e-PROMs is generally driven by an individual or a group of individuals. Therefore, it is worth considering how these systems could be integrated more widely, and as a result become more widespread.

As discussed, there is an assumption that collecting PROMs and feedback of their results will eventually have a positive impact on outcomes.[9;10;20;27-29;44] Santana and Feeny provided a framework to better explain the processes through which collecting PROMs can positively impact on outcomes by improving communication and engagement.[10;27] However, there is still weak formal empirical evidence to support the benefits of collecting PROMs and feeding the data back.[25]

One of the interviewees mentioned that while providing consultations to only those who need to be seen by a consultant may be perceived as "efficient", this may not be perceived as such by providers. Providers under the current system in the UK are reimbursed by the number of patients seen and consequently, consulting fewer patients can impact negatively on the revenue of the provider. This issue may not necessarily be pervasive but it stresses the importance of having an enabling system with the right incentives (or absence of disincentives) in place for the collection of PROMs and that the latter should be viewed holistically with the rest of the providers' systems. This also stresses the importance of being clear about the uses of PROMs, their intended and unintended effects.[32]

7.   AREAS FOR FUTURE RESEARCH

The results of this study highlight a number of areas where future research would be informative for the NCA. Table 4 provides recommendations for future research.

Table 4: Future research recommendations

Recommendation	Further considerations
Investigate how to maximise response rates at baseline and follow up.	Important for acceptability and inclusivity. Investigate differences in response rates for sub-groups (age, socio-economic, ethnicity) and how to counter this. Identify areas (clinical or demographic groups) where non electronic versions are potentially preferred and result in better response rates.
Investigate how to engage clinicians and users.	In the context of NCA, PROMs data collected will be likely used at national level. However to ensure that the data is collected, it is clear that it is important to engage professionals. Identify clear processes, ways and resources needed to properly engage professionals. There is a need to be transparent about the uses of PROMs and listen and address the fears and reservations of professionals adequately.
Investigate how to present the information to patients, clinicians, providers and commissioners?	It is essential that data is easy to understand, and provides the optimum amount of information to inform decision making. Ways to provide information about the characteristics and scoring methods of various PROMs to increase acceptability to clinicians should be investigated. For each PROM used, there will be cut-offs or clinically important score thresholds. Instrument developers can identify minimally clinically important differences to inform the use of the PROMs.
Evaluate the benefits of collecting PROMs.	This includes the benefits for clinicians, patients, managers and decision makers.
Carry out usability research into the presentation of the e-PROM systems across different modes of administration.	Will increase the ease of use to patients, and therefore the acceptability of the system.
Investigate how different clinical pathways would most benefit from e-PROMs.	For example, investigating the optimum time points to administer PROMs to support clinical decisions.
Carry out further equivalence research.	Across different administration methods Between proxy and patient report.
Investigate equity issues and the impact of this on the application of the systems.	For example, are translated versions available, and if not does this impact on completion rates in certain settings?

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APPENDIX 1   Semi structured interview questionnaire

Introduction

- Is it ok to audio record?
- Consent – any questions
- As per the information sheet, we may use verbatim quotes from the interview but we will not identify who you are. Is this acceptable to you?

Main interview

1. What is your involvement with e-PROMs?
2. Are you involved with routine collection of PROMs or are you collecting PROMs for a specific study?

Mode of administration and specifics of collecting e-PROMs

3. How do you collect e-PROMs?
4. Who fill in the PROMs?
5. When are the PROMs administered?
6. Where are the PROMs administered? (e.g. at home, in clinics)
7. Who administers the PROMs? (receptionists, clinicians)
8. What systems do you use to collect e-PROMS?
9. Did you develop the system you are using in-house?
10. What PROMs do you use and are they used with patients with specific conditions?
11. Has this changed/adapted over time based on your experiences?
12. How did you choose the specific PROMs that you are using?

Use of PROMs- benefits and impacts

13. How is the data fed back, and to whom? And when?
14. How do you use the data that is generated?
15. Has this led to changes in your practice over time?
    (Are there any screenshots that you are able to share with us?)
16. What benefits have you found from the use of e-PROMs?

Engagement

17. What made you start using e-PROMs?
18. How did you engage others to use e-PROMs?
19. What are compliance rates for both baseline and follow-ups?
20. What are completion rates for both baseline and follow-ups?
21. How do you encourage the ongoing collection of PROMs?
22. Are there characteristics of PROMS (either the PROMS or the systems used) that you have found are more important than others in terms of completion, etc?

