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# Patient Reported Outcome Measures (PROMs)

-Utility and Evidence

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A Background Paper prepared by the  
Institute for Innovation and Improvement,  
Waitemata District Health Board

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## Executive Summary

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Patient Reported Outcome Measures (PROMs) refer to any questionnaire completed by consumers of healthcare services, that is used to assess the impact of care on their health status. Typically, they record the patient's own assessment as to how treatment has, over time, affected their quality of life, symptom severity, daily functioning, sense of wellbeing and any other health outcomes which patients themselves have identified as being important to them. They provide a patient's perspective on treatment effectiveness – that is, whether treatment has actually made a positive difference to their lives. PROMs have long been used in clinical trials to assess outcomes of interventions. However, they are increasingly being added to more traditional outcome data for use as a quality improvement tool, in recognition of their positive contribution to patient-centred care, and the need to ensure maximal value is derived from our health services.

**Types of PROMs:** PROMs can be subcategorised as 'generic', 'disease-specific' or 'condition-specific'. Generic PROMs measure aspects of health that are common to most patients - such as physical functioning, role functioning, psychological symptoms and pain. They allow comparison of outcomes across conditions at a population health level and can be used to estimate the relative value or cost-benefit profiles of different interventions. As such, generic PROMs may be used by healthcare organisations to inform resource allocation decisions.

Disease-specific PROMs provide complementary information to generic PROMs, by measuring outcomes specifically relevant to patients with a particular disease eg, Prostate cancer-specific PROMs will assess continence and erectile dysfunction. When added to other disease-specific physiologic and performance outcomes, a much fuller picture of treatment effectiveness is produced.

Condition-specific PROMs apply to patients receiving care from a particular service sector or falling within a particular population group eg, mental health services, health of older people, and measure condition-relevant functional status or disability eg, the self-reported Kessler-10 Psychological Distress Scale used for clinical monitoring.

**Developing PROMs:** The world leader in the development of disease- and condition-specific PROMs is the International Consortium for Health Outcome Measurements (ICHOM), which has so far developed Standard Sets (suites of outcome measurement tools including PROMs) for 23 common diseases and conditions. By standardising the outcome measures and driving their adoption and reporting by physicians globally, accurate comparative benchmarking can occur across cultures and different management practices, enabling providers from different parts of the world to learn from each other and share best practices. It is important however, when deciding whether to adopt PROMs used overseas, that the local cultural context is taken into account – the essence of PROMs is that they reflect the outcomes that matter most to patients, and this will vary between patient populations due to different cultural perspectives on wellness and health. For example, the Hua Oranga PROMs tool needed to be designed specifically to measure mental health outcomes relevant to the needs of Maori mental health

patients. Psychometric criteria can also be used to evaluate the appropriateness of PROMs for use - to ensure reliability, validity, acceptability, interpretability and feasibility of the outcome measure chosen.

**Utility:** PROMs do not directly deliver improved outcomes or measurable benefits. They provide patient-centred information that can be used to stimulate and inform improvements in healthcare through several different routes. When collected, aggregated and analysed at a systems level, outcomes data is a powerful, 'real world' source of longitudinal data that can be used for:

1. Research into comparative treatment effectiveness and cost-effectiveness of care.
2. Benchmarking provider performance - hospitals and individual clinicians
3. Quality improvement monitoring
4. Informing patient choice of treatment
5. Informing patient choice of provider

Additionally, PROMs collected from individual patients are increasingly being fed back to clinicians for use in the clinical consultation, where they have proved useful for:

6. Monitoring patient progress and response to treatment
7. Health promotion - empowering patients to take greater control over their health
8. Screening and improved detection of problems, aiding diagnosis
9. Improving patient-centred doctor-patient communication – responding to the patient's concerns, and supporting shared decision-making.

**Implementation:** Rapid aggregation and feedback of PROMs data is essential, as is user-friendly presentation of the data, if PROMs feedback is to succeed in stimulating improvements in healthcare. For benchmarking to have maximal effect, transparency of outcomes is key (to stimulate learning and competitive improvement). Training should be given to front line clinicians in how to introduce, input, score and interpret PROMs. Videos of PROMs use can be particularly beneficial in supporting early implementation. Training should also be given to service managers, board members, and commissioners in how to interpret scores and what the limitations are to their use without further triangulation. A consistent observation is that clinicians are more likely to respond to PROMs programs if they feel the data is relevant to their own work and if they have been involved in selecting the indicators. The literature notes there are inherent tensions between the different uses of PROMs data, in particular audit and research compared to direct clinical care, that may influence PROMs content, how it is collated and fed back and thus its success. In this regard, there is a significant need for further research that clarifies the different functions of PROMs feedback and specifies the processes through which they can best achieve their intended outcomes. Any implementation of PROMs should also have built in systems for monitoring and evaluation.

PROMs are routinely collected via:

- i. Pre- and post- procedure questionnaires to assess hospital performance eg, the UK has been collecting pre- and post-operative condition-specific and generic PROMs from

all NHS patients undergoing hip and knee joint replacement, varicose vein and groin hernia surgeries since 2009.

- ii. Computer assisted questionnaires that capture generic PROMs common across a number of chronic conditions eg, the US-based Patient-Reported Outcomes Measurement Information System Initiative
- iii. Inclusion of PROMs within disease-specific clinical registries eg, the Swedish Healthcare Quality Registries
- iv. International initiatives to develop standard outcome measurement sets, including PROMs, to allow international benchmarking eg, ICHOM

Integrating PROMs into the electronic health record and linking this to clinical registries appears to be the least burdensome and most effective way that PROMs data is currently being collected, enabling the data to be used in multiple applications, as well as giving patients direct electronic access to their record, and the ability to input their PROMs remotely. The best example of this is the Swedish Rheumatology Quality Register.

**The rationale for using PROMs** includes their potential to:

- improve the accuracy of outcomes reporting
- reduce healthcare costs
- improve healthcare quality and safety – from benchmarking and, in particular, through publicising PROMs results to foster competition between providers, increase providers’ accountability to stakeholders, and motivate providers into quality improvement action to avoid reputational damage
- improve patient-centred individualised care

**Evidence base:** Unfortunately, the evidence base for PROMs use leading to better health outcomes is sparse in the literature. There have been attempts at systematic reviews, and while there is no evidence of actual harm caused by the use of PROMs, these have shown only modest benefit. The difficulty has been that the use of PROMs is still largely in its infancy, not widespread internationally, and programmes have been diverse – varying by PROM used, methods of collection, analysis and feedback, and context (patient population, recipients of the information) and level of aggregation of the data. This heterogeneity of individual trials makes it difficult to draw meaningful conclusions from systematic reviews of PROMs use currently. However, as the use of PROMs and standardisation of outcome tools continues to increase worldwide, and large-scale programmes such as the NHS PROMs mature and able to finally show true effects, the literature on PROMs and reliability of the evidence around them should also blossom. There are already some good examples of PROMs use such as the Martini-Klinik in Germany for prostate cancer care, which has evidenced superior benchmarked quality of life outcomes for its patients undergoing radical prostatectomy, at least in part as a result of including PROMs in the clinic’s performance data. An example arising from the NHS PROMs programme is CircleBath hospital, which made changes to its Enhanced Recovery Programme for hip and knee joint replacement surgeries, that have resulted in improved national benchmarked performance, and cost savings from reduced implant procurement costs and increased efficiency (reduced length of hospital stay). The Swedish Rheumatology Quality Register is a leading example of PROMs

being used in multiple applications - for research, direct clinical care and health promotion for patients with long term conditions. PROMs are also being used in primary care – for example, the How's Your Health programme (USA) uses an internet based, generic PROMs “check up” questionnaire that patients complete prior to a consultation. This has proved beneficial for diagnostic screening, monitoring control of long term conditions, health promotion and patient-centred care.

**Unintended consequences and potential barriers** to successful implementation have been described from international experience with PROMs programmes. These include:

- Gaming of performance data –data manipulation, or distortion of indicators, to give the appearance of better outcomes without any actual improvement in underlying performance. Includes effort substitution, threshold effects and avoidance of treating high risk patients
- Data credibility problems – concerns about the accuracy of hospital episodes coded data to which PROMs questionnaires are linked, concerns about the imperfections of case mix adjustment, the best timing for PROMs measurement in different care contexts, the level of data analysis, and whether it comes from a “trusted source”. Clinicians will not engage in PROMs if they do not perceive the data to be credible.
- Perceived primary motivation for PROMs use – clinicians are less likely to engage with PROMs if they perceive the primary motivation for their collection is as a tool for audit and performance review ie, as a top-down bureaucratic exercise. Instead, frontline clinicians need to see PROMs data as being directly meaningful to their clinical practice – this should influence the way in which PROMs programmes are introduced to clinicians for the best chance of success.
- Additional activity required – PROMs shine the light on poor performance but do not identify or explain the source of it. To do so requires clinicians to undertake additional audit activities – which assumes they have the time, resources, expertise, flexibility and willingness to implement such activities. If appropriate systems are not in place to support this additional activity, it will pose a barrier to PROMs success.

*The ultimate measure by which to judge the quality of a medical effort is whether it helps patients (and their families) as they see it. Anything done in health care that does not help a patient or family is, by definition, waste, whether or not the professions and their associations traditionally hallow it.*

- Berwick 1997

## 1. What are PROMS?

Patient Reported Outcome Measures (PROMs) are an emerging method of assessing quality of healthcare. They are tools for capturing patients' perspectives on the outcomes of their own treatment and care. With PROMs, the quality of healthcare intervention is valued or measured by its resultant effect or 'outcome' on the lives of patients – as reported directly by the patients themselves. Typically, patients complete standardised, validated questionnaires rating their health over time, before and after interventions, to get a measure of the effectiveness and safety of the care provided. In contrast with traditional clinically-focused metrics such as radiologic changes and laboratory or pathologic markers, the quality of healthcare is judged according to outcome measures that have been identified by patients as the results they care most about when seeking treatment - such as pain and symptom control, resumption of employment, ability to live independently, cosmesis of a surgical scar. PROMs therefore have a strongly pragmatic, functional character and overlap with quality of life measures. While they have long been used in clinical trials to assess health outcomes of interventions, PROMs are now increasingly being used as a quality improvement tool - promising to give an important insight into healthcare that only patients can provide. PROMs should be distinguished from patient reported experience measures (PREMs) which measure the patient's satisfaction with health services received (eg trust in staff, cleanliness, timeliness, dignity) but not the "outcome" of the service as such.

