Maximising the impact of patient-reported outcome assessment for patients and society

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ANALYSIS

Maximising the impact of patient reported outcome assessment for patients and society

Patient reported outcome measures can help drive global patient centred healthcare reform, but we need a more efficient coordinated approach to assessment if we are to fully realise benefits for patients and society, say **Melanie Calvert and colleagues**

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Key messages

- Patient reported outcome data are increasingly being used by a range of stakeholders in healthcare
- These data may offer major benefits to patients and society, but current use is fragmented and suboptimal
- We propose an integrated evidence based approach to data collection to meet multiple stakeholder needs

Over the past decade we have seen a global rise in the involvement of patients in coproducing research and decisions about their health and care. "Measuring what matters to patients" is recognised as central to improving patient care and service delivery, but patients need to be involved in deciding what to measure and how.[1]

One way to measure what matters is using patient reported outcome measures (PROMs), which are questionnaires completed by patients to assess the effects of disease or treatment (or both) on symptoms, functioning, and health related quality of life from their perspective. PROM data can be used to inform health technology assessment, pharmaceutical labelling claims, health policy and service improvement, and can support communication between patients and healthcare professionals.[2 3]

Here we discuss the current applications and potential benefits of PROMs in healthcare and challenges that reduce their potential to drive improvements in patient care. We focus on recent developments in the use of PROMs and consider strategies for efficient PROM data collection to maximise benefits for patients and society.

Current use and benefits

PROM assessment in research and routine clinical practice offers a range of potential benefits for individual patient care and for clinicians, regulators, healthcare management teams, commissioners, and policy makers (table 1).

The use of PROMs in research, particularly in clinical trials and observational studies, is well established and can provide valuable evidence on the burden of disease and the efficacy, effectiveness, and cost effectiveness of interventions from a patient perspective.[26 16 17] PROM data are increasingly being used to provide evidence for drug and device approval. Emphasis is being placed on involving patients throughout the innovation pathway, including the appropriate collection of PROMs informed by FDA and EMA guidance.[27 28]Aggregate PROM data have been used in routine practice for several years; for example, in the UK to assess provider performance in the primary care Quality and Outcomes Framework (QOF)[25] and in the NHS PROMs initiative.[2 29] Three PROMs (the PHQ9, HADS, and Beck Depression Inventory-II) were used as part of QOF to assess the severity of depression, to support clinical decision making, and to assess provider performance. However, the QOF indicator was dropped in 2013 owing to criticism regarding over-diagnosis using the tools and the potential for gaming.[25 30] PROMs have been used to measure health gain in patients undergoing hip or knee replacement, among other procedures, based on responses to questionnaires before and after surgery. Patients and referrers can use PROM data to help decide where to receive treatment: NHS Choices publishes provider level outlier data for PROM eligible procedures as part of a "score card."[31] The evidence to support using PROMs in

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this way is, however, limited,[32] and challenges with paper based "top down" PROM capture include high rates of missing data and lack of accessible feedback for use by clinicians and patients.[29]

By contrast, using PROMs at the individual patient level is relatively new. PROMs can be used to inform clinical decision aids, for shared decision making, and to tailor care to individual patient needs. Electronic capture of PROMs in clinic and between appointments allows real time monitoring of symptoms, flexible scheduling of hospital appointments in response to PROM data, early detection of problems, and prompt clinical intervention.[33] A US randomised trial of web based symptom monitoring in patients receiving chemotherapy showed that use of the tool was associated with better quality of life, fewer emergency hospital admissions, and increased survival.[8 9] In Denmark, the AmbuFlex telehealth system is being used to schedule outpatient appointments for chronic conditions, including asthma, chronic obstructive pulmonary disease, epilepsy, sleep apnoea, and cancer.[12 13] PROMs are completed by patients at home and used for decision support to evaluate the need for a consultation, reducing the need for unnecessary outpatient appointments. To date, 31 000 outpatients have been referred to AmbuFlex follow-up, and 115 000 telePRO based contacts have been completed.