Challenges

23. What are the costs of your process? Set up and ongoing?
24. What have been the main challenges and how have you surmounted them?
25. What is your opinion on how the use of e-PROMS will or should evolve?
26. What are the gaps that you think exist that knowledge/further practice in the area would help to encourage the wider use of e-PROMs?

- Are you aware of any literature – both published and grey – on these issues?
- Would you be happy for us to contact you if we have clarifying questions or follow-up questions later in the study?

APPENDIX 2 Case study: Measuring outcomes in Depression (MOD)

This appendix provides a summary of a study carried out by the Policy Research Unit in Economic Evaluation in Health and Care Interventions on the feasibility of collecting PROMs in secondary mental health services mainly with those accessing services dispensed by the Community Mental Health Teams (CMHTs). The case study has been added to this report as it investigates the collection of PROMs using tablets and has some useful lessons on the issue of collection and use of e-PROMs. The MOD involved interviews with service users and has the advantage of offering some insight of collecting and using e-PROMs from the patients.

Aims

- To assess the feasibility of PROMs with service users (all-age adults) accessing secondary mental health services.

- To assess acceptability of routine collection of PROMs including their usefulness and practicality (for service users, clinical staff, managers and commissioners).

Methods

The study was divided into four distinct phases. The development phase (Phase 1) involved preparatory work (Thomas Ricketts, Janice Connell and Mahmood Khan) with service users and staff to explore the acceptability of the project and inform the researchers how the subsequent phases were likely to take place. In the pilot phase (Phase 2), participants in one area of Sheffield were asked to fill in the EQ-5D and another measure which focuses on the symptoms of depression more specifically. Some participants filled in PHQ-9 and others filled in CORE-10. Participants could complete the questionnaires either on paper or using a tablet (electronic device). In the roll out stage (Phase 3), this was extended to the whole of Sheffield and Bradford. In the final phase of the project, stakeholder interviews were carried out by the University of Oxford (by Elizabeth Gibbons) to explore the acceptability and usefulness of collecting and using PROMs with service-users and providers.

Results

In phase 1, 50 participants were interviewed (service users n = 16; healthcare professionals n = 34). In general, the service users interviewed were more positive than healthcare professionals about the collection of PROMs. It is striking that healthcare professionals identified several potential issues that service users may have with using tablets and that these issues were not highlighted by the service users themselves. With regard to the use of tablets, on the whole the response was positive. For one staff group the response was initially negative until the tablet was demonstrated. None of

the respondents, staff or service users, felt they themselves would have any problems using the tablet and some service users might prefer it. One service user interviewed was excited by the prospect of using up to date technology.

> *Oh, I like that, the fun of it, just hope you don't answer the questions wrong, wow, that's pretty impressive isn't it. And I suppose as well it would make people feel that they are sort of up to date with things, you know what I mean, kind of being included in that, cos you do get a bit excluded (Service User 1-53)*

The advantage of saving time on data entry was recognized.

> *I think if you were going to use something like that all the time then that system (tablets) might be better because it would download straight to the system – because if you have a load of forms to fill in who is going to input it all (Staff Focus Group 3-168)*

Potential problems were identified for those with poor motor control and for those unfamiliar with computers, particularly older adults, it may increase anxiety.

> *I think it would be great for some, some people would much prefer that but I just see people being a little bit intimidated by it, when they are distressed (Staff Focus Group 3-105)*

A potential problem for people prone to paranoia was identified.

> *Great idea, but what if somebody is psychotic, or got delusional ideas, they might see that and think that there is a microphone in it or (yeah), or something dodgy about it if they have never seen something like that before (Staff Focus Group 2-73)*

There were also some concerns related to the amount of time it could take explaining to the patient how to use it, and pragmatically, paper methods afforded more flexibility as the measures could be left with the service user if there were time pressures.

> *Well I think we have got enough to do, I mean I struggle to get through things-, through my appointment time as it is without having-, there's constantly another thing, another thing, added on (Staff User Focus Group 3-100)*

> *I think paper gives you a bit more flexibility, so if you are running out of time, and you feel that they could do it, you can leave it with them, and if that goes wrong, or you can't get into it, the operators ability to use it (Staff Focus Group 2-78)*

Most concluded that it would be acceptable to present the service user with the tablet but if they were uncomfortable with it to use paper methods.

