The department has released this consultation paper to assist individuals and organisations to prepare submissions that would contribute to the collection of patient reported outcomes measures. It contains and outlines:

- the objectives of the collection
- the department’s procedures
- matters about which the department is seeking comment and information
- how to attend the public consultation forum
- how to make a submission.

Participants should feel free to comment on matters relevant to the study’s objectives.
Website
Information about this consultation, including any reports and submissions, can be found at the project’s website:


Key dates
Public consultation forums From 17 October 2016
Due date for submissions 28 October 2016
Release of final report December 2016

Public consultation forums are to be held
In the week beginning: Monday 17th October
Department of Health and Human Services
50 Lonsdale St

Please register via email: proms@dhhs.vic.gov.au

Submissions can be lodged
By email: proms@dhhs.vic.gov.au
By post: Patient Reported Outcomes study
System Intelligence and Analytics
Department of Health and Human Services
50 Lonsdale Street
Melbourne, Victoria 3000

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How to make a submission
1 Overview

The Department of Health and Human Services plans to collect Patient Reported Outcome Measures (PROMs) data on an ongoing basis from Victorian health services (including hospitals). It anticipates collecting data from 1 July 2017 for a limited number of patients and health services and to expand the collection thereafter.

PROMs are data obtained from structured surveys of patients about their assessment of their health outcomes. They differ from data obtained from patient experience surveys which focus on patient views and satisfaction of healthcare services. PROMs convey information about patients’ assessments of their health and their health-related quality of life. They are particularly useful for telling us about a patient’s health outcomes that are best known to the patient, best measured from the patient’s perspective, or where a clinician is not present.

There is a growing interest in the use of PROMs in Australia and overseas to:

- enable clinicians to benchmark their health-care practices
- monitor and benchmark the quality and patient safety of health services
- provide patients with a voice in determining which healthcare is important to them
- assist the department’s resource allocation decisions.

The department has an opportunity to facilitate and promote PROM collections and encourage consistency in existing and new PROMs collections.

The purpose of this consultation paper is to provide clinicians, health services, consumer (patient) representatives, research bodies and other interested parties an opportunity to contribute to the design of the pilot and a subsequent roll out of the program.

The department is committed to improving the value the community receives from Victorian health services. This includes improving those health outcomes most valued by the community. The collection and reporting of PROMs is an important part of this process.
2 Why is the department interested in PROMs?

2.1 A new strategic direction

The department is making a significant change in its strategic direction as indicated in its recently released strategic plan. The strategic plan sets out four strategic reform directions, which include person-centred services and care, and advancing quality, safety and innovation, and the enablers for success, which include data and evidence.

Within this framework, the department commits to commence in 2016-17 a systematic collection of patient and client reported outcomes data, and share it with service providers for assessing the effectiveness of and outcomes from care.

Although the department has long collected and reported quality and patient safety data, much of it tends to describe a fraction of a patient’s health outcomes. Mortality indicators, for example, are only relevant for the few patients who are at risk from mortality. There is scope for the department to collect more data to help it better understand the extent Victorian hospitals are improving the health outcomes of patients who are not at risk from mortality such as patients with hip and knee osteoarthritis, lower back pain and asthma patients. Collecting such data can improve its ability to monitor the performance of health services, coordinate policies between hospitals and other health services, and for health services and clinicians to benchmark their results.

2.2 What are PROMs?

PROMs are data obtained from structured survey questions that ask patients about their health and health-related quality of life, such as pain and discomfort, activities of daily living, mental health and family and social relationships. They are similar to clinical outcome and performance outcome measures but are obtained directly from the patient without amendment or interpretation by any party. PROMs are the only means by which some symptoms (such as pain and nausea), can be measured and the only way with which to convey the patient’s value judgement of their functioning and daily activities (US Food and Drug Administration 2006).

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2 Clinical outcome measures involve some clinical judgment or interpretation of the observable signs, behaviours, or other physical manifestations thought to be related to a disease or condition. Performance outcome measures involve the patient performing a task according to instructions of a health care professional (US Food and Drug Administration 2006).
PROMs (and PROM-like) questionnaires have been around for some time. The Rose Dyspnoea scale, a 4-item questionnaire that assesses the patient’s level of dyspnoea with common activities, has been in use since the late 1960s (Rose and Blackburn 1968). Since the 1990s it has been used as a clinical aid in treating coronary artery disease (Cleary et al. 1991).

