

November 2016

Patient-reported outcome measures

Literature review

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Published by the Australian Commission on Safety and Quality in Health Care
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Website: www.safetyandquality.gov.au

ISBN: 978-1-925224-74-0

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The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Williams K, Sansoni J, Morris D, Grootemaat P and Thompson C, Patient-reported outcome measures: Literature review. Sydney: ACSQHC; 2016

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Preface

This literature review report presents a synthesis of international evidence and experience in the collection and use of patient-reported outcome measures (PROMs) in healthcare systems.

PROMs are questionnaires which patients complete. They ask for the patient's assessment of how health services and interventions have, over time, affected their quality of life, daily functioning, symptom severity, and other dimensions of health which only patients can know. PROMs promise to fill a vital gap in our knowledge about outcomes and about whether healthcare interventions actually make a difference to people's lives.

This Preface is the Australian Commission on Safety and Quality in Health Care's (the Commission's) introduction to the report that follows. The report was written by Kathryn Williams and colleagues at the Australian Health Services Research Institute (AHSRI), University of Wollongong. In this preface, we briefly put the report into context and highlight some of its main messages and potential uses.

Why was this document commissioned?

In Australia, PROMs are an emerging method of assessing the quality of health care. They are not yet embedded in routine measurement at regional, jurisdictional or national level. Internationally, such routine and consistent measurement is being developed or is already embedded in the health systems of several Organisation for Economic Co-operation and Development (OECD) countries.

The Commission is scoping an appropriate role at national level to support the consistent and routine use of PROMs to drive quality improvement in a way that brings patients' voices and outcomes to the fore. Before scoping this role, it was necessary to learn about how PROMs are used in international health systems similar to Australia's, to build up a detailed picture of best practice, and to learn from other countries' experiences.

In particular, we were interested in answering the following four questions:

1. What is the rationale for collecting patient-reported outcome information?
2. What mechanisms are used internationally for the routine collection and aggregation of patient-reported outcome information at national or state/province level, and are there particular patient-reported outcome measures and conditions which are more commonly aggregated and reported at this level?
3. What are the reported uses of patient-reported outcome information in terms of quality and safety improvement?
4. What have been the reported impacts, benefits and challenges of collection of patient-reported outcome information at national or state/province level?

To assess the evidence base and to answer these questions, the Commission sought expressions of interest in mid-2016 for this literature review and its companion document, an environmental scan. The AHSRI at University of Wollongong made a strong submission based on extensive prior experience in PROMs-related research and in the application of PROMs within health services.

What were the main findings and recommendations?

The countries most advanced in implementing PROMs at a national or jurisdictional level are England, the Netherlands, Sweden and the United States, with increasing interest in a national approach in Canada. Perhaps the most striking finding from the review is the wide variety of purposes for which PROMs are now being used, in research, clinical practice and health services management. For example, they are used to promote shared decision making and self-management at the individual level of the clinical interaction as well as at the aggregate level as indicators of the quality of healthcare provided by an organisation.

Overall, the review shows that in many of the countries studied, PROMs are integral parts of a movement towards patient-centred systems of structuring, monitoring, delivering and financing health care. Increasingly, quality is being seen as defined by the patient, not just by the clinician or policymaker. It is therefore fitting that the patient assessment of quality made possible by PROMs are becoming widespread. The review also reflects on implementation challenges associated with PROMs, and notes that the evidence supporting PROMs is, for some applications, still equivocal.

The report makes several recommendations for the Commission's potential role in helping to build on this existing work to help embed PROMs in Australian health care. These will be taken into consideration (but not necessarily taken up) as the Commission develops its future work on PROMs.

How can this document help you?

The Commission intends that governments, researchers, managers, health professionals and consumer groups will find this document a useful resource when exploring how PROMs might help their organisation achieve a more person-centred approach to quality and safety improvement. The accompanying spreadsheet enables readers to filter and sort articles and resources referred to in the review.

The information contained in this review is based on a search of academic and grey literature databases between June and August 2016. The search was restricted to publications issued in the last ten years from Australia, New Zealand, countries of the UK, Ireland, France, Germany, the Netherlands, Norway, Finland, Sweden, Denmark, the USA and Canada.

What will the Commission do next?

The Commission is releasing a separate environmental scan alongside this literature review. We recommend reading the two reports together, as the literature review puts PROMs into a wider, international context and synthesises research evidence on best practice in their development, collection and use.

The Commission will now use the findings of the two documents as a basis for developing a series of options for a national framework and resources. These will support governments and health services around Australia to use PROMs in ways that are backed by evidence and which build on and learn from existing initiatives.

This work complements other current work at the Commission. Scoping the role of PROMs in assessing low-value care for certain conditions was one of the recommendations of the first *Australian Atlas on Healthcare Variation*, and the version two of the National Safety and Quality Health Service (NSQHS) Standards promotes a strong focus on person-centred care.

Patient-reported outcome measures: literature review

Prepared for the:
Australian Commission on Safety and Quality in Health Care

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November 2016

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Acknowledgements:

The authors would like to thank key staff from the funding body, the Australian Commission on Safety and Quality in Health Care, for their assistance. In particular, the ongoing support from Dr Jennifer Plumb and Ms Catherine Katz throughout the project is gratefully acknowledged.

Suggested citation:

Williams K, Sansoni J, Morris D, Grootemaat P and Thompson C, Patient-reported outcome measures: Literature review. Sydney: ACSQHC; 2016

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List of abbreviations / acronyms

ACI	Agency for Clinical Innovation
ACSQHC	Australian Commission on Safety and Quality in Health Care
AHOC	Australian Health Outcomes Collaboration
AHRQ	Agency for Healthcare Research and Quality
AHSRI	Australian Health Services Research Institute
AMHOCN	Australian Mental Health Outcomes and Classification Network
AROC	Australasian Rehabilitation Outcomes Centre
CADOSA	Coronary Angiogram Database of South Australia
CHSD	Centre for Health Service Development
CPAC	Clinical Priority Assessment Criteria
DICA	Dutch Institute for Clinical Reporting
ePPOC	Electronic Persistent Pain Outcomes Collaboration
HoNOS	Health of the Nation Outcome Scale
HRQoL	Health-Related Quality of Life
ICHOM	International Consortium for Health Outcomes Measurement
IRT	Item Response Theory
ISOQOL	International Society for Quality of Life
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NHS	National Health Service
NIVEL	Netherlands Institute for Health Services Research
NSQHS	National Safety and Quality Health Service (Standards)
OCSQ	Otago Condition Specific Questionnaire
OECD	Organisation for Economic Co-operation and Development
PCOC	Palliative Care Outcomes Collaboration
PCORI	Patient-Centered Outcomes Research Institute
PREMs	Patient Reported Experience Measures
PRIMHD	Programme for the Integration of Mental Health Data
PRO	Patient-reported outcome
PROMs	Patient-reported outcome measures
PROMIS	Patient-Reported Outcomes Measurement Information System
QALY	Quality-Adjusted Life Year
RFQ	Request for Quotation

Key messages

Patient-reported outcome measures (PROMs) ask patients to assess elements of their own health, quality of life, and functioning. The resulting data can be used to show how healthcare interventions and treatments affect these aspects of a person's day-to-day life.

This report presents the results of a literature review incorporating 393 journal articles, reports and other sources derived from a targeted search of the academic and grey literature. The purpose of the report is to synthesise available evidence about how PROMs are being used in Australia and elsewhere to inform and drive quality and safety improvement in health care.

Evidence to support the use of patient-reported outcome measures (PROMs) to inform quality improvement is growing internationally. The evidence is strongest for their use in understanding variation in clinical practice, as they can help in determining the relative effectiveness of different treatments and interventions. There is also good evidence that the use of PROMs enhances processes within the patient-clinician interaction.

There are three primary reasons cited in the literature for the adoption of PROMs:

- Patients are the best judges of the impact of their treatment on their pain, function, symptoms and quality of life.
- PROMs are a valuable support for patient-centred care.
- Systematic collection of PRO data informs efforts to improve quality and safety.

The four main mechanisms used internationally for the routine collection and aggregation of PRO information are:

- pre- and post-procedure data collection from patients undergoing selected elective surgeries to assess hospital performance (e.g. the NHS England PROMs program);
- computer assisted testing using banks of questions that capture generic patient-reported outcomes common across a number of chronic conditions (e.g. the US-based Patient-Reported Outcomes Measurement Information System initiative);
- inclusion of PROMs within disease-specific clinical registries (e.g. Swedish Healthcare Quality Registries); and
- international initiatives to develop standard outcome measurement sets, including PROMs, to foster international benchmarking (e.g. International Consortium for Health Outcomes Measurement).

At present, PROMs are being used to evaluate healthcare effectiveness at different levels of the health system, from the individual to the service and system levels. Their use during the clinical consultation and in multidisciplinary team discussions is thought to contribute to shared clinical decision making and patient-centred care. To be used at the service or system level, PRO data that are collected during the patient-clinician encounter can be aggregated, to support

comparative effectiveness research, performance measurement, population surveillance and an understanding of health care 'value' in terms of cost-effectiveness.

There is growing interest internationally in the routine integration of PRO information into these evaluation and decision-making activities at levels of health system beyond the clinical consultation. This has potential advantages for engaging clinicians, increasing the relevance of the data collected, building large-scale or national datasets efficiently and ultimately improving patient care. There is however a need for further theoretical development around the use and expected impacts of PROMs to guide implementation and evaluation at all levels.

Executive summary

Internationally, the healthcare environment is receptive to patient-reported outcome measures (PROMs) as a mechanism to incorporate patient perspectives in quality improvement, electronic data collections, value-based payments and shared decision making.

The current project documented how PROMs are being used in Australia and elsewhere to inform and drive quality and safety improvement in health care. The project incorporated an environment scan and a literature review. A targeted search of the academic literature was complemented by web-based searching for grey literature (i.e., published and unpublished reports, policy documents and other relevant material) from selected countries, namely: Australia, New Zealand, United Kingdom, Ireland, USA, Canada, and selected European and Scandinavian countries. A total of 393 sources (111 from the academic and 282 from the grey literature) were included in this review.

In this executive summary we describe the main findings of the literature review and their implications. Further details can be found throughout the remainder of the report.

Summary of findings

There are three primary reasons for the adoption of PROMs cited in the literature:

- Patients can be most accurate in describing their own symptoms, pain, function and quality of life.
- PROMs can be used in clinical settings to support shared decision making and patient-centred care.
- When collected systematically across providers (e.g. via clinical registries), PROMs generate valuable data on treatment effectiveness, adverse events and variations in healthcare delivery and outcomes to inform efforts to improve quality and safety.

Mechanisms for data collection using PROMs include: large, time-limited research projects; ongoing, routine data collection from providers feeding into national clinical registries; international collaborations to establish and implement standardised datasets; and the development of item banks for use in computerised adaptive testing.

The countries most advanced in implementing PROMs at a national level are England, the Netherlands, Sweden and the United States, with increasing interest in a national approach in Canada. Each country is adopting a slightly different emphasis. In England the focus is on hospital performance in selected elective surgeries; in the United States the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative focuses on PROs common to a number of chronic conditions; and in the Netherlands and Sweden PROMs collection occurs in the context of disease-specific and condition-specific clinical registries.

Few Australian clinical registries have so far included PROMs, but there is an emerging trend towards inclusion. Many Australian organisations are currently collaborating with the International Consortium for Health Outcomes Measurement (ICHOM) either as strategic partners, as participants in the development of health outcome standard measurement sets, or

as potential participants in international benchmarking activities. More than 40 other countries are also involved in such activities.

Uses of PROMs can be organised into three broad categories: clinician-patient interactions (micro level); descriptive and analytical studies such as comparisons of treatment effectiveness or understanding variation among providers (meso level); and population surveillance and policy (macro level). These three categories are not mutually exclusive but overlap and interact and all are capable of contributing to improvements in healthcare safety and quality.

At the micro level, the evidence indicates that PROMs have some positive impacts on processes within the clinician-patient interaction but little impact on individual health status outcomes. The evidence base is stronger for meso-level uses of PROMs, particularly in comparative effectiveness research where PRO data has been extensively used to investigate the relative benefits of different treatments. Increasingly, PRO data from registries are also being used for quality improvement purposes, such as understanding variations in care, costs and outcomes among providers. Using PRO data to inform value-based payment systems is an emerging, system-level use of PROMs. To date there has been little formal evaluation of the macro-level uses of PROMs but it is clear that there is growing interest within diverse health systems across the world in the potential benefits of PROMs.

In order to implement PROMs successfully and realise the potential benefits, several challenges need to be addressed. Information and communication systems are required to ensure that the data can be collected easily and accurately. Casemix or other risk adjustment approaches are required in order to ensure fair and accurate comparisons among providers. Barriers for administrators and policy makers include the resources required to collect and manage the data and the potential for misuse and unintended consequences. Importantly, PRO data needs to be presented in a way that is useful to providers and patients. Providers need to be able to use PRO data to know what and how to improve, not just to compare themselves with others.

It is important to use valid, reliable and appropriate instruments when selecting PROMs and minimise the burden on patients and healthcare teams in data collection. The process of integrating PROs into data collection for safety and quality monitoring and improvement requires methodological rigour and expertise. New information technologies can support the electronic capture of PRO data and facilitate real-time feedback to clinicians providing routine care. The integration of PROMs into electronic health records can also support data collection at an aggregate level and inform system-wide quality improvement and population surveillance.

Summary of implications and recommendations for Australia

There is potential to expand the use of PROMs in Australia. PROMs can contribute to person-centred care during the consultation and in multidisciplinary team discussions. PROMs can also be used to monitor outcomes of treatment (including post-discharge complications or adverse events) and to identify patients at risk of problems or in need of specialist intervention. PRO data is important in comparative effectiveness research, helping to define and guide better practice. In the wider health system (at the macro level), PRO data can be used by regulatory bodies and manufacturers to understand the risks and benefits of medical devices (e.g.

implants), surgical techniques or pharmaceuticals. This information contributes towards an understanding of health care 'value' in relation to costs.

There is a strong and coherent rationale for collecting and using PROMs. However, there is a need for further evaluation of the benefits (and risks) of PROMs in the clinician-patient interaction, for quality improvement and for guiding policy, payment systems and research agendas. Any implementation of PROMs in Australia should have built-in systems for monitoring, evaluation and iterative development.

A broad theoretical framework would be valuable in establishing a foundation for the development and implementation of PROMs and specifying expected impacts. This could drive and facilitate rigorous evaluation. It may be possible to build a theoretical model around an established quality framework.

Knowledge translation strategies need to be in place to ensure that high-quality information is fed back from PROMs collection to influence clinical practice and quality and safety improvement efforts. PROMs must be clearly linked with clinical guidelines and pathways and knowledge translation expertise is needed to help patients, professionals and the public to access and use this information effectively. Top-down leadership and decision making should be combined with bottom-up engagement of consumers, patients and health professionals, with formal processes for consultation and reaching consensus on the core framework of PRO data to be collected.

There is potential for integrating PROMs across multiple levels of users; data collected during the patient-clinician interaction could be fed into clinical registries to inform meso and macro applications of PROMs, maximising the value to clinicians, patients, organisations and the broader health system. However, a major challenge in integrating PROMs is reconciling the needs of stakeholders at each level.

It is recommended that the Commission:

1. Conducts an audit of Australian clinical quality registries with respect to PROMs use.
2. Undertakes further work to ascertain the barriers and facilitators to PROMs inclusion in clinical quality registries, based on the literature and consultations with key stakeholders and international experts.
3. Promotes PROMs inclusion in clinical quality registries; for example, by linking the collection and appropriate use of PROMs to criteria for assessing the quality of registries (as in the classification system used for the Swedish National Quality Registries).
4. Advocates for best practice in PROMs implementation, both in routine clinical practice and registry data collections; for example opportunities for data linkage with electronic health records.
5. Facilitates careful selection of appropriate PROMs instruments, including a review of multi-attribute utility measures within the Australian context.
6. Continues to monitor evidence of impacts of PROMs in the literature.

7. Advocates for a systematic approach to the monitoring and evaluation of the uses of PROMs in Australia with consideration of this to be built into any new initiatives.
8. Outlines a broad theoretical framework to guide the development and use of PROMs specifying expected impacts and directing both formative and summative evaluations of PROMs initiatives.
9. Engages in knowledge transfer and dissemination using specialist expertise to build and sustain patient, clinician and organisational support for investment in PROMs.
10. Develops a position statement about the merits of collecting and reporting PROMs and the potential for integrating them across different uses.
11. Explores the effectiveness of value-based payment systems in health care and their potential for implementation in the Australian health system.
12. Investigates risk adjustment options including casemix and risk stratification approaches in order to ensure fair and accurate comparisons among providers.
13. Assesses the feasibility of introducing selected PROMs into the indicator set for hospital quality and safety performance.
14. Establishes an Australian working group to provide leadership in the use of PROMs.

1 Introduction

After many years of use in clinical trials, there is now growing interest in using patient-reported outcomes (PROs) to support improvement in the safety and quality of healthcare delivery.¹ The Australian Commission on Safety and Quality in Health Care (the Commission) has engaged the Centre for Health Service Development, University of Wollongong, to examine the ways in which patient-reported outcome measures (PROMs) are currently being used in Australia and elsewhere, with a particular focus on the potential purpose and benefits of national-level collation or collection.

The Commission is an Australian Government agency that leads and coordinates national improvements in safety and quality in health care. Its mandate is to support the provision of high quality, safe and patient-centred healthcare services. It has taken a national leadership role in developing patient-reported experience measures (PREMs) and has undertaken a program of work in this field over the past five years.

One further way to ensure that health care is delivered in partnership with patients is to ask patients about their perspective on the impact of treatments and care through routine use of PROs. Recently the Commission has extended its interest in patient-centred care to include a review of the use of PROMs in routine care. The Commission is therefore seeking to scope an appropriate role in relation to PROs.

1.1 Background

Definitions of key terms (PROs, PROMs and PRO-PMs) are provided below. In the following sections these concepts are expanded further along with other key terms and placed in the context of the broader field of health outcomes assessment.

1.1.1 Key definitions

Patient-reported outcomes (PROs) encompass a wide range of measurable outcomes of care from the patient's perspective, including symptoms, quality of life and functional status.¹ They can be defined as follows:

A PRO is directly reported by the patient without interpretation of the patient's response by a clinician or anyone else and pertains to the patient's health, quality of life, or functional status associated with health care or treatment.²

The reliance on PROs is driven by the view that patients are the best judge of their own welfare.³

PROMs are the instruments used to measure PROs.⁴ The most common method for measuring PROs is asking consumers to complete standardised, validated questionnaires so that they self-assess their own wellbeing and functional status.⁵ Patients are asked to rate their health by responding to a series of items, which are then combined to represent an underlying construct such as pain, symptom severity, function or quality of life. In general, analysis of PROMs focuses on the change in scores following a health intervention, such as surgery or a course of

treatment.⁵ By comparing patients' self-reported health before and after the intervention, the outcomes of the care they received can be assessed.⁶

PROMs have long been included in clinical trials to assess the health outcomes of interventions, but are increasingly used as a quality improvement tool. Tools can be completed in order to monitor outcomes of individual care or to feed into 'registries' of clinical data that assist in identifying effective health care practice and benchmarking the performance of healthcare providers.

When PROs are aggregated across organisations or systems for the purposes of performance measurement, they are known as PRO-based performance measures (PRO-PMs).⁷ Creating appropriate PRO-PMs involves specifying relevant PROs, selecting appropriate instruments (PROMs) and collecting, aggregating and reporting them in standard ways to reflect an organisation's performance.

1.2 Scope of the project

This literature review is one component of a broader project which aims to document how patient perspectives are currently being used in Australia and elsewhere to inform and drive quality and safety improvement in health care. An important goal of the project was to assess the potential purpose and benefits of national-level collection or collation of PROMs. The overall project also included an environment scan⁸ which provided an overview of the collection and use of PROMs in Australia.

The narrative review, which is the subject of the current document, had a wider geographical and conceptual scope. It was limited to the collection and/or use of PROMs at the national and jurisdictional (state/province) level of the following countries:

1. Australia
2. New Zealand
3. United Kingdom
4. Ireland
5. USA
6. Canada
7. Selected European countries (France, Germany, Netherlands)
8. Selected Scandinavian countries (Sweden, Finland, Norway, Denmark).

1.3 Research questions

This narrative review seeks to answer the following questions:

1. What is the rationale for collecting PRO information?
2. What mechanisms are used internationally for the routine collection and aggregation of PRO information at national or state/province level, and are there particular PRO measures and conditions which are more commonly aggregated and reported at this level?
3. What are the reported uses of PRO information in terms of quality and safety improvement?

4. What have been the reported impacts, benefits and challenges of collection of PRO information at national or state/province level?

