TITLE PAGE

Title: Collecting Patient Reported Outcome Measures

Abstract

- Patient Reported Outcome Measures (PROMs) are potentially useful outcome measures that may be reported at the individual clinical, health service and/or health system level
- PROMs require clearly defined patient populations to enable comparisons, and are most meaningful when integrated with clinical datasets
- Where possible PROMs should be measured pre- and post- intervention using reliable and validated tools
- A variety of PROMs collection methods exist which each have strengths and limitations, with selection depending on their purpose and patient factors
- PROMs programs should be developed with high levels of clinician support and patient input to maximise collection of clinically relevant information

Keywords:

- Quality
- Patient
- Outcomes
- Health Services

Author Details:

1. Dr Susannah Ahern

Head, Registry Science Unit,

Department of Epidemiology and Preventive Medicine, Monash University

Corresponding author:

Susannah.ahern@monash.edu.au

Ph: (03) 9903 0139

Level 6, The Alfred Centre, 99 Commercial Rd, Melbourne Victoria 3004 Australia

2. Dr Rasa Ruseckaite

Senior Research Fellow

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Department of Epidemiology and Preventive Medicine, Monash University

3. Associate Professor Ilana N Ackerman

Monash Centre of Cardiovascular Research and Education in Therapeutics

Department of Epidemiology and Preventive Medicine, Monash University

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MAIN TEXT PAGE

What are the purposes of collecting PROMs?

Patient Reported Outcome Measures (PROMs) are increasingly recognised by a wide range of stakeholders including governments, clinicians, insurers and healthcare providers as a potentially valuable tool in the assessment and evaluation of clinical outcomes. The purpose of PROMs is to capture individuals' own assessment of their health or health-related quality of life, without interpretation by others. There is significant current momentum regarding collecting PROMs in clinical and registry settings internationally, and in some cases this is driving large scale investment in the development of patient-derived datasets, and potentially funding and reimbursement decisions¹. However obtaining clear clinical value from PROMs as from any largescale dataset is complex, and evidence regarding how to achieve this is still evolving. This article aims to describe some of the key considerations when collecting and reviewing PROMs data to enable clinicians to better understand its potential value and limitations.

PROMs are potentially useful depending on the medical condition/procedure. They are particularly valuable for long-term conditions where disability or symptoms may require ongoing medical support². In such settings, PROMs may have an important role in monitoring improvement or deterioration in quality of life, pain and function. For example in a study among patients with lung cancer receiving chemotherapy, it was shown that when compared with physician assessments, patient reports of symptoms were more reflective of patients' daily health status as measured by EuroQoL EQ-5D³. Internationally, PROMs have been collected particularly in cancer and musculoskeletal disease settings^{4; 5;6}. With acute procedures or interventions where mortality is the main adverse outcome, long-term PROMs may be less useful, particularly as the causal relationship between the event and the PROMs may reduce over time.

PROMS may be used at the individual clinical, health service and system level.

- At the **individual level**, PROMs may be incorporated into clinical care and reviewed during scheduled clinical assessments⁷. PROMs may also allow real-time feedback to individuals

compared with their patient cohort, and provide an assessment of their progress and well-being against others.

- At the **health service level**, PROMs may provide information regarding quality of care for particular patient cohorts, particularly when the information is benchmarked against other health services and risk adjusted for patient factors such as socioeconomic status, demographic variables and comorbidities. PROMs can also be used for comparative effectiveness analysis to evaluate an intervention⁸.
- At the **health system level**, PROMs may provide aggregate information regarding areas of strength and weakness in overall health service performance. They may provide data to support education and training programs or other system-wide process initiatives, early warning regarding potential device issues, and contribute to broader performance reporting frameworks.

It is important to identify for which purposes PROMs are being used as this will direct the development of the PROMs program including instrument selection, data collection methods, data ownership and sharing processes, and data analysis and reporting.

When to collect PROMs?

Experience and evidence to date recommend collection of PROMs pre- and post-intervention/treatment, although this is not always possible such as in acute emergencies, and where recruitment is via a third party (e.g. cancer registry recruitment may be via jurisdictional cancer registries). PROMs may additionally be collected late post-intervention following clinical stabilisation. Advantages of serial measurements of PROMs include an ability to study the trajectory of the PROM over the course of the disease or post-intervention; to quantify within-patient variability in PROMs; and to allow a patient to act as his/her own control in a comparative effectiveness study.

Principles of PROMs collection

As for all high quality clinical data, PROMs must be:

- **Feasible** – the data are able to be collected and used effectively.

- **Meaningful** – information collected is suitable for its purpose (is valid and reliable) and has high levels of clinician acceptability.
- **Minimal** – low data collection burden for both patients and staff

Where possible, PROMs should use validated instruments, including potentially both generic and condition-specific tools, noting that generic PROMs may not always provide sufficient detail for measuring change in a single patient over time. Condition-specific PROMs may be more responsive to subtle changes in the patient's condition, and are better suited to measuring outcomes at the individual level. Discussion of PROMs validation methods is beyond the scope of this article, but may include approaches such as Classical Test Theory or Item Response Theory (more commonly used for a larger number of items and larger datasets)⁹.