In recent years there has been a proliferation of PROMs instruments. According to Bryan et al. (2014), there were over 800 instruments in 2014 and more were being developed. They now cover a range of diseases and conditions and for different stages of disease progression. They are collected pre- and post-operatively (in the case of elective surgery) and over regular intervals (in the case of chronic disease management).

Although the department does not have a PROMs collection, a number of Victorian health services, clinical registries and networks have either been collecting PROMs or are in the process of adopting PROMs. For example, St. Vincent’s Hospital introduced its St. Vincent’s Melbourne Arthroplasty Outcomes (SMART) registry in 2005. Similarly, the Prostate Cancer Outcomes Registry (Victoria) has been collecting outcomes and PROMs data for prostate cancer since 2009. Heart Foundation Victoria recently developed the Heart Failure Toolkit which among other things identified a standard set of patient outcome measures.

2.3 How can PROMs be used?

The primary benefit of PROMs is that they provide the data that can help the department and clinicians understand the benefits of health care to patients from the patient’s perspective. Some of the possible uses for PROMs include:

- enabling clinicians to benchmark their healthcare practices
- identifying best practice by examining variations in clinical practice and their effect of patient outcomes
- monitoring and regulating the outcomes, quality and patient safety of health services
- understanding and managing the referral patterns between community and hospital care
- informing patients of the treatment offered by health services
- assisting the department with its resource allocation decisions.

Examples of where PROMs have been used include:

- assessing the cost-effectiveness in clinical trials and to evaluate new technologies (US Food and Drug Administration 2006, UK NICE 2013)
- monitoring the performance of hospitals — NHS England regularly collects PROMs data with which to calculate the health gains associated with hip and knee replacement

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3 Since not all patients are able to self-report their outcomes (such as young children, older people and anyone suffering from cognitive impairment), PROMs is taken to broadly encapsulate any related measured reported by the person, their family and/or carer.
surgery, varicose vein surgery and groin hernia surgery and is currently exploring the scope to collect PROMs for six long-term conditions (asthma, COPD, diabetes, epilepsy, heart failure and stroke) (Devlin and Appleby 2010)

• estimating the burden of disease and the benefits of health care — the UK National Institute for Health and Clinical Excellence (NICE) commonly uses PROMs data to estimate quality-adjusted life years (UK NICE 2013)

• allowing clinicians to benchmark and improve their clinical practices — the Prostate Cancer Registry in Victoria has routinely collected PROMs data the results of which have been instrumental in shaping clinical practices.

The type of design and implementation of a PROMs collection will depend on the purpose for which the data will be collected.

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Request for information

The department is seeking advice on how PROMs should be used in setting policy and shaping clinical practice. For what uses should PROMs data be used and not used in Victoria, both in the short and long term?
3 What is the department proposing?

The department is committed to establishing an ongoing Victorian patient outcomes collection. The collection will be a patient-level de-identified dataset that describes the health outcomes of patients undergoing treatment in Victorian hospitals and other health services. PROMs will be a centrepiece of the collection.

The department plans to use the collection for performance monitoring and for informing the design of future health policy. It also plans to collect the data in partnership with health services (including hospitals), clinical registries, networks and other bodies.

The partnership with health services and other entities is also expected to bring direct benefits to clinicians and health services themselves. A number of health services, clinical registries and networks are currently collecting or are considering collecting PROMs. A patient outcomes collection can improve the consistency with which PROMs data are collected and would allow health services and clinicians to improve their clinical practices by comparing and benchmarking their activities.

The department proposes to collect PROMs data from 1 July 2017. A pilot collection in 2017-18 will focus on a select number of health services and diseases, conditions and patients. The collection will be voluntary to start with and expanded over time.

The purpose of this consultation paper is to provide clinicians, health services, consumer (patient) representatives, research bodies and other interested parties an opportunity to contribute to the design of the pilot and subsequent roll out of the program.

Interested parties are invited to comment on each of the following topics.

3.1 Which diseases and conditions are to be included in the pilot?

The department has identified several candidate diseases and groups of patients — osteoarthritis of the hip and knee, prostate cancer, heart failure, and older persons — for which PROMs data can be collected during the pilot collection because:

- they account for a relatively large burden of disease
- there is a potential to reduce the variation in clinical practice and so improve patient outcomes
- a number of health services, clinical registries and networks have either ongoing PROMs collections or are about to introduce collections.