1.4 Structure of this report

The next section of this report provides background information on health outcomes assessment and further definitions of key terms relating to PROMs. This is followed by a detailed description of the literature review method and then presentation of findings, structured around the research questions. The discussion section summarises:

- Overall findings, focusing on patterns of PROMs collection and use at national/jurisdictional level for safety and quality improvement;
- A summary of the evidence on impacts of PROMs on policy and practice with particular reference to safety and quality impacts; and
- Implications of the findings for a national approach to PROMs collection or collation in Australia.

2 Health outcomes assessment

This section provides an overview of the different ways in which health outcomes are measured in the context of healthcare delivery and evaluation. Although the focus of this review is patient-reported outcome measurement, this needs to be seen in the broader context of health outcomes assessment. PROMs are rarely used in the clinical context as stand-alone measures, but are often used alongside other indicators.

There are a number of definitions available for health outcomes (including PROMs)³; in Australia the following operational definition is used:

*A health outcome is a change in the health of an individual, or a group of people or population, which is wholly or partially attributable to an intervention or series of interventions.*⁹

2.1 Clinician-reported outcome measures and outcome-related performance indicators

The three principal forms of health outcomes measurement (apart from PROMs) are: measures of physiological parameters (biomedical indicators); clinicians' ratings of their patients' health outcomes (to guide clinical treatment and care); and the routine collection of outcome-related indicators by healthcare organisations (to assess the organisation's performance).

To help guide clinical practice decisions, a range of standardised and validated measures of health status and health-related quality of life (HRQoL) can be used to assess the outcomes of treatment interventions. These measures can be clinician-rated as part of standardised clinical assessment (for example, the Health of the Nation Outcome Scales¹⁰), or they can be patient-rated (see Section 2.2 on PROMs below).

When the purpose of measurement is to gather information on health system or health service performance, a health outcome-related performance indicator may be used. This is:

*a statistic or other unit of information which reflects, directly or indirectly, the performance of a health and welfare intervention, facility, service or system in maintaining or increasing the well-being of its target population.*¹¹

Some outcome-related performance indicators are routinely collected by a healthcare organisation about patients. These indicators include rates of avoidable adverse events, hospital-acquired infection rates, time to treatment and unplanned readmission rates. Such indicators are often used for national comparisons of hospital performance. They are useful to highlight problems with processes, including variations in practice, and are sometimes important predictors of outcomes (e.g. in many diseases, longer 'time to receive treatment' leads to worse clinical outcomes). However, some of these performance indicators may be susceptible to influence by factors which are not under the control of the health service.³

2.2 Patient-Reported Outcome Measures (PROMs)

PROMs are tools for capturing the patient's perspective on the outcomes of their own treatment and care. They can be:

- 'generic' (measuring aspects of health status and quality of life which are common to most patients);
- 'disease-specific' (e.g. for a type of cancer); or
- 'condition-specific' (apply to a service sector such as rehabilitation or mental health services or a population segment such as the elderly).

There are thousands of disease-specific PROMs but they can only be completed by those with the disease concerned. The advantage of generic PROMs is that they allow comparison of outcomes across conditions.⁶ When used together, generic and disease-specific PROMs can provide complementary information.

2.2.1 Generic PROMs

Generic PROMs measure single aspects of health (e.g. pain) or cover multiple dimensions of health status. These multi-dimensional questionnaires generally include items on physical functioning, role functioning, psychological symptoms and pain. Some extend to additional domains such as sleep, social functioning and sexual functioning.³ Widely used examples of generic, multi-dimensional PROMs are the:

- Short Form-36 (SF-36)¹⁵
- SF-12¹⁶
- Nottingham Health Profile¹⁷
- Sickness Impact Profile¹⁸
- WHOQOL-Bref¹⁹.

McDowell provides reviews of many of these instruments.²⁰

Recently, a new generic measure, the PROMIS (Patient-Reported Outcomes Measurement Information System) Global Health-10 scale has emerged. This has been developed using both classical test theory and modern psychometric methods (e.g. item response theory, IRT). Approaches such as IRT can be used to refine measures and to make them suitable for computerised adaptive testing.^{21,22} Computerised adaptive testing (CAT) is a method of administering a questionnaire which minimises the time and effort required of respondents. Patients are only required to answer the minimum number of questions that are necessary, through statistical inference, to determine their final score. Being available in both CAT and traditional paper and pencil versions, the PROMIS measures are a useful development. However, as the Global Health-10 instrument has only been recently released, there is less data available about the validation of this measure than for the more established generic measures.³

If the goal of using a generic PROM is to estimate relative costs and benefits of different treatments, as in comparative effectiveness research, a range of multi-dimensional indices (also known as multi-attribute utility measures) are available.³ These are short health questionnaires designed to generate a single index value for the health state being measured. This single index or number can then be used to derive Quality-Adjusted Life Years (QALYs) with which costs data can be associated (see Section 2.3 below). Some commonly used measures of this type are the:

- Australian Quality of Life Scale (AQoL)^{23,24,25}
- EQ-5D (formerly the Euroqol)^{26,27}
- Health Utility Index 3 (HUI3)^{28,29,30}
- 15D^{31,32,33}
- Quality of Well-Being (QWB)^{34,35}
- Rosser Index³⁶
- Short Form-6 Dimensions.^{37,38}

There are a number of recent reviews that provide guidance on selecting a generic PROM instrument that is fit for purpose.^{39,3} As PROMs are often used to measure change in function for a cohort of patients following treatment⁵ or variation among patients receiving different treatments, sensitivity to small differences is an important psychometric characteristic of these instruments.

With regard to the multi-attribute utility measures the sensitivity of the tools varies significantly with the measurement method and by disease area.^{39,3} Richardson and colleagues found that the 15D, AQoL-8D and the SF-6D generally achieved better tests results on their rating and review criteria than the QWB and the EQ-5D-5L.³⁹ The EQ-5D has been widely used by the NHS in the UK as a measure of health gain⁴⁰ and by some Swedish registries⁴¹ (see also Appendix 2b and Appendix 2d). In Sweden since 2013, the EQ-5D-5L has been preferred as it is less prone to ceiling effects and there are now Time Trade Off values for the health states derived from the EQ-5D-5L.⁴² In the UK values for the EQ-5D-5L have recently been developed by the Office of Health Economics.^{43,44}

2.2.2 Disease-specific PROMs

Disease-specific PROMs are used with other disease-specific indicators which include clinical and physiological measures (e.g. blood pressure, serum cholesterol) and outcome-related performance indicators (e.g. time to receive treatment variables, complications and adverse events). Compared with generic instruments, disease-specific PROMs provide far more detailed information about a patient's experience of key symptoms across the trajectory of treatment and recovery for the disease. They are often adopted by disease-specific clinical registries.³

Some of these instruments incorporate generic elements such as perceived health status or health-related quality of life. Although this may seem an efficient approach, measurement errors can result from including both types of measures in one instrument (e.g. inadequate item representation on generic domains) and comparisons across conditions cannot then be made. Increasingly such 'blended' instruments are being displaced by modular packages which use a general health profile and a complementary disease-specific instrument as well as relevant clinical indicators and information such as demographics and co-morbidities.³

2.2.3 Condition-specific PROMs

Condition-specific PROMs do not focus on a particular disease but on a broader health condition or state. They include a range of functional status or disability measures used to assess the health of a particular population group such as the elderly or those with mental

health problems. Some brief mental health measures such as the self-reported Kessler-10 Psychological Distress Scale have also been used in population-based mental health surveys^{45,46,47} and in clinical monitoring. A comprehensive review of condition-specific PRO instruments can be found in a recent report by Sansoni.³

2.2.4 Outcome measurement suites

Recently, outcome measurement suites have been developed for conditions (e.g. chronic disease management, dementia, incontinence conditions, mental health, assessment and monitoring of the elderly and asthma) and for particular situations (e.g. assessment and monitoring in primary and community care). These are collections of PROMs and other items that are seen as relevant for the outcomes monitoring of these conditions. They usually contain patient information, medical history, medication use, service use, clinical indicators and generic and disease or condition-specific measures.³ For example, the International Consortium for Health Outcomes Measurement (ICHOM) produces health outcome standard measurement sets for diseases and for population groups.⁴⁸

2.2.5 PRO-PMs

Performance measurement is dominated by information that is routinely captured about patients as part of their hospital or health service attendance or admission. PRO-PMs are less frequently used health outcome-related performance indicators which use patient-reported outcomes to assess performance. PRO-PMs use PRO data aggregated across organisations or systems.⁷ For example, a PRO-PM may consist of the proportion of mental health patients whose scores on a standardised assessment tool fell below a clinically significant cut-off point following a given period of treatment at a particular service. PRO-PMs have a range of uses such as evaluating symptom control, identifying healthcare practices for which education or outreach programs might be needed, and facilitating self-care by helping patients understand how practices affect symptoms and functioning.⁷

2.3 Two broader examples of PROM applications

Apart from their use in clinical settings and in organisational performance measurement, PROMs have applications in government policy making. The relative effectiveness and cost-effectiveness of different healthcare interventions need to be determined when deciding on best clinical practice and on resource allocations. Such high-level policy decision making cannot simply be made on the basis of studies conducted under highly controlled conditions (such as Randomised Controlled Trials). They must also take account of evidence of 'real world' impacts of interventions where the patient population and management approaches are typically more diverse than that found in RCTs.^{12,13}

2.3.1 Clinical registries

One example of such a use of PROMs is in clinical quality registries. Registries are large, prospective studies of patient cohorts who all have a particular condition or disease and/or are receiving a particular treatment or intervention.¹² In addition to clinical and cost information, PROs are increasingly included in registries, although there is scope for further development.¹⁴ Disease- or condition-specific registries allow policy makers and providers to explore and generate hypotheses about which treatments are most effective and cost-effective and to track outcomes over a longer timeframe than an RCT allows. Because data are collected in 'real

world' settings, the patterns of treatment recorded in registries more accurately reflect everyday clinical decision making that is relevant to policy makers, providers and payers.¹²

2.3.2 Economic evaluation

One further way in which some PROMs (e.g. multi-attribute utility measures) can be used is for the calculation of the Quality Adjusted Life Year (QALY), which is a metric commonly used in determining cost-effectiveness of particular treatments or interventions. This is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. QALY units 'integrate side effects and benefits of treatment by combining, into a single number, mortality, morbidity, and duration of each health state'.³⁴ One QALY is equal to one year of life in perfect health. The approach assumes that QALYs can be aggregated across individuals.⁴⁹

The measure can provide a guide for choosing between treatments for a condition or can be used to compare the costs and benefits of treatments across conditions to inform overall health resource allocation decisions.

To determine the relative value of a health gain from a treatment or intervention when calculating QALYs, it is necessary to place a value on different states of health. This can be done using a generic health-related quality of life index such as the EQ-5D. The box below provides further information on how scores on the EQ-5D can be used to calculate QALYs.

Using the EQ-5D to calculate QALYs

The EQ-5D asks patients to report on five dimensions of their health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is scored on a three-point scale, where 1 = no problems, 2 = some problems and 3 = extreme problems. All possible combinations of scores across the five dimensions can be used to produce health state values. These values are the basis for a standardised assessment of the level of health gain achieved by different interventions, which can then be weighed against costs to determine relative cost-effectiveness.

At one extreme end of the scale, a person in excellent health may score 1 (no problems) on all five dimensions and that person's health state would be classified as 1,1,1,1,1. At the other end of the scale, a person in very poor health who reports extreme problems with all five dimensions would have a health state classified as 3,3,3,3,3. All possible combinations of scores across the five dimensions result in a total of 243 health states that can be described.

Each of these health states can be valued on a scale between 0 (death) and 1 (life) – usually using preference methods such as standard gamble or time trade off. For time trade off a person is asked how many years of life they are prepared to give up for a treatment that will return them to full health from this health state. These preference techniques provide the utility value for each health state.³

Improvement gained by a treatment can be classified on the same metric. For example, a treatment moves incontinence patients from a health state valued at .6 to .7, based on their improvements in HRQoL. The gains due to treatment need to be adjusted for the period of survival / life expectancy. For example, assume a person treated for incontinence survives 10 years. So the treatment has gained the patients one QALY (10 years survival*.10 improvement gained = 1 QALY) for their incontinence treatment. This is a measure of health gain.³ Gains can then be weighed against costs (e.g. \$10,000 per QALY for the incontinence treatment). In this way, standardised costs and gains can be compared across different treatments or conditions.

3 Methodology

3.1 Search strategy

The search strategy covered both academic literature (i.e. published, peer-reviewed journal articles) and grey literature (i.e. published and unpublished reports, policy documents and relevant materials obtained from a variety of sources, including websites of government departments, agencies and other organisations). Different strategies were used to search for the two types of literature.

For the academic literature, an EndNote database was established to organise articles and to manage references and citations. The research team searched multiple bibliographic databases and supplemented this with snowball searching (pursuing references of references and tracking citations forward in time) and searching by key authors in the field.

The search terms were selected after reviewing Medical Subject Headings (MeSH) from the US National Library of Medicine and using the NLM Medical Text Indexer (MTI) program. Key words were identified after hand searching references in journals such as 'Patient-Reported Outcome Measures' and reviewing two references provided by the Commission. This was essential, as some items of interest may not be indexed as subject terms in the MeSH thesauri.

A full list of search term combinations is available at Appendix 1. Key words identified included: patient-reported outcomes; patient-reported outcome measures; PROMs; patient-centred care, quality of care, healthcare quality, healthcare policy, and health outcomes benchmarking and performance measurement. The following databases were searched.

- MEDLINE
- CINAHL
- Google Scholar
- Scopus
- PsycINFO
- Centre for Reviews and Dissemination (University of York)
- Trove and Libraries Australia (to search for Australian theses), and Dissertations Abstracts (to search for overseas theses).

In addition, the following journals were hand searched (i.e. tables of contents were manually browsed for relevant articles).

- BMJ Quality and Safety
- Milbank Quarterly
- Health Services Research
- Health Affairs
- Implementation Science
- Value in Health

- Health Expectations
- Health and Quality of Life Outcomes
- Social Science and Medicine.

Cross-checking of the database and hand searches was carried out using several additional databases and websites using the terms already outlined in the academic database search as well as browsing recent material (2014 onwards). A title scan was conducted to identify relevant material and abstracts checked where more detail was required for inclusion in the review. The following databases and websites were cross-checked for additional material relevant to the review:

- New York Academy of Medicine (NYAM) grey literature database
- King's Fund Library
- National Health Service (NHS) Evidence
- Health Foundation
- Agency for Healthcare Research and Quality (AHRQ).

The grey literature search focused on the following countries: Australia and New Zealand, the United Kingdom and the Republic of Ireland, the USA and Canada, selected European countries (France, Germany, and the Netherlands) and selected Scandinavian countries (Finland, Norway, and Sweden). The websites and conference proceedings of international organisations, such as ICHOM, were also searched. Searches used the Google search engine and included national health websites, for example, the AHRQ (USA), the US National Quality Forum, the King's Fund (UK), the NHS (UK) and the Canadian Institute of Health Information. A full list of results from the grey literature search is available at Appendix 2.

3.1.1 Scope of the search

The search strategy focused on English language material relating directly to relevant national policy frameworks that promote or mandate PROMs and/or address issues relating to national collection and collation of PROMs. High-quality studies of the reported impacts of PROMs were also included when available.

Academic literature searching covered the period 2006-2016 and grey literature searching covered 2010-2016. The following were considered for inclusion:

- Existing reviews of the literature considered relevant to the implementation of PROMs at a national or state/province level;
- Empirical studies reporting the types of measures in use, rationale for use and level of uptake;
- Empirical studies reporting the use of PROMs in combination with other relevant measures capturing patient perspectives on safety and quality;
- Reviews and empirical studies presenting evidence of impacts on safety and quality;
- Reports on the uptake and use of PROMs at a national or state/province level.

The review included a wide range of both academic and grey literature. Therefore, we did not limit the evidence examined only to study designs at the highest levels of evidence (as classified by the National Health and Medical Research Council levels of evidence hierarchy) as this would lead to the exclusion of a large body of evidence relating to the use of PROMs.

Our scope excluded the substantial literature related to the use of PROMs in clinical trials or to substantiate medical product labelling claims, as the focus of this review is the use of PROMs in health service policy and practice. In addition, there many studies related to the development of particular PROMs. During initial discussions between the researchers and the Commission, it was agreed that the review could identify, where relevant, some specific PROM instruments in current use but would not provide detailed descriptions or assessments of instruments or items for measuring PROs. This is a separate task, which may be an avenue for future research.

It is important to note that this was a rapid review⁵⁰ which aimed to collect the essential information required to address the research questions with sufficient breadth to avoid bias and sufficient depth to provide insight and thus allow meaningful, reliable and useful conclusions to be drawn.

3.1.2 Academic literature: search results

The first stage of the review of the academic literature involved a scan of the electronic database search results by reading through titles and, where necessary, abstracts. During this initial scan, 707 articles identified as potentially relevant to the review were downloaded into EndNote for closer examination. Many articles were identified via more than one database, resulting in duplicate entries to EndNote, which were then checked and removed.

In hand searching, article titles were scanned for their relevance to the topic for each issue of the journal from 2014 to the present, including supplementary issues. Abstracts were scanned when a title suggested the article was relevant. Articles identified were placed in a separate folder for a second reviewer to provide feedback on their relevance and possible inclusion. Review of the full article was completed for those articles deemed relevant for inclusion. Through this process, 29 potentially relevant articles were identified, of which six were already in the EndNote database. A second staff member read the abstracts of the remaining 23 articles and identified four for inclusion. Most of the 19 excluded articles focused on validation of disease-specific or condition-specific PROMs; one was about PREMs and two related to the use of PROMs in clinical trials.

The cross-checking of the five additional databases listed above resulted in eight new articles. A second staff member read through the abstracts and identified three articles for inclusion. The remaining five were excluded because they focused on development and validation of specific instruments or clinical trials protocols.

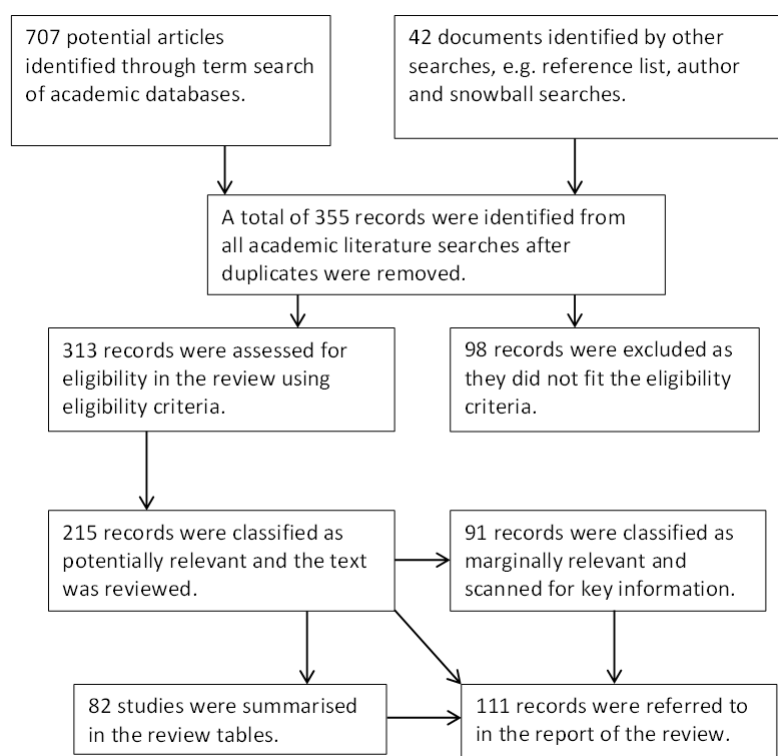
In addition to the seven articles identified in the hand searching and cross checking procedures, a further 35 were obtained through other sources such as snowballing from the reference lists of relevant articles. The total number of articles included in the EndNote database was 355.

The abstracts of all the articles in the database were read through and an initial cull took place to exclude those that were less relevant. These exclusions were checked by a second staff member. Following this review, a total of 98 articles were excluded for the following reasons:

- Studies of the psychometric testing or properties of a specific measure (67 articles)
- Evaluations of interventions which reported a variety of outcomes but without a major focus on PROs, including articles relating the use of PROMs in clinical trials or drug evaluations (31 articles).

The remaining references in the database were classified into groups based on their relevance to the research questions. During this process, a further 91 records were identified as marginal because they focused on the development of disease- and condition-specific PROMs or provided guidance on developing PROMs or measurement issues. They were scanned for relevant information (e.g. rationale for PROMs; challenges in implementing PROMs) and the specific diseases/conditions covered were noted. The remaining articles were categorised into three groups: electronic and web-based; impacts, benefits, challenges and critiques; and uses/mechanisms/systems/policy. A total of 82 key articles were summarised in the tables (Appendix 3); others were useful for background information and are referred to in the text.

Figure 1 PRISMA flow chart for academic literature searches



3.1.3 Grey literature: search results

To capture non-academic literature related to the use of PROMs in policy and practice, a grey literature search was undertaken for Australia and New Zealand, the United Kingdom and Ireland, the USA and Canada, and selected European countries.