Challenges to consider

Several challenges have hindered both uptake and benefit to patients of PROMs (box 1), with major problems found in PROM study design, implementation, reporting, and interpretation.[26] PROM data collection is fragmented, with limited coordination—if any—between teams responsible for research and routine care. Clinical disciplines often lack a standardised approach to assessment. Patients may be asked to complete multiple questionnaires, often with overlapping items, which can be burdensome and confusing. Furthermore, PROMs are often poorly or not reported, which limits their effects on patient care and is unethical.[29 38] Evidence shows that clinicians find that collecting PROMs improves clinical care and workflow and is "beneficial rather than burdensome."[4] But some clinicians think that these data are "subjective" and therefore biased or unimportant compared with laboratory findings.

Box 1: Current challenges in PROM assessment

PROM selection

- PROMs are not always designed and selected with patient input to ensure that they measure what matters
- Measurement properties, patient acceptability and burden, cultural validity, and interpretation guidelines are not always considered
- Inconsistency in PROMs used within and across disease specialties make comparisons difficult

Ethical concerns

- Patients may be unsure why they are being asked to complete a PROM, who will access their responses, and how the data will be used
- Patient burden of completing multiple questionnaires
- Inconsistent management of situations where PROM data show "concerning levels of psychological distress or physical symptoms that may require an immediate response"[34]
- Poor quality or no reporting of PROM data means that patients may complete multiple questionnaires for no discernible purpose
- Lack of PROM specific ethical guidance

Data collection, analysis, reporting, and interpretation

- Engagement and acceptance from stakeholders for PROM collection may be lacking
- Many clinical trials do not provide a clear rationale for PROM assessment[26]
- How the data will be used to maximise patient care has not always been fully considered, even in routine clinical practice[29]
- PROM data in research is commonly collected from a relatively small subset of the population, hindering wider applicability of findings. This may be more pronounced in trials with a "substudy" approach, or where appropriate, culturally validated, alternative language PROMs are not available
- Missing data hinder reporting and use, and approaches to minimising missing data are highly variable[26]
- Lack of consensus regarding analytical approach[35]
- Many clinical applications of PROMs have been developed in silos and remain unpublished, limiting sharing of implementation strategies, good practice, and results
- PROM results are often poorly reported and are difficult to access and interpret by patients and clinicians[36]

Data logistic problems

- Incompatible IT systems without integration with electronic health records and use across service providers
- Data stored in different formats
- Lack of relevant IT/health informatics expertise

Inefficient uncoordinated approach

- Development in silos leads to duplication of effort and inconsistency in collection methods, measures used, and data collected
- Lack of integration between routine data collected for population level initiatives and individual symptom monitoring, and between routinely collected PROMs and research data
- Missed opportunity to upscale datasets and enhance efficiency; no opportunity to "collect once, use many times"[37]

Integrated approach to PROMs

We need a strategic, coordinated, integrated approach to PROM assessment, a view supported by international qualitative research.[39] This approach should be aimed at creating a non-burdensome pathway for patients to provide meaningful PROM data that may be used to support shared decision making, as well as provide a patient centred data pipeline for audit, benchmarking, research, and real world evidence (fig 1). Routine remote PROM monitoring could be used to support not only patients at high risk of emergency admission but also the millions of people who have multiple long term health conditions to reduce unnecessary outpatient appointments, promote medicine adherence, and tailor care to individual needs. Beyond optimising healthcare resources, this approach offers

broader benefits to patients and society, with potential reductions in time off work, carer burden, and carbon footprint.

Crucially, the same PROM data could be aggregated to inform commissioning and service delivery decisions. Concurrently, the data could be incorporated into pragmatic trials to provide real world evidence of effectiveness and safety. Large scale "PROmic" data could be integrated with genomic, proteomic, metabolomic, clinical, and biomarker data and be used in prognostic models to inform patients of likely courses of symptom burden and functioning.[40]

Integrative approaches to PROM assessment should consider ways to reduce inefficiencies in data acquisition: a harmonised approach to the selection, collection, analysis, and reporting of PROMs, integration into the electronic health record, and guidance on the optimal presentation and use of data (fig 2).