The ideology behind PROMs follows the ideal of a patient-centred healthcare system. The purpose of healthcare is to improve quality of life – that is, to help patients achieve the health-related goals and results that truly matter to them. Aligned with this is a shift in thinking that, rather than focussing on treating 'medical conditions', we should be focussing on achieving holistic health outcomes that patients identify as being important to them and that actually make a positive difference to their lives. Accepting that patients, rather than clinicians, are the best judges of the impact of treatment on their lives, the 'value' of healthcare provided should therefore be defined by patient reported outcome measures;

$$Value = \frac{\text{outcomes that matter to patients}}{\text{cost per patient}}$$



This is the school of thought underlying “value-based healthcare” – which proposes healthcare providers should be reimbursed for actual results or outcomes, rather than volume of treatment services provided. Value based healthcare (VBH) sees outcomes as the true measure of quality; how well did the patient actually do in a holistic sense relative to how much did it cost to deliver those outcomes?<sup>1</sup> Since value is defined as outcomes relative to costs, it encompasses efficiency. VBH is about moving away from standardising processes, and into identifying the most important outcomes to measure per medical condition for the patient. The essence of VBH is the measurement of these outcomes and costs - armed with this outcome data, each organisation must then look into its own processes and decide on the best way to work to improve those outcomes.

While patient reported outcomes are more likely to supplement rather than replace other outcome indicators, PROMs are likely to become a key part of how all healthcare is funded, provided and managed in this country.

## 2. PROMs in context – the importance of outcomes measurement

*Managing costs without sacrificing quality is possible, but not when stakeholders are blind to the impact of their decisions. Outcomes data removes the blindfold and shines light on the results of procedures, processes, structures, and systems*

-ICHOM

In a resource constrained economic environment, healthcare organisations must ensure that the care they choose to provide produces the greatest health benefit for their patients and is provided in the most efficient and cost-effective way. In order to make best use of limited budgets, greater emphasis is being placed on determining the actual benefits of treatments, particularly when the results are marginal or unproven. The key question is not how many services are being provided or how long the people wait for them, but whether these services lead to a significant improvement in health. In other words, the central goal is to derive maximal “value” per health care dollar – the challenge being to align the way in which we deliver healthcare to achieve the value.

Aside from the economic imperative, there is an ethical onus on today’s healthcare providers that demands honesty and transparency about areas of uncertainty and certainty when communicating with the public about the effectiveness of health interventions. The paternalistic days of “doctor knows best” are long gone – it needs to be demonstrated that an intervention does actually produce health benefit and to what likely degree, including

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<sup>1</sup> Porter ME (2010) What is value in healthcare? New England Journal of Medicine. Vol. 363, No. 26, pp. 2477-81.

potential risks and side effects.<sup>2</sup> Outcome measurement and monitoring should therefore become a routine part of quality assurance activities and be integrated within the model of health care.

A **health outcome** can be defined as 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. When used to assess health service performance, various health outcome measurement tools can be applied – of which PROMs are one form. The resulting **health outcome-related performance indicator** can be defined as 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.<sup>3</sup> These health outcome performance indicators are chosen to capture the 6 domains of quality in healthcare provision – effectiveness, efficiency, equity, safety, timeliness and patient-centredness.

Internationally, PROMs are rarely used as stand-alone measures in the clinical context, so it is important to view them as sitting alongside and complementing the other routinely used health outcome indicators:

- **Clinician reported outcome measures** - ie, clinicians' ratings of their patients' health outcomes, to guide clinical treatment and care.
- **Physiological measures** / biomedical indicators.
- **Outcome-related performance indicators** routinely collected by healthcare organisations about patients (to assess the organisation's performance) eg, measures of time to treatment, rates of avoidable adverse events, hospital acquired infection rates, unplanned readmission rates, mortality. These can help identify problems with processes, including variations in practice, and are often used for national comparisons of hospital performance. Indicators such as 'time to treatment' may also be important predictors of clinical outcomes. The difficulty is that some of these performance indicators may be influenced by factors out of the control of the health service.

Systematic outcomes measurement can also allow an organisation to benchmark itself against other healthcare providers, who might provide care for the same condition(s) in a variety of different ways. Recognising the potential importance of comparative benchmarking as an inter-collegial learning resource and rapid means of sharing and disseminating 'best-value' practices, there have been calls to standardise outcome measurement tools internationally - so that organisations may engage in global comparative learning. Leading the world in this effort is the International Consortium for Health Outcome Measurements (ICHOM)<sup>4</sup>, formed by the Boston Consulting Group, Harvard Business School and the Karolinska Institute (Sweden). ICHOM's mission is "to unlock the potential of value-based healthcare" by

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<sup>2</sup> In New Zealand, health providers have duties under Right 6 (Right to be fully Informed) of The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>3</sup> Williams K, Sansoni J, Morris D, Grootemaat P and Thompson C, Patient-reported outcome measures: Literature review. Sydney: ACSQHC; 2016

<sup>4</sup> See ICHOM website: <http://www.ichom.org/>

defining a global Standard Set of outcome measures (including PROMs) for the most relevant medical conditions and driving adoption and reporting of these measures by physicians worldwide. By standardizing the measurement tool, ICHOM envisages health outcomes across cultures and different management practices can be compared, allowing providers from different parts of the world to learn from each other and share best practices. ICHOM presents itself as a platform for this to occur, seeking answers to questions such as: “Which providers deliver the best outcomes? and why do providers in other nations achieve similar outcomes when they use vastly different treatments?” ICHOM has so far published 23 Standard Sets covering more than 50 percent of the global disease burden.

### 3. Types of PROMs - generic and specific

By definition, a Patient Reported Outcome (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. PROMs are the instruments used to measure PROs.

PROMs can be divided into subgroups:

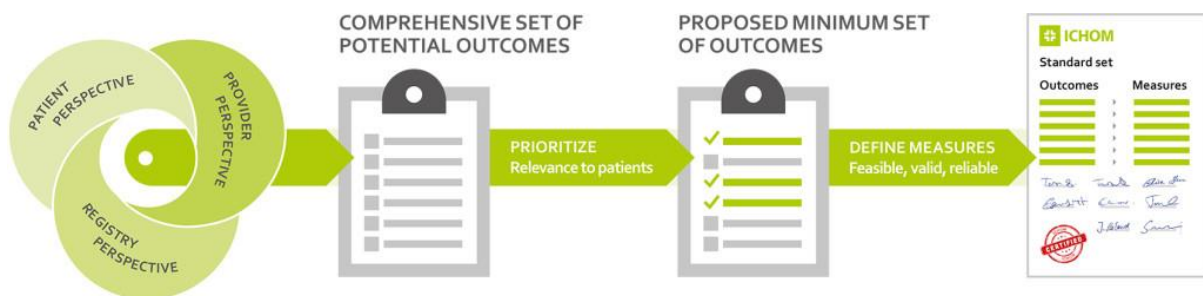
- (i) **Generic PROMs** – these multidimensional questionnaires measure aspects of health status and quality of life that are common to most patients - such as physical functioning, role functioning, psychological symptoms and pain. Generic PROMs allow comparison of patient reported outcomes across conditions at a population health level. Widely used examples include the Short Form-36 (SF-36), EQ-5D, HOPE, and PROMIS Global Health-10 scale. Generic PROMs can be used to estimate the relative value or cost-benefit profiles of different interventions and therefore assume particular importance in informing resource allocation decisions at a planning and funding level within healthcare organisations ie, what interventions are the most effective?
- (ii) **Disease-specific PROMs** - these questionnaires are completed only by patients with the disease concerned. For example, prostate cancer PROMs will enquire about continence and potency - and the score added to other disease-specific clinical and physiologic outcome measures (eg, histologic margins, PSA) and outcome related performance indicators (eg, time to treatment, complications) to provide a much more detailed picture of patients’ key symptoms throughout treatment and recovery from the disease. Disease-specific PROMs provide complementary information to generic PROMs and they are often adopted by disease-specific clinical registries, together with relevant clinical indicators, co-morbidities and demographics.
- (iii) **Condition-specific PROMs** – these PROMs apply to a broader health condition, service sector, or particular population group eg, mental health services, rehabilitation, health of older people. The health of these patients is assessed with patient reported measures of relevant functional status or disability. For example, the self-reported Kessler-10

Psychological Distress Scale (a brief mental health measure) has been used in population-based mental health surveys and in clinical monitoring.

## 4. How are PROMs developed?

The world leader in the development of disease- and condition-specific PROMs is the aforementioned International Consortium for Health Outcome Measurements (ICHOM), which incorporates PROMs within its suite of standardised outcome measurement tools.

ICHOM describes its process for defining disease-specific health outcomes as involving direct input from patient representatives, registry leaders, patient advocacy members and leading physicians from around the world. The ICHOM team facilitates the process of discussion and selection of outcomes that matter most to patients.



As of end 2017, ICHOM had completed 23 standard sets<sup>5</sup> covering 54% of the global disease burden. These include hypertension, chronic kidney disease, pregnancy and childbirth, inflammatory bowel disease, overactive bladder, colorectal cancer, breast cancer, heart failure, older people, dementia, coronary artery disease, localised prostate cancer, low back pain, cataracts, Parkinson's disease, craniofacial microsomia, depression & anxiety, advanced prostate cancer, cleft lip & palate, lung cancer, hip & knee arthritis, stroke, and macular degeneration.

### 4.1 Identification of appropriate outcomes

A critical first step in the development of PROMs is identifying the theoretical ideal or preferred outcome(s) for a given intervention – to ensure that the outcome tool will in fact measure the aspects of health that are important and relevant to those patients.

<sup>5</sup> See <http://www.ichom.org/medical-conditions/>

## Influence of local cultural factors on appropriate selection of PROMs

*“...[O]utcome measures must be relevant to the concepts of health and well being of each individual and group using the services; for example services for Maori must have outcome measures relevant to Maori.”<sup>6</sup>*

While there are a number of PROMs already developed and in use internationally (ICHOM included), it is important to acknowledge that perspectives on wellness and health outcomes vary between patient populations largely due to cultural factors. Particular consideration of cultural differences needs to be given prior to adopting PROMs used overseas - question to ask are; what is being measured? why? and is this relevant in the context of our local population’s views on health and sickness?