The main search terms were ‘Use of Patient-Reported Health Outcome Measures in (country/region)’ and ‘Benchmarking of patient-reported health outcome measures in (country/region)’ entered into Google. The first ten pages of results were checked. A few websites were found to have several pages relating to particular reports and each of these were entered and counted separately.

Internet page entries were excluded if they were advertisements, profiles of particular individuals or commercial companies (unless there was a relevant academic or government affiliation); did not relate to the target country of the search; or were duplicated entries. All entries were checked and searched for a focus on PROMs; entries about organisations which did not have a major focus on PROMs were excluded. The inclusions and exclusions were independently checked by two team members. Journal articles relating to PROMs were excluded from the grey literature tables but were forwarded to team members undertaking the academic literature search and review.

In addition, two Google Advanced searches were conducted and the first ten pages of results were scanned for each search. The searches used the following terms:

1. ‘patient-reported outcome measure’ +benchmark +benchmarking (PROM OR PRO).
2. Patient-reported health outcome measure PROM OR PRO ‘patient-reported outcome measure’ filetype:pdf.

Other supplementary searches were undertaken where necessary. For example, links available on one site could lead to an additional site. Of the 91 entries identified for the Australian grey literature, 36 were derived from supplementary searches. Other searches included PROMs and quality and safety in (region) and PROMs use in clinical registries in (region). Health department websites for each major country/region were also searched using these terms.

The Australian grey literature searches were cross-referenced to the Australian environmental scan results which used slightly broader search terms. A summary of the search results by country/region is provided in Table 1. The substantial numbers of entries for the country search in the first three main regions (Australasia 108, UK and Ireland 71, USA and Canada 67 –see Table 1 below) meant that we limited searches for European/Scandinavian information to a few illustrative examples of the use of PROMs within these regions.

Table 1 Grey literature search results by country/region

Country/Region	Included in review
Australia	91
New Zealand	17
United Kingdom	63
Ireland	8
USA	50
Canada	17
Western Europe (France, Germany, Netherlands)	23
Scandinavia (Sweden, Finland, Norway, Denmark)	16
TOTAL	285

4 Findings

We have synthesised the findings of the literature review in the following sections, each of which addresses a separate research question.

- Section 4.1: Rationale for PRO collection and use
- Section 4.2: Mechanisms for PRO collection
- Section 4.3: Use of PROMs in safety and quality improvement
- Section 4.4: Evidence of impacts
- Section 4.5: Challenges of PRO collection and use, and
- Section 4.6: Implementing PROMs (including principles, resources and data collection systems)

Details of each item we reviewed are presented in tabular format. This can be found in Appendix 2 for the grey literature and Appendix 3 for the academic literature.

4.1 Rationale for PRO collection

In their recent overview of the ‘state of the art’ of PRO collection in the United States, Lavalley and colleagues declared that the healthcare environment is ‘increasingly ready for widespread adoption’ of PROs due to efforts to incorporate patient perspectives in quality improvement, electronic data collections, value-based payments and calls from consumer organisations for shared decision making.^{51 p.576} These authors presented a compelling rationale for PRO collection, describing its value to consumers, providers and the health system. They give three main reasons to collect PROs which are reflected in the work of other researchers.

1. Patients can be most accurate in describing their own symptoms, pain, function and quality of life.
2. PROMs can be used in clinical settings to support shared decision making and patient-centred care.
3. When collected systematically across providers (e.g. via clinical registries), PROMs generate valuable data on treatment effectiveness, adverse events and variations in healthcare delivery and outcomes to inform efforts to improve quality and safety.

4.1.1 Allow accurate, unbiased reporting of outcomes

Numerous authors have made the point that clinical outcomes alone cannot capture all relevant information about treatment effectiveness; there are some things only a patient can report.^{6,52,53} This is not a new idea; it is well established that patients’ perceptions of their outcomes may differ significantly from clinicians’ assessments and this has contributed to a decline in the notion that ‘the doctor knows best’.⁵⁴ The following quote in relation to cancer patients sums up this argument.

Because symptoms are best described by patients who have them, including PROs as measures of treatment effectiveness or the differences among treatments provides essential information about the efficacy and toxicity of a treatment and its effects on function.^{52 p.1077}

For example, in his description of the NHS PROMs implementation, Timmins argued that:

A surgeon might report that the blood flow from a coronary artery bypass looks great but that is not much use if the patient reports that they still get out of breath and pained on exercise.^{53 p.1464}

Patients are most knowledgeable about their arthritis symptoms⁵⁵ and can best appreciate the full benefits, risks and costs of cancer therapies.⁵⁶ Systematically collecting patient perspectives avoids the problem of observer bias.⁶ In the context of spinal surgery, McCormick and colleagues stated that clinicians' reports were 'inherently biased' and therefore may not reflect the impacts of treatment on the ultimate goals of improving function and quality of life and reducing pain.^{57 p.99} Of course, PROs can be subject to bias and error but this problem also affects so-called 'objective' measures such as blood tests, interpretation of x-rays and physical examinations.⁵⁸

When looking at outcomes for individual providers or services, PROMs can be useful because they focus on what matters most to patients. In contrast, the indicators selected by services may not always assess outcomes that are most important to patients, as providers tend to measure outcomes for the interventions and treatments they bill for rather than for the full care cycle.⁵⁹ Because they capture highly relevant information, PROs are one source of 'real-world' data (along with clinical and economic outcomes) to inform healthcare decisions about effective treatments. Garrison and colleagues describe PROs as 'the only direct voice that an individual has in the health decision-making process'.^{12 p.329}

Collecting outcomes data from patients may have additional benefits. Response rates are likely to be improved (compared with clinicians), and reporting burdens on clinicians may be reduced.^{6,55} Patient involvement in outcomes reporting may also be health-promoting; for example, by improving adherence and allowing patients to monitor changes in their own condition.^{60,6,55}

Entwistle⁶¹ from the NHS Centre for Reviews and Dissemination, University of York (UK) refers to the necessity of honesty about areas of certainty and uncertainty when communicating with the public on the effectiveness of health interventions. Many of these issues are concerned with the questioning of the scientific basis of medicine and in association with this, a questioning of the 'medical model' of health care. In our current models of care, we can no longer assume that doctor knows best; it needs to be demonstrated that the health intervention does actually produce health benefit. This means that outcome measurement and monitoring should become a routine part of quality assurance activities and be integrated within the model of health care.³

4.1.2 Support patient-centred care in routine practice

The *Australian Safety and Quality Framework for Health Care* identified consumer-centred care as the first of three dimensions required for a safe and high-quality health system in Australia.⁶² Including this dimension in the framework reflects a growing recognition of the importance of placing patients and consumers at the centre of the healthcare system.

Several authors have advocated for the use of PROMs to facilitate shared decision making and patient-centred care. For example, Bitton and colleagues suggest that PROMs can help providers develop tailored recommendations for screening and prevention and promote a more personalised health system.⁶⁰ PROs can be used to develop accurate prediction models to estimate the value of particular screening tests. In routine care for cardiovascular disease, PROMs may contribute to holistic decision making and promote better quality care.⁶³ In spinal surgery, PRO data can help clinicians categorise patients according to severity of their disorder and thus plan appropriate treatment.⁵⁷ PROMs can also be used to assist in identifying patients most likely to benefit from palliative care.⁶⁴

Sprangers and colleagues found that PROMs can assist in the identification of patients who may be susceptible to poor quality of life, which in turn can enable better targeting of specific support, such as psychological and/or pharmacological treatment.⁶⁵ Similarly, Fung and Hays note that PROMs can assist clinicians to target interventions that will improve patient outcomes.⁶⁶ In addition, these authors note the importance of administering PROMs through the continuum of care, as they can provide information about patient preferences, behaviours and baseline HRQoL at the initial visit, and can help in evaluating disease progression or regression and treatment effects at subsequent visits.

Clinicians can use PROMs to assess the efficacy of the treatments they provide. An innovative example is the use of an app called mPOWER by surgical patients to track whether their surgical sites are healing properly and to feed this information back to clinicians via securely transmitted photographs.⁵¹ The technology allows providers to ask patients questions about their symptoms and pain following discharge from hospital, helping to improve early detection of problems such as infection.

Integrating valid outcomes data collection into ongoing, routine care is a cornerstone of efforts to improve outcomes.⁶⁷ Consultations between providers and patients are usually very brief but during these short encounters information is shared that will help determine treatments and, when relevant, promote self-care. This means that innovative methods are required to share information efficiently and effectively. PROMs can allow patients to provide important details about their symptoms, concerns and goals in a structured way, and real-time access to this information can help providers prioritise topics for discussion during the clinical encounter.⁵¹ It is important to ensure that the process of data collection does not place undue burden on patients or the healthcare team.⁶⁷ One way to achieve real-time use of PROs is by including measures in electronic health records.⁶⁰ This is discussed in more detail below (Section 4.6.3).

4.1.3 Provide data to drive quality improvement

At a system level, PROMs (along with clinical indicators) provide the means to assess the 'value' of a given health intervention to patients. 'Value' is defined as outcomes achieved relative to costs.^{59,68} There is a desire by governments to allocate funds within the health system to maximise 'value' in terms of health gains for the community. To do this, administrators require health outcomes data (including PROs) to determine the relative effectiveness of health interventions.³

Internationally, in those health systems where there has been a split between purchaser and provider functions (such as the UK), there has been increasing interest in outcomes as levers to

influence purchasing choices and to justify service provision.⁶⁹ In the US, the Federal Government intends to link PROMs to reimbursement arrangements for health maintenance organisations ('accountable care organisations'), such that the level of reimbursement is related to how patients perceive the value of their treatment outcomes.⁶ The measurement of 'value' rather than 'volume' by health organisations implies the use of relevant health outcome performance indicators including PROs. It also implies consideration of bundled payment mechanisms across the continuum of care (e.g. an integrated practice unit model) rather than payment for discrete services as the drivers of quality improvement and health system reform.⁶⁸

Patient-reported information (including PROs) is an essential input to any reform of healthcare payment and incentive systems.⁷⁰ If patient perspectives are not explicitly included, there is a risk that the things that matter most to patients will be marginalised. However, if financial incentives for clinicians are linked with appropriate PROs, this will focus attention on patient-centred care and promote quality improvement.⁷⁰

PROs data is also an important input into comparative effectiveness research. The outcomes data assembled systematically by clinical registries enables the investigation of relative effectiveness of different health interventions, as well as providing insights into variations in healthcare delivery and outcomes across different providers. Gliklich and colleagues, in a report for AHRQ, noted that as clinical registries can evaluate intervention effects in a 'real world' population, they can help fill information gaps about treatment options and responses, the natural history of the disease or condition and quality of life impacts of interventions.⁷¹ They argue that because PROs provide the patient perspective on all of these effects, they are vital components of any clinical registry.

PROMs can contribute to understanding differences in health expenditure across providers or regions of a health system and to ensuring that efficiency gains are not detrimental to the quality of care. If all providers can reduce costs to 'best practice' levels, resources will be freed to use elsewhere; however, patient outcomes must also be taken into account.⁷² Higher costs may not always be a sign of inefficiency if they are linked with better health outcomes.⁷²

In Australia in 2013–14, the cost of providing an average service was almost twice as high at one major metropolitan hospital (\$6,100) compared to another (\$3,100).⁷³ Similarly, admission rates for several common hospital procedures were examined across regional clusters of services and a 1.6-fold to 7.4-fold variation was found between locations.^{74,75} There was also considerable variation between urban and rural areas and between public and private hospital sectors. This report did not explore the degree to which the variations were warranted, but it did identify the need to address the lack of systematic outcomes monitoring for common health care interventions.

Significant variations in surgical intervention rates across Australia were identified in the recently published *Australian Atlas of Healthcare Variation*.⁷⁵ For example, in some areas, people aged 55 years and over had rates of knee arthroscopy that were more than seven times those than people living elsewhere. More than 33,000 operations were performed on this age group during 2012-2013. This was despite evidence that suggests knee arthroscopy is of limited value for people with osteoarthritis and may cause harm.⁷⁵ There were 17,000 lumbar spine

surgery admissions, including for spinal fusion procedures, on average each year from 2010 to 2013 despite there being limited evidence to support lumbar spine fusion surgery for those with painful degenerative back conditions.

Version 1 of the 'Atlas' recommends that variation in the delivery of health care could be better assessed by routine, nationally consistent use of PROMs for four conditions and procedures: radical prostatectomy, lumbar spine surgery, knee pain and cataract surgery.

4.2 Mechanisms for PRO collection

This section of the review represents a snapshot of the structures and processes currently being used in Australia and elsewhere to facilitate PROMs collection. Much of this information was derived from grey literature searching – that is, from material on the websites of government bodies and other institutions and from published and unpublished reports. This was supplemented by material from the published academic literature. Approaches to PRO data collection have varied from country to country and the intended uses of PROMs also vary between and within countries. Mechanisms for data collection include large, time-limited research projects; ongoing, routine data collection from providers feeding into national clinical registries; international collaborations to establish standardised datasets; and the development of item banks for use in computerised adaptive testing.

4.2.1 International

The largest international framework for the collection of PRO information is facilitated by the International Consortium for Health Outcomes Measurement (ICHOM). The initiative was founded in 2012 by Professor Michael Porter of Harvard Business School, Stefan Larsson of the Boston Consulting Group and Martin Ingvar of the Karolinska Institutet. It is a non-profit organisation supported by the founders' institutions and it has a large number of international strategic partners including the Scottish Government and the NHS in England. ICHOM has developed 20 standardised datasets for health outcomes measurement across a range of diseases (e.g. prostate cancer, dementia) and a further ten standard datasets are under development.

ICHOM currently convenes international expert groups to assess relevant PROMs and indicators for each disease or condition and to assemble standardised sets for outcomes evaluation. These have the potential to be used for international benchmarking. ICHOM recently announced the launch of their Global Health Outcomes Benchmarking (Globe) program and has partnered with ICON, a health consultancy company, to lead the data management, data warehousing and reporting for these activities. The Globe program will create a central repository where data, collected in accordance with the ICHOM Standard Sets, are securely compiled. A pilot benchmarking study in prostate cancer is about to begin, and the initial results from the outcome benchmarking activities will be available in late 2017.

The NSW Agency for Clinical Innovation in Australia has recently become a strategic partner with ICHOM, as has the Hospital Contribution Fund (HCF) Research Foundation.⁷⁶ Several other Australian organisations have links with ICHOM including the Australian Health Outcomes Collaboration, Australian Women's and Children's Health Network, Bowel Cancer Australia, Clinical Ophthalmology and Eye Health at the University of Sydney, Coronary Angiogram

Database of South Australia (CADOSA), the Department of Veterans' Affairs, Health Outcomes Australia, Movember Australia, Optometry and Vision Science at Flinders University, Ramsay Health Care, Royal Melbourne Hospital and the Victorian Prostate Cancer Registry. Representatives from some of these organisations, and other Australians with relevant expertise, have participated in the development of the ICHOM datasets. Approximately 40 Australians attended the 2016 ICHOM conference in London.

ICHOM also positions itself as part of the drive towards value (as opposed to volume) based payments. Measurements of value using outcome indicators can inform the use of bundled payments for an entire continuum of care for a disease or a population segment (e.g. the frail elderly, people with disabilities). These are seen as the drivers of quality improvement and health system reform.⁶⁸

Some countries, including the United States, are experimenting with bundled payments⁷⁷ to facilitate integrated care across sectors. Not all such experiments have included PROMs in their assessment of quality but have relied on process indicators and routinely collected performance indicators. They are therefore seen by some as falling short of truly value-based payment principles.^{78,79}

Porter and colleagues provide some examples of what they consider to be more effective examples of bundled payments, including joint replacement and spine surgery in Sweden and some current Centers for Medicare & Medicaid Services (CMS) models.⁶⁸ These examples make use of PROMs to assess effectiveness of integration. In Sweden, a bundled payment program for hip and knee replacement in Stockholm showed that complication rates reduced by 25 percent in the first two years, functional outcomes remained constant, length of stay fell by 16 percent and costs fell by 17 percent.⁸⁰ These initiatives showed that bundled payments could reduce cost while improving or maintaining patient health outcomes and thus improve value. Most countries are currently largely using volume-based payments for health care and a widespread transformation toward bundled payment mechanisms presents a significant structural and cultural change. PROMs are likely to play a significant role in such changes.

Various international societies provide conferences, training, and guidelines on PROMs use and mechanisms for data collection such as the International Society for Quality of Life Research (ISOQOL) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

4.2.2 Australia

In Australia, the principal current uses of PROMs are in research data collections as well as in outcomes benchmarking within and between state and national jurisdictions.

4.2.2.1 Research activities

Many research projects involving PROMs have been, or are being, undertaken in Australia. PROMs have been used to evaluate the effectiveness of health interventions and have themselves been evaluated to inform data collections and future research. Such research activities have been conducted, for example, by the Australian Health Outcomes Collaboration (AHOC),³ and the Psycho-oncology Cooperative Research Group.⁸¹ They may involve Australian organisations participating in the development of international outcome datasets such as those

being developed by ICHOM. Other organisations are involved in the field testing of PROMs in research settings and in demonstration projects (e.g. NSW Agency for Clinical Innovation, Ramsay Health Care and HCF Research Foundation). The Centre for Advances in Epidemiology and Information Technology has a particular focus on the development and applications of a web-based 'real time' IT platform (DiscoverQuick) for health outcomes monitoring and assessment. Some organisations also provide advice and training about the use and implementation of PROMs (e.g. AHOC; ISOQOL Australian Special Interest Group).

Some large Australian population health surveys (e.g. Australian Longitudinal Study on Women's Health) also collect PROMs. When linked with health service utilisation data and mortality data, these can provide evidence which fills a gap in information about the impact of health services on the lives of patients in the context of the Australian healthcare system.

4.2.2.2 *Benchmarking activities*

Some disease-specific clinical quality registries in Australia benchmark the outcomes of health service provision using clinical and health outcome-related performance indicators as such benchmarking shows the comparative performance of providers and thus can be used to inform quality improvement initiatives. Few of these registries have so far included PROMs which could provide useful feedback on the patient perspective of their treatment outcomes.

Some major national condition-specific data collections incorporating PROMs include the Australian Mental Health Outcomes and Classification Network (AMHOCN), but the Network's benchmarking activities appear not to have included the full PRO data collection as yet. The Australian Health Services Research Institute (AHSRI) has a number of sub-centres which undertake benchmarking of outcome data which include PROMs. The Palliative Care Outcomes Collaboration (PCOC) includes PROMs to benchmark the outcomes of palliative care services across Australia and the electronic Persistent Pain Outcomes Collaboration (ePPOC) uses PROMs to benchmark the outcomes of specialist pain services. The Australasian Rehabilitation Outcomes Centre (AROC) is currently including a patient experience survey, and is investigating the use of a PROM to include in its benchmarking activities. AHSRI and its sub-centre, the National Casemix and Classification Centre (NCCC), have particular experience and expertise in risk stratification which is essential when benchmarking outcomes. Another AHSRI sub-centre, the Australian Health Outcomes Collaboration (AHOC), has developed an Assessment Tool for Aged Care (primary and community care) which has the potential for an outcome monitoring application across aged care services in Australia.

Australia has previously demonstrated a major interest in the health outcomes approach (including the use of PROMs) from 1992-2008. This may explain the large number of Australian organisations that have retained expertise and/or an interest in the health outcomes approach and the application of PROMs (see Appendix 2a). The more recent focus on the benefits of value-based health care,^{59,68,80} and the clear benefits that can be associated with PROM use, may have the capacity to sustain the renewed focus on the use of PROMs in health care evaluation and quality improvement in Australia.

4.2.3 *New Zealand*

Currently, there does not appear to be widespread use of PROMs in New Zealand (see Appendix 2a). For example the Health Quality and Safety Commission has noted that PROMs

are a useful area for further development.⁸² PRO data is collected by some registries such as the Patient Cancer Outcomes Registry ANZ. New Zealand rehabilitation services also participate in the benchmarking of outcomes data by the Australasian Rehabilitation Outcomes Centre (AROC). The New Zealand total joint arthroplasty (TJA) registry has been collecting post-operative PROs since its inception in 1998.⁸³

Some Clinical Priority Assessment Criteria (CPAC) tools were developed to manage waiting lists and assess priority for surgery in NZ.^{84,85} Some CPAC tools, such as one for cataract surgery, included patient-reported data (e.g. items concerning the patient's condition and its effect on their function) and could be considered to be PROMs. An initial aim of the CPAC prioritisation scheme was to examine the health outcomes of patients that did and did not receive surgery. However, Black noted that using pre-intervention measures to determine eligibility for care is not a valid use of PROMs.⁶ More recently Chen developed the Otago Condition Specific Questionnaire (OCSQ) (a set of measures tailored for surgery).⁸⁵ The OCSQ was used to assess the PROs in a large cohort of patients over a three-year period following elective general surgery. The OCSQ was shown to be valuable in monitoring treatment efficacy, in identifying patients with suboptimal quality of life outcomes, and in facilitating the comparison of PROs between different conditions and treatments.

