Collecting patient reported outcomes measures in Victoria
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Collecting Patient Reported Outcome Measures

What are the purposes of collecting PROMs?

Patient Reported Outcome Measures (PROMs) capture individuals’ own assessment of their health or wellbeing without interpretation by a clinician or other people.

PROMs are variably useful depending on the particular condition/procedure. This means that they may be useful in combination with clinical and potentially other data to increase our understanding of how patient outcomes may be affected by a particular healthcare intervention or procedure. Their usefulness depends on how significant patient feedback is to quality of care assessment. PROMs are particularly useful for chronic diseases where disability and symptoms may require ongoing medical attention and management. 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-5D9 (Basch E, 2009). With acute procedures or interventions where mortality is the main adverse outcome, long-term PROMs may be less useful as the causal relationship between the event and the PROMs may reduce over time.

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

At the individual level, PROMs may be incorporated into clinical care and reviewed during scheduled clinical assessments. Individual patient feedback that suggests high levels of distress or disability may be escalated to appropriate care providers. PROMs may also allow real-time feedback to the individual compared with their patient cohort, providing an assessment of their symptoms and well-being against others which may be useful for reassurance or for identifying issues; and can be used for comparative effectiveness analysis to evaluate and intervention.

At the health service level, PROMs may provide information regarding patient outcomes and quality of care for particular patient cohorts that can be used by clinical units to identify potential areas for quality improvement, particularly if the information is benchmarked against other health services.

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 potentially be a part of a broader performance reporting framework.

It is important to identify which level(s) PROMs are being used for as this will direct the development of the PROMs program, from system design, including whether identified patient information is collected, to data collection methods, and to who is involved in review of data. A PROMs program that has primary objectives for health service and system quality improvement may be an appropriate place to start for an initial pilot program.

When to collect PROMs?

Experience and evidence to date recommend collection of PROMs pre- and post- intervention, although recognising that this is not always possible e.g. in acute emergencies (e.g. trauma or massive transfusion registries), and for registries where recruitment to the registry may be delayed if...
notification is via a third party (e.g. Prostate cancer registry referral is via jurisdictional cancer registries).

Advantages of serial measurements of PROMs include an ability to study the trajectory of the PROM over the course of the disease; 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 clinical registry data, PROMs must be:

- **Feasible** – able to collect and effectively use high quality data with patient eligibility clearly defined to enable comparison
- **Meaningful** – information collected is suitable for its purpose e.g. it contributes meaningfully to information regarding quality of care/health performance within a health service or across the health system and has high levels of clinician acceptability
- **Minimal** – to reduce data collection burden
- **Use validated** tools, including potentially both generic and condition-specific. These are tools that have test-retest reliability, internal consistence and ability to detect change. Information regarding appropriate choice of PROMs tools is available, such as the NIH PROMIS website [http://www.healthmeasures.net/applications-of-healthmeasures/inevaluating-quality-of-care](http://www.healthmeasures.net/applications-of-healthmeasures/in-evaluating-quality-of-care)

PROMs that are currently collected by Monash Clinical Registries include those for the Victorian State Trauma Registry (VSTR) and the Victorian Orthopaedic Trauma Outcomes Registry (VOTOR), the Out of Hospital Cardiac Arrest Registry (OHCA) in collaboration with Ambulance Victorian, the Prostate Cancer Outcomes Registry (PROC), and the Victorian Cardiac Outcomes Registry (VCOR).

### Patient Coverage

Clinical registries operate under an epidemiological framework where high levels of population coverage are required. The aim in clinical registries is to enrol all eligible patients at participating hospitals and to achieve over 90% coverage. This makes the data highly reliable on which to base health planning and quality improvement decisions. However, this is likely to be more expensive than a sampling approach.
Population sampling is an alternative to population coverage. The main issue with sampling is selection bias which may reduce representativeness and hence generalizability. Of sampling methods, the best method is random sampling, but this is often difficult in the real world setting. Other options include stratified sampling using key variables e.g. age, gender, socio-economic status. Convenience sampling or opt-in (self-selection) sampling are the least reliable sampling methods. While sampling may be less expensive, the results will be less reliable.

Data collection methods
PROMs are best captured prospectively and retrospective filling of data should be minimised due to possible 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 patient contact. This pilot may also be an opportunity to compare the effectiveness of different PROMs collection methods.