In New Zealand, the Maori perspective of wellness has been recognised in the development of “Hua Oranga”,<sup>7</sup> a cultural tool designed specifically to measure mental health outcomes relevant to the needs of Maori mental health patients. Thus Hua Oranga includes 4 dimensions of health outcome:

- Te Taha Wairua (Spiritual Dimension)
- Taha Hinengaro (Mental Dimension)
- Te Taha Tinana (Physical Dimension)
- Te Taha Whanau (Family Dimension)

Each dimension is placed within the mental health context and provides a consumer focused, holistic measure of outcome. Questionnaires are completed by the patient, the whanau, and clinician and the score aggregated. The tool was developed to inform mental health sector service planning and delivery and is designed to be used in conjunction with more condition specific, clinically focussed measures of outcome, eg, the “Hamilton Rating Scale” for depression.<sup>8</sup>

## 4.2 Applying psychometric criteria in PROM selection

In order for a PROMs program to be meaningful, first and foremost patients must be willing and able to provide the data. PRO data must be collected in a way that is acceptable and creates value to patients. Patients may struggle to complete PROM instruments for several reasons – low literacy, the effects of disease, visual impairment or limited mobility, confidentiality concerns, concerns about the effect PRO feedback may have on their relationship with their doctor, or where the measures or collection method chosen are perceived as culturally insensitive. It is also essential that the outcomes can be attributed

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<sup>6</sup> Mental Health Commission (1997). Blueprint for Mental Health Services. Mental Health Commission, Wellington: p 9.

<sup>7</sup> Kingi, T., & Durie, M.H. (2000). [Hua Oranga: A Māori Measure of Mental Health Outcomes \(TPH 00/01\)](http://www.massey.ac.nz/massey/fms/Te%20Mata%20Te%20Tau/Reports%20-%20Te%20Kani/T%20Kingi%20&%20M%20Durie%20Hua%20Oranga%20A%20maori%20measure%20of%20mental%20health%20outcome.pdf) Palmerston North: Te Pūmanawa Hauora, School of Māori Studies, Massey University Available at: <http://www.massey.ac.nz/massey/fms/Te%20Mata%20Te%20Tau/Reports%20-%20Te%20Kani/T%20Kingi%20&%20M%20Durie%20Hua%20Oranga%20A%20maori%20measure%20of%20mental%20health%20outcome.pdf>

<sup>8</sup> Mental Health Commission (1999), New Zealand’s National Mental Health Strategy; Review of Progress 1994-1999, Mental Health Commission, Wellington.

specifically to the care provided – valid causal links can only be made if the PROM chosen is specific and sensitive to changes in quality of care. Finally, providers will only act on PROMs data if they believe it to be valid ie, the PROM accurately represents outcomes of the care actually provided, and if they have the time and support necessary for implementation.

To assist with this, psychometric criteria can be used to evaluate and select the most appropriate PROMs for use.<sup>9</sup> These criteria include:

- **Reliability:** internal consistency (the extent to which items on a scale measure the same construct) and test-retest reliability (the stability of a measuring tool over time – assessed by administering the instrument on two different occasions and examining the correlation between test and retest scores)
- **Validity:** how well the content of a scale represents the conceptual domain it is intended to measure ie, does the instrument measure what it claims to measure? This is assessed by qualitative evidence from pretesting with patients during the questionnaire development stage, expert opinion and literature review and considers several factors; how well the scale correlates with a gold standard criterion measure (ask are there norms and clinical reference datasets available for comparison purposes?); evidence that a single entity (construct) is being measured and that items can be combined to form a single score; evidence the instrument has low correlation with measures of different constructs; the ability of the scale to differentiate known groups (eg, can the instrument differentiate between clinical subgroups and a healthy control group whose scores are expected to differ); the ability of the scale to detect significant change in health status over time (assessed by comparing scores before and after an intervention of known efficacy using various statistical methods).
- **Acceptability:** the quality of data (assessed by completeness and score distributions)
- **Interpretability:** a description of what a numerical score actually means (eg, the mapping of a point difference to a textual description)
- **Feasibility/burden:** the time, energy, financial burden, personnel or other resources required of respondents and those administering the instrument (ie, low rates of non-completion, short time to administer/complete, reasonable time and resources to collect, process and analyse data. This will factor in mode of administration – ie, self reported or structured interview? Administered via phone, tablet or online kiosk app?).

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<sup>9</sup> Smith S, Cano S, Lamping D, et al. Patient-reported outcome measures (PROMs) for routine use in treatment centres: recommendations based on a review of the scientific evidence. Final report to the Department of Health December 2005 London, UK. London School of Hygiene & Tropical Medicine; 2005.

## 5. How are PROMs collected?

There are four main ways in which patient reported outcomes are routinely collected:<sup>10</sup>

- i. **Pre- and post- procedure data collection**/questionnaires from patients undergoing selected elective surgeries to assess hospital performance eg, the NHS PROMs programme -commenced 2009, collects pre- and post-operative condition-specific and generic PROMs from patients undergoing hip and knee joint replacement, varicose vein and groin hernia surgeries.
- ii. **Computer assisted questionnaires that capture generic patient reported outcomes**, common across a number of chronic conditions eg, the US-based Patient-Reported Outcomes Measurement Information System Initiative
- iii. **Inclusion of PROMs within disease-specific clinical registries** eg, Swedish Healthcare Quality Registries
- iv. **International initiatives** to develop standard outcome measurement sets, including PROMs, to allow international benchmarking eg, ICHOM

## 6. Applying outcome measures

Measures of health outcome are of little value unless they are used and are able to contribute to health gains. PROMs do not directly deliver improved outcomes or measurable benefits. They provide patient-centred information (ie, how well patients perceive treatment has impacted their health) that enables providers and other stakeholders to make informed changes about the delivery of their services, so as to generate improved health outcomes. It is consistently noted that clinicians are more likely to respond to PROMs feedback if they feel the data is relevant to their own work and if they have been involved in selecting the indicators.

Research suggests that patients generally welcome systems that routinely use PROMs. However, patients opine that patient reporting systems must not misdirect the focus of the clinical encounter, burden patients, or focus only on factors that have value to clinicians. Patient advocates propose that PROMs systems must be co-developed by patients, the public, and professionals to obtain maximum value. They should be integrated with the patient's healthcare information and patients should be able to use the information when and where they choose, including for research.<sup>11</sup> Identifying the best way to incorporate PROMs in pre-existing medical record systems while safeguarding privacy may be challenging.

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<sup>10</sup> Supra note 3.

<sup>11</sup> Nelson Eugene C, Eftimovska Elena, Lind Cristin, Hager Andreas, Wasson John H, Lindblad Staffan et al. Patient reported outcome measures in practice *BMJ* 2015; 350 :g7818

PROMs feedback can be used to inform improvements in healthcare through several different routes –

At an aggregated systems level:

1. In research and audit – to ensure the patient perspective is included in the assessment of treatment effectiveness and cost-effectiveness of care eg, Martini-Klinik, ICHOM Standard Sets
2. As a key indicator of the quality of care patients receive from a healthcare provider eg, NHS PROMs programme.

As well as at an individual patient level:

3. To enhance communication between clinician and patient – to improve the detection of problems and to support shared decision-making about treatment through ongoing monitoring eg, Children and Young People's Improving Access to Psychological Therapies (CYP IAPT)<sup>12</sup> in England and Wales.
4. To empower patients to become more involved in their care – involving patients in the collection of outcomes data may be health promoting by improving adherence, having them monitor changes in their condition and encouraging self-management eg, Swedish Rheumatology Quality Register, How's Your Health (USA)

## Uses of PROMs

### Health System

- Performance assessment
- Value for money

### Healthcare provider organisation

- Benchmarking
- Quality improvement

### Clinical trials

- Screening
- Treatment outcomes

### Clinical practice

- Diagnosis
- Monitoring progress

### Informing patients or clinicians

- Choice of provider
- Choice of treatment

There are inherent tensions between the different uses of PROMs data that may influence how it is collated and interpreted and thus its success. Furthermore, the success of PROMs feedback is context dependent and these contextual differences influence the precise mechanisms through which it works and its impact on patient care. For example, using PROMs data as an indicator of service quality for surgical interventions in acute care is very different from its use as a quality indicator of GP management of long-term conditions within primary care.<sup>13</sup>

The literature stresses that the implementation chain from PROMs feedback to outcome improvement has many intermediate steps and may only be as strong as its weakest link. Benefits will fail to materialise if appropriate systems are not in place to facilitate the application of outcome measures in positive ways. Commentators note there is a significant

<sup>12</sup> Wolpert, M., Fugard, A. J.B., Deighton, J. and Görzig, A. (2012), Routine outcomes monitoring as part of children and young people's Improving Access to Psychological Therapies (CYP IAPT) – improving care or unhelpful burden?. *Child Adolesc Ment Health*, 17: 129–130. doi:10.1111/j.1475-3588.2012.00676.x

<sup>13</sup> Valderas JM, Fitzpatrick R, Roland M. Using health status to measure NHS performance: another step into the dark for health reform in England. *BMJ Q Saf Healthc* 2012;21:352–3.



need for further research that clarifies the different functions of PROMs feedback and specifies the processes through which they can best achieve their intended outcomes.<sup>14</sup>

Tips from implementation of the NHS PROMs programme include the importance of:<sup>15</sup>

- Explicit recognition of the need to disaggregate two aims—use of PROMs for research and audit versus use for direct clinical care, as content and feedback should vary according to the different purposes for using the PROM. PROMs as clinical tools need to be sensitive to the situation of the individual patients and able to help inform direct clinical decision-making and enhance the clinical care experience. Essentially, they act as a form of feedback – as tools to monitor for clinical change - and in this regard need to be distinguished from those PROMs that are only used, for example, to consider impact after an episode of care is complete. For example, the national UK initiative, Children and Young People’s Improving Access to Psychological Therapies (CYP IAPT), offers a suite of PROMs for clinicians to choose from, stressing the need for clinical judgement to be used in selection, so that the PROM is appropriate in context and utility.
- Rapid aggregation and feedback of data so that it is still perceived as relevant – otherwise, providers are less likely to initiate changes on the basis of ‘old’ data that may no longer be applicable to current practice; and in the case of individual application, clinicians will not get to see the completed questionnaires in time to use them in the patient consultation. One systemic review<sup>16</sup> examining the impact of PROMs feedback from medical registries on the process and outcomes of patient care noted that the most common success criteria were the timeliness of the data and trust in data quality, while a lack of trust in data quality was the most common issue raised with the studies.
- Presentation of data needs to be user-friendly and able to be easily interpreted, appropriate to the intended audience. For example, initially NHS PROMs data were fed back as a large spreadsheet, which was difficult for clinicians, managers and patients to understand, and may have contributed to the observed lack of impact on outcomes observed in the first three years of the programme.<sup>17</sup> The use of funnel plots, which enabled providers to compare their own performance with that of others, only commenced in 2011.
- Users of PROMs data should be encouraged to appreciate that PROMs data alone are unlikely to be able to yield reliable results and will need to be triangulated with other

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<sup>14</sup> Wolpert, M. Uses and Abuses of Patient Reported Outcome Measures (PROMs): Potential Iatrogenic Impact of PROMs Implementation and How It Can Be Mitigated *Adm Policy Ment Health* (2014) 41: 141.