There is a mental health data collection system known as the Programme for the Integration of Mental Health Data (PRIMHD), similar to and allied with AMHOCN, that collects outcome related indicators and standardised clinical assessments (e.g. HoNOS) and a self-report tool also appears to be collected by mental health services.⁸⁶ The Ministry of Health has mandated an Alcohol and Drug Outcome Measure for collection and reporting to PRIMHD from 1 July 2015 for all community-based outpatient adult addiction services. This instrument includes changes in use of alcohol and other drugs, lifestyle and wellbeing and satisfaction with treatment progress and recovery.

Te Pou, an organisation supporting mental health workforce development in New Zealand, also collaborates with AMHOCN in convening the Australasian Mental Health Outcomes and Information Conference. This conference is held every two years, alternating between New Zealand and Australia. It has a focus on outcome-related performance indicators, standardised clinical assessments (e.g. HoNOS) and condition-specific PROMs.

There has been some development of some culturally specific outcome measures for Māori^{87,88} and similar initiatives are reported on the Te Pou website. New Zealand provides an example for other countries with Indigenous populations in this regard.

4.2.4 United Kingdom

The major activities that relate to the use of PROMs in the UK are research activities and data collections from key research groups and more substantive outcome data collections for benchmarking as part of the mandated PROMs initiative in NHS England (Appendix 2b).

4.2.4.1 Research activities

Numerous academic groups in the UK and Ireland are using PROMs in clinical effectiveness research and in quality improvement (QI) applications (Appendix 2b provides examples of these

key groups). These organisations include the Health Foundation, the Institute of Applied Research, the King's Fund, the Health Service Research Unit and the Department of Public Health at the University of Oxford, the London School of Hygiene and Tropical Medicine, the Office of Health Economics, Quality and Outcomes of Patient-Centred Care Research Unit, and the Sheffield University School of Health and Related Research and their Health Economic and Decision Science Unit.

Apart from undertaking clinical effectiveness research more broadly many of these organisations are providing research support to the NHS PROMs initiative (see below). This may include undertaking pilot projects related to potential areas of expansion for the PROMs program, providing advice about the selection of PROMs, developing measures (e.g. for long-term conditions) and undertaking analyses of the PRO datasets.

4.2.4.2 *Benchmarking activities*

A major private sector healthcare provider, Bupa Hospitals (now Spire Healthcare), started collecting PRO data in the UK in 1998, following a malpractice case. By 2010 the organisation had collected PROs for more than 100,000 patient episodes of care.⁸⁹ Initially, data collection covered a wide range of procedures, but focus narrowed to one or two sentinel procedures for each specialty. Measurement of PROs employed both generic measures, such as the SF-36, and condition-specific questionnaires (such as the Vision Function-14 for cataract surgery and the Oxford hip and knee scores for joint replacement procedures).

At first, the primary driver for this initiative was to identify clinical 'bad apples' but over time it was considered that the collection of PROs offered the potential for continuous quality improvement and to provide feedback to health professionals and patients.^{89,90} One of the main benefits of the PRO data collection included the identification and sharing of best practices. This prompted a number of quality improvement practice changes such as changes to clinical pathways, enhancing communication with patients about their procedure and a greater focus on post-operative pain relief following hysterectomy. With the PROMs results (at hospital level) posted on their websites, Bupa Hospitals were able to promote and market the health-related quality of life benefits of the interventions they provided to the community.⁸⁹

Since 2009 it has been mandatory for NHS providers in England to collect outcomes data using PROMs in four areas of elective surgery: hip and knee replacement, groin hernia repair, and varicose vein surgery.^{3,6} Patients are administered PROMs questionnaires before and after their procedure. The preoperative questionnaire includes data on the patient's socio-demographic characteristics, the duration of their condition, their general health, any comorbidities, and whether they are undergoing a repeat/revision procedure. In addition, they are asked to complete a disease-specific PROM (Oxford Hip Score, Oxford Knee Score, or Aberdeen Varicose Vein Score) and a generic PROM (EQ-5D index and EQ-Visual Analogue Scale). A similar post-operative questionnaire is mailed to participants at a relevant time (three or six months) following their surgery which includes a patient-rated improvement item.

The PRO data are linked to Hospital Episode Statistics and a regular analysis of each provider's preoperative patient characteristics (age, sex, severity) and the mean change in the PROM scores adjusted for case mix is reported. Providers are identified and compared by means of funnel plots that show whether or not any provider's outcome is significantly different from

what would be expected. The overall results to date indicate positive outcomes for patients for these surgeries on both generic (EQ-5D) and disease-specific measures but the changes are more pronounced for major surgeries (hip and knee) than minor surgeries (e.g. groin hernia repair). Health gain, as measured by the EQ-5D, was substantial for the major surgeries.^{91,92,93}

This outcome benchmarking data can be used to identify ways to address practice variations.⁶ Examples of this are provided on the Health and Social Care Information Centre website with a supporting report.⁹⁴ Given that the costs of such data collections are quite substantial (estimated at GBP 825K annually), NHS England conducted a consultation survey in early 2016 concerning the use and benefits of PROMs collection in the UK and its findings will be of wide interest.⁹⁵ In the interim, a number of key orthopaedic groups and the National Joint Registry have placed their joint response on the web (see Appendix 2b). This response strongly endorses the PROMs program and it highlights the value that PROMs can provide in both comparative data to support quality improvement and for research purposes regarding outcomes.

At this stage NHS England holds one of the most substantial and important PROMs outcome benchmarking collections in the world. Routine use of PROMs in the health system is established in only a few other parts of the world such as Sweden and in parts of the US and with respect to mental health services in Australia. The NHS has developed expertise in dealing with PROMs 'big data' for outcome benchmarking purposes and this has not been without its measurement challenges. There are issues around response bias, recruitment bias and the most appropriate measure for provider comparisons to consider.^{6,96} Expertise in casemix classification methods appears essential as there have been some adjustments to this during the course of the initiative.⁹² There are also issues in how best to present outcomes data to patients, clinicians and provider groups.

Other procedures may be added to the NHS list in the future, and there have been some pilot projects into the possibility of measuring PROs in cancer, long-term or chronic conditions in primary care, dementia, and in cardio-vascularisation surgery (elective) (Appendix 2b).^{6,97} There are also opportunities to expand the use of PROMs within national clinical audits as most of the 50 established national clinical audits in the UK rely almost exclusively on clinician reports⁶ or on agreed sets of health outcome-related performance indicators (Health Episodes Statistics collection) rather than PROMs.

ICHOM (UK) has reported on a value-based health care project that has commenced in the UK.⁹⁸ The NHS Bedfordshire Clinical Commissioning Group (BCCG) is the public health care payer for Bedfordshire in England. In April 2014, BCCG launched a five-year contract for musculoskeletal care with Circle Partnership — a provider network — built on a capitation-based funding formula incorporating financial incentives for delivering improved patient and clinical outcomes. ICHOM claims this is the first payment model in England that pays for the results that matters most to patients (as measured using PROMs). However, this is a case study about the development of the project and no results were reported.

4.2.5 Ireland

Some Irish registries, such as the Irish Prostate Cancer Outcomes Registry and the Irish National Orthopaedic Register, include PROMs in their data collections. For example the Irish Prostate Cancer Outcomes Registry data collection uses a dataset recommended by the ICHOM Prostate

Cancer Working Group to allow for international benchmarking. PROMs are measured between diagnosis and treatment (baseline) and on an annual basis thereafter, providing information on these outcomes across the entire patient journey. The questionnaires measure key PROMs including physical wellbeing (e.g. functional status), HRQoL and utility in to document patients' perspectives and to facilitate future evaluation of the cost-effectiveness of therapies.

The Royal College of Surgeons Ireland is involved in a project to assess the psychometrics of a range of PRO measures (see Appendix 2b) which is relevant to the selection of measures for PROs collection. Some Irish researchers are particularly interested in the effectiveness of using PROMs as quality improvement tools, for example the Patient-Reported Outcomes: Feedback Interpretation and Learning Experiment (PROFILE) Trial.^{99,100} This trial tested whether providing benchmarked PROMs feedback to surgeons improved outcomes for patients undergoing hip replacement surgery. This involved collecting data from up to 1,500 hip replacement patients across 16 hospitals in Ireland (Oxford Hip Score, EQ-5D). No significant difference in patient outcomes was reported but it has been questioned whether this was an appropriate endpoint for this intervention³.

4.2.1 USA

In the United States, the major activities that relate to the use of PROMs are research activities, some of which also support clinical practice improvements, data collections for benchmarking purposes, and data collections to support performance-based payment initiatives.

4.2.1.1 Research activities

The Patient-Centered Outcomes Research Institute (PCORI), which is an independent non-profit, nongovernmental organisation located in Washington, D.C., was authorised by Congress in 2010. It uses government funds to support clinical effectiveness research with a particular focus on patient-centred outcomes research. PCORI is establishing a research network called PCORnet which is used to facilitate large-scale observational studies and clinical trials.

A study by Wu and colleagues was funded by PCORI to examine advances in the use of PROMs in electronic health records (EHR).¹⁰¹ The research provided 11 case studies from the US which can be found in Appendix 2c. One advantage of linking PROMs into the EHR is that data collected for one purpose can potentially be used for multiple different tasks, including clinical care, quality assessment and improvement, research and public reporting. Wu and colleagues noted that some organisations were more adept at making broader use of PROMs in the EHR for clinical, research and quality improvement purposes. Four recommendations for the effective integration and use of PROs in EHRs emerging from this research were the need to:

- customise EHR systems for context-appropriate use of PROs;
- balance research and practice goals;
- demonstrate value to patients, clinicians and institutions; and
- recognise the limitations of integrating PROs into EHRs.

There is widespread interest in using PROMs to evaluate healthcare quality in the US. The National Institutes of Health is part of US Department of Health and Human Services and is a

national medical research agency. Resources on the site provided links to over 200 articles, mainly academic, concerned with the use of PROMs in healthcare evaluation since 2012.

The Food and Drug Administration is mainly concerned with the use of PROMs in pharmaceutical economic evaluation but has produced the current operational definition of PROs² and provides guidance and recommendation concerning the use of PROMs which have broader applicability. A search of this site identified over 8,000 entries relevant to PROMs.

A major PROMs initiative to emerge from the US in recent years has been the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS), which was originally designed for research but has been expanded for use in clinical practice. PROMIS was established in 2004 as a collaboration of six primary research sites and a statistical coordinating centre. Its aim is to provide infrastructure that supports clinical research, specifically an item bank to measure patient-reported symptoms relevant to various common chronic conditions. Such a tool can help standardise research across different areas of PROs and also help clinicians in assessing treatment efficacy and adapting treatment accordingly.¹⁰²

The conceptual framework for PROMIS is based around the World Health Organisation's physical, mental and social framework. There were five initial sub-domains for developing the item bank: physical functioning, fatigue, pain, emotional distress, and social role participation.¹⁰² The measures have been constructed using modern test theory (e.g. item response theory) as well as classical psychometric techniques.

Patients may interact dynamically with the PROMIS item banks via a computerised adaptive testing system which uses item response theory to create tests that are tailored to their own health status but still psychometrically valid and reliable. Static versions (e.g. paper and pencil) are also available. It is anticipated that via PROMIS PRO assessment will be used regularly in clinical practice.⁵⁸ Such PROMs can be used to evaluate the outcomes of treatment, to monitor patients during their trajectory of recovery (quality improvement applications) and also have potential applications to the assessment of population health.

Recent consumer initiatives include the social media based 'PatientsLikeMe' website⁵¹ and the Dartmouth College 'How'sYourHealth' website. The latter website uses patient-reported assessment information (e.g. about function, health and lifestyle factors) to develop a health plan that the person can take to their GP. The measures are similar to PROMs but the application here is for initial assessment. Repeated measures over time could reflect on changes in health status. However, the application is not specifically related to a particular health intervention.

4.2.1.2 Benchmarking activities

Policy and legislative levers for expansion of PRO collection in the United States include the US *Health Information Technology for Economic and Clinical Health Act 2009*⁵¹ which promotes adoption of electronic health records. In addition, PRO data will be incorporated into the Medicare Merit-Based Incentive Payment System and other payment models. Pilot programs being rolled out for joint replacement and oncology include collection of PROs as input into payment models.⁵¹

A major initiative from the Centers for Medicare and Medicaid Services (CMS) is the Bundled Payments for Care Improvement Initiative. This is comprised of four broadly defined models of care, which link payments for the multiple services that beneficiaries receive during an episode of care. Under the initiative, organisations enter into payment arrangements that include financial and performance accountability (meeting quality thresholds/scores) for episodes of care. PROMs are employed as part of the assessments of quality, and the goal of the scheme is for higher quality and more coordinated care at a lower cost to Medicare. Although the evaluation of these initiatives is at an early stage, they reflect an increasing interest in value-based and integrated health care in the US.

One of the CMS bundled payment initiatives, the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) Initiative, uses validated PROMs as the basis for a total joint replacement episode management system.¹⁰³ This program is used to improve quality and report quality metrics. It has been in operation for four years and involves 250 surgeons and 25,000 patients.

The FORCE-TJR¹⁰⁴ team have designed a prototype system of real-time scored patient-reported assessments of pain and function and have piloted it in surgeons' offices. These scores, as well as trend and benchmark data, are available during discussions between patients and surgeons to support collaborative decision making about whether to have TJR surgery. Such timely and detailed information enables optimally individualised treatment. FORCE-TJR has recently received a large grant from PCORI to expand the application to a web-based system intervention that will provide individualised patient osteoarthritis care plans to patients and clinicians.

The National Quality Forum (NQF) has produced a report on PROs in performance management.¹⁰⁵ The report differentiates between a PRO (e.g. a patient reporting depression), a PROM which is a standardised measure of this (e.g. PHQ-9) and a PRO-PM (e.g. percent of patients with diagnosis of major depression or dysthymia and an initial PHQ-9 score > 9 with a follow-up score of < 5 at 6 months). The PRO-PM is a measure of the effectiveness of the care received for the treatment of depression. The proposal is that the NQF can endorse such PRO-PMs (but not PROMs themselves) using a range of stringent criteria. An endorsed PRO-PM is one that meets these NQF standards and can be used as a measure of quality improvement, for benchmarking and accountability purposes. However, it is noted that of the 674 NQF-endorsed measures, 208 are outcome-related and only 128 involve patient reporting.

The Agency for Healthcare Research and Quality (AHRQ) has a National Quality Measures Clearing House. This is a public resource for summaries of evidence-based quality measures and measure sets and also hosts the Health and Human Services Measures Inventory. The measures cover the domains of access, outcome, patient experience, process and structure. The outcome measures are largely health outcome-related performance indicators although there are some PROMs style indicators that relate to functional status before and after treatment. Gliklich and colleagues have produced a report for AHRQ concerning the incorporation of PROMs into registry data collections to facilitate outcomes benchmarking.⁷¹

There is a large body of work in the US concerned with the benchmarking of PRO data¹⁰⁶ and/or value-based health care which includes the benchmarking of outcomes data – usually

incorporating PROMs.^{78,79,107,108,109} The focus on value across all of this work is important because it contributes to a strong financial case for the use of PROMs (alongside the quality case) and is therefore likely to attract international interest.

4.2.2 Canada

Although there is an increasing use of PROMs in clinical registries and in research in Canada, their application still appears to be at a relatively early stage.

4.2.2.1 Research activities

There appears to be increasing interest in the use of PROMs for quality improvement. In 2011 the journal *HealthCare Papers* published an invited essay presenting a case for routine measurement of PROs in the Canadian health system¹¹⁰ along with commentaries.^{111,112,113} The journal's editor linked this interest in PROMs with political pressures and rhetoric around the increasing proportion of the Canadian budget consumed by health care and the need for reforms to lead to better value without compromising quality.¹¹⁴ The primary justification for use of PROMs was the high rate of patients with chronic health conditions using Canadian health care, the unsustainable rates of expenditure related to such patients, and the consequent need to know which interventions are most cost-effective for this group.¹¹⁰

This argument was supported by the earlier Regional Evaluation of Surgical Indications and Outcomes Project from British Columbia, which used generic (SF-36), disease- and condition-specific PROMs before and after surgery for a number of elective procedures. This study found wide variation in practice patterns and rates of intervention; including cases where surgery was difficult to justify (e.g. 31 percent of patients who had cataract operations had a pre-surgery visual function score of at least 91/100). The NHS England PROMs collection was also discussed. The *HealthCare Papers* essay authors made three recommendations: begin collection of PROMs for elective surgery; develop and implement PROMs for management of chronic conditions; and convene a Pan-Canadian working group to facilitate these actions.¹¹⁰

In one of the commentaries on the essay, the authors drew on their experiences in implementing PROMs through Cancer Care Ontario, which routinely collects symptom and psychological distress data in 13 regional cancer programs in Ontario.¹¹³ This collection is a performance expectation in the province and by 2010 data had been provided by more than 85,000 patients. The authors stated that there was 'evidence to support the value of these data in the clinical encounter between patients and clinicians.'^{113 p.43} Efforts are also underway nationally to facilitate collection of a similar core PRO dataset for cancer.

The Cancer Care Ontario work identified three key factors for successful implementation of PROMs: combining top-down leadership with bottom-up consultation with clinicians; access to technology to ensure direct data entry and interpretability of data; local coordination and change management efforts. Several implementation issues still need to be addressed: ideal frequency of PROMs collection; how to incorporate generic and disease-specific PROMs at the point of care; and how to collect PRO data routinely across multiple phases of illness and treatment including survivorship.

The question of how to integrate measurement across sectors within the health system remains unresolved, but the implementation of Health Outcomes for Better Information and

Care (HOBIC), an initiative to incorporate patient nursing care outcomes into electronic health records, might provide some insights into how this could be approached.¹¹³ A national version of HOBIC, called C-HOBIC, has recently been implemented. The purpose is to enable patient outcomes data collection across acute care, complex continuing care, long-term care and home care by using a systematic, structured language in assessments at admission and discharge (see C-HOBIC website in Appendix 2).

A Canadian PRO group has been formed with the goal of identifying priority issues for PRO application in clinical practice, research, population monitoring, measurement and methods, infrastructure needs, and resources required to develop and sustain a national Canadian PRO initiative and coordinate with similar international efforts.¹¹⁵ A set of pre-conference readings for the Canada PRO Initiative conference included the invited essay discussed above.¹¹⁰ Other topics included: PROMs transforming healthcare; PROMs in randomised trials; implementing PROMs in clinical practice; and the Patient-Reported Outcomes Measurement Information System (PROMIS). Papers from the meeting were published as a special issue of the *Journal of Clinical Epidemiology*. Some participants instigated a special interest group within ISOQOL and there were also links formed with a Canadian PROMIS group.

4.2.2.2 *Benchmarking activities*

The O'Brien Institute for Public Health outlined the role of the Canadian Institute for Health Information (CIHI) in reporting and benchmarking outcome data (largely clinical and health outcome-related performance indicators) and the *Canadian Patient Experience Reporting System*.¹¹⁷ In 2013-2014, CIHI conducted an environmental scan of PROMs, including a literature review and interviews with Canadian, UK, and US stakeholders. Leading examples of PROMs use in Canada were provided:

- Alberta Hip and Knee Registry
- Alberta Hip and Lung Transplant collection
- British Columbia PEAK project - knee arthroplasty
- British Columbia Spinal Cord Injury Registry
- Manitoba-Winnipeg Joint Replacement Group; Saskatchewan joint replacement and spinal surgery
- Statistics Canada Community Health Survey
- Ontario Electronic Rheumatology collection; and
- Ontario Initiatives Research Program (Toronto).

These initiatives make use of a variety of generic measures (EQ-5D, HUI, SF-36, SF-12, RAND) and disease-specific measures (e.g. WOMAC, Oxford Hip and Knee Scores).

The British Columbia Patient Safety and Quality Council provided an overview of outcome measurement and routine use of PROMs, which included the Regional Evaluation of Surgical Indications and Outcomes Project, a benchmarking project undertaken in Vancouver in the 1990s.¹¹⁶ Another use of PROMs in British Columbia is to assess Integrated Primary and Community Care (IPCC) using a range of generic tools (e.g. EQ-5D, SF-36, PROMIS GH).¹¹⁸

Challenges in PROMs use in this context included: diverse populations and validation; patient burden; measurement issues and use of PROMs in clinical practice and decision making. The authors suggested there are benefits in using PROMs and PREMs (e.g. Canadian Hospital Consumer Assessment of Healthcare Providers and Systems) together.¹¹⁸

In contrast, some Canadian organisations have been more cautious about the use of PROMs. Health Quality Ontario¹¹⁹ collects a range of healthcare quality and safety indicators (structure, process and outcome indicators). However, in a 2014 statement about the organisation's approach to assessing quality, there appears to be some ambivalence concerning the inclusion of PROMs indicators as per the NHS PROMs program. Health Quality Ontario acknowledge that PROMs have matured and are thought by some to be the most powerful levers for performance improvement, but point out that many different factors influence outcomes, including factors that are beyond the control of the healthcare provider, and in some cases it may therefore be more appropriate to focus on process indicators rather than outcome indicators.