Stakeholder engagement and cooperation

A national PROM strategy should be developed with input from patients, clinicians, academics, industry, regulators, ethicists, and policy makers to ensure that the system and data meet stakeholder needs. We have found that engagement from patients, senior management, nurses, consultants, and allied healthcare professionals is essential to successful delivery of PROM specific strategic goals.[10 13 29]

Establish which outcomes to measure

PROMs should measure outcomes that correspond to stakeholder needs. Identifying these outcomes and what matters to patients should be a priority. Regulatory agencies may focus on physical symptoms and functioning to inform licensing and labelling claims, whereas patients and health policy makers may be more interested in other domains of health related quality of life, such as participation in social activities and emotional wellbeing.[41] Stakeholder relevant PROMs can be identified through patient involvement, qualitative research, or core outcome sets. These provide a set of standardised outcomes to be assessed in routine practice or effectiveness trials. They often include traditional clinical outcomes, such as all cause mortality, alongside measures of symptom burden, functioning, and disease control, which can be measured using PROMs. Several core outcome sets are available from the International Consortium for Health Outcomes Measurement[42] and the Core Outcome Measures in Effectiveness Trials initiative[43]; further efficiencies may be gained, however, if a single core outcome set can be generated for research and routine practice for a clinical area or a broader set of conditions, such as inflammatory diseases.

Selection of PROMs

Identifying and selecting valid, reliable tools that are acceptable to patients from the target population may be challenging. The Consensus Based Standards for the Selection of Health Measurement Instruments initiative and the Evaluating the Measurement of Patient Reported Outcomes programme provide useful guidance to support the review of measurement properties.[44 45] Selected PROMs should have been developed with patient input,[27] but this is not the case for many commonly used measures. A further challenge is the use of different measurement scales, which make it difficult to compare across measures. The Patient Reported Outcomes Measurement Information System (PROMIS) aims to provide measures scored on a common scale across global, physical, mental, and social health domains. The PROMIS items can be used for computerised adaptive testing to reduce patient burden.[46] Further benefits of PROMs may be realised through individualised measures, but research in this area is scarce.[32] Ultimately, the utility of the measure may differ depending on context and purpose, but wherever possible systems should be designed with multiple use in mind.

Developing a governance framework

Patients need to know who will access their data and how their data will be used. Clearly this has important consent implications for integrative PROM collection, which must meet data protection regulations. PROM data may reveal worrying levels of psychological distress or physical symptoms that may require an immediate response, known as a "PRO alert."[34] Clear response pathways for the management of PRO alerts should be in place, and issues around legal liability for failure to act must be considered. Overarching guidance on governance would help implementation of PROMs and promote efficiency in delivery.

Integrated approach to electronic capture of PROMs

Health informatics systems should be developed to capture PROMs in a standardised way that will allow patients and clinicians to access data at the point of care, incorporating flexible permissions that allow the patient to choose how their data will be used. National institutes for data science in healthcare should play a pivotal role in infrastructure developments. Operational and logistical matters—such as patient identification, usability of the system by diverse patient groups, automated reminders, algorithms for PROM alert management, and reporting mechanisms—require careful consideration to encourage compliance, ensure smooth workflow, and promote data quality. To fully realise the benefits and to meet multiple stakeholder needs, PROM data should be aggregated with clinical and "omic" data; for example, to facilitate case mix adjustment for comparison of service providers and for use in prognostic models.[40]

Analysis, reporting, interpretation, and dissemination of PROM data

Data will need to be analysed and reported using different templates tailored to stakeholder needs. PROM data are currently presented in a wide range of formats and further research is needed to optimise their presentation for accurate interpretation of the data and to make it useful.[47] We have found that training and support is needed during early adoption.