<sup>15</sup> Ibid.

<sup>16</sup> van der Veer SN, de Keizer NF, Ravelli ACJ, Tenkink S, Jager KJ. Improving quality of care. A systematic review on how medical registries provide information feedback to health care providers. *Int J Med Inform* 2010;79:305–23.

<sup>17</sup> Varaganam M, Hutchings A, Neuburger J, Black N. Impact on hospital performance of introducing routine patient reported outcome measures in surgery. *J Health Serv Res Policy* 2014;19:77–84.

data sources. For example, at the level of service evaluation, consideration will need to be given to case mix variables, staffing variables and other indicators of quality such as level of complaints, drop out rates and referrer satisfaction. Furthermore, data should be interpreted in relation to underlying theories of processes and mechanisms.

- Training should be given to front line clinicians in how to introduce, input, score and interpret PROMs. Videos of PROMs use can be particularly beneficial in supporting early implementation. It may also be helpful to explore the different ways PROMs data can be used directly with patients.
- Training should be given to service managers, board members, commissioners and others in how to interpret scores and what the limitations are to their use without further triangulation.
- Any targets in relation to PROMs use should be related to stage of implementation of PROMs (for example whether a service has just started to use PROMs) and should concentrate on clinical use of data to inform practice, rather than assessing success of implementation in terms of how much data has been collected for central analysis.
- Review - if outcome measurements are introduced it will be important that reviews of the process take place. Due to the uncertainties around how best to utilise PROMs, as well as inevitable changes to the health system over time, the application of outcome measures must be regularly scrutinised and accordingly adjusted. For example, formal review of the NHS PROMs programme<sup>18</sup> in October 2017 resulted in the removal of varicose vein and groin hernia repair surgeries from the mandatory PROMs collection scheme, because they were analysed as delivering limited value relative to the burden of collection.<sup>19</sup> The rationale was that varicose veins are not a major cause of patient debility and surgical treatment for them had become much less frequent. The PROM for groin surgery was of limited value because patients often had minimal symptoms (surgery is offered mainly to reduce the risk of requiring emergency surgery rather than relieve symptoms) and there was no condition-specific PROM for groin-hernia surgery.

Commentators note that further research is needed into PROMs use regarding: how best to safely interpret and report the data; how often to use in clinical practice; how best to introduce them; how much change is enough; and when not to use PROMs.

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<sup>18</sup> NHS England. National Patient Reported Outcome Measures (PROMs) Programme Consultation Report, October 2017. Available at: <https://www.england.nhs.uk/publication/national-patient-reported-outcome-measures-proms-programme-consultation-report/>

<sup>19</sup> <https://www.england.nhs.uk/wp-content/uploads/2017/10/proms-provider-ending-collections-letter.pdf>

6.1 Integrating PROMs into the EHR carries the greatest potential for PROMs data collected for one purpose to be used in multiple other beneficial ways ie, for clinical care, quality assessment and improvement, research and public reporting. Linking information on PROMs to patients' medical records and other datasets would allow proper evaluation of broader government health policies as they affect equity: not just how much benefit, but who benefits and by how much. Do certain groups in society benefit less than others from treatments?

US research examining 11 case studies of PROMs-EHR linking in the US makes four recommendations regarding the effective integration and use of PROMs in EHRs: (i) customise EHR systems for context-appropriate use of PROMs; (ii) balance research and practice goals; (iii) demonstrate value to patients, clinicians and institutions; and (iv) recognise the limitations of integrating PROs into EHRs.<sup>20</sup>

## 7. Why should we use PROMs? What are the theoretical benefits and evidence of effect?

The potential theoretical benefits that can arise from the use of PROMs is undisputed in the literature. However, the decision to embark on a new system of performance measurement cannot be taken lightly – implementation is costly, time consuming and resource-intensive, adding administrative burdens to clinicians and patients. For this reason, evidence of real-world benefit from PROMs becomes important. Unfortunately, the literature is sparse on evidence and the consistent comment is that there is a need for further good quality research in this area. The difficulty has been that the use of PROMs is still largely in its infancy, not widespread internationally, and programmes are extremely diverse – varying by PROM used, methods of collection and analysis, purpose of feedback, patient population, setting, format and timing of feedback, recipients of the information and level of aggregation of the data. There have been attempts at

### NHS PROMs programme, UK

NHS England currently holds one of the most extensive PROMS “big data” collections for outcome benchmarking in the world. Since 2009, the NHS has been collecting condition-specific and generic PROMs from patients pre- and post-operatively for four elective surgeries – hip replacement, knee replacement, varicose veins and groin hernias. The PROMs programme’s stated objectives are to enable: (i) Department of Health and NHS England to monitor progress towards strategic objectives; (ii) local commissioners and service providers to assess, from the perspective of the patient, the provision of treatment and care, with the aim of improving quality of care; (iii) patients and clinicians to make an informed choice on the course of treatment.

All pre-operative patients who are about to undergo surgery are asked to complete generic PROMs (EQ-5DTM , EQ VAS) and the relevant disease-specific PROM for hip (Oxford Hip Score) and knee surgery (Oxford Knee Score) and varicose vein surgery (Aberdeen Varicose Vein Questionnaire ), This is repeated post-operatively - at 3 months for varicose vein and knee patients, and at 6 months post-knee and hip surgery. The degree of health gain is the difference between the before and after PROM scores. This is calculated for all patients having the surgeries in a NHS hospital, risk-adjusted, and presented on a funnel graph together with the England average and the 95% and 98% control limits. This information is also publicly available on the MyNHS website. As of October 2017, mandatory PROMS collection for the hernia and vein surgeries saw them as delivering limited value relative to the burden of collection.

<sup>20</sup>Wu AW., Jensen RE, Salzberg C and Snyder C (2013) Advances in the use of Patient Reported Outcome Measures in Electronic Health Records. Center for Health Services and Outcomes Research, Johns Hopkins Bloomberg School of Public Health, Baltimore.

systematic reviews, and while there is no evidence of actual harm caused by the use of PROMs, these have shown only modest benefit at best. However, the heterogeneity of the trials included makes it difficult to draw meaningful conclusions from these reviews. Studies from the US may also be of limited value in the NZ context because of the different, privatised system of health funding in North America – which becomes relevant when evaluating how PROMs work to improve the quality of care in a competitive healthcare market. One of the most relevant examples NZ can learn from is the UK’s National PROMs programme<sup>21</sup>, commenced in April 2009 and described by one commentator involved as, “a major experiment - in terms of rolling out a new form of intervention – PROMs”.<sup>22</sup> Where available, results from the PROMs programme are given in the following section, which explores the theoretical benefits of using PROMs and the evidence base in the literature as to their actual impact.

## 7.1 Improving the accuracy of outcomes reporting

Clinical outcomes alone cannot give the complete picture of treatment effectiveness. Outcomes of pain, function, quality of life and symptoms are most accurately described by patients themselves, rather than clinicians. It is well established that patients’ perceptions of their outcomes may differ significantly from clinicians’ assessments.<sup>23</sup> For example, McCormick et al found spinal surgeons’ reports are “inherently biased” and therefore may not truly reflect the impact of spinal surgery on ameliorating pain and function.<sup>24</sup> Systematic collection of PROs can help counter clinicians’ observer bias which can affect the interpretation of x-rays, blood tests and physical examination findings.<sup>25</sup> A further benefit from utilising PROMs may be an improvement in response rates from patients (compared with clinician reported outcome measures),<sup>26</sup> at least for major surgery - the NHS PROMs programme has shown high rates of patient participation for hip and knee joint replacements (more than two thirds of patients complete pre- and post-op questionnaires), but much lower levels of patient engagement for groin hernia and varicose vein surgeries (fewer than half of patients even complete the pre-op questionnaire).<sup>27</sup>

## 7.2 Reducing healthcare costs

If treatment decisions from the outset are made based on patient reported outcomes, patients are more likely to receive appropriate, high quality care, at the right time. Healthcare costs

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<sup>21</sup> <http://content.digital.nhs.uk/media/16547/full-PROMs-benefits-case-study/pdf/promscasestudy.pdf>

<sup>22</sup> Supra note 14

<sup>23</sup> Supra note 3

<sup>24</sup> McCormick JD, Werner BC and Shimer AL (2013) Patient-reported outcome measures in spine surgery. *The Journal of the American Academy of Orthopaedic Surgeons*. Vol. 21, No. 2, pp. 99-107.

<sup>25</sup> DeWalt D and Revicki D (2008) Importance of patient-reported outcomes for quality improvement. National Quality Measures Clearinghouse, Agency for Healthcare Research and Quality.

<sup>26</sup> Black N (2013) Patient reported outcome measures could help transform healthcare *BMJ(Online)* Vol 346, p167.

<sup>27</sup> Patient Reported Outcome Measures (PROMs) in England - 2012-13, Special Topic: Patient engagement with PROMs by demographic characteristics, procedure type and self-reported pre-operative health. Available at: <http://digital.nhs.uk/catalogue/PUB16482>

will be reduced by avoiding unnecessary treatments and medical errors. Systematic measurement enables constant improvement – asking, have we gotten better results for our patients? Can we do this more efficiently?

In terms of resource allocation decisions, data driven outcomes figures will help policy makers, planners and funders of care to select those services/interventions that achieve results. The advantage of PROs is that they are a source of highly relevant, ‘real world’ data on treatment effectiveness (and cost), as opposed to most clinical trial results. Potential challenges noted in the literature include: getting consensus from payers on the relative value of subjective PROs, and issues about how much weight should be given to various PROMs into decision making.<sup>28</sup> In terms of evidence, commentators<sup>29</sup> have noted the scarcity of trials that have included health service outcomes as endpoints – thus more research is required to support PROM cost-benefit in terms of patient safety, clinical burden, and health services usage.