Santana and colleagues conducted an environmental scan of the types of patient-reported measures collected and how they are applied across the province of Alberta.¹²⁰ Findings were that a wide array of measures was used – 15 different types of PROMs – in a diverse set of patient populations. Different generic and disease-specific measures were used, making outcome benchmarking of PROMs across institutions and regions difficult. In addition, there was no standardised approach to linking PROMs and PREMs with electronic health records.

4.2.3 Europe – France, Germany, Netherlands

In Europe the Netherlands appears to be leading the way in the inclusion of PROMs in national registry collections. The development of clinical registries began in 2009¹²¹; and they are clinician-led and payer-funded (including Ministry of Health and industry groups). There are now 19 clinical registries collecting outcomes data. The Dutch Institute for Clinical Reporting (DICA) is funded by the Dutch Association of Insurance Companies and sits as a neutral enabler between payers, providers and clinicians to facilitate development of and collaboration on the collection, analysis and benchmarking of outcomes data.

Until recently, this registry-based data collection has largely been concerned with clinical and health outcomes related performance indicators although 'value' benefits have already been derived from this (e.g. a reduction in complication rates and reduced cost). Recently DICA has moved towards outcome-linked payments, partnering with ICHOM and intends to adopt ICHOM outcome measurement sets, which include PROMs, into these registries. Once a registry is fully operational, the costs of outcome measurement are embedded in Diagnosis-Related Group payments from payers, which are fixed, prospective payments for the care of patients based on diagnosis. If providers fail to measure these outcomes adequately, they risk losing reimbursement for the collection of this data. This is not the first time the country has used value-based payments; in 2007 a successful bundled payment model for Type 2 Diabetes and later for Chronic Obstructive Pulmonary Disease were developed.⁷⁹

Some examples of registries including PRO data are the National Quality Registry for Parkinson's disease¹²² and the registries concerned with low back pain and prostate cancer are using ICHOM standard sets for outcome measurement which include PROMs.

The Netherlands Institute for Health Services Research (NIVEL) is the national institute for health services research in the Netherlands. Its domain is applied and applicable multidisciplinary health services research with a view to advising health policy. It is conducting a number of research projects related to PROMs, and is convening a European conference on patient participation in health care research and innovation. The EMGO Institute of Health and Care Research has supported the development of Consensus-based Standards for the selection of Health Measurement Instruments (COSMIN).¹²³

In Germany, the Martini Klinik has become the largest prostate clinic in the world with over 2,000 operations per year. It has a focus not only on survival data but symptoms (incontinence and sexual function) and HRQoL following surgery.¹²⁴ Following the initial recovery period, a follow-up occurs annually. The Klinik demonstrates superior performance on a range of indicators compared with prostate cancer treatment in Germany overall. It is perceived as a leading example of using analysis of health outcome and PRO data to improve practice.⁶⁸

An integrated care bundled payment system has been adopted by the West German Headache Centre.¹²⁵ The Centre demonstrates better migraine outcomes in terms of the reduction of (patient-reported) missed work days and in terms of the costs associated with treatment when compared other providers in Germany.

In France, the Mapi Research Trust is a non-profit organisation facilitating access to information about patient-centred outcomes, promoting the use of scientific approaches in this field and encouraging exchanges between academics, pharmaceutical companies and international organisations around the world (e.g. ISOQOL, ISPOR, IQOLA, Cochrane Collaboration and ERIQA). Mapi hosts databases including one specifically for PROM instruments and others more concerned with clinical trials and pharmaceutical evaluation. It has a major interest in the translation and adaptation of instruments to enable cross-cultural research. It also provides a newsletter and webinars concerning particular instruments and PRO measurement issues. It has links with AHOC in Australia and Mapi representatives have participated in a number of the Australian Health Outcomes Conferences. The Mapi Research Trust Patient Reported Outcomes Quality of Life Instrument Database (PROQOLID) is an important resource for obtaining information about PROMs. It has a public domain which provides summary information and a subscriber domain with more extensive information to assist in the selection of PROMs and related measures for research and practice studies.

The European Observatory of the World Health Organisation reports on health indicators for Europe.¹²⁶ Most indicators concern survival data and health outcome-related performance indicators; the use of PROMs is only briefly mentioned. The report¹²⁶ mentions that PRO data collection is more common in the UK and the Netherlands than in other countries.

The World Health Organisation was also involved in the development of the WHOQOL-BREF.¹²⁷ This instrument is a leading generic PROM. The WHOQOL-100 quality of life assessment was developed by the WHOQOL Group with 15 international field centres, simultaneously, in an attempt to develop a quality of life assessment that would be applicable across cultures. The WHOQOL-BREF is a 26 item shorter version. It has been used internationally mainly in population health research.

4.2.4 Scandinavia – Sweden, Finland, Norway, Denmark

In Sweden, the use of PROMs is linked with national disease-specific quality registries which were established in the mid-1970s with PROMs included from 2000 onwards.⁶ Sweden arguably leads the world in the provision of comprehensive quality registries. There are more than 100 registries, benchmarking treatment costs and outcomes for a broad range of diseases and conditions, including dementia and mental health conditions (see Swedish Quality Registry website, Appendix 2d). In 2012-13, a little over 40 percent of the 103 registries included a generic or disease-specific PROM in their collection.¹²⁸ Uptake of PROMs has been rapid in the intervening years; approximately 90 percent of the registries now include PROMs and approximately 50 percent include a generic measure such as the EQ-5D or the SF-36.⁴¹ Swedish registries are certified according to the quality and comprehensiveness of their data. For registries to be certified at Level 2 (of 3 levels with 1 being the highest rating) they must incorporate PROMs.⁴¹ This might help to explain the recent uptake of PROMs by these registries.

A leading registry is the Swedish Rheumatology Quality Registry which has developed a clinical decision support tool (a dashboard) that aims to allow the patient and the provider to work together to optimise health according to what matters to the patient. The structured data from each visit are immediately exported to the national registry, thereby facilitating collaboration and leveraging the use of the data for improving patient population health. Appendix 2d provides a number of examples of Swedish Quality Registries, and a recent book has been published on the subject.¹²⁹

Several value-based bundled payment schemes are in use in Sweden. As previously noted, the bundled payment program for hip and knee replacement in Stockholm (Ortho Choice commenced in 2009) resulted in substantial reductions in complication rates, length of stay and costs, while functional outcomes remained constant.⁸⁰ Currently there are eight bundled payment initiatives being tested in Sweden: osteoarthritis, spine surgery, obstetrics, obesity - bariatric surgery, stroke, diabetes, osteoporosis and breast cancer.¹³⁰ SVEUS is the national platform for collaboration between key stakeholders to develop value-based monitoring and reimbursement systems.¹³⁰

The Swedish Association of Local Authorities and Regions/Swedish National Board of Health and Welfare also produced the report *Quality and Efficiency in Swedish Health Care Regional Comparisons*.¹³¹ This is a report largely based on indicators of survival, processes of care (e.g. wait times), and health outcome-related indicators (e.g. complications, readmission rates) across regions in Sweden. There is PROs information for some conditions and diseases (e.g. musculoskeletal conditions, joint replacement and urinary incontinence). For stroke, some patient-reported data were collected concerning functional skills (e.g. activities of daily living), whether rehabilitation needs had been addressed and patient satisfaction. The data in this report have not been casemix adjusted, but it provides an example of the inclusion of PROs data in national quality and efficiency reporting.

The Norwegian Institute of Public Health reports on health registries in Norway.¹³² It provides a brief overview of population-based health registries in Norway and Nordic countries (including Denmark). It uses the example of the medical birth registry of Norway which includes data on

risk factors, health, and health outcomes (births, mother, and father) that can be linked to other registries. Research applications included the consequences of preterm birth and the recurrence of preeclampsia across generations. Apart from population registries, there were 19 national medical quality registries and there was a major drive to improve data quality and data relevance in these registries. Some registries included PRO data. The Centre for Rehabilitation in Rheumatology appears to collect PRO data and Norway is collaborating with ICHOM on the collection of data for the low back pain standard outcome measurement set.

In 2000 Finland's National Institute for Health and Welfare began tracking health outcomes and costs data for eight major health problems (acute myocardial infarction, stroke, hip fracture, angioplasty, bypass surgery, preterm birth, hip and knee replacements).¹³³ Large risk adjusted variations in both costs and outcomes were identified and it was also found that higher costs did not necessarily achieve better outcomes. The Perfect Project and the Finnish Intensive Care Program provide local examples of outcome benchmarking activities which can be used to improve practice. To date the data are largely concerned with clinical and health outcome related performance indicators.

In Finland the health system faces the challenges of escalating costs, eroding access, an ageing population and expanding inequalities.¹³³ Some reforms have recently been introduced to streamline a fragmented health system (known as the SOTE reforms) but none of these has directly addressed the issue of health care value (i.e. producing better outcomes at reduced cost). It has been recognised in Finland that an increased focus on 'value' is required, which implies the routine collection and monitoring of health outcomes indicators (including PROMs), as well as integration of clinical practice around the full cycle of care (e.g. bundled payments).^{133,134}

A European Observatory WHO report also notes that there is no systematic use of PROMs in the Danish health system although they feature in some clinical databases as well as in scientific studies.¹²⁶ However, WestChronic is a generic integrated PRO system largely used to support clinical decision making; and a Danish registry collection is using the ICHOM low back pain standard outcome measurement set.¹³⁵

It is clear that the use of PROMs to assess and benchmark patient outcomes is far more widespread in Sweden than in other Scandinavian countries. Sweden could also be considered a world leader in the development of comprehensive National Quality Registries, many of which now include PROMs. It is also a leading country in testing value-based health care applications through the use of bundled payment mechanisms.

4.3 Use of PROMs in safety and quality improvement

There are three levels of application for PROMs to support quality and safety improvement in health care: clinician-patient interactions (micro level); descriptive and analytical studies such as comparisons of treatment effectiveness or understanding variations among providers (meso level); and population surveillance and policy (macro level).¹³⁶ This grouping is based on the three 'arenas of application' of cancer outcomes research, first outlined in a monograph which emphasised the importance of collecting PROs in cancer.¹³⁶

- **Micro level:** PROMs are used to understand, evaluate and enhance interactions between patients and providers, including the decisions made about treatment. These uses require individual-level data collected in real time from patients and delivered to clinicians in a timely way for use during the consultation. PRO data aggregated across groups of patients (e.g. within registries at the meso level) may also be used to inform decision-making.
- **Meso level:** PROMs are used to understand the factors that influence outcomes. Uses at this level include comparative effectiveness research, studies examining patterns of care variation or service utilisation, RCTs of intervention efficacy, and clinical modelling, evaluation and priority-setting analyses to aid clinical decision making. Uses of outcomes data at this level interact with those at other levels. For example, studies at the meso level may illuminate links between processes and outcomes and thus inform clinical practice; or they may test hypotheses suggested by macro-level analyses and thus guide policy making.
- **Macro level:** PROMs are used to help decision makers establish and evaluate policies designed to benefit whole populations. This includes population surveillance of trends in outcomes; identifying factors associated with ‘value’ in health care to inform payment models; and informing quality improvement activities at a system level, such as standards setting, adherence to clinical guidelines and performance measurement across health care organisations.¹³⁶

Currently PROMs are most commonly used at the meso level, with greater focus on other levels increasing in recent years. However, one source of data – such as PROMs collected by a clinical quality registry – can have uses at multiple levels (e.g. see case studies¹⁴ of how the Swedish Rheumatology Quality Registry is used for both shared care and quality improvement).

4.3.1 Micro level

As described above (Section 4.1.2), PROMs can be used to inform clinical decision-making and thus help provide patient-centred care. Use of computerised testing means PROMs scores can be available immediately for use in the clinical consultation. When using PROMs to monitor treatment effectiveness, clinicians need to be realistic about what change in scores to expect as this can take time, depending on the diagnosis and type of treatment.⁵⁸ There is also a risk (common to any system that requires real-time documentation) that providers become fixated on their computer screens, serving the needs of electronic health record keeping rather than observing their patients and responding to their signals.⁷⁰

PRO data can be useful in several phases of the management of individual patients: during the initial history-taking and physical examination, complementing any laboratory tests or imaging; during the treatment; and at follow-up.¹³⁷ Selecting an appropriate PROM can be seen as analogous to choosing a laboratory or imaging procedure; the clinician needs to understand what the test can do and whether it is appropriate in a given situation.¹³⁷

Donaldson described in detail the processes involved in using PROMs in routine oncology practice.¹³⁸ Assessment requires staff time to distribute and patient cooperation to complete the questionnaire, which then needs to be scored and formatted into a useable form ready for decision making. Actions in response to PROMs might include referrals, rehabilitation or provision of self-care information. Treatment plans may be changed. This may alter the

clinician's work flow and efficiency and have other consequences for patient care that should be monitored. Periodic reassessment will also be required.

Rather than adding all these tasks into existing practice, Donaldson proposed a radical reorganisation of care around PROMs. PROs could be the centre of interactions between patients and clinicians with prospective, real-time collection and use. Whereas now care is organised around 'visits', it could be reorganised around a continuous flow of information that enables patients to access help when needed. This in turn would feed into informed, shared decision making. Using PROs in this way would represent a 'disruptive innovation' rather than incremental change in routine practice.¹³⁸

A taxonomy of six different applications of PROs divides uses along two dimensions: level of aggregation (individual or group) and whether the tool or data are used during direct clinician-patient interactions.¹³⁹ At the individual (non-aggregated) level, PRO data can serve in screening, monitoring and promoting patient-centred care. Information collected during a consultation may also be used to facilitate communication within a multidisciplinary team which may discuss the patient's care in his/her absence.

At the group (aggregated) level, PRO data can be incorporated into decision aids to inform patients about, for example, the likely consequences of a treatment for their quality of life or functioning.¹³⁹ Away from the clinician-patient interface, aggregated PRO data is useful for evaluating the effectiveness of routine care, comparing providers and assessing the appropriateness of different treatments. Greenhalgh offered a number of suggestions for facilitating the use of PRO data in clinical decision making, including:

- Fostering local ownership in the implementation of PROMs
- Feeding back information on multiple occasions
- Feeding PRO data back to clinicians other than the medical profession
- Providing management guidelines and/or training in the use of PROMs and interpretation of PRO data.¹³⁹

Successful implementation would rely on a whole-of-system approach:

For PROs to be successfully adopted by clinicians, they need to fit into the existing ways in which care is organised and could be used as means of reorganising that care to better meet the needs of patients.^{139 p.120}

4.3.2 Meso level

The most common uses of PROMs currently are at the meso level. Aggregated PRO data are used to assess the performance of providers, promote informed patient choice of provider, or to compare the (cost) effectiveness of different types of treatments. Another important use of PROs at the meso level is in adverse event reporting. Patient-reported adverse events include symptoms such as fatigue and nausea which can be recorded during consultations. These effects are often underestimated by clinicians whereas patient reporting is more reliable and there is also likely to be a higher reporting rate.¹⁴⁰

If provided with aggregated PRO data in a useable, understandable format, patients can decide where to have treatments based on other patients' reports.⁶ In England, PROMs are an important component of outcomes measurement for local Clinical Commissioning Groups. Providers can use them to report on their performance; doctors can use them in revalidation processes; and PROMs can also inform productivity calculations.⁶ The five PROMs currently used by NHS England to assess elective surgery outcomes allow comparison of PROs across NHS organisations. In discussing this rich, new source of patient-reported data, Wise¹⁴¹ quoted John Appleby, Chief Economist at the King's Fund:

This is going to be hugely valuable for a variety of reasons. It can contribute to patient choice. It will also be very useful for commissioners of health care, as it will give a strong measure of the quality of care. The information can also be used in contracts to set goals for providers.

PRO data from registries are often used for assessing the comparative effectiveness of different treatment strategies.¹ Recent studies have demonstrated the use of the NHS PRO data for this purpose. For example, data from hernia surgeries provided by 164 hospitals in England to 17,463 patients over a one-year period (April 2009 to March 2010) were used to estimate effectiveness of surgery, quantify health gains and compare different types of interventions.¹⁴² The outcome measure was average change in EQ-5D scores for each hospital, adjusted for case mix and translated into Quality-Adjusted Life Years (QALYs). While the different types of hernia surgery had similar costs, laparoscopic surgery had a lower cost per QALY, indicating better value for money.

Also using the first year of NHS PRO data (2009-10), Appleby noted that approximately half of groin hernia and varicose veins patients reported an improvement in their HRQoL after surgery (although the percentage of patients with no change or poorer health was also relatively high), whereas approximately 90 percent of patients having hip replacement and 80 percent having knee replacement reported an improvement after surgery.⁹¹

The systematic collection of PROs by Bupa Hospitals described in Section 4.2.4.2 was accompanied by website publication of data from the SF-36 (a generic measure of function). The intent was to demonstrate possible benefits of certain treatments or interventions and to assist patients in understanding potential benefits of surgery. PRO data (SF-36 scores) were published from before and after hip surgery and were compared with scores from a similar cohort of the UK general population. Hip surgery resulted in patients feeling much better, albeit with lower levels of physical health, than people of a similar age.⁸⁹

Routinely collected PROMs can also be used to examine the extent to which cost variation among hospitals is associated with variation in health gains.⁷² Further research drawing on the NHS PRO dataset used hospital-level data from the EQ-5D and condition-specific instruments (Oxford Hip and Knee Scores, Aberdeen Varicose Vein Questionnaire) that had been completed by patients before and after elective surgery for hip or knee replacement, varicose veins or groin hernia repair. Surgeries were performed in public hospitals between April 2009 and March 2010.

Analysis of PRO data performed for this study found that average costs varied considerably among providers. Patients receiving hip or knee replacement reported greater increases in health status following surgery than those undergoing hernia or varicose vein surgery. Costs per patient were higher for hospitals with lower average initial health status. There was evidence of a non-linear relationship between costs and patient-reported health outcomes for hip replacement but not the other surgery types. The findings have implications for quality incentive schemes as costs of improved quality are not constant across the range of quality and the relationship also varies by procedure. These results cast doubt on the claim that some hospitals have higher costs because they are producing better outcomes.⁷²

A further use of PROMs at the meso level is identifying factors associated with positive responses to surgery or other treatments. An innovative use of PRO data is demonstrated by Swedish research to examine factors related to the success of cataract surgery and identify areas where PROs and clinician-reported outcomes diverged.¹⁴³ This analysis provided impetus and focus for quality improvement in eye surgery. Other research examined factors that predicted the risk of subsequent joint arthroplasty in patients who have had primary hip or knee arthroplasty.¹⁴⁴ This study found that, along with the patient's age, two PROMs were significant predictors of the surgical trajectory for osteoarthritis patients after their first lower limb arthroplasty. These PROMs (one-year post-operative Oxford Hip Score and the pre-operative Oxford Knee Score), with associated defined score cut-points, were identified as important markers for joint arthroplasty failure. PROMs can inform surgeons and patients about the likelihood of future joint failure and can also identify those patients who might require enhanced surveillance.¹⁴⁴

The use of PROMs in registries can help to make the registry data more meaningful to patients. A recent analysis argued that many clinical registries have not realised their potential because they have failed to include patient perspectives in their design, oversight and operation.¹⁴ This omission limits the relevance of the data collected, and also means patients cannot use the data to support self-management or shared decision making.¹⁴ In contrast, patient-centred registries could help health services move towards a model of continuous learning and improvement ('learning health system') in which information is collected and used to facilitate care in real time as well as for service improvement and research.

Key features of the patient-centred registry-based learning model are a social network of patients and their families and a network of clinical teams that collaborate to produce and share comparative and longitudinal data. Data are collected, stored and used digitally. The model would be expected to demonstrate impacts on health care via improved adherence to evidence-based practice and 'rigorous trials of new approaches'. Results would be widely disseminated and power shared among stakeholders. Mechanisms to support a 'registry-based learning system' would include:

- Systems to feed patient-reported and clinical data to patients and the point of care
- Meaningful summary reports and decision support aids based on PRO data
- Patient networks to foster social support and learning
- Clinician networks to support interdisciplinary care teams

- Collaborative networks to share expertise and conduct research aimed at improving outcomes.

4.3.3 Macro level

Uses of PRO data at the macro or system level include quality assessment of healthcare organisations and efforts to link quality or 'value' to payment mechanisms. PROMs can be also be used to evaluate the impact of new ways of providing care or other policy and practice changes.⁶

There are national and international level initiatives concerning the implementation of value-based health care and the use of bundled payment systems which, with the appropriate use of PROMs, clinical and health outcome related performance indicators, survival and costs data, have been shown to significantly enhance value in health care.^{59,68,78,79,80,107,121,130,133} There is a growing evidence base to support the use of bundled payments and/or other associated value-based reimbursement strategies (e.g. as per the Dutch reimbursement model for national registries).