System evaluation

Integrating PROM data will require iterative development and improvement. The cost effectiveness of PROM systems, impact on workflow and user satisfaction, and potential biases associated with multiple uses of data should be rigorously assessed.[48]

Conclusions

Routine collection, processing, and sharing of PROMs may offer huge benefits to society through better health outcomes and use of resources. There is clearly much to do to maximise the benefits of PROMs for patients and society. A crucial first step is to establish a national multi-stakeholder steering group, involving patients, clinicians, PROM methodologists, regulators, policy makers, and NHS digital to standardise PROM data and to establish and share knowledge and good practice. Integrated approaches to data collection will help promote optimal efficient

collection, reduce patient burden, and enable us to harness patient centred data alongside health and biomedical outcomes to tackle healthcare challenges at scale. Greater collaborative multi-stakeholder efforts are required both nationally and internationally for the benefits of PROMs to be realised.

Contributors and Sources: MC wrote the first draft of the article, which arose from a series of discussions about the topic with coauthors. The piece draws upon broader discussions from the Centre for Patient Reported Outcomes Research (CPROR) Institute of Advanced Studies workshop led by MC, DK, and GP in February 2018 and attended by JMV and NH and from discussions with Ethan Basch, distinguished visiting professor, in November 2017. MC is director of CPROR at the University of Birmingham and leads cross cutting PROM research at the NIHR Birmingham Biomedical Research Centre and the NIHR Surgical Reconstruction and Microbiology Research Centre at the University Hospitals Birmingham NHS Foundation Trust and the University of Birmingham and Health Data Research UK Midlands. She led development of the SPIRIT-PRO and CONSORT-PRO extensions. DK is an NIHR fellow, deputy director of CPROR and is leading development of PRO systems in routine NHS practice. GP is a patient partner and member of the CPROR executive. JMV is president of the International Society for Quality of Life Research, has recently provided advice to the Organization for the Economic Cooperation and Development on developing patient reported indicators of health system performance, and recently completed an NIHR funded programme of research on PROMS in primary care (NIHR/CS/010/024). NHH led the development and implementation of the AmbuFlex PRO system in Denmark and is leader of the WestChronic research unit at the Aarhus University Research Clinic, Herning, Denmark. MC is guarantor.