*“Services cannot know if they are operating effectively unless they can systematically measure improvements in the health of the people who use the services. In the absence of measuring outcomes, it is difficult to determine whether funds are being spent in the most effective way.”<sup>30</sup>*

#### 7.2.1 Example case study:

##### **CircleBath hospital (UK) - using PROMs to inform better clinical practice, improve efficiency and lower costs.**

An example from the NHS PROMs programme is CircleBath<sup>31</sup> hospital, which used PROMs data analysis to help shape its Enhanced Recovery Programme for hip and knee replacement surgery. PROMs data was influential in 5 changes to the Programme – (i) revisions to the joint replacement care pathways (eg, standardised ‘daily goals’ and variance forms for pathway deviations to identify trends and ensure corrective action); (ii) introduction of group-based Joint School sessions (patient education for 2 weeks pre-op, about the standardised patient pathway and the importance of their role in rehabilitation); (iii) creation of a hip and knee clinical network to standardise the surgical process - including: use of a standardised prosthesis; ceasing drainage for knee replacements; standardising anaesthesia protocol for knee replacement re local anaesthetic infiltration and use of infusion pump 48h post-procedure, which has dramatically lessened the need for strong post-op painkillers; (iv) providing an additional physiotherapy appointment to NHS patients – at 2 weeks post-knee surgery or 12 weeks post-hip replacement surgery. This change is a specific example where a component was introduced to the Pathway as a result of PROMs data; (v) using PROMs data to monitor the Enhanced Recovery Programme

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<sup>28</sup> Supra at 11.

<sup>29</sup> Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, and MacGillivray S. [What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials](#) *Journal of Clinical Oncology* 2014 32:14, 1480-1501

<sup>30</sup> Mental Health Commission (1999). New Zealand’s National Mental Health Strategy; A Review of Progress 1994 – 1999. Mental Health Commission, Wellington

<sup>31</sup> See <http://content.digital.nhs.uk/media/16547/full-PROMs-benefits-case-study/pdf/promscasestudy.pdf>

and measure the success of pathway changes – via in-house PROMs reports which are shared regularly with operational teams.

Evidence of benefit: the 5 changes made to care pathways as a result of PROMs data contributed to the following measurable benefits:

- Improved quality of care / health gain – evidenced by improvement in national benchmarked performance, above the England average, for primary hip and knee joint replacement surgeries from 2011/12 onwards (CircleBath moving above the upper 95% control limit threshold ie, becoming a positive outlier for hip replacement from 2012/13 onwards)
- Improved efficiency – shown by a reduction in length of hospital stay (LoS) for both knee and hip replacement elective surgeries over the time period 2011/12 to 2013/14. This is credited mainly to the introduction of Joint School, empowering patients to take charge and become more involved in the recovery process; ceasing knee drainage and standardising the anaesthesia protocol – which has improved pain control for patients, enabling earlier mobilisation by the physiotherapy team. The reduction in average LoS translates to a reduced total bed day cost per procedure. For hip replacement average LoS reduced from 3.9 to 3.1 days equating to a saving of £181 per patient. For knee replacement, average LoS reduced from 3.9 to 3.4 days, translating to an average bed cost saving of £158 per patient.
- Cost saving from reduced procurement cost of hip and knee replacement implants - by standardising the implant brands used at CircleBath, this has enabled bulk ordering with a reduction in procurement cost of approximately £290 per hip replacement implant, and approximately £600 per knee implant.

A crude value-for-money assessment suggests CircleBath has been able to improve patient outcomes (effectiveness) and, in parallel, reduce implant costs (economy), bed day costs (economy) and average LoS (efficiency) ie, the improvements in PROMs scores do not appear to have been at the expense of increased costs or reduced efficiencies. A more complete value-for-money assessment has not been reported, but would require other measures, such as the cost of physiotherapy assessment, cost of pre-op sessions, average length of time in pre-op sessions, average length of time per physiotherapy appointments, readmission rates and mortality rates.

## 7.3 Improving healthcare quality and safety

*“... it’s an ethical imperative for doctors to measure outcomes and compare the results of different treatments. Physicians can use health outcomes data to evaluate how they’re doing compared to their peers worldwide. In turn, this gives physicians a unique opportunity to learn from one another and improve the way they provide care.”*

- ICHOM

### 7.3.1 The underlying theoretical mechanisms

Public reporting of health outcomes and benchmarking or comparing results of providers against each other is theorised to improve healthcare quality by motivating providers to perform as good as, or better than, their peers. For this competitive mechanism to work,



transparency is key. Berwick *et al.*<sup>32</sup> suggest two pathways through which public reporting of performance data may improve patient care: a change pathway, whereby providers take steps to change clinical care, and a selection pathway, whereby patients, commissioners, regulators and referring clinicians choose high-performing providers over lower-performing providers. The hypotheses are that providers will be motivated to respond with quality improvement initiatives because:<sup>33</sup>

- (i) *Providers will be more accountable to stakeholders for their quality outcomes – publicising performance data makes it easier for the public to see where unacceptable services are being provided and to exert local pressure for them to be improved. Similarly, it allows government to exert evidence-based pressure on those providers who are underperforming.*

For example, one of the key drivers for the public reporting of hospital and surgeon cardiac mortality outcomes in the UK was to ‘reassure patients, their carers, hospital managers, commissioners, healthcare regulators and politicians about the quality of surgical care’.<sup>34</sup> A King’s Fund paper also suggests PROMs can be used by commissioners to: monitor the performance of the providers from whom they commission services; specify minimum performance on PROMs via their contracts with those providers; and incentivise providers to improve patient health by linking payment to performance on PROMs.<sup>35</sup>

- (ii) *Providers’ professional ethos and values mean they are intrinsically motivated to maintain good patient care, and will take steps to improve if feedback highlights that there is a gap between their performance and expected standards of patient care. By providing doctors with comparative, benchmarked data, they will compare themselves with their peers, which is important in stimulating quality improvement. PROMs data is intended to “act as a focus and a starting point for providers, first to identify the reasons for their performance, and then to identify what they need to do in order to improve.”<sup>36</sup> It places responsibility on providers and managers to use PROMs data to monitor *their own* performance and, implicitly, to then take steps to improve this.*

An example is the experience of private sector provider Bupa (now owned by Spire), which pioneered the routine collection of PROMs data to monitor its surgical outcomes in the UK. Bupa’s then chief executive, Andrew Vallance-Owen describes quality improvement arose because surgeons competed with each other, not for

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<sup>32</sup> Berwick DM, James B, Coye MJ. Connections between quality measurement and improvement. *Med Care* 2003;41(Suppl. 1):I30–8. 10.1097/00005650-200301

<sup>33</sup> Greenhalgh J, Dalkin S, Gooding K, et al. Functionality and feedback: a realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures data to improve patient care. Southampton (UK): NIHR Journals Library; 2017 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK409456/>

<sup>34</sup> Bridgewater B, Keogh B. Surgical ‘league tables’: ischaemic heart disease. *Heart* 2008;94:936–42.

<sup>35</sup> Devlin NJ, Appleby J, Buxton M, Vallance-Owen A. Getting the Most Out of PROMs: Putting Health Outcomes at the Heart of Decision Making. London: The King’s Fund; 2010. Available at: <https://www.kingsfund.org.uk/publications/getting-most-out-proms>

<sup>36</sup> *Ibid*

patients, but for the professional prestige associated with having better outcomes than their peers: “Doctors are quite competitive . . . Once they see each other’s data they want to do as well or better. So you get continuous quality improvement out of this.”<sup>37</sup>

Evidence: A UK survey<sup>38</sup> examined the impact of confidential feedback to NHS trusts from four national clinical audits – the National Oesophago-Gastric Cancer Audit, National Bowel Cancer Audit, National Head and Neck Cancer Audit and National Lung Cancer Audit. The majority of respondents perceived the audits as useful to identify opportunities for quality improvement (88%), to facilitate team discussions on quality and safety issues (86%) and to benchmark outcomes at their own NHS trust with those of their peers (84%). Roughly two-thirds of respondents indicated that the audits had increased their awareness of levels of performance and practice patterns among their peers. These findings support the theory that the audit feedback increases awareness of peer performance and enables recipients to identify opportunities for improvement. Just over half of all respondents (56%) indicated that they had implemented service improvements and 42% indicated they had changed aspects of their own clinical practice. Those who had been able to make changes had done so in the knowledge of how they compared with trusts locally, while those who did not make changes did not have these data available to them - supporting theories of benchmarking, that peer comparison motivates providers to improve through peer competition.

- (iii) *Providers wish to protect their professional or institutional reputation, which may have been damaged by being publicly labelled a poor performer.* Despite providers’ intrinsic desire to improve quality of care, private benchmarking feedback may not provide sufficient motivation to overcome competing priorities and lack of time, knowledge and resources, which can act as barriers to initiating quality improvement measures. Exposing outcomes data in the public domain is seen as means of shaming low-performing providers into action, on the premise that it is reputational damage that motivates providers to take steps to improve patient care.<sup>39</sup> This theory is supported by a US study<sup>40</sup> which assessed the relative impacts of private versus public reporting. It found that public reporting served to accelerate improvements in quality of care provided, and that publication placed additional pressure on providers to improve care, particularly those who were poor performers.

There are a large number of other studies, mostly from the US and Canada, that have attempted to evaluate whether or not public reporting of performance data leads to improvements in patient outcomes and the process of care. A large systemic review of

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<sup>37</sup>Timmins N. NHS goes to the PROMS. *BMJ* 2008;336:1464–5. 10.1136/bmj.39618.627951.80

<sup>38</sup>Taylor A, Neuburger J, Walker K, Cromwell D, Groene O. How is feedback from national clinical audits used? Views from English National Health Service trust audit leads. *J Health Serv Res Policy* 2016;21:91–100.

<sup>39</sup>Marshall MN, Shekelle PG, Leatherman S, Brook RH. Public disclosure of performance data: learning from the US experience. *Qual Health Care* 2000;9:53–7.

<sup>40</sup>Hibbard JH, Stockard J, Tusler M. Does publicizing hospital performance stimulate quality improvement efforts? *Health Aff* 2003;22:84–94.



over 198 studies,<sup>41</sup> conducted for the US Agency for Health Research and Quality in 2012, found overall there was a small decline in mortality following public reporting after controlling for trends in a reduction of mortality. However, individual studies varied in their findings and the majority of studies evaluated the public reporting of mortality rates (rather than PROMs) only. It concluded that quality improvement is more likely to occur in a competitive market and following low performance.