The current rounds of the CMS Bundled Payments for Care Improvement Initiative⁷⁷ in the US and the bundled payments schemes currently being tested in National Quality Registries in Sweden¹³⁰ also provide examples of national policy initiatives. The NHS PROMs initiative in England, although largely concerned with assessing the comparative effectiveness of providers, may also be viewed as a national quality improvement and policy initiative.¹⁴⁵ The recently commenced international benchmarking projects using ICHOM standard sets for health outcomes assessment (which include PROMs)⁶⁸ might well have implications for national policy initiatives in the future.

At the simplest level, PROMs can be integrated into quality assessment by encouraging services to report on the percentage of patients who complete relevant PROMs.⁵⁸ This approach focuses only on the processes of including patient perspectives in assessing care quality; it is a necessary, but not sufficient step towards improving quality. To move towards improved outcomes would require a second element, namely the ability to assess change in scores at the individual or population (aggregate) level.⁵⁸ Standards for acceptable change would need to be established; these could be defined in terms of average change in scores, but to aid interpretation it may be preferable to look at changes that take scores beyond a clinically meaningful threshold score, normative comparisons, or how many patients meet criteria for remission or minimal symptoms.⁵⁸ Using PROs for quality assessment or performance evaluation in this way requires them to be transformed into PRO-based performance measures (PRO-PMs).¹ Guidance for developing appropriate PRO-PMs is available and is discussed in Section 4.6.2.

In recent years, there have been moves in the United States and elsewhere towards incorporating PRO data into value-based payment systems for healthcare providers. Understanding value requires measures of both costs and outcomes at the patient level.¹⁴⁶ Opportunities exist to reduce costs and improve outcomes without limiting access to necessary care.¹⁴⁶ However, to realise these potential benefits, accurate information on health outcomes is required to overcome the problem of perverse incentives:

The inability to properly measure cost and compare cost with outcomes is at the root of the incentive problem in health care and has severely retarded the shift to more effective reimbursement approaches ... Institutions may be penalized when the improvements they make in treatments and processes reduce the need for highly reimbursed services.^{146 p.396}

The recent *Medicare Access and CHIP Reauthorization Act (2015)* will accelerate a move towards value-based payments to physicians.⁷⁰ By 2017, all physicians who participate in fee-for-service Medicare will be affected by the Medicare Value-Based Payment Modifier which will adjust payments based on physician quality data. A standardised PREM (the Clinician-Group Consumer Assessment of Healthcare Providers and Systems survey) will provide input into these quality measures and contribute to the allocation of physicians to cost/quality tiers.⁷⁰ It is unclear from this source whether specific PROMs will also be included.

Failing to include PRO data in pay-for-performance mechanisms can be problematic. In England, the Quality and Outcomes Framework, introduced voluntarily to many general practices from 2004, was designed to support performance-based payments and standardised quality improvement in primary care.⁹² However, the initial set of indicators incorporated minimal patient-reported information.⁷⁰ For example, in the primary care domain, two patient experience measures (one based on average time spent with clinician, and the other on survey results) contribute to quality measures linked to provider incentives, and there are no patient-report outcome measures. Only two of 146 such quality measures are therefore reported from the patient's perspective.⁷⁰ Due to the lack of emphasis on PROs, patient-valued aspects of care actually declined in the years immediately following implementation of the Quality and Outcomes Framework.⁷⁰

Finally, PROMs are seen as a valuable component of evaluations of healthcare innovations,^{147,148} demonstrated by an appraisal of evidence regarding the introduction of new implants in hip and knee replacement¹⁴⁹ and robot assisted laparoscopic techniques.³

Patient engagement in research is now formally required for funding from several programs in the US (e.g. via Patient-Centred Outcomes Research Institute or PCORI) and is encouraged in Canada (by the Canadian Institutes of Health Research and the new Canadian Strategy for Patient-Oriented Research) and the UK (e.g. through INVOLVE and the National Institute for Health Research, which is conducting a strategic review of the options for patient engagement).¹⁵⁰ There is a need for a framework or toolkit explaining how to embed patient engagement in PRO research.¹⁵⁰

4.4 Evidence of impacts

In this section we review the literature on the impacts of PROMs and PRO collection and use. The discussion focuses mainly on the benefits of individuals' PRO data for the clinician-patient interaction (micro level uses) and the benefits of aggregated data for quality improvement activities (meso level uses) as this is where most evaluation activities have occurred. There is very limited academic literature available regarding impacts on policy (macro level uses) although the grey literature search identified some relevant reports.

4.4.1 Micro level

There have been several reviews of the literature on impacts of PROMs in the clinician-patient interaction. The evidence of benefits in this context appears to be mixed.

Valderas and colleagues conducted a systematic review that included 28 randomised controlled trials (RCTs) which had examined the impact of PRO measurement into clinical practice. Eleven trials used generic PROMs and 17 used condition- or disease-specific PROMs.¹⁵¹ Potential benefits of using PROMs in daily clinical practice were identified as:

- facilitating detection of physical or psychological problems;
- monitoring disease progression and providing information about the impact of prescribed treatment;
- facilitating patient-clinician communication;
- monitoring outcomes as a strategy for quality improvement or to reward presumed superior care.

Most studies identified effects from the introduction of PROMs on at least one of these processes. However, effects on patient health status were less frequently assessed and observed. The impact of PROMs was limited in most trials. The authors concluded:

whereas there are some grounds for optimism in the possible impact of measurement of PRO in clinical practice (specifically in improving diagnosis and recognition of problems and patient–physician communication), considerable work is still required before clinicians can invest resources in the process and rely on consistent evidence for the benefits for their patients.^{151 p.191}

Another systematic review found that the routine use of PROMs increased frequency of discussion of patient outcomes during consultation and in some trials was associated with improvements in symptom control, increases in supportive care measures and patient satisfaction.¹⁵² However, statistically significant findings were limited and effects sizes were small to moderate. The findings of these more recent reviews are consistent with those from an earlier review by Greenhalgh and Meadows.¹⁵³ In that review, studies demonstrated that clinicians viewed PRO data as valuable in overall patient assessment and that feedback of PRO information to clinicians increased the detection of psychological problems, and functional problems to a lesser extent. However, evidence for changing patient management or improving patient outcomes was again found to be scarce. The findings indicated that the effectiveness of PROMs in routine practice may depend on the manner in which they are implemented.

For screening and monitoring uses in the clinical setting, feeding back PRO information to clinicians appears to improve their detection of problems but not necessarily the way they respond (e.g. in terms of providing referrals or extra consultations) or the patient outcomes they achieve.¹³⁹ There is little evidence on the impact of PROMs on patient-centred care including clinician-patient agreement on the patient's health status, patient adherence to physician advice or medication, or patient satisfaction.¹³⁹ For multidisciplinary team care, there is some evidence that the use of PROMs has modest benefits for patient satisfaction. Overall, feeding back PRO information to clinicians had a greater impact on discussion and detection of

problems during the consultation than on subsequent management decisions or health outcomes.¹³⁹ This may be because clinicians prefer to think of PROs as supplementary information rather than the main determinant of their decisions.¹³⁹

The impact of PROMs in oncological settings was examined by Chen and colleagues.¹⁵⁴ The systematic review of 27 studies found “growing evidence supporting the routine collection of PROs to enable better and patient-centred care, especially in cancer settings”.^{154 p.22} More specifically, there was strong evidence that well-implemented PROs improve patient-provider communication and patient satisfaction, and growing evidence that it improves the monitoring of treatment response and the detection of unrecognised problems. Again, the evidence-base was weak or absent with regards to the impact on changes to patient health behaviours, patient management and improved health outcomes. Despite observing promising indications that the number and quality of studies was increasing, Chen and colleagues noted several limitations in the literature including:

- Lack of large cluster RCTs
- Lack of generalisability of findings
- No studies with a comprehensive theoretical model and framework.¹⁵⁴

Regarding the lack of strong evidence for PROMs improving patient outcomes, Fayers has suggested that the modest benefits may be concealed by trial design issues, including physician effects and contamination.¹⁵⁵ Suggestions relating study designs to counteract these issues were provided, and implications were discussed, particularly the use of cluster-randomised trials to manage contamination effects, and the use of multi-level or nested hierarchical analysis to allow for physician effects.¹⁵⁵

One RCT which did use nested hierarchical analysis demonstrated benefits of PROMs for some patients.¹⁵⁶ The trial involved 28 oncologists and 286 cancer patients (in intervention, attention-control and control groups) and assessed the effects of collection and use of HRQoL PRO data. Results showed that routine assessment of HRQoL in cancer patients improved physician-patient communication, and benefited some patients with improved HRQoL and emotional functioning. Impacts on physician-patient communication were also shown in a longitudinal study, using the dataset from the aforementioned RCT.¹⁵⁶ In a separate study, Takeuchi and colleagues found that regular collection of PROMs and feedback of data to oncologists was related to discussion of more symptoms over time, although no effect was observed for discussions about function.¹⁵⁷

Another cancer-related RCT that demonstrated benefits of PROMs use for patients involved 10 physicians and 214 palliative chemotherapy patients.¹⁵⁸ This randomised crossover trial used HRQoL PROMs at three consecutive outpatient visits and found that use of the measure in routine practice increased communication, had a statistically significant impact on patient satisfaction with emotional support from the physician, and had modest effects on patient management (mainly increased levels of counselling) and quality of life (although these latter two were not statistically significant).

The value of mental health PROMs in predicting functional outcomes has been shown in a study by Eisen and colleagues.¹⁵⁹ A sample of 446 veterans receiving mental health services in the United States had clinician-assessed and self-reported mental health assessments at baseline and three months. Clinicians used the Global Assessment of Functioning (GAF) scale and self-reported mental health assessments were the Behavior and Symptom Identification Scale (BASIS-24), the Brief Symptom Inventory (BSI), and the Veterans/Rand Short Form-36 (VR-36). Findings demonstrated the incremental value of self-report measures in addition to clinician-assessed measures with regard to predicting two of the three functional outcomes assessed in the study, namely inpatient hospitalisation and paid employment. Summarising the implications of their results, and the potential benefits of systematic collection of mental health PRO data, the authors stated:

At the aggregate level, these benefits might include obtaining systematic information about course of illness, comparative, and cost-effectiveness of specific treatment interventions and overall health system performance. At the individual level, benefits might include individualized information about clients' specific strengths and deficits, progress in identified areas, and target areas for further treatment.^{159 p.187}

In summary, the limited evidence suggests that using PROMs in routine clinical practice has some positive impacts on certain processes within the clinician-patient interaction but little impact on health outcomes.⁶

Many of the studies showing positive impact of PROMs were conducted in cancer care; there is a need to look at the impacts of PROMs in a wider range of healthcare settings. Encouragingly, further research is being conducted that may provide more definitive evidence of impacts and benefits. A protocol was recently submitted for a Cochrane review to examine the impact of the routine use of PROMs in clinical practice.¹⁶⁰ The objective of the review is to assess impacts in several areas, namely:

the process of care (including patient-physician communication, professionals' awareness of patients' quality of life, diagnosis and recognition rates, treatment rates, health services and resource use, as well as patient behaviour); patients' and professionals' experiences of care; and health outcomes (both generic and disease-specific, using both routinely used clinical measures and PROs).^{160 p.3}

4.4.2 Meso level

There is a substantial body of evidence to support the use of PROMs at the aggregate (meso) level in comparative effectiveness research. PROMs are used to evaluate the impact and outcomes of treatment interventions, and the use of PROMs in clinical research is increasing.^{3,4,65,161} PRO data can be important in explaining the relative benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. Such data can also help patients to decide whether to have a particular medical intervention or to choose between treatments for their condition. For example, Brettschneider and colleagues found evidence of the informative value of PROs in health technology assessment, particularly for the evaluation of health benefits as well as for economic evaluations.¹⁶²

Another important use of aggregate PRO data is in quality improvement. An early example of this was the work undertaken by Bupa Hospitals in the UK from 1998. Collection and routine use of PROMs facilitated continuous quality improvement and enabled changes to clinical practices in its hospitals. Additional benefits of using PROMs were reported as identifying poorly performing clinical teams and clinicians and identifying and sharing best practices which, in some instances, were seen to improve patient outcomes.⁸⁹

Boyce and Browne reviewed the use of PROMs as quality improvement tools.¹⁰⁰ Consistent with findings on the micro-level uses of PROMs, reported above, these reviewers demonstrated that this meso-level use of PROMs did improve patient-clinician communication and the processes of care for individual patients, but have consistently shown minimal influence on patient health status outcomes. For example, the outcomes for patients operated on by surgeons who had received peer benchmarked PRO data were not statistically different from the outcomes of patients operated on by surgeons who did not receive feedback.¹⁰⁰ However, as quality improvement initiatives are patient management interventions, rather than health treatment interventions, it may be unrealistic to expect group changes in health status.³ Quality improvement initiatives may not be expected to have strong impacts on health status outcomes because they target the process of care delivery (e.g. the degree of patient monitoring or coordination) rather than the treatment itself (e.g. specific aspects of surgery). Further, well-validated generic PROMs are somewhat insensitive when used to assess care delivery interventions.³

A case study report released by the Health and Social Care Information Centre in the UK also reports on the use of PRO data to drive quality improvement.⁹⁴ Specific examples were provided of NHS Foundation Trusts using PRO data to review and evaluate their performance and programs and to make clinical changes which resulted in improved aggregate health outcomes (e.g. improvements on Oxford Hip Score and Oxford Knee Score).

Noting that other initiatives and activities (not PROMs alone) are likely to have contributed to improvements and benefits, some examples provided in the report are as follows.

- Barnsley Hospital NHS Foundation Trust used PRO data to evaluate stages and components of their Enhanced Recovery Pathway (a program for enhanced recovery from hip and knee replacement surgeries) and implement revisions to the pathway where appropriate. Revisions included: implementation of PROMs at eight weeks and three months post-discharge, analysis of this data to identify activities patients had difficulty with post-discharge and address these in post-op appointments, and using PRO data to help build a successful case for employment of an additional physiotherapist. The measurable benefits that were achieved included moving above the lower 95 percent control limit threshold for Oxford Hip Score and Oxford Knee Score between 2012/13, meaning that the Trust was no longer a negative outlier within England for primary hip replacement surgeries and primary knee replacement surgeries respectively.
- Derby Hospitals NHS Foundation Trust uses provider-level PRO data to compare local performance against the England average and, if Derby is reported as a negative outlier for any measure, the issue is escalated to the Trust's Management Executive Committee. This process identified that Derby was below the lower 95percent control limit for adjusted

average health gain for Oxford Knee Score in 2009/10 and below the England average in 2010/11. In response, a multidisciplinary team was set up to review the care pathway and subsequently changes were made to pain relief protocol. This resulted in Derby moving above the threshold for Oxford Knee Score between 2010/11 and 2011/12 as well as retaining their position above the England average in 2012/13.⁹⁴

- Other examples on how PROMs have informed clinical practice were reported for Circle Bath, Harrogate and District NHS foundation Trust, Northumbria NHS Healthcare Foundation Trust and the Royal Orthopaedic Hospital NHS Foundation Trust.⁹² A recent case study⁴⁰ linking PROMs and data from the National Joint Registry also identified that one implant brand had a significantly higher health gain for knee and hip replacement surgery outcomes. Using this finding as a catalyst, in late-2011, Northumbria switched implant brands.

4.4.3 Macro level

Recent studies concerning value-based health care and bundled payments systems have been shown to enhance value in health care.^{59,68,78,79,80,107,121,126,130} This is an emerging field of study but there is an increasing evidence base to support the use of bundled payments and/or other associated value-based reimbursement strategies. The results of the current rounds of the CMS Bundled Payments for Care Improvement Initiative⁷⁷ in the US will be of interest as will the results from the eight bundled payment schemes currently being tested in Sweden.¹³⁰

The policy shift toward value based health care and health outcomes evaluation using PROMs is gaining momentum internationally and is particularly evident in countries such as the US, UK, Sweden and the Netherlands (see Section 4.2). ICHOM actively promotes value-based health care as well as international outcomes benchmarking using standard measurement sets to assess health outcomes data. Such international benchmarking activities have potential to provide some rich data to support quality improvement initiatives in the future. Numerous international health sector agencies (including Australian agencies) are currently collaborating with the ICHOM initiatives. Such activities have increased the interest in health outcomes evaluation (including the use of PROMs) by health systems internationally.

In their review of impacts of PROs in cancer treatment, Chen and colleagues found no studies examining the high-level impact of PRO collection on health care organisations, health system improvement or population health. They concluded that evidence was weak or lacking regarding the effectiveness of PROMs for improving transparency, accountability, public reporting activities, and performance of the health care system.¹⁵⁴

A more recent study examined changes in provider performance following feedback of data from the NHS England PROMs program.¹⁶³ There were no apparent impacts on inter-provider variation over time, nor in the proportion of providers deemed 'outliers'. The minimal impact on provider behaviours suggested a need for greater attention to effective communication of results and provision of guidance on how to respond to PROMs feedback.¹⁶³ Some NHS Foundation Trusts have used PRO data to improve clinical practice and patient outcomes.⁹⁴

The grey literature suggests some positive impacts at this level. The NHS PROMs program is currently undergoing consultation and review to determine whether it offers value for money.

In response, several organisations have highlighted the benefits of PROMs they have observed.⁹⁵ The National Joint Registry and key orthopaedic groups strongly endorse the program and they emphasise the value of PROMs in providing comparative data to support quality improvement and for research purposes regarding outcomes.¹⁶⁴ They noted that the PROMs program itself had highlighted online a number of case-studies where these approaches have led to individuals hospitals improving their practice (e.g. improvements to pathways for hip and knee surgery and improved provision of rehabilitation services for these patients). The use of PROMs had also highlighted potential implant failure, allowed changes in care paths to be monitored for their effect on patient outcomes and PROMs evidence had also been used to inform and revise guidelines for these surgical procedures. The Office of Health Economics pointed out that PRO data are vital to understanding the effectiveness and cost-effectiveness of NHS services.¹⁶⁵ For this reason, they strongly urged NHS England to continue to use a brief, generic PRO questionnaire in combination with a detailed, condition-specific measure, where available. Generic PRO data was argued to provide the crucial common denominator with which to measure outcomes across treatments and diseases. The release date for the final report of this review is unknown.

Haywood and colleagues reported on the findings of a 'World Café' event exploring aspects of patient engagement with HRQoL and PRO-related research, with patients as research partners in the research process.¹⁵⁰ Despite most participants' positive view of the potential for the active involvement of patients in healthcare research and evaluation (in particular HRQoL and PRO research), a significant concern was the lack of evidence on the impacts of patient involvement to support investment in this area. The two main themes emerging from the event were: the need for good practice guidelines to embed patient engagement within HRQoL and PRO research; and the need for rigorous evaluation to establish an evidence base of impacts and benefits.

4.5 Challenges of PRO collection and use

Several authors have described barriers to implementation of PROMs.^{166,167} These exist whether PROMs are used in routine patient-clinician interactions, for quality improvement or comparative effectiveness research, or to guide health policy and funding decisions. In order to implement PROMs successfully and realise the potential benefits, the associated challenges need to be acknowledged and addressed. These challenges are of two main types: whether the data provide an accurate picture of performance across different treatments or providers; and whether the data can be presented in a useable form so that the potential benefits of PROMs are realised and sustained.

4.5.1 Accuracy of data collection and reporting

If PRO data are to be aggregated and used to compare outcomes from different treatments or providers, it is essential that outcomes can be attributed to care quality.⁶ This requires the selection of instruments that are specific and sensitive to change in order to establish causal links.¹⁶⁸ It also involves judgements about when to measure and what level of analysis is appropriate for a given outcome.⁶

As health is a culturally variable concept, care is needed when trying to interpret PROs obtained from different countries. A number of sophisticated psychometric techniques have been

suggested to improve the comparability of PRO data across countries and cultures, as well as using comparable, homogenous groups across cultures. Providing clinically meaningful labels to outcome scores can also improve reliability when using PROs for measuring healthcare quality.¹⁶⁸

PRO data can provide evidence to inform payers and policy makers in terms of decision-making about drug coverage and treatments.¹⁶⁹ However, challenges associated with using PROMs in this way include the difficulty of gaining consensus from payers on the relative value of subjective PROs and issues about how best to use PRO data in their decision making.^{169,170}

PROMs experts who were interviewed for a qualitative study supported the integrated collection and use of PROMs for the purposes of both clinical care and performance management, but had concerns about its feasibility.¹⁷¹ It was seen as a complex task; in order to be sustainable, systems are required to support and engage clinicians. In addition, different stakeholders can have different agendas for PRO collection which might not be compatible. For instance, clinicians were worried that administrators will use data for individual performance management without adequate risk adjustment, whereas measure developers worried about the reliability and validity of data collected by clinicians, especially if data were then to be used to determine reimbursement.¹⁷¹

PROMs compare favourably with other common clinical measures in terms of reliability.¹⁶⁸ However; some uses of PROMs are of questionable validity. For example, there are dangers in using PROMs inappropriately to ration care or allocate funds preferentially to treatments.⁶ Reviewers of the NHS England PROMs initiative have highlighted difficulties with response bias, recruitment bias and the most appropriate measure for provider comparisons.^{6,96}

When asked about the types of PROMs change metrics (techniques for the measurement of patient change over time) that might be useful, clinicians emphasised the need to take into account a baseline or starting point, and also differences in patient characteristics that might affect the outcomes of care.¹⁷² In focus groups in the same study, patients also acknowledged the need to account for 'some hospitals starting with patients who were sicker than they might be in other hospitals'.^{172 p.177} Thus it would seem that some sort of mechanism for adjusting data according to risk (e.g. casemix adjustment) is required when using PROMs for performance measurement purposes. Experts disagreed on whether such a mechanism should be simple (i.e. limited adjustment to avoid obscuring relevant differences in providers' outcomes) or sophisticated (i.e. adjusting for all possible confounders to address fears about the misinterpretation of data, leading to possible 'cherry-picking' of patients).¹⁷¹ The preferred approach among those experts appeared to be a middle ground: stratifying patients into sub-groups in order to serve the need for risk adjustment without creating other problems. This issue requires further investigation in the local context as no Australian experts were interviewed for the study.