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Table

Table 1| Use of PROM data by stakeholders, and current data collection

Use of PROM data	Examples	Main stakeholder	Data source/availability of data
Individual patient management:			
Inform shared decision making Tailor care to individual needs	Partners HealthCare has collected more than 1.2 million PROM scores in 75 clinics across 21 specialties, including urology, orthopaedics, psychiatry, and primary care, since 2012. Providers have said that PROMs can improve physician satisfaction, physician-patient relationships, shared decision making, and workflow efficiency[4] A US study of outcomes reported by patients (n=2013) undergoing postmastectomy breast reconstruction using implant or autologous techniques assessed patient psychosocial and sexual wellbeing two years after surgery using the BREAST-Q PROM. Researchers found that patients who underwent autologous reconstruction were more satisfied and had greater wellbeing than those who chose implant reconstruction.[5]	Patient/clinicians	Research/routinely collected data when available
Screening/monitoring	The improving access to psychological therapies (IAPT) programme has transformed treatment of adult anxiety disorders and depression in England. Over 900 000 people access IAPT services each year. The outcome monitoring system ensures that IAPT obtains symptom scores before and after treatment, which are used to inform treatment planning[6]	Patients/clinicians	Research/routinely collected data in specific patient/population groups
Facilitate communication	Using health related quality of life assessments improved patient-physician communication and enabled doctors to identify a greater proportion of patients with moderate-to-severe health problems in several domains, compared with standard care[7]	Patient/clinicians	Research/real time monitoring in routine practice (pockets of excellence but not widespread)
Facilitate early identification of problems and improve patient outcomes Allow rapid referral to specialist services when necessary	Remote symptom monitoring in patients receiving chemotherapy at Memorial Sloan Kettering Cancer Centre reduced emergency department admissions by 7%, hospital admissions by 4%, helped patients stay on treatment longer, improved patient quality of life by 31%, and increased survival on average by five months at low cost.[8 9] In the UK similar work is in development with current studies, for example, in chronic kidney disease and cancer[10 11]	Patient/clinicians	Research/real time monitoring in routine practice (pockets of excellence but not widespread)
Reduce unnecessary outpatient appointments for stable patients	Ambuflex telePRO system, Denmark: see main text[12 13]	Patients/clinicians	Currently not in widespread use in UK
Inform choice of healthcare provider	NHS PROMs programme: see main text	Service users/patient	Limited data available
Individual prognosis on symptom and functioning	The multiple sclerosis impact scale 29 (MSIS-29) assesses quality of life in people with multiple sclerosis. MSIS-29 scores are associated with risk of 10 year mortality, even after adjusting for known risk factors for mortality such as age, sex, and baseline disability score[14]	Patient/clinician	Research data when available
Population level health management:			
Patient focused drug and device development to inform licensing and labelling claims	The regulatory endpoints providing the basis for FDA approval of ruxolitinib for intermediate or high risk myelofibrosis included an improvement in symptoms measured with the modified Myelofibrosis Symptom Assessment Form version 2.0 diary[15]	Regulatory agencies (patients/clinicians/policy makers through subsequent use)	Research data when available
Understanding short and longer term effects of treatment	In the CARE-HF trial, PROM data were used to measure the effectiveness of cardiac resynchronisation, to assess the patient journey and longer term effects of treatment, and to inform cost effectiveness analyses and health technology appraisal[16 17]	Patient/clinicians/policy makers	Research data/routine practice data when available
Inform clinical guidelines	The European Society of Cardiology guidelines for the diagnosis and treatment of acute and chronic heart failure recognise improving quality of life as a key goal of treatment[18]	Clinical guideline developers/clinicians/patients	Research data when available
Inform commissioning	Commissioning groups have used PROM data from the Oxford Knee Score to consider the subgroups of patients that may benefit most from knee and hip replacement and varicose vein surgery.[19]	Service users/policy makers	Research/routine clinical data when available

Table 1 (continued)

Use of PROM data	Examples	Main stakeholder	Data source/availability of data
Inform health technology assessment/reimbursement	A cost effectiveness analysis of the three most commonly chosen types of prosthesis for total hip replacement showed that lifetime costs were generally lowest with cemented prostheses and that postoperative quality of life and lifetime quality adjusted life years were highest with hybrid prostheses[20]	Health technology assessment agencies	Research data when available
Stratified care/integration with other "omics"/big data	The Mayo Clinic Cancer Center measured overall quality of life, pain, and fatigue at over 30 000 clinical visits between 2010 and 2016. Between 20% and 50% of patients, depending on oncology clinic, reported quality of life deficits and underwent clinical interventions or treatment modifications as a result.[21]	Patients/service managers/clinicians	Research data when available (currently not widespread)
Protect patient safety through postmarketing surveillance	The Patient Reported Outcomes Safety Event Reporting Consortium was convened to improve safety reporting by better incorporating the patient perspective. "Real world" data from PROMs can contribute important new knowledge about the benefits and risks of drugs[22]	Service users/researcher-policy maker	Research/real world data when available
Service improvement/value based care	Aneurin Bevan University Health Board, Wales, has collected PROMs across a range of clinical settings including irritable bowel disease and Parkinson's disease and is using the data to inform service delivery and implement value based healthcare.[23]	Service users/service manager	Research or audit data when available
Audit/benchmarking of providers	NHS PROMs programme: see main text National Quality Forum, US [24]	Service users/service manager	Audit data
Pay for performance	The Quality and Outcomes Framework[25]	Service users/policy makers	Audit data