Example: A recent development in the UK is the “My NHS” website, which is accessed from the NHS Choices website.<sup>42</sup> This website is intended to act as a tool to enable patients, commissioners and providers, to access comparative data on performance in primary care, secondary care, and health and social care. Some outcomes data on individual surgeons and dentists is included. Accessible data includes the national PROMs programme, the National Patient Experience Surveys, the Quality and Outcomes Framework, the National Mental Health and Learning Disability Minimum Dataset, CQC inspections and surgical mortality data. It responds to previous research concluding there was significant scope for quality competition between providers in the NHS, which could be facilitated by publicising provider PROM scores more widely, presenting PROM data in a way that is meaningful to patients, and ensuring GPs know their local providers’ PROM scores (given that GPs’ advice heavily influences their patients’ choice of secondary provider).<sup>43</sup> There was general consensus that performance comparison should include the performance outcomes of individual surgeons - patients wanted to know about their own surgeon rather than the whole hospital, and clinicians felt their personal performance could be under-rated by poorly performing colleagues.<sup>44</sup>

- (iv) *Providers feel threatened by the potential loss of market share that could occur if patients decided to choose alternative, higher-performing providers.* This assumes that if outcome measures are made publicly available, consumers will actively consider the data, discriminate between poorly performing and higher-performing hospitals and make their selection based on quality - thereby either driving out low quality providers or putting pressure on them to improve care.

In NZ’s public health system, best performing providers could be identified and government or DHB contracts placed accordingly.

In reality however, this patient choice-driven market force mechanism is likely to have the least impact on driving quality improvement. Commentators highlight the

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<sup>41</sup> Totten AM, Wagner J, Tiwari A, O’Haire C, Griffin J, Walker M. Closing the quality gap: revisiting the state of the science (vol. 5: public reporting as a quality improvement strategy). *Evid Rep Technol Assess* 2012;208.5:1–645.

<sup>42</sup> <https://www.nhs.uk/service-search/performance-indicators/organisations/hospitals?ResultsViewId=1015>

<sup>43</sup> Gutacker N., Siciliani L., Moscelli G. & Gravelle H., Centre of Health Economics, University of York, PROMs and Hospital Choice. Available at <https://www.kingsfund.org.uk/sites/default/files/media/Nils%20Gutacker%20-%20PROMs%20and%20hospital%20choice.pdf> (accessed 1 December 2017)

<sup>44</sup> Hildon, Z., Allwood, D. and Black, N. (2015), Patients' and clinicians' views of comparing the performance of providers of surgery: a qualitative study. *Health Expect*, 18: 366–378. doi:10.1111/hex.12037

fact that patients vary widely in their desire to seek out quality information and in their capacity to understand and use it to make rational choices.<sup>45</sup> A realist synthesis of the evidence<sup>46</sup> suggests that patients in the UK do not use publicly reported quality information to inform their choice of hospital, but instead rely on their personal experience, the opinions of friends and family and advice from their GP to make the choice. Geographical location is also a significant factor and NHS patients have been observed to remain very loyal to their local hospitals, even when such hospitals have well-reported care failings.<sup>47</sup> Rather, it is suggested that quality improvement is driven by providers in order to provide patients with a good experience of care and maintain their loyalty, so that through word of mouth, the hospital will maintain a good reputation and the patient's family and friends will likely choose to go there too. Providers also take steps to be as good as or better than their peers, which in turn enhances their reputation and means that GPs / peers are also more likely to refer patients to them. Publicly reported quality information itself plays little or no role in these processes; it is only perceived as a threat if it is misrepresented in the media, and could therefore damage reputation. If patient choice is to be promoted as a quality driver, it may therefore be best to concentrate effort on ensuring GPs are aware of the outcomes data of their local providers. However, in a state-funded health system, it is generally accepted that outcomes data will drive improvements via provider peer comparison and an intrinsic desire to improve care, rather than through patient choice and market forces.

### 7.3.2 Example Case Study:

#### **The Martini-Klinik, Germany – PROMs applied to research, benchmarking, shared clinical decision-making in prostate cancer**

*“Martini-Klinik has shown that if you measure what matters, you can become the best in your field and that doing so attracts patients from all over Germany and more broadly in Europe”*

- Michael Porter

The Martini-Klinik<sup>48</sup>, a small private clinic of the University Hospital Hamburg-Eppendorf, has been collecting PROMs data for the past 25 years and has become a world leader in the treatment of prostate cancer, attracting patients from all over Europe. For men undergoing radical prostatectomy, the Martini-Klinik produces a quality of life for its patients far superior to other prostate centres throughout the rest of Germany.

Improved outcomes: the Klinik has a 5-year survival rate (95%) that is similar to the rest of the country (at 94%). However, it is its quality of life outcomes that have improved dramatically as a result of PROMs data feedback. Only 6.5% of Martini-Klinik patients report urinary incontinence at 1 year post-prostatectomy compared to the national rate of 43%; and severe erectile dysfunction occurs in 34.7% of Klinik patients, compared to 75% in Germany as a whole.

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<sup>45</sup> Marshall M, McLoughlin V. How do patients use information on health providers? *BMJ* 2010;341:c5272.

<sup>46</sup> Supra note 33

<sup>47</sup> West D. Exclusive: patient choice is not key to improving performance, says Hunt. *Health Service Journal*, 26 November 2014.

<sup>48</sup> See Martini-Klinik website: <https://www.martini-klinik.de/en/for-patients/>

Informing treatment effectiveness: Importantly, the over two decades worth of outcomes data collected can be fed back to Martini-Klinik patients, informing prognosis and treatment decisions. Patient satisfaction has been consistently high for many years with 98% to 100% of Martini-Klinik patients reporting they “would recommend the service to a friend or their brother”.

Results	German average	Martini Clinic
Fully continent	56.7 %	<b>93.5 %<sup>1</sup></b>
Severe incontinence <sup>2</sup>	4.5 %	<b>0.4 %</b>
Severe erectile dysfunction (1 year) <sup>3</sup>	75.5 %	<b>34.7 %</b>
Ureteral injury	0.6 %	<b>0.04 %</b>
Sepsis	2.5 %	<b>0.04 %</b>
Pulmonary embolism	0.8 %	<b>0.1 %</b>
Delayed wound healing	1.7 %	<b>0.9 %</b>
Rectal injury	1.7 %	<b>0.2 %</b>
Thrombosis	2.5 %	<b>0.4 %</b>

1 Definition of fully continent: incontinence pads are unnecessary or are only used for safety

2 More than 5 incontinence pads per day

3 Including patients suffering from erectile dysfunction previous to the operation

Source: *BARMER GEK Krankenhaus Bericht 2012, Martini Clinic Database*

Published in "Case Study: Martini Klinik: Prostate Cancer Care" by Michael E. Porter, Jens Deoberg-Wittram, Clifford Marks, Harvard Business School,

Hartwig Huland, co-founder of the Martini-Klinik, credits the clinic’s success to three main factors:

1. **The power of data - studying Patient Reported Outcomes:**

The Martini-Klinik database of longterm outcomes dates back to 1992. Outcomes are collected post-operatively at one week, three months, and thereafter yearly – with patients being contacted every year and asked a set of standard questions. The Martini-Klinik hires four employees to organise this - a service that is not included in most surgical clinic budgets – but data management and infrastructure is an essential investment for quality improvement to follow. In 2013 alone, answers from 15,000 questionnaires were assessed. Outcomes data regarding cure rates and quality of life (continence and virility) are continually updated and analysed by the Klinik’s in-house biostatistician. This is used in research (Martini-Klinik publishes between 50 – 70 papers per year), and in clinical practice for shared decision-making - results can be explained to each patient based on his tumor’s individual characteristics. Measuring outcomes data has also served as a strong driver for medical innovation at the Klinik – when there are unexpected outcomes, clinicians can react to them.

Most importantly however, the data analysis is used for benchmarking, to improve surgical performance. A culture of transparency is key. The 11 Martini-Klinik surgeons sit down together every six months to compare their personal operative results (data is adjusted to account for case-mix). “If somebody is particularly good, we may adopt their approach, so that we all improve. If a surgeon is not doing so well on a particular type of patient, a colleague can look over their shoulder for a while” explains Huland.

2. **Specialisation:** The Martini-Klinik is the only European institution exclusively dedicated to the diagnosis and treatment of Prostate Cancer. This is an example of an “integrated practice unit” – a specialised “one-stop-shop” with all relevant services including imaging, radiotherapy, surgery, complementary medicine, oncology for advanced disease, prostate-cancer specific psycho-oncological counselling, under one roof. Integrated practice organises services around diseases, rather than shunting patients from department to department around a general hospital. The high volume of prostatectomy surgery associated with this specialisation at Martini-Klinik is thought to be pivotal in achieving excellence. Care and outcomes are focussed solely on prostate patients. As testament to this, patient satisfaction is extremely high. Since 2011, Martini-Klinik has been performing over 2,200 radical prostatectomies annually, the highest number worldwide. By end 2017, the clinic plans to recruit an additional 2 surgeons, bringing the number of procedures up to 3,000 per year. In comparison, urology departments in German general hospitals would typically do around 100 prostatectomies per year, while bigger US centres, such as Mayo Clinic or Johns Hopkins Hospital perform between 800 to 1000.
3. **Jobs for life / Egalitarian organisational structure:** Martini-Klinik has abandoned the traditional university hospital hierarchy for a flat organisational structure - where all Martini-Klinik faculty members are of equal rank and have lifelong positions at the clinic. They are all high-volume specialist surgeons who have done more than 1,000 procedures. In addition, the clinic has an associated faculty of radiologists, radiation oncologists, anaesthetists, an oncologist, a pathologist and a psycho-oncologist – who all spec in prostate cancer care but remain members of their own departments.

The Martini-Klinik experience with outcomes measurement and quality improvement was sought after by the International Consortium for Health Outcome Measures (ICHOM) in creating its Standard Set of outcomes for localised prostate cancer. In collaboration with 26 other experts, Martini-Klinik co-founders, Hartwig Hulan and Markus Graefen, were instrumental in developing the ICHOM standard set – which acts as a guide to what should be documented before and after treatment. The standardised measures enable global comparison of outcomes, allowing prostate centres around the world to learn from each other. Localised prostate cancer was the fourth disease to be addressed by ICHOM for standard set development. The Martini-Klinik strategy has been replicated in other disorders – for example, ICHOM has also looked at how eating disorders are managed at Germany’s Schön Klinik, joint replacement at the Hoag Institute in Southern California, and cataract surgery at India’s Aravind Eye Hospital – all provider institutions who are producing superior outcomes in their specialty fields, and operate as integrated practice units providing multidisciplinary care for a single medical condition.