> *It's one of those things where you take this out, and you take a piece of paper, and if this doesn't work you give them the paper (Staff Focus Group 1 -119)*

Phase 2 of the project focussed on the logistics of data collection including ironing out technological problems. In Phase 3 of the project, 258 participants were recruited at baseline. Out of the 258 at baseline, only 13 completed the measures using tablets. The list of practical difficulties highlighted during data collection included:

- Insufficient use of the tablets during the pilot phase means that problems with the technology are still arising.

- This is still an experimental technology of the Trust and therefore subject to a separate ongoing trial.

- Mobile version of the system for training is used by the developers for testing and not always available to staff which makes it difficult to train staff in using tablets.

- No dummy clients have been set up on the live version for testing/training purposes.

- Wireless availability and signal strength varies across the Trusts.

- Tablets could take a long time to synchronise with network.

- Tablets needed to be synchronised daily and often staff did not do this, meaning that the tablet was not ready for use when needed.

- Some professionals were nervous about using a new technology and presenting it to the patients.

As a result of the above problems, the project staff undertook the following to mitigate the issues.

- A MOD tablet training manual had been produced for staff which covered issues like charging, synchronisation, as well as general use.

- Wireless was set up at one of the sites that did not previously have this facility.

- A new training version of the Mobile Training version was installed which synchronised faster.

- Each CMHT has its own test client on the Mobile training system.

- Individual training on the use of tablets had been offered to staff and has been taken up by some staff.

However, by that stage, despite the technological problems having been addressed, healthcare professionals involved in data collection had stopped using the tablets and could not be persuaded to use them.

Data collection using paper proved to be very challenging. It was not possible to calculate a response rate per se but this figure was significantly below the sample of 800 that was hoped for. Follow-up data was only collected from only 38 participants representing only 15% of those recruited at baseline.

In the ultimate phase of the project, 38 participants were interviewed in Sheffield and Bradford (service users n=16; healthcare professionals n = 22). These included people from service-users groups, psychiatrists, nurses, managers and administrators from the mental health teams that took part in the study. Staffs involved in supporting the research at the two trusts were also interviewed.

The main barriers were the level of engagement with research, and the degree of understanding and knowledge about PROMs were factors that seemed to underpin people's experiences and views. Healthcare professionals also reported increasing demands on their time with the rising number of assessments and associated paper-work. This was identified by Boyce at al. (2014).

In terms of the relevance of the PROMs, there was concern about their content of the PROMs (CORE and PHQ). Healthcare professionals viewed the content to be too narrow and simplistic, specifically in relation to the complexity of service-users' conditions in secondary care. Service-users, on the other hand, focused more on the potentially distressing nature of some of the items; specifically items relating to self-harm. Furthermore, service-users were concerned about the consequences of their responses. The generic measure (EQ-5D) was viewed by some as containing questions that were not relevant to mental health and difficult to assess. For example, asking about ability to care for themselves; whilst they may not have physical problems in doing so, they may less motivated to do so at times. It was therefore difficult to provide an accurate answer to the question. Some people did see the value of the questionnaire, in that it may identify other problems.

Generally, there was more appreciation for the use of PROMs in individual patient care and monitoring; this was from both service-users and healthcare professionals. Service-users could also see benefits of PROMs facilitating discussion with their healthcare professional and for monitoring change, specifically if they were improving. However, concern was expressed about the impact of observing no change or worsening scores.

There was some preference for collection of PROMs data at every visit from both healthcare professionals and service-users. However, this was dependent on the frequency of visits and

complexity of the service-users' condition. For those service-users who accessed services frequently, PROMs data collection at every visit was perceived to be of little value and burdensome.

The logistics and practicalities of collecting PROMs data were considered challenging. Whilst it was feasible to collect PROMs in reception prior to the service-user's appointment, ensuring that this coincided with feedback to clinical care was problematic. Service-users were clear that completing PROMs with their healthcare profession was preferred. Healthcare professionals were more sceptical and concerned about using valuable consultation time.

Conclusion

This case study highlights the challenges of collecting PROMs, both in using paper and electronic means. It is clear that the use of technology at both sites at that time was not mature enough to support the collections of PROMs electronically. For successful implementation of PROMs, the technological challenges need to be fully addressed before engaging staff. As mush support as possible needs to be provided to staff before the roll out as well as during data collection. Lack of engagement from clinicians was a major barrier as they perceived this as a research project and therefore could not perceive the potential relevance of PROMs in clinical decision-making. Healthcare professionals suggested that different ways of completing the questionnaire - paper-based, email, mobile phone apps - must be used to maximise engagement and response rate.