The department would consider other candidate diseases and conditions that fit these criteria including those that meet these criteria over time.
The candidate diseases and conditions do not have to be those that are treated in hospital settings alone. There is scope to improve the coordination of primary health care and hospital policies by collecting PROMs data for chronic diseases and conditions managed in the community such as diabetes, mental health, cardiovascular disease, back pain and asthma.

Request for information

The department is seeking advice on which diseases and conditions instruments should be collected in the pilot trial and for a subsequent expansion. Generally, consideration will be given to the scope for PROMs to improve:

- clinical practice
- health outcomes
- resource allocation.

Advice is also sought on which chronic diseases and conditions could be suitably collected from community settings.

For the pilot program, consideration will be given to those diseases and treatments for which a PROMs collection can be implemented in time for 1 July 2017.

3.2 Which PROMs questionnaires to use?

PROMs can be broadly categorised into two types: generic and condition-specific instruments.

**Generic instruments** contain questions that ask about a patient’s health-related quality of life for a variety of diseases and conditions. Health-related quality of life is broadly defined to include various dimensions such as pain and discomfort, physical function, mental health, and family and social relationships. Some of the more commonly used generic instruments include the Assessment of Quality of Life (AQoL), EuroQol EQ-5D, the Short Form set of questionnaires (SF-36 and SF-12) and the Patient-Reported Outcomes Measurement Information System (PROMIS).

An attraction of generic instruments is that they provide a common measure across different patient and population groups and can be used to estimate the burden of disease of a population. A limitation of generic instruments is that they tend to be less sensitive to specific changes in a patient’s health than condition-specific instruments.

**Condition-specific instruments** measure a patient’s health-related quality of life for a particular disease, condition or part of the body. Many clinical assessment tools, such as the Rose Dyspnoea and the Oxford hip and knee scores are condition specific. The standards developed by the International Consortium for Health Outcomes Measurement (ICHOM) are intended to be used as condition-specific instruments.
The attraction of condition-specific instruments is that they are more sensitive to targeted changes in a patient’s health status. As a result, they are potentially valuable in helping clinicians deliver patient-centred care. However, their lack of generality limits their usefulness in providing an assessment of a person’s overall health-related quality of life, and to compare across patient groups.

It is not uncommon for both generic and condition-specific instruments to be collected at the same time. For example, NHS England collects both the EQ-5D instrument and the Oxford hip score for hip replacement surgery. Similarly, NSW Health is considering the suitability of the PROMIS-10 generic instrument and the condition-specific ICHOM standards.

The department has identified the PROMIS-10 and the ICHOM standards as candidate instruments. PROMIS-10 is a computer-adaptive testing survey instrument that has the potential to yield more accurate estimates of a patient’s general health status than traditional paper-based instruments. The ICHOM standards provide detailed condition-specific assessments and are potentially comparable across jurisdictions and countries. A number of health services and clinical registries have already begun to collect data or are planning to collect data according to the ICHOM standards.

Request for information

The department is seeking advice on which generic and condition-specific instruments are currently being used or developed by health services, clinical registries and associations including for those diseases and conditions described in section 3.1.

In recommending a suite of instruments, the department will have regard to:

- the appropriateness of the instruments
- the extent to which the instruments are currently in use or are being developed
- the extent to which the instruments will permit benchmarking across Australia and internationally
- whether the instruments can be implemented by 1 July 2017.

3.3 Who will take part in the pilot and how will data be collected?

A major challenge with implementing a PROMs collection is to identify which health services, clinical registries and networks, and other bodies are to take part in the initial collection, and to identify the methods by which PROMs data will be collected. The choice of participant and collection method is closely connected because the decision of who collects the data will influence how the data is collected, stored and made available for use by others.
Who will collect the data?

A review of current practices indicates two broad approaches that could be used to collect PROMs data.

• Health service based — In this approach, each health service is responsible for collecting PROMs data at both the pre-treatment and post-treatment phases. The health service would be responsible for ensuring that patients remain enrolled in the collection after treatment. The data would be collected in accordance with a standard set of counting and reporting rules and would be made available to the department in regular instalments.

• Registry or network based — In this approach, a clinical registry or network is responsible for implementing a standard set of counting and reporting rules. Its member health services would provide the initial (pre-treatment) PROMs data after which the registry or network would be responsible for undertaking follow up surveys and maintaining patient enrolment and data quality. The registry or network would then be responsible for providing the data to both its member health services as well as the department.