## 7.4 Improving direct clinical care

### **Facilitating patient-centred consultation, informed shared decision-making, and health promotion**

PROMs have potential to improve the quality of the preoperative consultation and change the way in which doctors inform patients about their treatment options. Presenting patients with treatment data about the outcomes they care most about will improve informed, shared decision-making. PROMs ensure that the patient voice is heard; because what matters to patients, and what doctors *think* matters to patients, may not always correlate eg, Swedish psychiatrists were surprised to find their bipolar patients identified “being in fulltime employment at age 30yrs” as the most important outcome or indicator of mental health care

effectiveness.<sup>49</sup> Outcomes focused care promotes a more individualised, patient-centred approach to care and treatment planning – real-time access to a patient’s PROMs data during multidisciplinary team discussions and the clinical consultation enables providers to explore their patients’ views and expectations and tailor treatment accordingly.

Evidence from the literature suggests PROMs are useful to enable patients with long-term conditions to raise or share their concerns with doctors, and increases the detection of problems, but they have much less impact on patient management or outcomes.<sup>50</sup> For example, chemotherapy regimens would not be changed on the basis of the PROMs data alone, but PROMs data are sometimes used to legitimise changes.<sup>51</sup> A 2014 systematic review<sup>52</sup> looking at patients receiving active anticancer treatment in 24 unique controlled trials, found some studies showing evidence that the use of PROMs increases the frequency of discussion of patient outcomes during consultations and are associated with improved symptom control, increased supportive care measures, and increased patient satisfaction with emotional support – almost all patients appreciated having been asked about their emotional well-being during treatment. However, the review concluded that, irrespective of the type of cancer, the impact of PROMs on patient outcomes was weak overall, as changes in practice as a result of PROMs availability fell short of significance. PROMs feedback was more likely to impact intervention for patients’ physical symptoms rather than their quality of life or psychosocial problems. In focus groups, clinicians have raised concerns that PROMs may raise issues that they do not feel trained to address or cannot do anything about.<sup>53</sup> This may explain qualitative observation that oncologists use a number of different strategies to close down discussions of issues raised by PROMs, such as fatigue, when they perceive the problem to be outside of their clinical remit.<sup>54</sup> This has prompted commentators to emphasise the need for training and support to be given to frontline clinicians on how to actively incorporate PROMs feedback into the clinical encounter, with clear system guidelines in place to guide their responses to patient issues raised.

Use of PROMs as clinical tools in mental health settings has been shown to improve patient experiences and outcomes for people at risk of treatment failure<sup>55</sup>. They are being promoted as ways to foster increasingly collaborative models of patient-clinician interaction and shared

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<sup>49</sup> Barbro Friden, CEO of Sahlgrenska University Hospital interview. View at <https://www.youtube.com/watch?v=540SSt-lnz4&feature=youtu.be>

<sup>50</sup> Valderas JM, Kotzeva A, Espallargues M, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. [Review] [64 refs]. *Qual Life Res* 2008;17:179–93.

<sup>51</sup> Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, and MacGillivray S. [What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials](#) *Journal of Clinical Oncology* 2014 32:14, 1480-1501

<sup>52</sup> Ibid

<sup>53</sup> Supra note 33

<sup>54</sup> Greenhalgh, J., Abhyankar, P., McCluskey, S. et al. How do doctors refer to patient-reported outcome measures (PROMs) in oncology consultations? *Qual Life Res* (2013) 22: 939. <https://doi.org/10.1007/s11136-012-0218-3>

<sup>55</sup> Bickman, L., Kelley, S. D., Breda, C., de Andrade, A. R., & Riemer, M. (2011). Effects of routine feedback to clinicians on mental health outcomes of youths: Results of a randomized trial. *Psychiatric Services*, 62(12), 1423–1429.

decision making, and to help ensure service users' voices are heard, particularly in the context of work with children, young people and other groups who are dependent on carers to access services.<sup>56</sup>

#### 7.4.1 Example Case study:

### **PROMS in a clinical registry linked to EHR – The Swedish Rheumatology Quality Register – research, direct clinical care, and patient empowerment, health promotion.**

The Swedish Rheumatology Quality Register (SRQ) was started in 1995 to improve the care and treatment of patients with rheumatoid arthritis (RA). Today, it includes clinical data on 87-95% of Sweden's RA patient population from more than 60 rheumatology clinics throughout the country. Over time, SRQ has also expanded to cover other rheumatic diseases including ankylosing spondylitis, psoriatic arthritis, myositis and systemic lupus erythematosus. A major strategic advantage of SRQ is that it is fully integrated in healthcare and used to improve care. Clinical data collected for SRQ comprise the same measures regularly taken in routine medical care to track outcomes (blood tests, inflamed joint counts etc), and the web-based interface is linked to the electronic medical record, so that data only needs to be entered once – reducing the burden of data collection for physician and patient and making SRQ feasible and useful in daily clinical practice. At registration into SRQ and at each subsequent rheumatology visit, information is collected on disease activity (DAS-28), disability (HAQ), health-related quality of life (EQ5D), drug initiation (DMARD, corticosteroid use, NSAID, biologics), drug discontinuation and reason for discontinuation. The registry framework also allows for simple electronic reporting of adverse events.

Research: The data is collected to answer a range of clinical questions which include, but is not limited to, evaluating the safety and effectiveness of new rheumatic treatment options. Data collection is nationwide, population-based and ongoing – reflecting the changing state of the patient population and making it possible to provide answers to current, clinically relevant research questions. This is in contrast to many other registers which are often designed to answer one research question. Comorbid conditions are not included in SRQ, however this information can be obtained by linking individual patients' personal identity numbers to other national health registers and quality of care registers in Sweden. For example, the National Patient Register gives information on hospital discharges and non-primary care outpatient visits; the Cause of Death Register contains all deaths in Sweden; the Prescribed Drug Register enriches SRQ with prescription drug dispensing from both the treating rheumatologist and other physicians; and other disease registers eg, for stroke, cardiovascular disease. By maximising the use of data from other registers to enrich data about the SRQ population, the clinical data collected for SRQ can be minimised – only data specific to the rheumatic disease is entered into the quality of care register. The enriched data makes SRQ a powerful research database. It can be utilised for research into the safety of treatment regimes – where information on comorbid conditions and concurrent drug treatments are needed. Linkage of SRQ to data on sick leave and disability compensation held at the Social Insurance Office also allows evaluation of the economic burden of the disease from a societal perspective. Researchers also have the opportunity to conduct randomised controlled trials within the enriched register framework, which allows analysis of the longterm effectiveness of treatments and cost effectiveness analysis using real world data collected over long term and at low cost.

Patient empowerment: Patients have a personal identifier to access their information held in the registry, and the system is easy for patients to input their own patient-reported information from their personal home computers or touchscreen tablets in the waiting room. Patients enter their self-assessments of disease activity prior to each consultation. At the clinical consultation, the patient's data is visually displayed on a user friendly 'dashboard'

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<sup>56</sup> Supra note 14



showing a longitudinal overview of the patient's disease activity, disability and treatment history over time. This is used to facilitate discussion and shared decision making about treatment, and helps patients to understand why their pain may vary, encouraging them to take a greater role in self-management and lifestyle changes. Online cognitive behavioural therapy programmes are provided to support lifestyle changes. The sense of patient-control is encouraged by giving patients with inactive disease the choice about whether or when to make a follow-up appointment, eg, wait until an increase in pain occurs, and with whom – a rheumatologist or a specialist nurse for checkup. Online and other activities are given to share experience with fellow patients and provide mutual support. Patients are also encouraged to suggest improvements to clinical services and in designing changes via online and other methods. In all these ways, patients benefit from participation in the register by being involved in their own care, which leads to higher participation rates and better quality of data obtained. Physicians benefit because the SRQ data assists in decision-making and can be fed back into the clinic to increase quality of care. Experience suggests that the registry dashboard helps engage and empower patients and increases their confidence that they can manage and control their condition. Clinical outcome measures seem to improve after patients start measuring, reporting, and sharing responsibility for the management of their condition with their physician. It has been reported that patients in one region (Gävle County) that implemented routine use of PROMs in clinic visits had less disease activity, as measured by C reactive protein, than patients in regions where structured communication with doctors was not necessarily part of routine care.<sup>57</sup>

#### 7.4.2 Example case study:

#### **PROMs in primary care - How's Your Health, USA - screening, patient empowerment, health promotion<sup>58</sup>**

How's Your Health is a community-based approach to improving health outcomes that centres around an anonymous, free online survey (<http://www.howsyourhealth.org/>) that lets people assess their health and receive information tailored to their particular needs. The idea behind How's Your Health is to put the patient in control - recognising that patients do not always have the same ideas as clinicians do, the survey gives them a chance to express what they are concerned or thinking about<sup>59</sup> - making them feel they can contribute to their care. Disseminated on the internet since 1999 free of charge to primary care practices, the HowsYourHealth survey system provides clinicians with an immediate and standard source of information about patients' function, diagnosis, symptoms, health habits, preventive needs, capacity to self manage chronic conditions, and their experiences of care. Patients enter all the data themselves, usually from home or within the doctor's office, mainly using tick boxes in response to questions. They have the opportunity to share their "check-up" data with the office staff, receive information tailored to their needs, and create a personal health plan for tracking and sharing their health status and behaviours. They can also access tools to help build confidence and skill in self management and better understand the risks and benefits of treatment. The system collects generic PROMs, including COOP/WONCA measures on pain, mobility, mental health, age and sex specific preventive health needs, and self management capacity for common risks and conditions. For practice improvement, the system also provides a summary of aggregated patient data (with national benchmarks) and a secure registry to target interventions at groups of patients with similar needs (such as those with diabetes, emotional problems, or low confidence to self manage health problems). Primary care practices typically build HowsYourHealth into the routine "annual check-up," and report that the tool often brings to light important concerns that GPs were unaware of, such as domestic abuse, without the GP having to spend time actively collecting these data.

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<sup>57</sup> Nelson Eugene C, Eftimovska Elena, Lind Cristin, Hager Andreas, Wasson John H, Lindblad Staffan et al. Patient reported outcome measures in practice *BMJ* 2015; 350 :g7818

<sup>58</sup> Ibid

<sup>59</sup> <http://www.commonwealthfund.org/publications/spotlights/2004/hows-your-health>

Patients control their HowsYourHealth information and its security without the requirement of a personal identifier or password.

The HowsYourHealth system is used by hundreds of practices in the United States and Canada. Empirical observations from practices are used to expand knowledge about implementation and customisation. For example, experience has shown that using patient volunteers rather than practice staff to implement HowsYourHealth is often more successful.