4.5.2 Stakeholder engagement and knowledge transfer

Lipscomb and colleagues outline a number of barriers to PROMs use relating to stakeholders.¹⁶⁶ Although they were specifically exploring PROs in cancer care, these barriers are also relevant in wider healthcare contexts. For patients, the barriers include response burden, concerns about confidentiality and the fact that they may be asked to provide sensitive information.

Clinicians may doubt whether PROMs are really useful and have concerns about the time and effort involved in collecting them. Barriers for administrators and policy makers include the resources required to collect and manage the data and the potential for misuse and unintended consequences.¹⁶⁶

In order to realise the potential benefits of PROMs, first and foremost, patients must be willing and able to provide data.^{6,60} Using PROs in routine practice must therefore be done in a way that is acceptable and creates value for patients.¹³⁸ Patients may struggle to complete instruments due to low literacy or the effects of disease, or may have concerns about confidentiality or the effects of the data collection process on their relationship with the clinician.¹³⁸ Patients with disabilities such as limited mobility or visual impairment may find it difficult to complete PROMs and care should be taken in designing systems and measures to ensure they can participate fully.⁵¹ Speakers at the ISOQOL 16th annual conference emphasised the value of the patient's voice and the importance of measures that are culturally sensitive.¹⁶⁸

Using PROMs to assess the outcomes of treatment requires patients to complete repeated measurements. The feasibility of obtaining follow-up questionnaires from patients after surgery has been demonstrated in the NHS England PROMs program, but is likely to be more difficult with patients who have chronic conditions where the follow-up measure may be administered a long time after the original measure and seem less relevant, especially if it is not tied to an appointment.¹⁷¹ Response rates are likely to fall compared with acute conditions, and may not be uniform across populations or providers, affecting the validity of using the data to examine variations in outcomes.

Clinicians also need to be convinced of the value of PROMs for their practice and be supported to use them appropriately. If clinicians are unfamiliar with the instruments they are expected to use, or lack the time to use them, these are serious barriers to widespread adoption in routine practice.¹³⁸ Clinicians may be less likely to use PROMs if use is not linked with incentives (e.g. reimbursement), or if they are concerned that using such tools will affect their relationship with patients.¹³⁸

Further, the clinician-patient interaction with PROMs needs to be supported adequately with resources for efficiently collecting, reporting and interpreting the data. Reliable, attractive platforms are required for data entry; systems are needed for optimising flow of PRO data to providers; data must be relevant and actionable; and work is required to ascertain what small score changes mean in clinical terms and when providers should act.⁶⁰ Timely communication among stakeholders is needed, including procedures for responding to PRO information.¹³⁸

Lavallee and colleagues have acknowledged that PRO data collection and interpretation is likely to increase staff workloads but improvements to health information systems have the potential to address this barrier (e.g. use of tablets, mechanisms that allow patients to collect outcomes at home before or after a visit to a provider, computer-adaptive testing, incorporating PROMs into electronic health records).⁵¹ Efficient use of information technology is one of the major challenges of implementing PROMs in routine practice⁶ (see also Section 4.6.3).

Importantly, PRO data needs to be presented in a way that is useful to providers and patients.⁶ Providers need to be able to use PRO data to know what and how to improve, not just to compare themselves with others.¹⁶⁸

The meaningful use of PRO data was among the issues explored in interviews with 58 experts in PROMs.¹⁷¹ Use of PROMs was seen as requiring the clinician's full engagement and willingness to share information with the patient, effectively making it 'worth their while' to complete questionnaires. As one expert said, patients are willing to put in the effort to take part in a survey, 'if they feel that the results are actually being used for their treatment'.^{171 p.766} In order to facilitate this sharing of information, clinicians need to have the results provided to them in a form that can be easily interpreted and used in diagnosis and treatment. This requirement for clarity and interpretability is even more critical when the data are aggregated and fed back to organisations for quality improvement purposes, or used at the system level to understand variation in performance among providers or services.¹⁷¹

There is an art and science to presenting data in a form that can be readily used and understood, and these aspects of PROMs have been explored in a number of studies.^{172,173} Patients and providers have differing views on the kinds of presentations that are most meaningful.¹⁷⁴ Clinicians who were consulted at a series of meetings said they would prefer multiple measures of change in PROMs and were comfortable with quantitative data presentation. In contrast, patients who attended focus groups tended to find quantitative data difficult to understand and 'preferred an outcome to be defined in terms of an experience rather than a number'.^{174 p.179} While clinicians focused on the accuracy of the data, patients were primarily concerned with its interpretability. The authors drew lessons from the study around how best to explain the metrics and clarify common misunderstandings. They concluded that for patients, it was especially important to use language that made the metrics personally meaningful and linked to familiar scaling (e.g. percentages) and to experiences.

Strategies for communicating HRQoL (and other PRO) findings to patients, providers and other decision makers were discussed at a Clinical Significance Meeting Group organised by the Mayo Clinic, along with statistical issues such as defining and interpreting meaningful differences in scores and accounting for 'response shift', where the meaning of scores changes over time as patients adapt to their illness.¹⁶⁶

4.5.3 Demonstrating benefits and avoiding iatrogenic consequences of PROMs

Focusing on the use of PROMs in cancer research, Lipscomb and colleagues concluded that 'our knowledge of the role that PRO measures play or could play is still based more on anecdote than analysis'.^{166 p.296} They advocated for a well-designed program of research to identify where PROMs are useful, the conditions required for success, and strategies for enhancing their usefulness. Case studies and other in-depth qualitative approaches would be employed in order to understand how healthcare decisions are made, how information is used in the process and what characteristics of the information are most influential.¹⁶⁶

Negative impacts associated with using PROMs are also examined in the literature. Wolpert, although an advocate for PROMs, has acknowledged potential iatrogenic consequences of the use of PROMs for audit and research purposes.¹⁶⁷ These relate mainly to the burden on clinicians and patients and anxiety about the potential use of such measures to limit access to

health services. She also notes, with reference to recent approaches to national collection of PROMs in England, how little is known about the psychometric properties, impact or utility of many measures being used. To avoid negative impacts, and to enable PROMs to inform research and audit and to support clinical practice, Wolpert provides the following recommendations.

- Explicit recognition of need to disaggregate two aims—use of PROMs for research and audit versus use for direct clinical care.
- Training for front line clinicians in how to introduce, input, score and interpret PROMs in context of collaborative working.
- Training for service managers, board members, commissioners and others in how to interpret scores and what the limitations are to their use without further triangulation.
- Further research into PROMs use in clinical practice: how best to safely interpret and report the data: how often to use in clinical practice; how best to introduce; how much change is enough; when not to use.^{167 p.144}

4.6 Implementing PROMs

The review identified a number of articles and reports referring to the development of guidelines or standards for selecting PROMs, implementing systematic PRO collection and reporting PRO data in user-friendly ways. Several authors have commented on the need for a ‘tool kit’ or similar best practice guidance for the use of PROMs, to minimise the burden of data collection and maximise data quality, usefulness and impact.

4.6.1 Selection of appropriate measures

It is important to use valid, reliable and appropriate instruments when selecting PROMs. The dimensions below should be considered when selecting instruments and measures for outcome evaluation.³

RELIABILITY: consistency of measurement, e.g. internal consistency and test/retest reliability.

VALIDITY: does the instrument measure what it claims to measure? There are different types of validity –content, construct, criterion, concurrent, convergent, discriminant etc.

DISCRIMINATORY POWER / discriminant validity: is the instrument able to discriminate well between groups, for example, healthy public versus people with major diseases?

RESPONSIVENESS/SENSITIVITY to CHANGE: can the instrument detect change in health status over time?

AVAILABILITY OF COMPARATIVE DATA: are there norms and clinical reference datasets available for comparison purposes?

TYPE OF INSTRUMENT: generic health status measure, condition- or disease-specific measure, profile or index.

STYLE OF INSTRUMENT: for example, is it better to use a self-report instrument or a rating scale or a combination of both? Is a self-report inventory the best instrument to use with severely disturbed patients?

PRACTICAL UTILITY: is the instrument too long/short, is it easy to administer and use, is it easy

to score, will there be respondent burden, etc.?

FREEDOM FROM CONFOUNDING FACTORS: for example, social desirability of responses, inappropriate questions associated with missing data, literacy level of the survey etc.

RELEVANCE and SUITABILITY OF APPLICATION: for example, whether the generic and/or disease-specific measures adequately capture the relevant domains for the condition or disease concerned.

MODE OF ADMINISTRATION: self-reported or structured interview, telephone administration, tablet or online kiosk application etc.

CULTURE, GENDER and AGE APPROPRIATENESS: are there translations/adaptations for other cultural groups, are all the items suitable for both genders, and are there versions suitable for use with children/adolescents? Some instruments need linguistic validation for use in the Australian context.

An examination of the above criteria indicates that some expertise in psychological measurement may be required in selecting and administering measures and in interpreting the data that is derived from such measures.^{6,167} Staff members who are involved in routine data collection need adequate training and briefing concerning the purpose and the proposed methods of the PRO data collection.

Other authors such as Valderas and colleagues have raised some concerns about the selection of the EQ-5D in both the NHS England PROMs program and the use of this instrument in the National GP Patient Survey.¹⁷⁵ This paper was written shortly after the introduction of both initiatives but some of the issues raised appear to be more applicable to the latter initiative. One of their main concerns was the lack of sensitivity of the EQ-5D as an outcome measure to reflect health system performance over time. Other authors have also raised issues related to the sensitivity of the EQ-5D in a range of applications.^{3,39,176} Recent efforts to address these concerns are described above (Section 2.2.1).

Although Valderas and colleagues were in favour of using PROs, they argued that the choice of instrument (and the then proposed timeframe for implementation) could undermine credibility and support for the PROMs initiative:

...there is a risk that any issues potentially arising from the use of health status measures may be considered as a failure of the measurement model itself rather than a problem in the construction and interpretation of specific indicators.^{175 p.353}

They referred to the National Committee on Quality Assurance in the US as an example of how to go about establishing validity of quality indicators for the health system.

4.6.2 Standards, guidance and toolkits

A committee within ISOQOL has developed a *User's Guide for Implementing Patient-Reported Outcomes Assessment in Clinical Practice*.¹⁷⁷

Topics covered by the user guide include:

- identifying goals (e.g. screening, monitoring progress, promoting patient-centred care by providing feedback to the patient or using as common frame of reference for multidisciplinary teams, or to aggregate and use to identify strengths/weaknesses in care, or for outcomes benchmarking);
- selecting patients, setting and timing;
- choosing the questionnaire (e.g. generic versus specific; static versus dynamic);
- administration and scoring (including electronic health records and applications);
- reporting results (e.g. providing results to clinicians with other relevant data so can be easily used in practice; deciding when and whether to discuss results with patients);
- interpreting scores (whether to present as current or change scores; providing some way to gauge meaning of score such as reference or normative scores or benchmarks or minimally important clinical differences);
- responding to issues raised by PROs (providing guidance to clinicians, helping them understand implications of scores and how to respond); and
- evaluating impact on practice (evaluation designs; defining ‘value’).¹⁷⁸

A position statement was released by the Mayo Clinic to educate community hospital stakeholders about the merits of collecting and reporting PROs, as well as the importance of strategically consolidating measurement throughout the enterprise.¹⁷⁹ According to this paper, a good PROM is:

1. simple (i.e. it can be read by a 12 year old)
2. brief – not more than 12-15 minutes to complete
3. developed with input from patients
4. reliable, valid and responsive to change
5. easily scored and interpreted.¹⁷⁹

Implementation of PROMs within registries has been supported by a toolkit developed in the US as a joint initiative of three registries: Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR); Comparative Effectiveness Research Translation Network (CERTAIN); and Kaiser Permanente National Total Joint Replacement Registry) facilitated by Academy Health’s Electronic Data Methods Forum and supported by the US Agency for Healthcare Research and Quality.⁵¹

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) established a task force to look at using ‘real-world’ data in making health care decisions, particularly relating to payment and coverage decisions.¹² ‘Real-world’ data were defined as data that originated from sources other than conventional RCTs. Several ‘best practice’ documents to guide PRO collection are mentioned in the article, one of which is an ISPOR task force report on translation and cultural adaptation of PROMs.¹²

The US National Quality Forum has developed a pathway for developing PRO-PMs which starts with PROs, identifies appropriate PROMs, specifies required standards and so on.¹⁴⁰ The process of integrating PROs into data collection for safety and quality requires methodological rigour and it is best to involve experts to conduct qualitative and quantitative assessments of the validity of proposed instruments. Ideally, questionnaires should not be longer than 50 items (10 minutes to complete) and will use electronic data capture where possible to minimise patient burden and missing data. To ensure PRO data is accepted and used for quality and safety improvement, results should be published in a user-friendly form.¹⁴⁰

Although aimed mainly at clinical trials, the US Food and Drug Agency guidelines for the use of PROMs provide basic principles relevant for a range of stakeholders and uses.¹⁸⁰ These include understanding what and why you want to measure something, being certain that the PRO instrument measures what it is intended to measure, and relating measures to *a priori* hypotheses regarding treatment outcomes.¹⁸⁰

4.6.3 Electronic and web-based systems for PROMs collection

Some authors have explored the relevance of new information and communication technologies for the electronic capture of PRO data to facilitate applications in routine care. These can include the use of personalised digital assistants, automated telephone survey systems, tablet computers and web kiosks at clinics, interactive voice response system (IVRS), and PROMs sent over the internet to patients for completion at home on a computer or device.^{181,182,183,184,185} The advantage of an electronic PROM is that there is no need for data entry and data scoring as this is automated and the presentation of results can be conducted in real time and fed back to the clinician, thus reducing administrative burden.¹⁸⁶ Chang¹⁸⁷ and Jensen and colleagues¹⁸⁸ also note that electronic systems allow for computerised adaptive testing methods which can reduce the patient burden in completing PROMs. There is also the potential to include the data in the electronic health record to allow for routine patient review.^{60,182,189}

Atreja and Rizk compared the use of tablet and paper-and-pencil PROM forms and found that 70 percent of patients in a gastroenterology clinic found the tablet computer easy to use and 71 percent preferred the electronic PROM to a paper-based version.¹⁸¹ Similarly, in a study comparing the use of tablet, IVRS, and paper-and-pencil PROM forms, Bennett and colleagues found each mode acceptable to participants; 86 percent of participants reported 'no problems' responding to the questionnaire using tablet, compared to 72 percent and 98 percent for IVRS and paper respectively.¹⁸⁵ However, another study found that when tablet devices are used, issues may arise with wireless connectivity and patients' lack of familiarity with the device; all but one patient needed assistance to complete the electronic PROM.¹⁸³ In addition, there may be cultural differences that affect access to and comfort with the tablet technology.¹⁹⁰ For example, in one study conducted in the United States, white Caucasian participants were more likely to complete a tablet survey than other cultural groups.¹⁸¹ Using online and electronic technologies with all patients may not be possible as lack of access to technology may be a barrier for some patients and for some patients paper-and-pencil forms will still be required.⁵¹

An electronic PROM and its associated paper-based PROM must be tested for their equivalence to ensure that the changes to the PROM made to adapt it for electronic use do not undermine its validity.¹⁹¹ These problems are not insurmountable but demonstrate the importance of

carefully planning data collection procedures when adopting new technologies. A systematic review and meta-analysis conducted by Muehlhausen and colleagues concluded that the migration of paper-based PROMs to electronic PROMs with only minor to moderate changes produce equivalent instrument versions and thus do not require quantitative equivalence studies. Further work is needed to establish this definitively and to standardise migration and reporting practices.¹⁸⁶ Similarly, a study by Bennett and colleagues found moderate to high levels of agreement across the three modes examined (web-enabled touchscreen tablet computer, IVRS and paper).¹⁸⁵

A number of studies provide examples of the inclusion of electronic PRO data into the electronic health record.^{60,182,189,192} One advantage of linking the PRO data into the electronic health record is that data collected for one purpose can potentially be used for multiple different tasks, including clinical care, quality assessment and improvement, research, and public reporting.¹⁹² Many of these applications require the development of fairly sophisticated electronic PROMs systems (see below). However a study by Fritz and Dugas examined the extent to which clinicians at a German teaching hospital accessed the PRO data (for two PROMs) for routine care or research purposes.¹⁸⁹ Clinicians were more likely to access the PRO data for research purposes (74 percent – 100 percent) than routine care (56 percent – 74 percent). This suggests that clinicians may need to be trained and encouraged in the use of PROMs for routine care but also suggests the need for electronic PROMs systems to address both routine care applications and research applications.

Results from a study by Snyder and colleagues examining the use, usefulness and acceptability of a web tool (PatientViewpoint) to collect PROMs in clinical practice in the US were generally positive, supporting the feasibility and value of such a system.¹⁸⁴ The tool allowed for patients to complete questionnaires from home and was reported to be useful by both patients and clinicians; the majority of patients found the system easy to use, aided recall of symptoms / side effects and helped them feel more in control of their care. However, there were difficulties experienced by patients and clinicians in interpreting scores.

Two studies reviewing 16 electronic PROMs systems from the US found that the available systems varied significantly in their complexity and their capacity to address both routine care and research applications.^{182,192}

There are Australian examples of similar systems. DiscoverQuick is a real-time application for health outcomes assessment and monitoring developed by the Centre for Advances in Epidemiology and Information Technology. It can be used across multiple sites concurrently and has also included a randomisation application for recruitment to clinical effectiveness studies and clinical trials. Sansoni and colleagues¹⁹³ used DiscoverQuick for aged care assessment across multiple sites in Australia, finding that the real time access to data is an important and useful feature.¹⁹⁴ Schuler and Miller report a pilot study on the PROsaq prototype, which is based on the use of smart devices. The prototype was developed to show the technical feasibility of a lean, low-cost electronic PRO system that integrated with the oncology information system MOSAIQ, to produce improved routine patient care and improved data for clinical research.¹⁹⁵

Although electronic PROMs systems have great potential for use in health care there are considerable costs involved in their initial development. Such systems also need to be fine-tuned to the particular application, pilot tested before broader implementation and designed for ease of use. Consideration still needs to be given to avoiding undue burden on patients and the healthcare team even though this may be reduced by electronic data capture.⁶⁷ In addition, as noted by Bennett and colleagues, the mode of administration should be responsive to patient and provider preference.¹⁸⁵

5 Discussion

The findings section of this report (Section 4) has addressed the research questions, presenting the literature on the rationale for PROMs, mechanisms for collecting PROMs, reported uses of PROMs for quality improvement and other purposes, and the evidence on impacts of PROMs on quality and safety outcomes and implementation challenges. This discussion section summarises the findings and links them with recommendations for future steps to facilitate improvements in healthcare quality and safety.

First, we consider how PROMs are being collected and used for safety and quality purposes and what might be required to facilitate such collections and uses in Australia. Second, the rationale for PROMs is contrasted with the available evidence on the impacts, and a framework for assessing impacts of health outcomes measurement is presented. Finally, we draw together the implications of the findings for a national approach to PROMs in Australia.