Figures

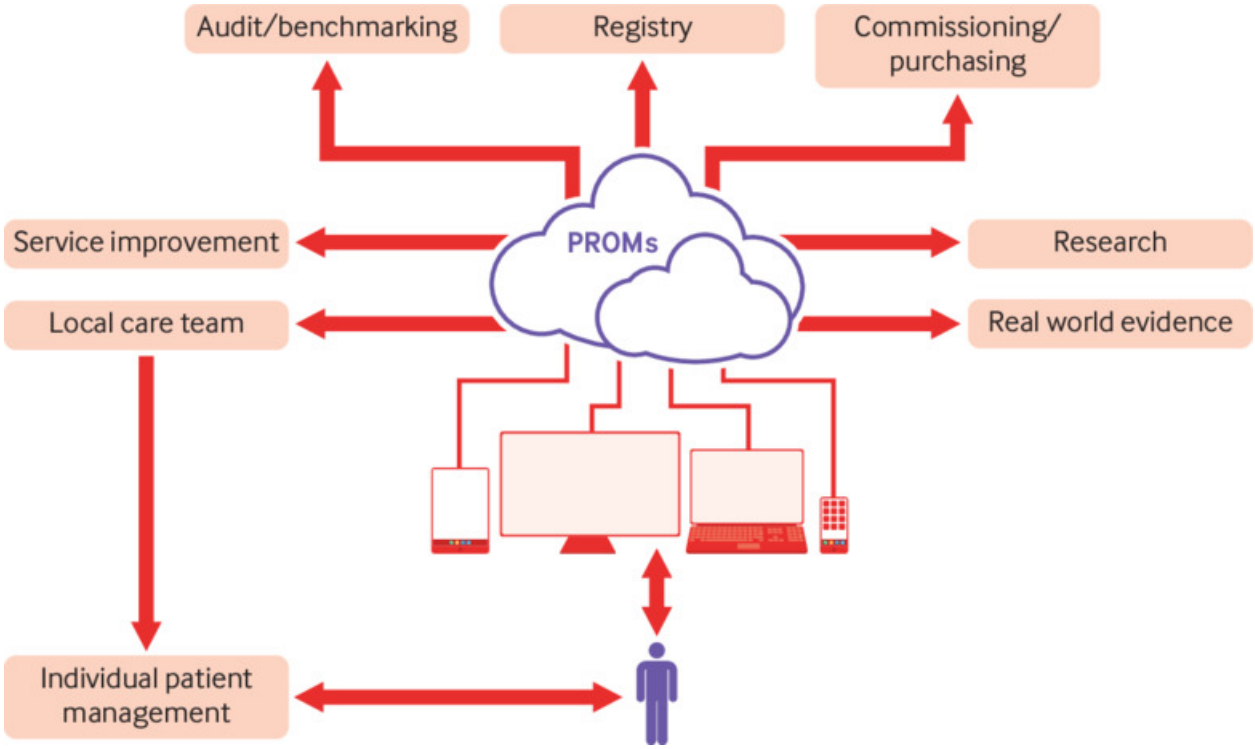

Fig 1 Integrated assessment of PROMs to meet multiple stakeholder needs

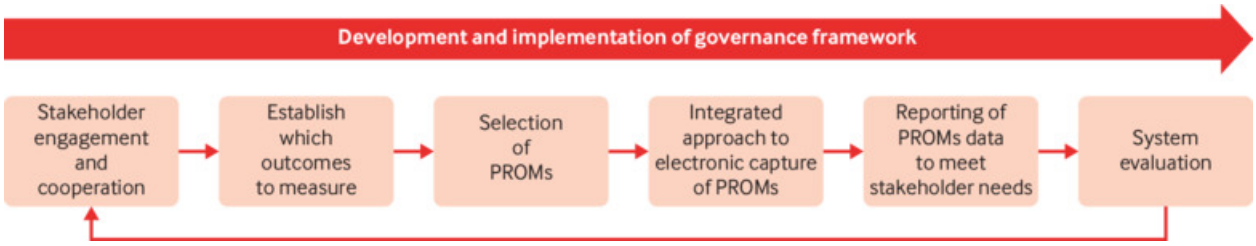

Fig 2 Steps to realising a fully integrated PROM system