Evidence: A controlled trial involving 45 primary care physicians and 1651 patients aged  $\geq 70$  years found that the HowsYourHealth system significantly improved patient ratings of overall care quality and their understanding of important risks (such as falls and advance planning of care). Patients also reported that it helped with daily activities, emotional issues, and social support<sup>60</sup>. Another controlled trial involving 47 primary care physicians and 644 adults with pain and emotional problems showed sustained improvement when HowsYourHealth was combined with a problem solving intervention supported by a nurse educator.<sup>61</sup>

## 8. Lessons learned – unintended consequences and potential barriers to successful PROMs implementation

### 8.1 PROMs to assess appropriateness of referrals to secondary care

At the start of the NHS PROMs program, the UK Department of Health identified the potential for PROMs data to be used “to establish whether referrals for elective procedures are appropriate by examining variation in baseline PROMs scores across the country.”<sup>62</sup> Pilot PROMs data analysis<sup>63</sup> however, found little health gain on average, measured by the EQ-5D following surgery for varicose vein repair, and it was suggested that ‘at least £144 m is being spent annually on carrying out operations on people who either have no significant complaints about their health before surgery or report that their condition is changed or worse afterwards’.<sup>64</sup> In response to this, other commentary<sup>65</sup> advised that it is not possible to identify patients who will not benefit from the procedure preoperatively – highlighting that the misuse of PROMs data to restrict access to elective surgery is one of the possible unintended (but not unforeseen) consequences of the PROMs programme. Later, Department of Health guidance shifted away from any reference to assessing the appropriateness of surgery towards simply observing relative health status variation before undergoing surgery,

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<sup>60</sup> Wasson JH, Stukel TA, Weiss JE, Hays RD, Jette AM, Nelson EC. A randomized trial of using patient self-assessment data to improve community practices. *Effect Clin Pract* 1999;2:1-10.

<sup>61</sup> Ahles TA, Wasson JW, Seville JL, Johnson DJ, Cole BF, Hanscom B, et al. A controlled trial of methods for managing pain in primary care patients with or without co-occurring psychosocial problems. *Ann Fam Med* 2006;4:341-50

<sup>62</sup> Department of Health. Guidance on the Routine Collection of Patient Reported Outcome Measures (PROMs). London: Department of Health; 2008.

<sup>63</sup> Devlin NJ, Parkin D, Browne J. Using the EQ-5D as a Performance Measurement Tool in the NHS. Report No. 09/03. London: Department of Economics, City University London; 2009.

<sup>64</sup> West D. Unneeded surgery may be costing the NHS millions. *Health Service Journal*, 14 May 2009.

<sup>65</sup> Black N. Patient reported outcome measures could help transform healthcare. *BMJ* 2013;346:f167.



which could establish benchmarks. In October 2017, mandatory PROMs reporting for varicose vein and groin hernia surgeries stopped because the data was proving to be of little value.

## 8.2 ‘Gaming’ of performance data

This refers to data manipulation, or distortion of indicators, to give the appearance of better outcomes without any actual improvement in underlying performance. Commentators<sup>66</sup> describe several ways this might occur including: changing the way data is recorded or coded; modifying the definition or interpretation of the indicators; and ‘effort substitution’ or ‘tunnel vision’, where organisations focus on the areas of care measured by the performance data to the detriment of other important, but unmeasured, areas of care. There is also potential for ‘threshold effects’, where poor performers feel pressure to improve, but high performers have the perverse incentive to let their performance deteriorate towards the target mean; and the avoidance of treating sicker, high-risk patients in order to avoid poor publicly reported outcomes.

## 8.3 Data credibility

Numerous critiques in the literature concern whether or not the PROMs data actually reflect the quality of patient care and the validity of the ‘outlier’ label. If clinicians do not perceive the data as credible, they will not use them to initiate changes in the quality of clinical care.

One argument is that the success of public reporting depends, in the first instance, on the **accuracy of the underlying data** used to produce performance reports or indicators. For example, in the UK, many have questioned the accuracy of Hospital Episode Statistics (coding) data, either to produce indicators themselves, or in the case of PROMs data, to link PROMs questionnaires to patient episodes. The perceived difficulty is that these administrative databases were originally developed for a different purpose, that of enabling hospitals to bill insurers or commissioners for care provided, rather than for quality improvement purposes – and they therefore “have well recognized limitations in characterizing patients, clinicians and institutions.”<sup>67</sup>

A second question is whether or not **case mix adjustment** can ensure that performance data provide a valid indicator of the quality of care provided by an organisation. For meaningful comparisons to be made between hospitals, outcomes data must be adjusted for variations in patient characteristics (baseline health, co-morbidities) that may influence the patient’s response to care, but are not under the control of the hospital. However, the risk adjustment model that should be used has been the subject of much debate – as different models can produce different findings, even when applying the same variables and data.<sup>68</sup> Other critics have warned that even if an agreed risk-adjustment method could be derived, case-mix adjustment is always imperfect because there will always be unmeasured prognostic factors

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<sup>66</sup> Supra note 33

<sup>67</sup> Naylor CD. Public profiling of clinical performance. *JAMA* 2002;287:1323–5.

<sup>68</sup> Iezzoni LI, Ash AS, Shwartz M, Daley J, Hughes JS, Mackiernan YD. Judging hospitals by severity-adjusted mortality rates: the influence of the severity-adjustment method. *Am J Public Health* 1993;86:1379–87.

that may influence outcomes. Therefore, judging hospitals on their quality of care based on risk-adjusted comparisons cannot guarantee that like is being compared with like.<sup>69</sup>

Despite acknowledging that the ‘perfect’ method of case adjustment is unachievable, others argue that this should not prevent the publication or feedback of performance data. Instead, they advocate that the credibility of data can be enhanced by involving all stakeholders in the development of performance indicators from the outset, and the risk of imperfect case-mix adjustment can be reduced by using multiple different forms of performance data – “Well balanced performance profiles should include a sensitive array of process-of-care measures, carefully chosen clinical outcomes, and patient perception and satisfaction surveys.”<sup>70</sup>

The **timing of when to measure PROMs** so that they can be accurately attributed to an intervention is also a contentious issue. Too soon after treatment will fail to capture the full benefit of the procedure on patient outcomes, while too long afterwards makes it difficult to disentangle other intervening factors, unrelated to the procedure, that are likely to have affected outcomes. For example, in the NHS, postoperative PROMs data are collected 6 months after knee and hip replacements. This timeframe was based on ‘clinical consensus’, and reasoning that outcomes feedback needs to be timely enough to increase the likelihood of stimulating health-care providers to review and improve the quality of their care. However, at 6 months, it is not assumed that a patient has reached the maximum benefit of the operation, and some have expressed concern that the use of 6 months as the cut-off point does not capture the longer-term benefit of the interventions.<sup>71</sup>

Debate also concerns the **level of analysis** at which PROMs and other performance data should be published. Currently most PROMs data are provided at the level of the hospital, with the implication that it is variation in the care between hospitals that gives rise to variation in outcome. Some have argued that this does not enable patients to distinguish between the quality of individual surgeons, and that surgeon-level data are required. However, others have questioned the utility of surgeon-level data, as the numbers may be too small to permit meaningful comparisons between surgeons; also because surgeons work in teams, their outcomes reflect the work of the team and not just the individual surgeon.

Finally, it is important that the data is perceived by recipients to come from a “**trusted source**” for it to be viewed with credibility. For example, performance data that is reported by government or for-profit organisations that might be seen as having ulterior motives, may not be perceived to be independent. In comparison, partnerships between the health service and respected professional bodies and academic institutions may be seen as more trustworthy.

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<sup>69</sup> Lilford R, Mohammed MA, Spiegelhalter D, Thomson R. Use and misuse of process and outcome data in managing performance of acute medical care: avoiding institutional stigma. *Lancet* 2004;363:1147–54.

<sup>70</sup> Naylor CD. Public profiling of clinical performance. *JAMA* 2002;287:1323–5.

<sup>71</sup> Maynard A, Bloor K. Patient reported outcome measurement: learning to walk before we run. *J R Soc Med* 2010;103:129–32.

## 8.4 Primary motivation for PROMs implementation

Commentary<sup>72</sup> on the experience of implementing PROMs in the NHS mental health service highlights how tensions can arise when providers perceive different motives for the collection and use of performance data – in this case PROMs data was being used to support clinical decision-making for individual patients, as well as being used for performance management. It was observed that what clinicians perceive to be the **primary motivation** for the introduction of PROMs collection in clinical practice, influences their degree of clinical engagement and willingness to trial the process. It may therefore be crucial to introduce frontline clinicians to PROMs through a lens of collaborative working, shared decision making, and the usability of PROMS as part of clinical conversations, rather than as tools primarily used for audit or performance review. Describing the introduction of ‘intensive outcomes monitoring’ into Children and Young People's Improving Access to Psychological Therapies (CYP IAPT) in England and Wales, the authors noted, “There is strong emphasis in the development of this approach on the need for measurement to be directly meaningful to clinical practice. The approach cannot work, and may even be harmful, if the measures are introduced as a top-down bureaucratic exercise..”<sup>73</sup> The CYP IAPT approach involves parents and/or the young person answering questionnaires at each visit, and aims to use PROMs to improve care in 3 ways – feedback of measures to clinicians will inform direct clinical work; review of data nationally to monitor consistency of care across the UK (done quarterly); and annual data modelling to produce UK intervention norms, which can then be fed back, for example, to improve detection of unusually slow recovery.

## 8.5 Burden of additional audit activity required

One shortcoming of performance monitoring is that while it can identify whether healthcare professionals perform better or worse than their peers, it does not explain why their performance differs – ie, PROMs do not provide information on which aspects of the care process are attributable to poor performance. The difficulty is that in order to identify the source of any problems, clinicians will have to undertake additional audit activities, which “assumes that professionals have the time, resources, knowledge, expertise, flexibility and willingness to implement such activities.”<sup>74</sup> Without this however, a PROMs program will fail to result in improved health outcomes.

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<sup>72</sup> Supra note 14.

<sup>73</sup> Wolpert, M., Fugard, A. J.B., Deighton, J. and Görzig, A. (2012), Routine outcomes monitoring as part of children and young people's Improving Access to Psychological Therapies (CYP IAPT) – improving care or unhelpful burden?. *Child Adolesc Ment Health*, 17: 129–130.

<sup>74</sup> Boyce MB, Browne JP. The effectiveness of providing peer benchmarked feedback to hip replacement surgeons based on patient reported outcome measures – result from the PROFILE (Patient-Reported Outcomes: Feedback Interpretation and Learning Experiment) trial: a cluster randomised controlled study. *BMJ Open* 2015;5:e008325.