5.1 PROMs collection and use

There is considerable potential to expand the use of PROMs in Australia. It is clear from the international academic and grey literature that in several countries, PROMs are increasingly being used at the level of individual healthcare organisations, to support clinical practice and patient-centred care. Such micro-level uses of PROMs require electronic or web-based systems for quick, easy collection and processing of patients' data. They will also require support from higher-level data collection mechanisms such as clinical registries. These can and should play a valuable role in feeding aggregate PRO data back to clinicians in a useable form to provide guidance for clinical decision making. Registries also help establish standards for quality improvement and benchmarking purposes; PROMs have the potential to fill a significant gap in these data collections, ensuring that the outcomes most important to patients are taken into account in organisational and system-level decision making. PROMs are an essential input to comparative effectiveness research, providing insights into the factors that contribute to variations in healthcare treatment outcomes. PROMs are also used to inform economic analyses of the relative costs and benefits associated with different healthcare providers. This use of PROMs is coming to the fore as several countries move towards 'value'-based payment systems in health. Also at the system level, PROMs are a valuable component of population health surveillance and can help shape research agendas, the formulation of clinical guidelines and priorities for health policy.

The Commission could consider ways to enhance PROMs collection for a range of purposes, particularly in clinical effectiveness research and in routine care. Both these applications would be considerably enhanced by promoting the inclusion of PROMs in Australian clinical registries. Generic and disease- or condition-specific PROMs could be useful in this context. Sweden has incorporated some PRO data in approximately 90 percent of its registries⁴¹ and the Netherlands (DICA) has begun to include PRO data (ICHOM standard sets) in most of its clinical registries.¹²¹ Routine use of registry-based PRO data can extend into the patient-clinician encounter. For example, the Swedish Rheumatology Quality registry (SRQ; see Appendix 2d) has PROMs, clinical examination and laboratory data incorporated into a clinical decision support tool that aims to allow the patient and the provider to work together to optimise health according to what matters to the patient. The structured data from each visit is immediately exported to the

national registry, thereby enabling collaboration and leveraging the use of the data for improving patient population health.

A classification system for National Quality Registries is used in Sweden and those that include PRO data are given a higher rating which may serve as a driver for the inclusion of PROMs in registries. Although the literature review indicated that some registries (disease, symptom, sector of care) in Australia already use PROMs, the use of these data to inform clinical practice and quality improvement does not appear to be such a widespread activity particularly in disease-specific registries. To support such a recommendation, an audit of Australian registries could map registry-based PROMs use and could articulate the potential facilitators (e.g. incentives) and barriers to their more widespread uptake, possibly using stakeholder and expert interviews.

Franklin and colleagues described a set of requirements for successful collection of PROMs within total joint arthroplasty registries⁸³ but these apply equally across a range of clinical registries. The following elements are considered essential:

- Choosing suitable instruments to measure PROs;
- Developing innovative methods to ensure complete data and sustainable collection; and
- Addressing technical challenges of extracting data from electronic health records, where possible.⁸³

Further, to ensure sustainability of data collection within registries, PRO data 'must be valuable to multiple stakeholders to justify the incremental costs of their collection'.^{83 p.3485} Although adding PROMs to a clinical registry may be time consuming, 'if stakeholders value and use the data, the PROs will gain broader use and dissemination'.^{83 p.3485}

A valid, reliable generic PROM would be a valuable addition to clinical quality registries, enabling comparison across conditions and treatments. This could be complemented by disease- or condition-specific measures where available. The NHS England PROMs initiative makes use of both generic measures (e.g. EQ-5D) and disease-specific measures. The EQ-5D and the EQ-5D-5L are examples of multi-attribute utility measures that can be used to assess health gain (in terms of health state valuations before and after treatment) and when associated with costs and life expectancy data generate QALYs which can be used to determine the cost-effectiveness of such interventions. This provides information about 'value for money', and it has the potential to identify the most cost effective treatments for a disease or condition.^{140,142} However, there are concerns in England that there are some dangers in using PROMs inappropriately to ration care or to allocate funds preferentially to treatments.⁶ Other authors have raised other concerns about the sensitivity of the EQ-5D measure^{3,39,175} both across conditions and in such a broad application as the evaluation of national health system performance. Further research and development work is required to identify a multi-attribute utility measure that is suitable for, and widely accepted in, the Australian healthcare context.

As well as collection via registries, there may be advantages to integrating the use of PROMs across the micro, meso and macro levels. A recent qualitative study involving 58 PROMs experts found strong support for integration of PRO collection and use across both routine clinical care

and performance management.¹⁷¹ Advantages are that data only need to be collected once, enhancing efficiency and reducing burden; and that aggregated data fed back to its original sources is likely to be more relevant and meaningful. Some disadvantages were also identified, and these have been alluded to above as challenges for PRO use and collection (Section 4.5). Obtaining valid, reliable data in a sustainable way is a complex exercise requiring considerable resources and efforts to engage stakeholders. In order to realise the potential benefits, 'providers, patients and purchasers of care must [first] agree on a common vision'.¹⁷¹

Training is important for the effective use of PROMs.^{3,167} Some familiarity with PROs and psychological measurement may be required for the selection and administration of measures/indicators and the interpretation and use of the resulting data for quality and safety improvement. The Commission may have a role in providing support for training activities (e.g. conferences, workshops) in conjunction with other partners. For example, the Australian National Health Outcomes Conferences, which ran for 14 years from 1994 to 2008, provided a useful training function and kept Australian agencies and health professionals informed of the major developments occurring locally and internationally in this field.

Innovative methods for collecting PRO data are required to minimise burden on patients and clinicians so that the collections are as complete as possible.⁸³ Numerous authors have discussed the need to build PROMs into electronic health records and health information systems. The required technology is now more readily available, and evidence is accumulating that electronic data collection produces equivalent data to paper-based systems:

Truly, if we are to go the PROMs route, the advent of digitization makes this a perfect moment in history to move forward.^{114 p.5}

More sophisticated electronic systems can incorporate PROMs with patient socio-demographics, clinical indicators and information (e.g. x-rays, test results) to enable the monitoring of patient outcomes through the trajectory of care, to facilitate clinical and shared decision making and, at the same time, to support clinical effectiveness research.

5.1.1 Recommendations

It is recommended that the Commission:

1. Conducts an audit of Australian clinical quality registries with respect to PROMs use.
2. Ascertains the barriers and facilitators to PROMs inclusion in clinical quality registries, based on the literature and consultations with key stakeholders and international experts.
3. Promotes PROMs inclusion in clinical registries; for example, by linking the collection and appropriate use of PROMs to criteria for assessing the quality of registries (as in the classification system used for the Swedish National Quality Registries).
4. Advocates for best practice in PROMs implementation, both in routine clinical practice and registry data collections; for example opportunities for data linkage with electronic health records.
5. Provides resources to support careful selection of appropriate PROMs instruments, including a review of multi-attribute utility measures within the Australian context.

5.2 Safety and quality impacts of PROMs

The review identified many articles and reports in which the authors presented a strong and coherent rationale for collecting and using PROMs in the ways outlined above. These arguments rely on the idea that patients, not clinicians or administrators, are best placed to understand how the health care they receive affects important health outcomes such as pain, quality of life and function. The insights available from PROMs could provide essential information to drive patient-centred care and quality improvement and to inform health policy and research agendas.

The evidence on impacts is less clear cut: evaluation of the impact of introducing PROMs at the micro level appears to be at an early stage of development. There is reasonable evidence of improved processes, such as communication, within the clinician-patient interaction. However, studies of PROMs in this context have not yet convincingly demonstrated improvements in health status outcomes. One explanation for the mixed findings on impacts of PROMs in clinical practice is the wide variety of ways in which PROMs are used. In their review, Valderas and colleagues noted that there was no consistency among studies in the instruments used, the timing and method for completing the instruments, how and when the information was fed back to clinicians, the nature of the information provided, or the training given.¹⁵¹ Other authors have pointed to a lack of theoretical development around the causal mechanisms and intermediate steps for behaviour change in clinicians and patients that are proposed to lead to distal outcomes such as improved health status or satisfaction.^{111,139}

The evidence base is stronger for meso-level uses of PROMs, particularly in comparative effectiveness research where PRO data has been extensively used to investigate the relative benefits of different treatments. Increasingly, PRO data from registries are also being used for quality improvement purposes, such as understanding variations in care, costs and outcomes among providers. Sansoni notes the relatively early stage of development of research on the use of PROMs with regard to quality improvement and the 'need for further consideration of the best ways to integrate health outcomes assessment within the quality of care improvement cycle and to also consider this across the continuum of care'.^{3 p.12}

Using PRO data to inform value-based payment systems is an emerging, system-level use of PROMs. To date there has been little formal evaluation of the macro-level uses of PROMs but it is clear that there is growing interest across the world in the potential benefits of PROMs for diverse health systems (e.g. in United States, Canada, England and Sweden).

There is a need for further evaluation of the benefits (and risks) of PROMs in the clinician-patient interaction, for quality improvement and for guiding policy, payment systems and research agendas. Any implementation of PROMs in Australia should have built-in systems for monitoring and evaluation. This should include, for example, description, documentation and evaluation of the following aspects of a PROMs program:

- which instruments are used and how they are used in different contexts
- how the data are provided to clinicians and services
- whether PRO data meets the needs of clinicians and services and how this can be improved
- effectiveness of the knowledge transfer activities conducted to disseminate the data

- changes in clinical practice, funding mechanisms, research agendas or policy that could potentially be attributed to the PROMs program.

Several authors have criticised the lack of a broad, theoretical framework to guide the development and use of PROMs measures.^{111,139} It may be possible to build a theoretical model around an established quality framework. For example, Cummings suggested the use of the Institutes of Medicine quality framework which emphasises the following qualities of health systems and processes: safe, effective, patient-centred, timely, efficient and equitable. As well as establishing a foundation for development and implementation, a theoretical framework for PROMs would specify expected impacts, thus driving and facilitating rigorous evaluation.¹¹¹

Further, there is a need to continue monitoring the academic literature and key organisations internationally for new studies of the impacts of PROMs, particularly for important, large-scale initiatives such as PROMIS and the UK PROMs program. In her commentary on a series of papers on the potential for PROMs in the Canadian health system, editor Peggy Leatt sounded a cautionary note about the level of current evidence linking PROMs with improved health care quality:

I am not saying there is not a causal connection; however, before investing all sorts of time and money setting up a new outcomes-reporting system, let's understand the relationship more precisely and via multiple domestic and international examples.^{114 p.4}

This view was echoed by the PROMs experts interviewed by Van der Wees and colleagues regarding the potential for integrated PROMs measurement systems.¹⁷¹ These authors stated that, 'the science that supports the use of PROs as performance measures is still rudimentary compared with other areas of measurement'.^{171 p.769} The emerging use of PROMs to support value-based incentive programs raises issues such as access to care, about which little is known to date.¹⁷¹ There is, therefore, a need for further research to explore the various impacts of PROMs.

A potentially useful model for understanding the different types of impacts that might be expected from the systematic collection and use of PROMs is the Outcomes Research Pyramid.¹³⁶ At the lowest level of the pyramid, outcomes data (including PROMs) enhances the knowledge base and informs further research. At the second level, outcomes data has an impact on policy making in health. At the third level, use of PROs and other health outcomes data leads to changes in health care practices. At the peak of the pyramid, these changes in research, policy and practice ultimately impact on patients' health and wellbeing. The goal of the research agenda is to scale this pyramid; however, progress upwards is not linear but is likely to be 'recursive, interactive and dynamic'.^{136 p.6} Successful work at each level will influence levels above and below.

5.2.1 Recommendations

It is recommended that the Commission:

6. Continues to monitor evidence of impacts of PROMs in the literature.
7. Advocates for a systematic approach to the monitoring and evaluation of the uses of PROMs in Australia with consideration of this to be built into any new initiatives.

8. Outlines a broad theoretical framework to guide the development and use of PROMs specifying expected impacts (and hypothesised mechanisms of impact) on quality and safety, directing both formative and summative evaluations of PROMs initiatives.
9. Engages in knowledge transfer and dissemination using specialist expertise to build and sustain patient, clinician and organisational support for investment in PROMs.

5.3 Implications for a national approach to PROMs in Australia

In discussing the potential for introducing systematic PROMs collection in Canada, Howell and Liu argued that equal attention to three conditions would be needed in order to realise benefits for population health.¹¹³ First, knowledge translation strategies need to be in place to ensure that high-quality information is fed back from PROMs to influence clinical practice. PROMs must be clearly linked with clinical guidelines and pathways and knowledge translation expertise employed in helping clinicians access and use this information effectively. Second, top-down leadership and decision making should be combined with bottom-up engagement of clinicians, with formal processes for consultation and reaching consensus on the core framework of PRO data to be collected. Third, these authors emphasised that PROMs should be person-centred. They gave the example of the PROMIS system¹⁰² which has a taxonomy of outcomes that broadly covers the relevant physical, emotional and social domains and dimensions of health, particularly for chronic disease.¹¹³ In order to support person-centred care, PROMs should not be based solely on disease-focused systems of care but on 'health, wellness, functionality, symptom management etc. or, in other words, on a holistic view of the person',^{111 p.26}

One of the main challenges in implementing PROMs is reconciling the needs of different stakeholders. Using PROMs in clinical practice should not unduly interfere with work flow.¹⁷¹ Nevertheless, healthcare providers need to commit to using standardised protocols for data collection to ensure data are reliable and valid. Clinicians, patients, administrators and policy makers must all see PROMs as serving their best interests, even though they may have different requirements for information.¹⁷² Appropriate analysis and tailored data presentation will be an essential aspect of any PROMs program; specialist statistical and knowledge translation expertise should be used to ensure that communication efforts meet the needs of all stakeholders. Stakeholder engagement is crucial to the success of PROMs and any misuse of data is likely to erode trust and thereby compromise the program's sustainability.¹⁷¹

Any attempt to measure value in health care must incorporate patient perspectives. In their review of the links between PROs and payment mechanisms, Schlesinger and colleagues⁷⁰ warn that pay-for-performance may not serve patients' best interests if it diverts clinicians' attention from the outcomes that are most valued by patients. However, such payment systems could be improved if incentives are tied to patient perspectives including PROs, 'incentivised' patient-reported information is complemented by other forms of patient feedback, and appropriate support is available for clinicians to interpret and respond to patient-reported information.

The use of value-based payment systems is an emerging field but there is a growing evidence base to support the use of bundled payments and other associated value-based reimbursement strategies. For example, bundled payments systems, which draw upon data from PROMs along with clinical and health outcome related performance indicators, survival and costs data, have

been shown to significantly enhance value in health care.^{59,68,78,79,80,107,121,126,130} The results of the current rounds of the CMS Bundled Payments for Care Improvement Initiative⁷⁷ in the US should also be of interest as will the results from the eight bundled payment schemes currently being tested in Sweden.¹³⁰ It was beyond the broad scope of this project to examine the evidence concerning value-based health care (including bundled payment systems) in detail and thus it is suggested that the Commission might consider a more comprehensive review of value-based payment systems and how such approaches might be implemented in the Australian health care system.

The Commission could explore the inclusion of selected PROMs in the indicator set for hospital quality and safety performance as per the Swedish example¹³¹ but there is a need for further consideration of casemix / risk adjustment of the data. This may be particularly relevant for the four areas (radical prostatectomy, lumbar spine surgery, knee pain and cataract surgery) identified in *Australian Atlas of Healthcare Variation*.⁷⁵ The Commission has already formed advisory groups to identify strategies to detect and address unwarranted variation which may include the potential use of PROMs or PRO-PMs for these four issues. The Commission might consider funding some scoping work on the potential use of PROMs in these areas from teams with psychometric expertise in the selection and evaluation of PROMs and in casemix (risk adjustment) methods.

Studies using the NHS PRO data to date have indicated positive outcomes for patients for specified elective surgeries on both generic (EQ-5D) and disease-specific measures, but the changes in health gain are more pronounced for major surgeries (hip and knee) than minor surgeries (e.g. groin hernia repair).^{91,92,93} The benchmarking of providers has already led to some quality improvement initiatives by providers.^{92,93} Based on these early, promising results, other countries including Canada¹¹⁰ are proposing a similar program for elective surgery. Collecting outcomes for a similar set of surgeries to other countries would have the advantage of allowing international benchmarking comparisons between Australian and overseas providers. These, combined with evidence on best practice, would be useful in identifying actions for quality improvement. Alternatively, the choice of types of surgery for examination could be reconsidered in view of Australian priorities as identified in the *Australian Atlas of Healthcare Variation*.⁷⁵

The requirements for a national approach to PROMs can be summed up as follows:

The meaningful use of PRO requires a system that provides validated, precise, accurate, and robust symptom assessment that is brief, minimizing burden on both patients and healthcare teams, and maximizes feasibility for quality improvement and research. Moreover, the system needs to allow for iterative modifications, as necessary, and ongoing data analysis to help direct individual patient care as well as for population health efforts.^{146 p.406}

A large number of Australian organisations are currently collaborating with ICHOM either as strategic partners, as participants in the development of health outcome standard measurement sets, or as potential participants in international benchmarking activities. Over 40 other countries are also involved in such activities. ICHOM's initiatives should be actively

monitored and the available expertise drawn on as a resource to assist in PROMs development in this country.

5.3.1 Recommendations

It is recommended that the Commission:

10. Develops a position statement on about the merits of collecting and reporting PROMs and the potential for integrating them across different uses.
11. Explores the effectiveness of value-based payment systems in health care and their potential for implementation in the Australian health system.
12. Investigates risk adjustment options including casemix and risk stratification approaches in order to ensure fair and accurate comparisons among providers.
13. Assesses the feasibility of introducing selected PROMs into the indicator set for hospital quality and safety performance.
14. Establishes an Australian working group to provide leadership in the use of PROMs.

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Appendix 1 Search terms and results: academic literature

Source	Initial search	Limiters/Expanders	Results
CINAHL Plus	S1: patient reported outcomes OR patient-reported outcomes OR patient reported outcome measures OR patient-reported outcome measures OR PROMs	Publication date 2006-2016, English language, exclude MEDLINE records. Search modes: Boolean/Phrase	498
	S2: patient-centred care OR patient-centered care OR health care quality OR health care policy OR performance measurement	Publication date 2006-2016, English language, exclude MEDLINE records. Search modes: Boolean/Phrase	32,156
	S3: S1 AND S2	Expanders: apply equivalent subjects. Search modes: find all my search terms	41
DARE	'patient reported outcomes'	2006-2016	25
		Manual title scan conducted	5
Google Scholar	All in title: patient reported outcomes	2006-2016, exclude patents and citations	2420
		English language only; without the words 'clinical', 'trial', 'trials', 'product' or 'products'	1860
		Without the words 'primary', 'community', 'mental'	1800
		With at least one of the words 'safety', 'quality', 'policy'	188
MEDLINE	S1: patient reported outcomes OR patient-reported outcomes OR patient reported outcome measures OR patient-reported outcome measures OR PROMs	Search modes: find all my search terms	33,866
	S2: as for S1	Publication date 2006-2016, English language. Expanders: apply equivalent subjects. Search modes: Boolean/Phrase	6459
	S3: as for S2	Limited to review articles*. Search modes: Boolean/Phrase	1146
	S4: health care quality OR health care safety OR quality improvement OR performance measurement OR quality of care OR patient-centred care OR patient-centered care OR health care policy	Search modes: Boolean/Phrase	13,711
	S5: S2 AND S4	Expanders: apply equivalent subjects. Search modes: find all my search terms	184

Source	Initial search	Limiters/Expanders	Results
ProQuest Dissertations and Theses A&I	Title search: patient reported outcome		45
		Manual title scan conducted	8
PsycINFO	S1: patient reported outcomes OR patient-reported outcomes OR patient reported outcome measures OR patient-reported outcome measures OR PROMs	Publication date 2006-2016. Search modes: Boolean/Phrase	1561
	S2: quality of care OR health care quality OR health care policy OR patient-centred care OR patient-centered care OR performance measurement	Publication date 2006-2016. Search modes: Boolean/Phrase	32,210
	S3: S1 AND S2	Tests/Measures/Assessment. Search modes: Boolean/Phrase	154
Scopus	TITLE-ABS-KEY (“patient reported outcome measures” OR “patient-reported outcome measures” OR “patient- reported outcomes” OR “patient reported outcomes” OR PROMs) AND (“patient- centered care” OR “patient- centred care” OR “quality of care” OR “health care quality” OR “health care policy” OR “performance management”	Publication date > 2005. English language. Include subject areas: mult OR medi OR nurs OR dent OR heal OR mult OR deci OR econ OR psyc OR soci. Exclude subject areas: bioc OR neur OR engi OR arts OR math OR comp OR econ OR agri OR phys OR envi. Limit to exact keywords: “outcome assessment”, “outcome assessment (health care)”, “health care quality”, “patient-reported outcomes”, “treatment outcome”, “patient outcome assessment”, “patient reported outcome”, “patient- centered care”	127
TROVE	Title phrase: “patient reported outcome measurement”	Publication date 2006-2016. English language	9
		Manual title scan conducted	0
TOTAL RESULTS			707

Note. Final results for each search are shown in **bold** and are summed to create the total. *This search was discarded as it was considered too limiting to focus only on review articles.

Appendix 2 Grey literature - tabular summary

Refer to corresponding Excel spreadsheet provided with this report.

Appendix 3 Academic literature - tabular summary

Refer to corresponding Excel spreadsheet provided with this report.

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