Each approach has its advantages and disadvantages. Many health services have been collecting condition-specific PROMs so the task of collecting data may not be a significant departure from current practice. However, the sophistication of data collection and storage systems vary across health services, so some might find it difficult to provide audited data in a timely manner. Some health services might find it difficult to track patients for follow-up questionnaires long after treatment, and there is a risk of duplication and unnecessary response burden for patients seeking treatment from more than one health service.

The advantage of clinical registries is that they track patients across multiple health services, are generally better resourced to maintain patient enrolment and high response rates, and are able to link a patient’s PROMs with other clinically relevant data. Clinical registries are governed by strict confidentiality requirements which influence their ability to share patient-level data with parties outside their member clinicians and hospitals.

Notwithstanding who collects the data, there is a case to ensure that for each disease and condition being reported, that there is also an active community of clinicians and health services — a clinical network — whose role is to:

• develop new performance measures; compare and benchmark the performance member clinicians and health services

• provide a forum for clinicians and health services to exchange ideas

• develop best practice models of care.

Such communities are necessary to ensure that the collection and reporting of PROMs ultimately improves clinical practices.
The department is mindful that the collection of PROMs will vary on a case-by-case basis according to the disease and condition. The department is inclined to use existing collections, including those maintained by health services and clinical registries, as foundations for a state wide PROMs collection.

Request for information

The department invites health services, clinical registries and networks to participate in the PROMs collection both for the pilot program and for subsequent collections.

It is seeking advice on:

• what roles health services, clinical registries and networks, and other bodies should have in collecting, storing and supplying PROMs data
• how PROMs should be collected for those diseases and conditions for which there are no existing data collection frameworks.

The department invites clinical registries wishing to participate to propose how patient-level registry data might be made available to the department on an ongoing basis.

What other data will be collected?

The collection of PROMs data will be accompanied by a collection of complementary data that are needed to contextualise the data. Examples of relevant data include the patient’s age, gender, comorbidities and relevant medical history, and other non-patient reported outcome measures.

Not only will the department be taking advice on the relevant PROMs measures, it will also be taking advice from participants on what other data are necessary for it to collect.

Should the collection be a census or sample survey?

PROMs data can be collected as either a survey sample of patients and hospitals or it can be a census of all patients. The extent to which the patient population is measured depends on the purposes for which the data are being collected. If, for example, the objective is to monitor the performance of hospitals or to measure the burden of disease in the community, a survey sample would be sufficient. Alternatively, if instead the objective is to understand the effect of clinical practices on patient outcomes, then a more thorough collection is warranted.
Since existing PROMs in Victoria are concerned with improving clinical outcomes for patients, the department is inclined to collect data for both generic and condition-specific PROMs across all relevant patients of participating health services and clinical registries and networks.

Request for information

The department invites advice on whether data should be collected as a sample survey or a census of the participating patient and hospital population.

What will be the collection method?

There are various methods by which PROMs data can be collected, stored and transferred. When PROMs were first introduced, pre-treatment questionnaires were completed using pen and paper in an outpatient’s department or consultation room and followed up with a mail-out questionnaire. While this approach entails comparatively few overhead costs to establish it, it has some major limitations:

- manual coding is labour intensive (and therefore costly once the number of survey returns increase) and prone to data error (which can limit the usefulness of the data)
- response rates, particularly for follow-up mail-out questionnaires, tend to be low.

The department is committed to collecting data in a manner that minimises the inconvenience to patients and clinicians, improves the accuracy of data capture, supports clinical improvement, and facilitates the effortless storage and retrieval of data.

With this in mind, the department is exploring the use of a single online portal. The online portal would allow:

- patients to complete their questionnaires using a variety of devices such as app-enabled devices in an outpatients department, from their home email and computer assisted telephone questionnaires
- clinicians to access, review and download their patients’ data
- the department to extract an agreed minimum dataset for the Victorian patient outcomes collection.

A decision whether to adopt an online portal will depend on an assessment of the relative benefits and costs. An online portal is expected to involve a relatively high up-front investment but less effort for health services, registries, networks and the department over time. An online tool will also need to meet legal requirements regarding data security and patient confidentiality.
Request for information

The department invites advice on options for online data capture, storage and retrieval that meets the requirements of patients, clinicians, and the department.

- What are some of the possible functions of an online portal?
- What are the costs of establishing and operating an online portal?
- What are the legal implications of data security and patient confidentiality for an online portal?

What resources will be needed?