<table>
<thead>
<tr>
<th>Collection tool</th>
<th>Strengths</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>Paper-based/mail</td>
<td>May be preferred by elderly</td>
<td>Low response rates (&lt;25% anecdotal)</td>
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<td></td>
<td></td>
<td>Data completeness an issue as is no in-built item validation</td>
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<td></td>
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<td>Expensive (costs of stationary, mail)</td>
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<td>Data needs to be re-entered into database</td>
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<tr>
<td>Phone – call centre</td>
<td>Potential high response rates (&gt;80% anecdotal)</td>
<td>Expensive; staff paid at hourly rate (offset by higher response rate)</td>
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<td></td>
<td>May be effective also as a second-line tool for initial non-responders</td>
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<td>Protocols may enable patient interaction and referral/escalation</td>
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<tr>
<td>Email</td>
<td>Cheap, convenient</td>
<td>Potentially low response rate</td>
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<td></td>
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<td>May not have accurate details of patient email address and may change</td>
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<td></td>
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<td>PROMS may need to be integrated into registry database which may incur a</td>
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<td></td>
<td></td>
<td>cost</td>
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<tr>
<td>Web portal</td>
<td>May be user-friendly and convenient</td>
<td>Response rates for this method</td>
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<tr>
<td></td>
<td>Data immediately integrated with registry (doesn’t require further entry)</td>
<td>unknown</td>
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<td></td>
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<td>May require ongoing system IT administration support</td>
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<tr>
<td>iPad</td>
<td>Used in clinic setting</td>
<td>Consumer preference may vary</td>
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<td></td>
<td>May capture information with minimal per patient cost</td>
<td>Initial cost outlay</td>
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<tr>
<td></td>
<td>Data immediately integrated with registry (doesn’t require further entry)</td>
<td>Not widely used at present – many trials underway</td>
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PROMs may be:

- Incorporated into an existing data set such as a clinical registry
- Collected de-novo
Monash recommend that given the lack of high quality evidence regarding use of PROMs in isolation, it is more meaningfully collected as a composite quality measure i.e. in conjunction with an existing clinical data set. Other advantages of collecting PROMs for existing Monash Clinical Registries are:

- Governance and ethical framework already exists (requires amendment)
- Awareness of registries among health services and clinicians
- Additional benefits of linking to clinical data are valued by stakeholders
- Co-ordination of PROMs across patient groups may lead to efficiency e.g. Trauma, ICU, Massive Transfusion Registry as the outcome measures are shared across 3 patient groups that intersect
- Data collection process and expertise exists within Monash
- Available IT capability to incorporate additional data modules within Monash
- Clinical data analysis capability highly evolved within Monash

**PROMs collection model**

Using the model of PROMs collected in conjunction with an existing clinical data set such as a clinical registry, Monash proposes the following collection process;

1. Clinical registry governance and ethics processes (generally using opt-out consent) approve the addition of prospective PROMs collection using validated generic and condition-specific questionnaires. This is incorporated into the patient consent process and explanatory statement for new patients.
2. For new patients, PROMs are collected at baseline where possible and at identified future time-points. The most appropriate technology to use will be identified by the registry governance committee and health services and will depend on factors including patient demographics and access to technology, dataset requirements, and follow up requirements.
3. Baseline PROMS data would be integrated (either automatically or manually depending on the technological tool used) into the clinical registry.
4. Clinical registry staff would identify patients for follow up and would provide requests for follow up PROMs to the sites or the patients. A range of methods may be used to provide high follow-up completion rates.
5. PROMs data ‘dumps’ would be sent to the DHHS VHPA on a regular basis, enabling analysis of data by the DHHS as well as by the clinical registry.
6. If an objective of the PROMs is to review and provide real-time patient-level data to the site for clinical management and escalation, then a specific proposal regarding this could be developed in conjunction with health services.

**Data governance and custodianship**

Monash considers that independent administration and oversight of the data is important to avoid perceptions of bias or conflicts of interest. It is recommended that the overall project be led by a Project Steering Committee with representatives from the key stakeholders (DHHS, registries, health services, consumers).

For a pilot of PROMs data integrated with existing clinical registries, there would require to be a contractual arrangement between the registries and DHHS that would articulate:
• The purpose of the PROMs collection and reporting
• The role and responsibilities of the different bodies (DHHS, health services, registries, consumers) in this process
• Funding to support the pilot and its management (may be shared between the health services and the registries)
• Ownership of the data (generally considered to be owned by the participating health services)
• Custodianship of the data (generally considered to be by the registries)
• Analysis of the data
• Access to the data by potential interested parties including researchers and health services
• How the data will be used by DHHS

Summary
• PROMs are a variably useful composite outcome measure depending on the particular condition/procedure, and may be used at the individual, health service or health system level
• They require clearly defined populations and are most usefully aligned with clinical datasets
• Where possible they require measurement pre and post intervention and to use validated tools
• There are a number of different collection tools depending on the purpose and patient factors
• PROMs should be administered by an independent experienced institution to avoid bias
• Governance of the process should involve a range of stakeholders including consumers

Potential PROMs Pilots
Monash Clinical Registries has a number of clinical registries that would be suitable and available for participating in a DHHS PROMs pilot. These registries are submitting their own brief specific proposals that align with this overall PROMS submission.

Contacts
For further information please don’t hesitate to contact:

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References