Information to assist in appropriate choice of PROMs instruments is available, including published guidelines regarding the selection of PROMs measures¹⁰ and through publicly available resources such as via the National Institute of Health (NIH)'s *Patient-Reported Outcomes Measurement Information System (PROMIS)*¹¹, and the European Organisation for Research and Treatment of Cancer (EORTC)'s range of questionnaires that assess quality of life in cancer patients (<http://groups.eortc.be/qol/>). Based in the United States, the *International Consortium of Health Outcome Measures (ICHOM)*'s PROMs Standard Sets include over 20 sets of outcome measures for common cancers, cardiovascular diseases and many others¹²⁰. Selecting instruments that are available in multiple languages is an important consideration for healthcare settings with culturally diverse patient populations.

Increasingly sophisticated methods of managing and implementing PROMs items also include item banking, where individual items and their related information are stored in a repository for future potential use; and computer-adaptive-testing, a computer based application that adapts to the respondent's situation using an iterative algorithm of question selection. Such approaches have recently been implemented in a multi-centre study of eye functioning and health in South Australia.^{13;14}

Cohort Coverage

The gold standard for PROMs coverage is to capture all eligible patients across participating settings (hospitals, clinics, primary and aged care) as part of routine clinical care. This makes the data highly reliable as a basis for individual management and quality benchmarking. Sampling is an alternative when PROMs are not undertaken for individual clinical management purposes, however selection bias may reduce sample representativeness and hence generalizability. Of sampling methods, the most reliable method is random sampling, but this is often difficult to obtain in the real world setting. Other options include stratified sampling using key variables e.g. age, gender or socio-economic status, or clustered sampling within health services. Convenience sampling or opt-in (self-selection) sampling are the least reliable sampling methods, as studies have identified that non-responders or missing data may skew PROMs results, as those lost to follow up may represent a subgroup of patients who have disengaged due to poor outcome or satisfaction^{15;16}.

Data collection methods

PROMs are best captured prospectively, and retrospective collection of data should be minimised due to possible recall bias and missing data. Data may be collected by a wide variety of methods, each with their strengths and limitations. Different methods may be suitable for different patient demographics, different conditions, at different follow up times, or for initial and secondary (reminder) patient contact. A recent systematic review by Muehlhausen¹⁷ identified that paper and electronic capture methods were quantitatively comparable, supporting current interest in migration from paper-based to electronic survey tools.

[Insert Table 1 here]

Data governance and custodianship

PROMs may be incorporated into an existing dataset such as a clinical registry, or collected de-novo. Given a lack of evidence regarding the usefulness of PROMs in isolation, it is recommended that PROMs are collected as a composite quality measure in conjunction with existing clinical data. Examples of such composite PROMs collection includes prostate cancer registries as the sampling

frame for the international collection of prostate cancer PROMs across multiple jurisdictions⁴; the British Spine Registry, established in 2012 and with over 27,000 patient records, is the collection tool for PROMs after surgery with over 12,000 forms being directly entered by patients¹⁸; and the National Health Service (NHS) in the United Kingdom has a longstanding and mandatory PROMs program for outcomes from hip and knee replacement surgery, varicose vein surgery, and hernia repair. In such models, the addition of prospective PROMs data may be incorporated into the patient consent process and explanatory statement for new patients without requiring de novo ethics approval.

PROMs collection should be led by a group with representatives from the key stakeholders including clinicians and patients to maximise collection of meaningful information ¹⁹.

Conclusions

Collecting patient reported outcomes is a resource-intensive process. The purpose(s) of collection and reporting must be clearly defined from the start, and will inform the design of the project. PROMs are not an alternative to current patient hospital experience or satisfaction reporting, but instead are designed to provide information regarding physical or psychosocial wellbeing from the patient's perspective at specific points in time over the course of an illness or recovery from treatment. They are most beneficial if collected in a systematic and epidemiologically sound way and in conjunction with clinical data where they are then able to inform individual treatment decisions, site quality improvement programs and system-wide performance measures. As with all health data, high level engagement by clinicians and consumers and an ability to embed within routine clinical care processes are essential for implementation success and sustainability.

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Table 1: Strengths and limitations of different PROMs data collection methods

Collection tool	Strengths	Limitations
Paper-based/mail	<ul style="list-style-type: none"> • May be preferred by elderly 	<ul style="list-style-type: none"> • Data completeness an issue as is no in-built item validation • Expensive (costs of stationary, mail) • Data need to be individually entered into database
Phone – call centre	<ul style="list-style-type: none"> • Potential high response rates (>80% anecdotal) • May be effective also as a second-line tool for initial non-responders • Protocols may enable patient interaction and referral/escalation 	<ul style="list-style-type: none"> • Expensive; staff paid at hourly rate (offset by higher response rate) • Primarily feasible for short questionnaires
Email	<ul style="list-style-type: none"> • Cheap, convenient 	<ul style="list-style-type: none"> • Potentially low response rate • May not have accurate patient contact details • PROMS may need to be integrated into registry database which may incur a cost
Web portal +/- access via SMS messaging	<ul style="list-style-type: none"> • May be user-friendly and convenient • Data immediately integrated with 	<ul style="list-style-type: none"> • Response rates for this method unknown • May require ongoing system IT

	registry (doesn't require additional entry)	administration support <ul style="list-style-type: none"> • May be less accessible for older patient groups
iPad application	<ul style="list-style-type: none"> • Used in clinic setting • May capture information with minimal per patient cost • Data immediately integrated with registry 	<ul style="list-style-type: none"> • Consumer preference may vary • Initial cost outlay for equipment and interface design • Not widely used at present – many trials underway

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Author/s:

Ahern, S;Ruseckaite, R;Ackerman, IN

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