Many health services, clinical registries and networks are likely to have an incentive to implement a PROMs collection if the expected benefits to improved clinical practice (including patient outcomes) are greater than the expected costs of staff, information technology and licence fees. Moreover, health services, registries and networks would have an incentive to participate in a state-wide program because this would allow them to benchmark their performance across the state and across jurisdictions.

Depending on the way in which PROMs data are collected, some smaller health services may require assistance to implement a PROMs collection as they may not have the capacity to recruit suitably trained staff to follow up patients, audit data and to invest in up-to-date information technology that link PROMs data to a patient’s medical records.

Request for information

The department invites health services, clinical registries and networks to describe their existing data collection, storage and supply methods.

3.4 Who will use and have access to the data?

The department takes seriously its responsibility to protect patient confidentiality and to improve the quality of health policy design. The department’s objectives regarding PROMs will be to:

- collect such data that would help it develop appropriate health policies to improve the health outcomes of Victorians
- collect and store and report these data in a manner that protects patient confidentiality
- meets its obligation to monitor and report on the performance of health services.
In addition to the patient level outcomes and morbidity data, the department proposes to collect a number of additional data items that may include the patient’s age, gender, their hospital’s patient number and the hospital’s campus code. These will be collected in accordance with strict governance protocols.

The purpose of collecting these data items is to permit the department to link the outcomes data with other data held by the department such as the cost data (the Victoria Cost Data Collection) and hospital diagnosis and procedure data (the Victorian Admitted Episodes Dataset). Data linkage would assist the department to meet its objective of developing better health policies. Data linking would be undertaken in the secure environment of the department’s Centre of Victorian Data Linkage.

Even though the department proposes that the outcomes dataset be linked to other hospital administrative datasets, the department is committed to ensuring that the Victorian patient outcomes collection only be publicly available as a de-identified patient-level dataset. This is no different to the department’s long-standing practice of collecting and reporting the Victorian Admitted Episodes Dataset and the Victorian Emergency Minimum Dataset and other linked datasets.

Request for information

The department invites suggestions on how to ensure that patient confidentiality is protected while at the same time promoting accessibility to potentially useful and valuable data.
4 What will happen after this consultation?

4.1 Report preparation

This consultation paper forms part of a formal consultation process that is expected to run until 28 October 2016. The department will publish a report with options and a recommended strategy for implementing PROMs in December 2016. Between the conclusion of the formal consultation process and the finalisation of the report, the department will continue to work closely with interested parties.

4.2 Implementation

Between the release of the report and the start of the pilot program on 1 July 2017, the department will liaise with health services, clinical registries and networks and other bodies with the implementation of PROMs to ensure they are on track to commence collecting from 1 July 2017.

4.3 Pilot program and evaluation

The pilot program is expected to run between 1 July 2017 and 30 June 2018. The department will monitor the data submissions and liaise with the pilot participants, making changes where necessary.

In late 2017, the department will also begin discussions with other health services, clinical registries and networks for the inclusion of additional diseases and health services for the 2018-19 collection.

From early 2018, the department will begin an evaluation of the pilot program. The evaluation will cover a range of topics covering the usefulness of the pilot program and the lessons for the future roll out. It is expected that the evaluation will form part of a regular cycle of improvements to the data collection.
References


Devlin, N.J. and Appleby, J., 2010, Getting the most out of PROMs: putting health outcomes at the heart of NHS decision-making, The King’s Fund, London.


How to make a submission

How to lodge a submission

Submissions should be emailed to the department at:

proms@dhhs.vic.gov.au

with ‘PROMs submission’ in the email header.

By post: Patient Reported Outcomes study
System Intelligence and Analytics
Department of Health and Human Services
50 Lonsdale Street
Melbourne, Victoria 3000

Due date for submission

Please lodge submissions by **28 October 2016**.

How to prepare a submission

Submissions may range from a short letter outlining your views on a particular topic to a much more substantial document covering a range of issues. Where possible, you should provide evidence, such as relevant data and documentation, to support your views. Please note that:

- Any submission, except for any attachment supplied in confidence, is available to the public upon request.
- This is a public review and all submissions should be provided as public documents for others to read.
- Cause would need to be shown for any submission or part of a submission to be treated confidentially.
- Material supplied in confidence should be clearly marked ‘IN CONFIDENCE’.
- For privacy reasons, all personal details (for example, home and email address) will not be made publicly available. Please do not provide these details in the submission.
- The department prefers to receive submissions as a Microsoft Word (.docx) files. PDF files are acceptable if produced from a Word document or similar text based software.
- Track changes, editing marks, hidden text and internal links should be removed from submissions.